



**MANAGED SERVICES AGREEMENT  
FOR LABORATORY SERVICES**

**BETWEEN**

**[ • ] HEALTH BOARD**

**AND**

**[ • ]**

**File Ref: XPFC/160 JMcC/LW**

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## MANAGED SERVICES AGREEMENT

between

### [ • ] HEALTH BOARD

constituted pursuant to the National Health Service (Scotland) Act 1978 (as amended) and having its principal office at [ • ]

(the “**Board**” which expression shall include its statutory successors and assignees)

and

[ • ]  
registered as a Company in [ • ], (registered number [ • ]) with a  
registered office at [ • ]  
(the “**Contractor**”)

WHEREAS:

- A. The Board wishes to contract for the provision of the Managed Services;
- B. Pursuant to a process for selecting a contractor to provide the Managed Services to the Board, the Board issued an invitation to tender to inter alia the Contractor; and
- C. The Board and the Contractor have agreed that the Contractor will provide the Managed Services on the terms of this Agreement.

**NOW, THEREFORE**, in accordance with terms and conditions contained herein, the Contractor and the Board hereby agree as follows:

### 1. DEFINITIONS

- 1.1 In addition to the terms which may be defined elsewhere in this Agreement, the following words and phrases in this Agreement (including the Recitals and the Schedule hereto), shall have the following meanings:

|                                    |                                                        |
|------------------------------------|--------------------------------------------------------|
| <b>“Acceptance” and “Accepted”</b> | means issue of an Acceptance Certificate by the Board; |
|------------------------------------|--------------------------------------------------------|

|                                 |                                                                                                  |
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| <b>“Acceptance Certificate”</b> | means written confirmation issued by the Board to the Contractor in accordance with Clause 4.16; |
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|--------------------------------|-------------------------------------------------|
| <b>“Acceptance Checklists”</b> | means the Contractor’s checklists detailing the |
|--------------------------------|-------------------------------------------------|

|                                                        |                                                                                                                                                                                                                                                                                                                   |
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|                                                        | <p>matters to be considered and signed off in relation to the installation and commissioning of the Equipment, all other Components of the Solution appropriate to each Site, and Reagents/Consumables at each Site, and completion of each stage of the Implementation Plan, as detailed in Schedule Part 6;</p> |
| <b>“Actual Capital Price”</b>                          | <p>means the actual capital expenditure incurred by the Contractor on an arms length basis in relation to the purchase of Equipment and refresh thereof in accordance with the Equipment Refresh Programme;</p>                                                                                                   |
| <b>“Actual Variable Costs”</b>                         | <p>means an amount calculated in accordance with paragraph 3 in the Financial Schedule;</p>                                                                                                                                                                                                                       |
| <b>“Additional Permitted Purpose”</b>                  | <p>means, if any, such other permitted purpose for the Processing of the Personal Data which, although relating to the Purpose, is in addition to the Purpose and which is a purpose which the Contractor requires to undertake by a Legal Requirement;</p>                                                       |
| <b>“Affected Employees”</b>                            | <p>means those employees which the Contractor identifies as being subject to TUPE at the expiry or termination of this Agreement;</p>                                                                                                                                                                             |
| <b>“Agreed Form”</b>                                   | <p>reference to a document being in the Agreed Form is a reference to the form of the relevant document (or where appropriate, the form of relevant document on disc) agreed between the parties and for the purpose of identification initialed by each of them or on their behalf;</p>                          |
| <b>“Agreement”</b>                                     | <p>means this agreement together with the Schedule and all documents referred to herein;</p>                                                                                                                                                                                                                      |
| <b>“Appropriate Safeguards”</b>                        | <p>means a legally compliant mechanism(s) for the transfer of Personal Data to a country outside the EEA in respect of which no adequacy decision has been made by the European Commission, as such mechanism(s) may be permitted under the Data Protection Legislation from time to time;</p>                    |
| <b>“Automated Reagent Inventory Management System”</b> | <p>means the automated reagent inventory management system to be provided as part of the Solution;</p>                                                                                                                                                                                                            |
| <b>“Base Price”</b>                                    | <p>means the price of the Equipment detailed in the Financial Model as at the Commencement Date;</p>                                                                                                                                                                                                              |
| <b>“Board Data”</b>                                    | <p>means any and all data owned by the Board including, without limitation, Patient Information;</p>                                                                                                                                                                                                              |
| <b>“Board Default”</b>                                 | <p>shall have the meaning ascribed to it in Clause 21.9;</p>                                                                                                                                                                                                                                                      |
| <b>“Board Party”</b>                                   | <p>means employees, agents and sub-contractors of the Board (excluding the Contractor and any Third Party Suppliers);</p>                                                                                                                                                                                         |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| <b>“Board Property”</b>           | means any property (including Intellectual Property Rights) belonging to the Board made available to, or used by, the Contractor, in providing the Managed Services;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>“Board Responsibilities”</b>   | means the responsibilities of the Board listed in Schedule Part 10;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>“Board Testing Period”</b>     | shall have the meaning ascribed to it in Clause 4.15;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>“Business Co-ordinator”</b>    | means the person appointed by each Party who is responsible for maintaining business and technical liaison between the Parties and for facilitating progress of matters relating to this Agreement on the behalf of the respective Parties;                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>“Change Control Procedure”</b> | means the change control procedure detailed in Schedule Part 9;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>“Change in Control”</b>        | means any change in the control of a Party caused by the sale or other disposal of any legal, beneficial or equitable interest in any of the equity share capital of that Party (including the control over the exercise of voting rights conferred on that equity share capital or the control over the right to appoint or remove directors), “control” having the meaning given to it in the Income and Corporation Taxes Act 1988, provided that a Change in Control shall be deemed not to have occurred if after any such sale or disposal the same entities directly or indirectly exercise the same degree of control over the Party in question; |
| <b>“Change”</b>                   | has the meaning given to that term in Schedule Part 9;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>“Charges”</b>                  | means the charges payable by the Board to the Contractor in respect of the Managed Services, as set out in, and payable in accordance with, the Financial Schedule;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>“Clarifications”</b>           | means the clarifications to the Contractor’s Response contained in Schedule Part13 ;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>“Clause”</b>                   | means a clause of this Agreement;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>“Code of Connection”</b>       | means completion of a network access agreement between the NHS Connecting for Health and the Contractor or any of the Contractor’s sub-contractors which authorises the Contractor or that sub-contractor to access the Scottish Wide Area Network;                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>“Commencement Date”</b>        | means [ • ];                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

**CLO NOTE: This date will be inserted nearer the time an award is to be made. It can be the latest date of execution of the contract by both parties or a different agreed date.**

|                                   |                                                                                                                                                                                                                                                                                                                                                                                                           |
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| <b>“Community Benefits”</b>       | means any activity, obligations and/or undertakings identified as community benefits or their equivalent in the Invitation to Tender, the Contractor’s response thereto or otherwise in this Agreement;                                                                                                                                                                                                   |
| <b>“Competent Authority”</b>      | means the governmental authority in a member state of the European Union that has competence in relation to the Regulations, as defined in Section 5 of Annex III of the Regulations;                                                                                                                                                                                                                     |
| <b>“Complete System Downtime”</b> | means Unapproved Downtime resulting in Reportable Results not being reported from the relevant System ;                                                                                                                                                                                                                                                                                                   |
| <b>“Component”</b>                | means a constituent part of the Solution a number of which are categorised into Band A, Band B, or Band C System, as detailed in Schedule Part 1, and “Band A Component”, “Band B Component” and “Band C Component” shall be construed accordingly;                                                                                                                                                       |
| <b>“Confidential Information”</b> | means:- <ul style="list-style-type: none"> <li>(i) in respect of the Board all Patient Information or information which otherwise constitutes sensitive personal data; and</li> <li>(ii) in respect of both parties information, the disclosure of which would, or would be likely to, prejudice substantially the commercial interests of either Party, including trade secrets and know-how;</li> </ul> |
| <b>“Consumables”</b>              | means all regularly useable items required by the Board to enable it to perform Processes (excluding Equipment and Reagents), including without limitation caps, tips and cups;                                                                                                                                                                                                                           |
| <b>“Contract Year”</b>            | means each year of the Contract commencing on the Commencement Date and each anniversary thereof and ending on the day preceding the following anniversary of the Commencement Date;                                                                                                                                                                                                                      |
| <b>“Contractor’s Response”</b>    | means the Contractor’s tender submitted in response to the NHS Requirement;                                                                                                                                                                                                                                                                                                                               |
| <b>“Controller”</b>               | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                                                                                 |
| <b>“Core Hours”</b>               | means 8am to 8pm, Monday to Friday, and 8:00am to 1:00pm Saturday;                                                                                                                                                                                                                                                                                                                                        |
| <b>“Data Loss Event”</b>          | means any event that results, or may result, in unauthorised access to Personal Data held by the Contractor or any Sub-processor under or in connection with this Agreement, and/or actual or potential loss and/or destruction and/or corruption of Personal Data in breach of this Agreement, including but not limited to any Personal Data Breach;                                                    |

|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <b>“Data Protection Impact Assessment”</b> | means an assessment by the Controller of the impact of the envisaged Processing on the protection of Personal Data;                                                                                                                                                                                                                                                                                                                     |
| <b>“Data Protection Legislation”</b>       | means (i) the GDPR and any applicable national implementing Laws as amended from time to time; (ii) the DPA 2018 to the extent that it relates to the Processing of Personal Data and privacy; and (iii) any other Law in force from time to time with regards to the Processing of Personal Data and privacy, which may apply to either Party in respect of its activities under this Agreement;                                       |
| <b>“Data Protection Officer”</b>           | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>“Data Subject”</b>                      | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>“Data Subject Request”</b>              | means a request made by, or on behalf of, a Data Subject in accordance with access and other rights granted pursuant to the Data Protection Legislation to access their Personal Data;                                                                                                                                                                                                                                                  |
| <b>“Default”</b>                           | means any failure by the Contractor to perform its obligations under this Agreement;                                                                                                                                                                                                                                                                                                                                                    |
| <b>“Detailed Implementation Plan”</b>      | means the more detailed version of the Implementation Plan developed and agreed by the parties pursuant to Clause 4;                                                                                                                                                                                                                                                                                                                    |
| <b>“Direct Costs”</b>                      | shall mean all out-of-pocket expenses incurred by the Board, including, but not limited to, the expenses of patient notification and/or recall, the destruction or return of Reagents/Consumables, and the cost of replacement Reagents/Consumables, sourcing, delivery and implementing alternative Equipment, removal of existing Equipment, training, repeating Processes;                                                           |
| <b>“Directive”</b>                         | means Directive 2014/24/EU of the European Parliament and of the Council on public procurement;                                                                                                                                                                                                                                                                                                                                         |
| <b>“Dispute Resolution Procedure”</b>      | means the procedure detailed at Clause 25;                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>“Downtime”</b>                          | means time when a Process cannot be performed due to: <ul style="list-style-type: none"> <li>(i) the non-availability of necessary Equipment due to a mechanical or electrical malfunction with the Equipment or a related piece of equipment;</li> <li>(ii) the non-availability of the Solution Management System(s) ;</li> <li>(iii) any Equipment or Reagent producing results that are outside of the stated analytical</li> </ul> |

variation, as detailed in the Specification;

- (iv) any part of the Solution which supports the necessary Equipment being not fully operational to a level which would support full and proper use and enjoyment of the Equipment and/or results;
- (v) the non-availability of any Reagent and where any Reagent is not fully operational to a level which would support the key functions or applications of that Reagent;
- (vi) any reason which results in safety concerns regarding the ongoing operation of any Component of the Solution and/or use of a Reagent needed to perform a Process (other than safety concerns which arise as a result of the act or omission of the Board or any Board Party);

**“DPA 2018”**

means the Data Protection Act 2018;

**“DP Losses”**

means all liabilities and amounts, including all:

- a) Direct Losses;
- b) costs and expenses relating to reconstitution and/or correction of the Personal Data and any and all records comprising the same; and
- c) to the extent permitted by Law:
  - (i) administrative fines, penalties, sanctions, liabilities or other remedies imposed by a Supervisory Authority; and
  - (ii) compensation to a Data Subject ordered by a Supervisory Authority;

**“ECJ”**

means the Court of Justice of the European Union;

**“EEA”**

means the European Economic Area;

**“Environmental Requirements”**

means the operating and environmental conditions specifically required at each Site to enable optimal operation of all Components the Solution and Reagents/Consumables, including without limitation water quality/volume/pressure requirements, air temperature, operating space, and electrical supply availability, as detailed in Schedule Part 5;

**“Equipment”**

means analysers and other equipment to be provided by the Contractor or a Third Party Supplier for use by the Board, including microscopes and fridges and also including software, hardware, middleware, network connections and interfaces required to enable the effective operation thereof, the details of which are set out in Schedule Part 1, as may be updated from time to time;

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <b>“Equipment Refresh Programme”</b> | means the equipment refresh programme contained in Schedule Part 12 (Equipment Refresh Programme);                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>“Facility Manager”</b>            | means the person appointed by the Contractor who is responsible for the co-ordination and delivery of the Managed Services;                                                                                                                                                                                                                                                                                                                                                                             |
| <b>“Final Acceptance”</b>            | means formal written acceptance issued by the Board of satisfactory completion of <u>ALL</u> of the Contractor’s obligations under the Implementation Plan following the occurrence of Milestone Acceptance in respect of all Key Milestones and Milestones, as detailed in the Implementation Plan, issued in accordance with Clause 4;                                                                                                                                                                |
| <b>“Final Acceptance Date”</b>       | means the date of written confirmation issued by the Board to the Contractor that Final Acceptance has occurred;                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>“Financial Schedule”</b>          | means Schedule Part 3 ;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>“Fixed Charge”</b>                | means the Charges identified as <b>“Fixed Charges”</b> in the Appendix to Schedule Part 3;                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>“Gain”</b>                        | means the amount by which the Actual Capital Price is less than the Base Price;                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>“GDPR”</b>                        | means the General Data Protection Regulation (Regulation (EU) 2016/679);                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>“Gold Standard”</b>               | means a range of testing to be performed as defined in the Contractor’s checklists, which will be agreed with the Contractor. Gold standard testing is expected to include installation qualification and technical performance verification confirming results produced are compliant with the Contractor’s declared sensitivity and specificity, IT testing including middleware and connectivity testing, and full operational functionality testing including utility checks (power, drainage etc); |
| <b>“Health Board”</b>                | means an entity established pursuant to the National Health Service (Scotland) Act 1978 (as amended);                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>“Implementation Plan”</b>         | means the high level plan detailed in Schedule Part 6(A) and includes work to be undertaken by the Contractor;                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>“Implementation Services”</b>     | means those services to be delivered by the Contractor at each and every Site in relation to <u>inter alia</u> preparation of the relevant Site, and delivery, off-loading, configuration, installation, commissioning testing of all Components of the Solution prior to commencement of live use of any Components of the Solution by the Contractor at the Site, as detailed in Schedule Part 6B;                                                                                                    |

|                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>“Index”</b>                                  | means the Consumer Prices Index or if that index ceases to be published, such alternative index as the auditors of the Board (acting as experts and not as arbiters) shall determine from time to time as being a comparable index for the purposes of this Agreement;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>“Information Commissioner’s Office”</b>      | means the United Kingdom’s Supervisory Authority;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>“Intellectual Property Rights” or “IPRs”</b> | <p>means rights, title and interest in:</p> <ul style="list-style-type: none"> <li>(a) patents;</li> <li>(b) trade marks, and trade and business names (including service marks);</li> <li>(c) design rights, registered designs;</li> <li>(d) utility models;</li> <li>(e) copyright (including copyright in software programs);</li> <li>(f) database rights;</li> <li>(g) know-how, (including trade secrets and confidential business information); and</li> <li>(h) formulae, processes, results;</li> </ul> <p>in each case whether registered or unregistered registerable or not, and including (i) any pending applications or rights to apply for registrations of any of these rights, and (ii) any similar or analogous rights to any of these rights, whether arising or granted, in the United Kingdom or in any other jurisdiction;</p> |
| <b>“Invitation to Tender” or “ITT”</b>          | means the Board’s invitation to tender in respect of the Managed Services issued to <u>inter alia</u> the Contractor on [ • ];                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>“Joint Controller”</b>                       | shall have the meaning given in Article 26 of the GDPR;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>“Key Milestone”</b>                          | means those Milestones identified as Key Milestones in the Implementation Plan (as may be amended from time to time, or superseded by dates incorporated in the Detailed Implementation Plan);                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>“Law”</b>                                    | means any law, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of Section 2 of the European Communities Act 1972, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements with which the Board and/or the Contractor is bound to comply;                                                                                                                                                                                                                                                                                                                                                                                                                            |

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| <b>“Legal Requirements”</b>             | <p>means any legislation and/or common law insofar as applicable to the Managed Services or any part thereof and/or any Component of the Solution and/or Reagents/Consumables including without limitation:-</p> <ul style="list-style-type: none"> <li>(a) any subordinate legislation; and</li> <li>(b) any legislative act of the European Union or the Commission of the European Community which without further enactment has legal effect within the United Kingdom;</li> </ul>                                                                                                                                                                                                                                                                                                    |
| <b>“Longstop Date”</b>                  | <p>means the date occurring three (3) months following the Planned Final Acceptance Date;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>“Managed Services”</b>               | <p>means the services to be provided by the Contractor to the Board in relation to the provision and maintenance of all Components of the Solution and Reagents/ Consumables necessary to enable the Board to carry out the Processes, including <i>inter alia</i>:-</p> <ul style="list-style-type: none"> <li>(1) the provision, installation, commissioning, implementation, operation and maintenance of all Components of the Solution;</li> <li>(2) the provision of inventory ordering and stock control in respect of Reagents/Consumables;</li> <li>(3) training in respect of all Components of the Solution and the Reagents/Consumables; and</li> <li>(4) all other aspects of the services to be provided hereunder;</li> </ul> <p>all as detailed in the Specification;</p> |
| <b>“Managed Service Failure”</b>        | <p>each incident in relation to a performance or availability issue experienced in respect of any Component of the Solution or any Reagent;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>“Middleware”</b>                     | <p>means the Software which links the SCCRS to certain Components of the Solution;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>“Milestones”</b>                     | <p>means the milestones detailed in the Implementation Plan, (as may be amended from time to time, or superseded by dates incorporated in the Detailed Implementation Plan) and “<b>Milestone</b>” shall be construed accordingly;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>“Milestone Acceptance”</b>           | <p>means formal written acceptance of satisfactory completion of each stage of the Contractor's obligations under the Implementation Plan, (or Detailed Implementation Plan, once agreed) issued in accordance with Clause 4;</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>“Milestone Acceptance Procedure”</b> | <p>means the procedure for achieving Milestone Acceptance of all Components of the Solution in</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

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|                                        | respect of each stage of the Implementation Plan (or the Detailed Implementation Plan), as detailed in Clause 4;                                                                                                                                                                                                                                  |
| <b>“Milestone Go Live”</b>             | means commencement of live use of the part(s) of the Solution implemented as a <b>“Milestone”</b> (and associated Reagents and Consumables), following Milestone Acceptance in respect of that Milestone;                                                                                                                                         |
| <b>“Minimum Requirements”</b>          | means those requirements identified as such in Schedule Part <b>[X]</b> (Processing, Personal Data and Data Subjects);                                                                                                                                                                                                                            |
| <b>“Net Gain”</b>                      | means the amount (if any) by which the Gain exceeds the Loss;                                                                                                                                                                                                                                                                                     |
| <b>“New Contractor”</b>                | means any person or entity who is awarded an agreement to provide services equivalent to the Managed Services in place of the Contractor (including the Board or other Health Board in the case of the provision of such services being provided in-house by the Board or to NHS Scotland) following the expiry or termination of this Agreement; |
| <b>“NHS Requirement”</b>               | means the requirement issued by the Board as part of the ITT;                                                                                                                                                                                                                                                                                     |
| <b>“NHS Scotland Health Board(s)”</b>  | means any Health Board in Scotland constituted pursuant to the National Health Services (Scotland) Act 1978;                                                                                                                                                                                                                                      |
| <b>“Party”</b>                         | means a party to this Agreement;                                                                                                                                                                                                                                                                                                                  |
| <b>“Patient Information”</b>           | means information relating to the identity, medical condition or history of any patient or prospective patient of the Board or any other Health Board and any and all data (including results generated by use of the Equipment and/or Reagents, and data stored in the SMS or otherwise) generated and/or derived therefrom;                     |
| <b>“Performance Specifications”</b>    | means the required performance capabilities and characteristics in respect of each item of Equipment as detailed in the Specification;                                                                                                                                                                                                            |
| <b>“Permitted System Downtime”</b>     | has the meaning given in Annex 1 to Schedule Part 11;                                                                                                                                                                                                                                                                                             |
| <b>“Personal Data”</b>                 | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                         |
| <b>“Personal Data Breach”</b>          | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                         |
| <b>“Planned Final Acceptance Date”</b> | means the date by when the parties agree that it is expected that Final Acceptance will occur, as specified in Schedule Part 6;                                                                                                                                                                                                                   |
| <b>“Process”</b>                       | means an activity listed in the Specification which the Board requires to perform using the Solution and                                                                                                                                                                                                                                          |

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|                                                | Reagents/Consumables, as listed in the Specification, and <b>“Processes”</b> means all or some of them;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>“Processing”</b>                            | shall have the meaning given in the GDPR and the terms <b>“Process”</b> and <b>“Processed”</b> shall be construed accordingly;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>“Processing Instructions”</b>               | shall have the meaning given in Clause 18.4;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>“Processor”</b>                             | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>“Product Action”</b>                        | has the meaning given to that term in Clause 12.3.1;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>“Protective Measures”</b>                   | means appropriate technical and organisational measures which must include the Minimum Requirements and may also include, without limitation: pseudonymising and encrypting Personal Data; ensuring confidentiality, integrity, availability and resilience of systems and services used by the Contractor and, where relevant, by any Sub-processor in connection with the performance of the obligations imposed on the Contractor pursuant to or under this Agreement, including but not limited to the performance of the Services; ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident; and regularly assessing and evaluating the effectiveness of such technical and organisational measures adopted from time to time by the Contractor and, where relevant, by any Sub-processor; |
| <b>“Public Holiday”</b>                        | means 25 and 26 December; and `1 and 2 January;;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>“Purpose”</b>                               | has the meaning set out in Clause 18.4;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>“Quarterly Period”</b>                      | means each period of three (3) months starting 1 April, 1 July, 1 October, 1 January;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>“Quality Systems and cGMP Requirements”</b> | means all applicable standards relating to manufacturing practices for the Reagents promulgated under the Regulations, in the form of laws, regulations or guidance documents including but not limited to, (i) 21 CFR Part 820 (Quality Systems Regulations), as amended or updated from time to time; (ii) cGMP, the current Good Manufacturing Practices as described in 21 CFR Part 211, as amended or updated from time to time; and (iii) guidance issued by The Medicines and Healthcare Products Regulatory Agency, including Bulletin No 12, as amended or updated from time to time. The applicable Quality Systems and cGMP Requirements for any batch of Reagent shall be those regulations in effect when such lot is manufactured;                                                                                                      |
| <b>“Reagent Specifications”</b>                | means the product labelling, packaging and performance specifications for each Reagent supplied                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

under this Agreement;

**“Reagent” or “Reagents”**

means reagents and methods supplied to the Board by the Contractor pursuant to this Agreement for use by the Board in the performance of Processes, as set out in Schedule Part 2, as such reagents and methods may be amended or supplemented from time to time in accordance with this Agreement;

**“Recall”**

has the meaning attributed to it in Clause 12.3.1;

**“Regulations”**

means The Medical Devices Regulations 2002, and all updates, replacements or supplements thereto, implementing the In Vitro Diagnostic Directive 98-79-EC, or any replacement or supplementing legislation governing in vitro diagnostic devices in the European Union as implemented in the United Kingdom during the term of this Agreement;

**“Relief Event”**

has the meaning given to that term in Clause 36;

**“Replicated Equipment”**

shall have the meaning ascribed to it in Clause 4.10;

**“Representative”**

shall have the meaning given in the GDPR;

**“Reportable Results”**

means the final results of an analysis of a patient sample carried out utilising the Solution;

**“Resolved” or  
“Resolution”**

means that the Managed Service Failure has been fixed such that the relevant Component of the Solution or Reagent in question is again available and performing at least to the standard required under this Agreement and capable of delivering Reportable Results to another connected Component and is otherwise delivering that System's functionality (as defined in the Specification) and that the Board has received an explanation from the Contractor of the nature of the problem and the actions taken by the Contractor to effect the fix, and “Resolve” shall be interpreted accordingly;

**“Restricted Person”**

means any person who has an interest in the production of:-

- (a) tobacco products; and/or
- (b) alcoholic beverages; and/or
- (c) arms or ammunitions.

**“Routine Planned Maintenance”**

has the meaning given to it in Schedule Part 11;

**“SCCRS”**

means Scottish Cervical Call Recall System;

**“Schedule”**

means the schedule in fifteen (15) parts annexed as relative hereto;

|                                              |                                                                                                                                                                                                                                                                                                                                                            |
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| <b>“Screening Services”</b>                  | means laboratory services in relation to cervical cytology screening;                                                                                                                                                                                                                                                                                      |
| <b>“Semi Fixed Charge”</b>                   | means the Charges identified as <b>“Semi Fixed Charges”</b> in the Appendix to Schedule Part 3;                                                                                                                                                                                                                                                            |
| <b>“Serious Incident”</b>                    | means an incident involving a Reagent that is reportable to a Competent Authority pursuant to any Legal Requirements;                                                                                                                                                                                                                                      |
| <b>“Service Deductions”</b>                  | means the service deductions which, if applicable, shall be payable by the Contractor, all as calculated in accordance with Schedule Part 11;                                                                                                                                                                                                              |
| <b>“Service Hours”</b>                       | means twenty four (24) hours, a day, on every day of the year;                                                                                                                                                                                                                                                                                             |
| <b>“Service Levels”</b>                      | means the service levels in respect of the Managed Services and performance of the Solution, as detailed in Schedule Part 11;                                                                                                                                                                                                                              |
| <b>“Service Points”</b>                      | has the meaning given to it in Schedule Part 11;                                                                                                                                                                                                                                                                                                           |
| <b>“Sites”</b>                               | means the various premises operated by the Board at and in respect of which the Managed Services are to be provided under this Agreement, all as detailed in the Specification including the processing laboratories, as may be varied and/or supplemented at the request of the Board from time to time and <b>“Site”</b> shall be construed accordingly; |
| <b>“Solution Management System” or “SMS”</b> | means insofar as applicable at each Site, the equipment, hardware, software, middleware, interfaces and network connections to be provided by the Contractor to manage the operation of the Solution at each Site;                                                                                                                                         |
| <b>“Solution”</b>                            | means all equipment and systems for undertaking or associated with Processes to supplied to the Board under this Agreement including, without limitation, the:- <ul style="list-style-type: none"> <li>• Equipment;</li> <li>• Solution Management System; and</li> <li>• Automated Reagent Inventory Management System.</li> </ul>                        |
| <b>“Specification”</b>                       | means the NHS Requirement, the Contractor’s Response and the Clarifications attached hereto as Schedule Part 13, as the same may be amended from time to time in accordance with this Agreement;                                                                                                                                                           |
| <b>“Sub-processor”</b>                       | means any third party appointed to process Personal                                                                                                                                                                                                                                                                                                        |

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                               |
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|                                | Data on behalf of the Contractor in connection with this Agreement;                                                                                                                                                                                                                                                                                                                                                           |
| <b>“Supervisory Authority”</b> | shall have the meaning given in the GDPR;                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>“System”</b>                | means a system as listed in Annex 2 to Schedule Part 11, comprising certain Equipment and other Components (such Equipment and other Components being as detailed in Schedule Part 1);                                                                                                                                                                                                                                        |
| <b>“System Downtime”</b>       | is time when a Component part of a System is affected by Unapproved Downtime;                                                                                                                                                                                                                                                                                                                                                 |
| <b>“Term”</b>                  | means the period from the Commencement Date until the expiry of five (5) calendar years from the date of Final Acceptance or until expiry of any extension if extended in accordance with Clause 21.1;                                                                                                                                                                                                                        |
| <b>“Test Turnaround Time”</b>  | means the period calculated in accordance with paragraph 7.2 of Schedule Part 11;                                                                                                                                                                                                                                                                                                                                             |
| <b>“Third Party Supplier”</b>  | means any individual, company, partnership, or entity other than the Contractor or the Board that is subcontracted to the Contractor for the provision of aspects of the Managed Services, including any Component of the Solution and/or Reagents/Consumables, to the Board, as identified in the Specification, and such alternative or additional Third Party Suppliers as may be approved by the Board from time to time; |
| <b>“Transfer”</b>              | means novation or transfer in whole or in part;                                                                                                                                                                                                                                                                                                                                                                               |
| <b>“Transferee”</b>            | means any party to whom a Transfer is made;                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>“Treaty”</b>                | means the Treaty on the Functioning of the European Union;                                                                                                                                                                                                                                                                                                                                                                    |
| <b>“TUPE”</b>                  | means the Transfer of Undertaking (Protection of Employment) Regulations 2006, as such may be amended, replaced or updated from time to time;                                                                                                                                                                                                                                                                                 |
| <b>“Unapproved Downtime”</b>   | is Downtime which is not caused by the occurrence of Routine Planned Maintenance or an event of Force Majeure, or a Relief Event;                                                                                                                                                                                                                                                                                             |
| <b>“Unique Equipment”</b>      | shall have the meaning ascribed to it in Clause 4.10;                                                                                                                                                                                                                                                                                                                                                                         |
| <b>“Unitary Charge”</b>        | means the annual amount payable by the Board to the Contractor calculated in accordance with the provisions of the Financial Schedule;                                                                                                                                                                                                                                                                                        |
| <b>“Unsuitable Person”</b>     | means a person whom the Board considers, acting reasonably, should not be involved in the provision of the Managed Services. Characteristics which might inform the Board’s decision regarding the suitability                                                                                                                                                                                                                |

(or otherwise) of a person include:- appearance, personal hygiene, demeanor, displaying aggressive or threatening behaviour, and the use of rude, abusive, racist, sexist or otherwise discriminatory language;

**“Workaround”**

means a temporary mechanism to alleviate the effects of a Managed Service Failure pending the Contractor effecting a Resolution;

**“Working Day”**

means each weekday excluding Saturday, Sunday and Public Holidays which are recognised by the Board; and

**“Works”**

means the works specified in Schedule Part 6.

## **2. INTERPRETATIONS**

2.1 In this Agreement, unless there is something in the subject or context inconsistent therewith:-

2.1.1 words importing the masculine include the feminine and words importing the neuter include the masculine and feminine; and

2.1.2 words importing the singular include the plural and vice versa.

2.2 Any reference to an Act of Parliament includes any modification, extension or re-enactment thereof for the time being in force.

2.3 Headings are included in this Agreement for ease of reference only and shall not affect the interpretation or construction of this Agreement.

2.4 References to Clauses, and to the Schedule are, unless otherwise provided, references to clauses of, and the schedule to, this Agreement.

2.5 In the event and to the extent only of any conflict between the Clauses and the Schedule, the Clauses shall prevail. In the event of any inconsistency between the Specification and the other parts of the Schedule, the other parts of the Schedule will prevail over the Specification.

2.6 Where an obligation is expressed hereunder as being performed by a Third Party Supplier the Contractor shall procure performance of such Third Party Supplier obligation

by the Third Party Supplier in question, failing which it shall perform such obligation itself. The Contractor shall be liable for any failure or omission in the discharge of any and all obligations expressed as to be performed by a Third Party Supplier.

### **3. CO-OPERATION, LIAISON AND DUE DILIGENCE**

3.1 The Contractor agrees to co-operate and liaise, at its own expense, with other contractors to the Board as necessary to ensure successful performance of this Agreement and delivery, by any of the Board's other contractors, of their obligations to the Board.

3.2 The Contractor acknowledges that it has had an opportunity to carry out a thorough due diligence exercise in relation to its obligations under this Agreement, including in relation to the specific requirements of each Site, and has received all information required by it in order to determine whether:-

3.2.1 it is able to deliver the Managed Services in accordance with the terms of this Agreement; and

3.2.2 the Sites, and all aspects of the Board's operations, including its IT configuration, existing equipment, networks, and operating practices, are suitable for the delivery, installation and operation of all Components of the Solution and the provision and effective delivery and enjoyment by the Board of the Managed Services.

3.3 The Contractor acknowledges that, as of the Commencement Date, the Board has not unreasonably denied access to any information in response to a request by the Contractor to enable it to carry out its due diligence. Any issues which the Contractor considers may impact on the Board's enjoyment of the Managed Services, (or the cost, quality, quantity or type thereof) must have been notified by the Contractor, in writing, to the Board prior to the date of signature of this Agreement.

3.4 The Contractor acknowledges that it is not entitled to recover any additional costs from the Board which arise from, or be relieved from any of its obligations as a result of, any

change to any aspect of the matters related to the due diligence exercise, or information received as a result thereof. Without prejudice to the foregoing, each party shall notify the other in writing of any such changes of which it becomes aware during the performance of this Agreement and the Contractor shall in particular advise the Board of any such change which affects its ability to perform the Managed Services or meet any Service Levels. To avoid doubt this shall not include any Change which must be addressed through the Change Control Procedure.

3.5 Save as provided in this Agreement, no representations, warranties, conditions or other terms, express or implied, statutory or otherwise, as to condition, quality, satisfactory quality, performance or fitness for purpose are given or assumed by the Board and all those representations, warranties and conditions are excluded, save to the extent that any exclusion is prohibited by law.

3.6 The Board shall be liable to the Contractor only in respect of any provision to the Contractor of any information, documents or data which is incorrect.

#### **4. IMPLEMENTATION AND ACCEPTANCE**

4.1 The Contractor and the Board will, within thirty (30) days of the Commencement Date, or such longer date as they agree, discuss and agree the Detailed Implementation Plan.

4.2 The Contractor recognises that the Implementation Services require to be performed in a live hospital environment and, as such, the Board may from time to time be unable to timeously comply with any requirements upon it under the Implementation Plan or Detailed Implementation Plan (as the case may be). The Board may also require that the Implementation Plan and/or the Detailed Implementation Plan be changed, and in such an event the Parties shall agree and effect such Changes in accordance with the Change Control Procedure. No additional charges shall be applied by the Contractor as a result of any delay in the Implementation Plan or Detailed Implementation Plan (as the case may be), or arising out of any such Change. Any delay on the part of the Board to comply with any requirements upon it under the Implementation Plan or Detailed

Implementation Plan (as the case may be) shall not be considered to be a breach of this Agreement but shall, insofar as it causes a delay on the part of the Contractor to perform any obligations incumbent upon the Contractor under the Implementation Plan or Detailed Implementation Plan (as the case may be), result in an extension of the time permitted to the Contractor to perform such obligations equivalent to the length of the Board's delay, pending an appropriate Change to the Implementation Plan or Detailed Implementation Plan (as the case may be) being formally effected.

- 4.3 Subject to the foregoing provisions the Contractor shall perform the Implementation Services as required under this Agreement for the delivery, installation, commissioning, testing and Acceptance of all relevant Components of the Solution, and all relevant Reagents and Consumables at each Site, and provide any necessary training to enable use and full and proper enjoyment of all Components of the Solution and Reagents/Consumables, by the Board at the Site, in accordance with the Implementation Plan (and, once agreed, the Detailed Implementation Plan).
- 4.4 All documentation and/or systems which require to be supplied, implemented or effected to enable full enjoyment of the Managed Services by the Board and/or full use by it of the Solution and Reagents/Consumables at each Site shall be supplied, implemented and/or effected as necessary by the Contractor.
- 4.5 The Contractor shall be responsible, in collaboration with the Board, for preparing each Site prior to delivery of any Component of the Solution to the appropriate Site, and shall provide any labour, material and plant required (in accordance with the Implementation Plan, once agreed, the Detailed Implementation Plan and the Specification) for the delivery, off-loading, positioning, installation and commissioning, and testing, at each Site, of all Components of the Solution, and for any further work required to achieve Milestone Acceptance in respect of each Milestone.
- 4.6 Work in respect of Implementation Services shall commence on the date specified in the Implementation Plan or, once agreed, the Detailed Implementation Plan in respect of each Milestone, or on such other date as is specified by the Board. The Contractor shall

contact the Board at least five (5) Working Days prior to commencement of Implementation Services at each Site to confirm arrangements.

- 4.7 The Contractor shall, at its own expense, promptly remove from the Site any packaging used for all Components of the Solution and dispose of the same in an environmentally sympathetic manner.
- 4.8 Satisfactory completion of each Milestone must be Accepted by the Board by the dates specified in the Implementation Plan or, once agreed, the Detailed Implementation Plan for such Milestone Acceptance to occur.
- 4.9 If any Milestone Acceptance has not occurred prior to the relevant date when such Milestone Acceptance is scheduled to occur (as stated in the Implementation Plan or, once agreed, the Detailed Implementation Plan) then the provisions of Schedule Part Seven (7) shall apply in relation to failure to achieve such Acceptance by the required date.
- 4.10 If only one instance of certain Equipment types and models are to be provided as part of the Solution, then for those types and models of Equipment ("**Unique Equipment**"), the provisions of Clauses 4.13 to 4.22 below shall apply. For all other Equipment ("**Replicated Equipment**"), the provisions of Clauses 4.12 to 4.22 shall apply.
- 4.11 For each Replicated Equipment type and model the Contractor shall, following its delivery and installation at the first Site where such Replicated Equipment is to be used, undertake Gold Standard testing with the Board by reference to the Acceptance Checklists. Such Gold Standard testing shall be used to determine that the Replicated Equipment in question performs in accordance with the Specification, and that all results are within a range that is acceptable to the Board and such results acceptable to the Board. Once agreed the results of the Gold Standard testing will be known as the "**Gold Standard Results**".

## **Equipment Acceptance**

- 4.12 When requested to do so by the Board the Contractor shall complete its Acceptance

Checklists in respect of a particular item of Equipment, and provide these to the Board. The Board will then undertake its own Acceptance Testing in respect of the relevant item of Equipment. The Board shall be entitled to check any claims made by the Contractor in its Acceptance Checklists. In testing the performance of any Replicated Equipment, the Board shall have regard only to the Gold Standard Results. For each Unique Equipment type and model the Board shall be entitled to test the Unique Equipment to determine that it performs in accordance with the Specification, and that all results are within a range that is acceptable to the Board.

- 4.13 If the Board is satisfied in all respects, having regard to the Acceptance Checklists and the results of the tests it performs on the Equipment, that the Instrument performs in all respects in accordance with the Specification (or Gold Standard Results as the case may be), it shall confirm that in writing to the Contractor and Acceptance in respect of such item of Equipment shall be deemed to have occurred on the date of issue of such written notice.
- 4.14 If the Board (acting reasonably), having regard to the Acceptance Checklists and the results of the tests it performs on the Equipment, is not satisfied that the Equipment performs in all respects in accordance with the Specification (or Gold Standard Results as the case may be), it shall notify the Contractor in writing and invite the Contractor to remedy any issues or deficiencies identified. The Contractor shall forthwith rectify such identified issues or deficiencies and shall again invite the Board to undertake Acceptance on the Equipment.
- 4.15 Prior to the date on which Milestone Acceptance of any part of the Implementation Plan (or, once agreed, the Detailed Implementation Plan) is due to occur in accordance with the Implementation Plan, the Contractor shall complete the Acceptance Checklists, and provide these to the Board. The Board will then undertake its acceptance procedures in respect of the relevant Implementation Services and Components of the Solution covered by such part of the Implementation Plan or Detailed Implementation Plan as the case may be. The Board shall be entitled to check any claims made by the Contractor in

its Acceptance Checklists. In testing the performance of any Replicated Equipment, the Board shall have regard only to the Gold Standard Results. For each Unique Equipment type and model the Board shall be entitled to test the Unique Equipment to determine that it performs in accordance with the Specification, and that all results are within a range that is acceptable to the Board. The Board shall have twenty (20) Working Days to carry out such testing (“**Board Testing Period**”).

- 4.16 If the Board is satisfied in all respects, having regard to the Acceptance Checklists and the results of the tests it performs on the Solution, that all relevant Components of the Solution, and Reagents and Consumables at a Site perform in all respects in accordance with the Specification (or Gold Standard Results as the case may be), and that the relevant stage of the Implementation Plan or Detailed Implementation Plan as the case may be has been successfully completed in all respects, it shall issue an Acceptance Certificate to the Contractor within the Board Testing Period, and Milestone Acceptance in respect of such part of the Implementation Plan or Detailed Implementation Plan as the case may be and the relevant Milestone shall be deemed to have occurred on the date of issue of such Acceptance Certificate.
- 4.17 If the Board (acting reasonably), having regard to the Acceptance Checklists and the results of the tests it performs on the Solution, is not satisfied in any respect that all relevant Components of the Solution and Reagents and/or Consumables perform in all respects in accordance with the Specification (or Gold Standard Results as the case may be), and/or considers that the relevant stage of the Implementation Plan or Detailed Implementation Plan as the case may be has not been properly and fully complied with, within the Board Testing Period it shall notify the Contractor in writing and invite the Contractor to remedy any issues or deficiencies identified. The Contractor shall forthwith rectify such identified issues or deficiencies and shall again invite the Board to undertake the Acceptance Procedure.
- 4.18 If the Board does not notify the Contractor in writing pursuant to Clause 4.17 above, then within the Board Testing Period it shall be deemed to have accepted such part of the

Implementation Plan or Detailed Implementation Plan as the case may be. Milestone Acceptance in respect of the relevant Milestone shall be deemed to have occurred on the date of expiry of the Board Testing Period.

- 4.19 The provisions of Clauses 4.16 and 4.17 shall, without prejudice to the application of the provisions of Schedule Part 7 (L&A Damages) and Clause 21 (Termination), be reapplied and continue to apply and be so reapplied until the Board is satisfied in all respects that all relevant Components of the Solution and Reagents/Consumables perform in all respects in accordance with the Specification, that the Implementation Plan or Detailed Implementation Plan as the case may be (or relevant Milestone thereof) has been complied with, and Milestone Acceptance achieved. The Contractor agrees that the Board may elect to use certain items of Equipment notwithstanding that Milestone Acceptance in respect of the relevant Milestone may not have occurred. The Contractor agrees that the Board shall be entitled to do so, and that such use will not give rise to Milestone Acceptance (or deemed Milestone Acceptance) in whole or in part.
- 4.20 Once the Board has confirmed to the Contractor that the final Milestone has been successfully completed and Accepted (or, pursuant to Clause 4.13, Milestone Acceptance has been deemed to occur), Final Acceptance shall be considered to have occurred.
- 4.21 Any dispute arising between the parties in relation to the Acceptance Procedure shall be dealt with under the Dispute Resolution Procedure.
- 4.22 The Board and the Contractor will establish an implementation project group ("**Implementation Group**") which meets regularly to agree the details of implementation and to monitor progress in relation to the performance of the Implementation Services. The parties may by agreement vary the Implementation Plan or Detailed Implementation Plan as the case may be in which event any variations so agreed shall be deemed to vary this Agreement with effect from the date of their written agreement.

## 5. THE PRE-INSTALLATION WORKS AND STANDARDS

- 5.1 No later than eight (8) weeks in advance of its proposed commencement of the Works, the Contractor shall provide to the Board a copy of the building contract or contracts which it proposes to enter into in relation to the Works. The Board shall have a period of four (4) weeks to comment on the proposed building contract. In the event that the Board wishes changes to be made to the said building contract it shall advise the Contractor accordingly. The Contractor shall not commence or instruct commencement of the Works without receipt of the Board's written consent to the terms of the building contract to be entered into by the Contractor in relation thereto. Notwithstanding the foregoing, the Contractor shall remain wholly responsible for the design and implementation of the Works.
- 5.2 The Board shall be responsible for appointment of a Principal Designer under the Construction (Design and Management) Regulations 2015 ("**CDM Regulations**") and such Principal Designer shall perform all obligations incumbent upon him as detailed in the Regulations. Notwithstanding the foregoing, in undertaking the Works and installation of any Equipment the Contractor shall comply with the CDM Regulations and, without prejudice to the foregoing generality, the Contractor shall:-
- (a) assume the role of Principal Designer;
  - (b) product Risk Assessments; and
  - (c) undertake Site Induction;
- as all such terms are defined in such CDM Regulations.
- 5.3 The Contractor shall provide notification to the Health and Safety Executive in respect of the Works.
- 5.4 For the purposes of the CDM Regulations, "**Practical Completion**" shall be deemed to occur at successful completion of the Acceptance Procedure.
- 5.5 The Contractor shall, at its sole expense, undertake the pre-installation works in

Specification and the provisions in Schedule Part 6.

- 5.6 The Contractor shall undertake the Works in accordance with any standards notified to the Contractor by the Board.
- 5.7 Any disputes in relation thereto shall be referred to the Dispute Resolution Procedure.
- 5.8 If the Works are delayed at the request of the Contractor, the Contractor shall be liable to the Board for any reasonable costs that the Board can demonstrate it incurred as a direct result of such delay.

## **6. MANAGED SERVICES PROVISION – GENERAL**

- 6.1 The Contractor will provide the Managed Services in accordance with the Specification and this Agreement. Without limitation to the Contractor's obligation to provide the Managed Services and otherwise to comply with the Specification, the Contractor will, in accordance with the Specification and this Agreement:-
  - 6.1.1 undertake all work required to prepare the Site in accordance with the Implementation Plan and the Specification;
  - 6.1.2 procure, deliver, install, commission, maintain and repair all Components of the Solution;
  - 6.1.3 procure and deliver the Reagents and Consumables, as required by the Board, and provide inventory management and stock audit services utilising an Automated Reagent Inventory Management System to ensure an adequate supply of all Reagents and Consumables is maintained at the Sites at all times during the period of this Agreement, bearing in mind the use requirements of the Board for each Site;
  - 6.1.4 commence provision of all Managed Services relating to each System from the Milestone Go Live date in respect thereof;
  - 6.1.5 ensure compliance with the Service Levels and Performance Specifications at all times;

- 6.1.6 ensure all Components of the Solution are regularly upgraded to ensure continuity of performance and availability (including, where necessary, software, middleware, and hardware upgrades);
  - 6.1.7 provide an online diagnostic service which transmits analytical, operational but not patient data automatically to service support enabling proactive problem solving in respect of the Equipment and the Solution Management Systems;
  - 6.1.8 provide training and educational services, consultancy and design services as detailed in the Specification; and
  - 6.1.9 complete and maintain Code of Connection throughout the Term.
- 6.2 All statements and representations made to the Board in connection with this Agreement, including the Contractor's representations that the Solution, as at the Commencement Date and thereafter throughout the Term, shall conform to the drawings and/or plans submitted by the Contractor as part of its response to the Invitation to Tender, are to the best of its knowledge and belief, true and accurate and that it will advise the Board of any fact, matter or circumstance of which it may become aware which would render any such statement or representation to be false or misleading.
- 6.3 Notwithstanding any rule of law to the contrary the Board shall be entitled (without being required to resile from or rescind this Agreement) to claim damages from the Contractor in respect of any breach of the undertaking specified in Clause 6.1 and 6.2 subject to the limits of liability and exclusions contained in Clause 20.2 (Limits of Liability)
- 6.4 The Contractor's account management team together with the Contractor Facility Manager will track and communicate to the Board laboratory personnel the performance of the Managed Services including Reagent development and supply, Equipment development and maintenance, and Consumables variability, and will ensure regular and open communication with relevant Board personnel to maximise the quality and consistency of the services provided by the Contractor to the Board.
- 6.5 The Contractor will, on request by the Board, provide additional services in relation to

such matters as the Board may elect and which are not otherwise provided as part of the Managed Services, such services to be provided in consideration of the Contractor's quoted daily rate for such services, as detailed in the Specification or as charged to the Contractor's other equivalent customers, whichever is the lower.

6.6 The Contractor shall comply with the Legal Requirements in the performance of its obligations under this Agreement. The Contractor shall, at its cost, take all steps necessary to ensure that its obligations continue to be performed in accordance with the terms of this Agreement following any change in the Legal Requirements.

6.7 All Intellectual Property Rights (including without limitation copyright) in any deliverables arising from the performance of services as referred to above and all Intellectual Property Rights arising (i) from the Processes performed utilising any part of the Solution and/or Reagents/Consumables; and (ii) in relation to the service level reports, and other reports prepared by the Contractor hereunder, shall be owned by the Board. All Intellectual Property Rights in and relating to Board Data including Board Data contained within an item of the Solution is and shall remain the property of the Board.

6.8 The provisions of the Financial Schedule will be adhered to by the Board and by the Contractor.

## **7. THE SOLUTION**

7.1 The Board shall perform the Board Responsibilities.

7.2 The Contractor shall adhere to all requirements specified in the Implementation Plan (or detailed Implementation Plan, as appropriate) including those in relation to:-

7.2.1 the timing and order of installation and commissioning of each part of the Solution;

7.2.2 the required locations for each Component comprising the Solution to be installed at the Site, and any physical constraints and/or network, interface or system compatibility issues relating to each Site;

7.2.3 any methodology requirements to be adhered to in connection with the

Implementation Services, as detailed in the Implementation Plan (or Detailed Implementation Plan, as appropriate); and

7.2.4 building works, including, without limitation, making good all finishes to walls, ceilings and floors.

7.3 Other than in respect of Equipment which by its nature is moveable, the Board agrees not to move, remove or alter any item of Equipment which have been installed, without the written permission of the Contractor, unless the Contractor commits a material breach of this Agreement, or the Agreement is terminated or expires, or if safety or operational reasons require.

7.4 The Board may require the Contractor to change any aspects of the Managed Services, and such changes shall be effected, and charged for (if appropriate) in accordance with the Change Control Procedure. The Board may, at its option, require that the location and/or any aspect (including the size) of the Sites be changed and/or supplemented and may also require the addition of further or alternative premises and/or further or alternative locations at the existing Sites.

7.5 Once all Implementation Services have been completed, including for the avoidance of doubt all Implementation Services relating to planned re-configurations of the Board's service (as detailed in the ITT), the Board will meet all subsequent and previously non-disclosed reasonable and pre-approved associated costs related to the movement of Equipment and IT connectivity and/or connectivity of Equipment, to any alternative or additional sites, such costs to be calculated on the basis of the rates specified in the Specification or the Contractor's then current daily rates for such services, whichever is the lowest.

7.6 The Contractor warrants and undertakes that the all Components of the Solution:-

7.6.1 shall be fully compatible with, and capable of seamlessly interfacing and operating with, the Board's existing equipment and systems, and shall be compliant with the requirements of the Specification;

- 7.6.2 are able to support, and to be operated in accordance with, the processes and data management and IT mechanisms otherwise employed by the Board including without limitation SCCRS;
- 7.6.3 will operate on the basis of a common platform and produce uniform results capable of being sent between the Sites and capable of being read, stored and otherwise used across all sites of the Board; and
- 7.6.4 will be able to be safely accommodated and operated to the levels detailed in the Specification in the area designated by the Board at each Site.
- 7.7 The Contractor warrants and undertakes that all Components of the Solution specified in the Specification shall be capable of operating in the manner detailed in the Specification, and with the hardware and other system requirements detailed in the Specification and in accordance with the Service Levels.
- 7.8 All operating and environmental requirements specifically required to enable optimal operation of the Solution and Reagents/Consumables, including without limitation water quality/volume/pressure requirements, air temperature, operating space, and electrical supply availability, are detailed in Schedule Part 5 as “**Environmental Requirements**”. The Contractor confirms that, as the Commencement Date, each Site is able to meet the Environmental Requirements.
- 7.9 The Board may measure the performance of the Equipment to ascertain, over any period of time it selects and notifies to the Contractor, if it is (individually and collectively) performing in accordance with the Service Levels. In the event that any one or more items of Equipment are, in terms of the Board’s measurements (which the Contractor will be entitled to inspect and verify), not performing in accordance with the Service Levels in two or more Quarterly Periods, the Contractor undertakes to forthwith replace the relevant items of Equipment with equivalent items of Equipment which can meet the relevant Service Levels.
- 7.10 The parties agree and understand that the Board will have no legal title to or ownership

rights in respect of any Component of the Solution or the Reagents/Consumables.

7.11 The Contractor warrants that throughout the term of this Agreement:

7.11.1 it is and will remain the legal and beneficial owner of the Contractor's Equipment and (if supplied directly by the Contractor) all other Components of the Solution; and

7.11.2 all Third Party Suppliers providing any Component of the Solution to the Board are and will remain the legal and beneficial owners of, and retain title to, any such equipment.

7.12 All risk of loss or damage to any Component part of the Solution and to Reagents/Consumables shall be borne by the Contractor excepting loss and damage to any Component part of the Solution caused by any wilful, deliberate or reckless act of the Board, which shall be borne by the Board subject always to the limit of liability in Clause 20.2.

7.13 Upon the proper termination or expiry of this Agreement the Contractor shall, within twenty (20) Working Days following the date of termination, and subject to prior compliance with the provisions of Clause 21.13, and to the exercise by the Board of the option detailed in Clause 21.13.1(vii), remove all Components of the Solution from the Sites.

## **8. CONTRACTOR PERSONNEL**

8.1 The Contractor must employ and/or engage sufficient appropriately trained and qualified staff to ensure that its obligations are discharged at all times and in all respects in accordance with the Specification. The Contractor must ensure that a sufficient reserve of staff is available to perform its obligations in accordance with the Specification during holidays or absences.

8.2 The Contractor must employ for the purposes of this Agreement only such persons as are careful, skilled and experienced in the duties required of them, and must ensure that every such person is properly and sufficiently trained and instructed, and carries out the

Contractor's obligation hereunder with regard to:-

- 8.2.1 the task that person has to perform;
- 8.2.2 all relevant provisions of the Agreement;
- 8.2.3 all relevant rules, policies, procedures and standards of the Board and the requirements of the Specification;
- 8.2.4 fire risks and fire precautions and security (both in respect of the Board's data and each Site(s));
- 8.2.5 the need for those working in and for the National Health Service to observe the highest standards of hygiene, courtesy and consideration;
- 8.2.6 the requirements of the Health and Safety at Work Act 1974; and
- 8.2.7 the requirements of all other relevant legislation and codes of practice relevant and applicable to each and every Component of the Managed Services, including without limitation operational codes and any other guidance published by the Medicines and Healthcare Products Regulatory Agency.

8.3 The Contractor must ensure its staff and all others engaged by it to perform the Managed Services wear a visitor's badge, which clearly shows the organisation which they work for, at all times when they are on the Board's premises.

8.4 In selecting staff for consideration for employment and in employing its staff, the Contractor shall, and shall procure that the Third Party Suppliers shall:-

- 8.4.1 advise staff that they are subject to the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975;
- 8.4.2 not engage staff under the age of 18 years in the provision of the Managed Services;
- 8.4.3 ensure that it complies with the Board's duties as an equal opportunities employer; and

8.4.4 procure that all relevant staff satisfactorily complete all documentation,

processes and vetting required by the Board including an appropriate Disclosure Scotland vetting process.

- 8.5 Save as expressly provided in this Agreement, the Contractor shall be entirely responsible for the employment and conditions of service of the Contractor's staff, and those of any Third Party Suppliers. The Contractor undertakes to ensure that neither its nor the Third Party Suppliers' staff are considered, by operation of law or otherwise, to be employees of the Board, and undertakes to indemnify the Board in respect of any losses, claims or expenses arising as a result of such staff being so considered.
- 8.6 The Board may at any time during the Term by issuing written instruction to the Contractor, and provided it is able to identify an incident or an aspect of the relevant individual or their performance which the Board reasonably considers justifies such a step, including without limitation any failure in respect of the requirements of Clause 8.4.4, require the Contractor to immediately:-
- 8.6.1 remove or procure the removal of any Unsuitable Person from a Site; or
- 8.6.2 procure that no Unsuitable Person is employed or engaged directly or indirectly by the Contractor in the provision of any part of the Managed Services.
- 8.7 The Contractor shall procure that it maintains its own personnel policies and procedures covering all such matters as the Board acting reasonably may from time to time direct (which shall include but not be limited to discipline, grievance, equal opportunities and health and safety). The Contractor shall procure that the terms and the implementation of such policies and procedures comply with the law and good practice and that they are published in written form and that copies of them (and any revisions and amendments to them) are forthwith issued to the Board.
- 8.8 The Contractor must ensure that those individuals engaged by it in connection with the Managed Services do not smoke on the Board's premises.
- 8.9 The Contractor shall not, and shall procure that Third Party Suppliers shall not, at any time during the Term or during the period of six (6) months after its expiry or earlier

termination, actively solicit any employee of the Board unless the Board has given its consent to such employee accepting employment with the Contractor.

## **9. PERFORMANCE RECTIFICATION**

9.1 Each of the Board and the Contractor will nominate a Business Co-ordinator, and advise the other of their name and contact details. The Board's Business Co-ordinator and the Contractor's Business Co-ordinator shall meet together at regular intervals to be agreed (and not less than once in each month) to review and minute overall progress, resolve difficulties and discuss other matters in connection with the Implementation Plan (or Detailed Implementation Plan, once agreed) and provision of the Managed Services.

9.2 The Contractor shall provide the Board with a written report, on a monthly basis, prior to Final Acceptance and in respect of each Quarter thereafter giving details of:-

9.2.1 (prior to Final Acceptance) progress in relation to the Implementation Plan (or Detailed Implementation Plan, once agreed);

9.2.2 any problems encountered in the provision of the Managed Services; and

9.2.3 any failure to meet the Service Levels during the relevant period.

9.3 The Contractor shall report to the Board in writing on a quarterly basis particulars of its performance in respect of all Managed Services including any delay, failure or interruption of performance (by reference to the Service Levels, or otherwise).

9.4 Without prejudice to the rights and remedies of the Board, if at any time the Contractor fails to perform its obligations set out in this Agreement, including without limitation failing to provide the Managed Services in accordance with the Service Levels:

9.4.1 the Contractor shall within seven (7) days of the earlier of (1) the date upon which it becomes aware of the failure; or (2) receipt of notice of the failure from the Board advise the Board in writing of the failure and of the steps that the Contractor shall take to address the failure;

9.4.2 at no additional charge to the Board, the Board may require the Contractor to (a)

re-perform the aspect of the Managed Services in relation to which there was a failure to perform; and (b) as soon as practicable, arrange all additional resources as reasonably necessary to perform its obligations set out in this Agreement in accordance with the Service Levels (including where necessary substituting or supplementing items of Equipment with alternative or additional items with a greater capacity), and to ensure that the failure does not recur at any time and to provide to the Board a plan setting out how the Contractor intends to fulfil this obligation.

9.5 Without prejudice to the other rights or remedies of the Board under this Agreement, if at any time:

9.5.1 the Contractor has committed any breach of its obligations under this Agreement;

9.5.2 more than four hundred (400) Service Points have been accrued for any Solution in a Quarterly Period; and/or

9.5.3 where in a Quarterly Period a single Component is the cause of twenty five percent (25%) or more of System Downtime;

then (without prejudice to its other rights and remedies hereunder and at law) the Board may, but is not obliged to, give written notice (a “**Warning Notice**”) to the Contractor setting out the matter or matters giving rise to such notice and containing a reminder to the Contractor of the implications of such notice. Any such notice shall state on its face that it is a Warning Notice.

9.6 Without prejudice to the other rights or remedies of the Board, if the Contractor receives a Warning Notice the Board may, by written notice to the Contractor, reasonably increase the level of its monitoring of the Contractor’s performance of its obligations under this Agreement, in respect of the Managed Services (or relevant part thereof) to which the Warning Notice relates, until such time as the Contractor shall have demonstrated to the reasonable satisfaction of the Board that it will perform (and is

capable of performing) its obligations under this Agreement.

9.7 If at any time the Contractor is in breach of its obligations under this Agreement such that any element of the Managed Services has become materially unfit for purpose and/or the Contractor cannot deliver that element of the Managed Services, and this has a material adverse impact on the Board's operations (a "**Fundamental Failure**"), the Board may, without prejudice to the other rights or remedies of the Board, by written notice to the Contractor, require the Contractor to put forward within two (2) Working Days of such notice a reasonable programme for remedying the Fundamental Failure and ensuring that the relevant element of the Managed Services is restored to a condition that makes it fit for purpose in compliance with the Specification. The programme shall specify in reasonable detail both the manner in which the Contractor proposes to remedy the Fundamental Failure and the date by which the Contractor proposes to remedy the Fundamental Failure.

9.8 Where the Contractor puts forward a programme in accordance with Clause 9.7, the Board shall have ten (10) Working Days from receipt of the same within which to notify the Contractor (acting reasonably) that it does not accept the programme, failing which the Board shall be deemed to have accepted the programme. Where the Board notifies the Contractor that it does not accept the programme as being reasonable, the parties shall endeavour within the following three (3) Working Days to agree any necessary amendments to the programme put forward. In the absence of agreement within that three (3) Working Day period, the question of whether the programme (as the same may have been amended by agreement) will remedy the Fundamental Failure in a reasonable manner and within a reasonable time period (and, if not, what would be a reasonable programme) may be referred to either party for resolution in accordance with the Dispute Resolution Procedure.

9.9 If:

9.9.1 the Contractor puts forward a programme pursuant to Clause 9.7 which has been accepted or is deemed to be accepted by the Board or has been

determined to be reasonable and the Contractor fails to achieve any element of the programme or remedy the Fundamental Failure by the end date of the programme (as the case may be); or

9.9.2 any programme put forward by the Contractor pursuant to Clause 9.7 is rejected by the Board as not being reasonable, and, if referred to the Dispute Resolution Procedure, a finding against the rejection is not made,

then, without prejudice to Clause 20 (Indemnification, Liability and Insurance), the Contractor shall reimburse the Board a sum equal to the Charges the Board has paid, or (as appropriate) shall waive any charges the Board had been due to pay to the Contractor in respect of the Managed Services in respect of which there has been a failure to perform, since the date of the failure of the Managed Services (which date shall, if disputed by the Contractor, be resolved in accordance with the Dispute Resolution Procedure).

9.10 Where a single Component is the cause of twenty five or more percent (25%) of System Downtime in a Quarterly Period the Contractor shall replace such Component within thirty (30) Working Days.

9.11 The provisions of this Clause 9 shall be without prejudice to any other rights or remedies of the Board including the Board's rights to recover loss not compensated for by way of payments made in accordance with Clause 9.9 above.

## **10. THIRD PARTY SUPPLIER DEFAULT**

10.1 If a Third Party Supplier acts or fails to act in such a way that it results in a breach by the Contractor of this Agreement in respect of the element of the Managed Services provided by such Third Party Supplier the Board shall, without prejudice to its remedies under this Agreement, be entitled to require that the Contractor change such Third Party Supplier within a time period acceptable to the Board following the Board providing notice to that effect, and the Contractor shall ensure that its contracts with each Third Party Supplier allow it the requisite flexibility to do so. All costs associated with removing

from the Sites any Component(s) of the Solution in these circumstances, and to making good any damage caused thereby, and all costs relating to discontinuing use of affected Reagents/Consumables, loss of utility of such Reagents/Consumables or any Component of the Solution, retraining, and Direct Costs, and costs or losses otherwise suffered or incurred by the Board, will be met by the Contractor.

10.2 In the event that a Third Party Supplier suffers any of the events referred to at Clause 21.2.1, and without prejudice to the Board's rights hereunder, the Contractor shall be required to forthwith source an alternative third party satisfactory to the Board to provide equivalent services, Reagents/Consumables and/or any Component parts of the Solution as had been provided by the Third Party Supplier in question. All costs associated with removing any Component parts of the Solution from any or both Sites in these circumstances (including the cost of extracting all Board Data therefrom), and to making good any damage caused thereby, and all costs relating to discontinuing use of affected Reagents/Consumables, loss of utility of such Reagents/Consumables and/or other Component parts of the Solution, retraining and Direct Costs, and costs or losses otherwise suffered or incurred by the Board, will be met by the Contractor.

10.3 The Contractor guarantees that replacement of any Third Party Supplier in accordance with Clause 10.2 shall not result in any increase in the charges payable by the Board in accordance with the Financial Schedule and will be at a cost to the Board which is no greater than the relevant aspects of the Managed Services provided by the previous Third Party Supplier. If the Contractor is not able to source and procure the relevant aspects of the Managed Services (and alternative Reagents/Consumables and/or any Components of the Solution as the case may be) acceptable to the Board within a timescale acceptable to the Board then the Board may without prejudice to its remedies otherwise under this Agreement, at the Contractor's cost, source its own services, instruments, and/or products (as the case may be) and the Contractor shall, subject to the limit of liability in Clause 20.2, indemnify and hold the Board harmless against, and reimburse the Board on demand in respect of, any expenses, liabilities, damages, costs

(including legal costs) and claims arising out of such circumstances including, without limitation, Direct Costs.

- 10.4 For the avoidance of doubt, the Contractor may not discontinue the provision to the Board of a Consumable/Reagent or any Component of the Solution provided by a Third Party Supplier, and/or its arrangements with any Third Party Supplier, other than in the circumstances referred to at Clauses 10.2 and 10.3 above, or with the prior written agreement of the Board.

## **11. PRODUCT QUALITY AND QUALITY ASSURANCE**

### **11.1 Manufacture**

11.1.1 The Contractor shall manufacture and/or supply the Reagents to be supplied as part of the Managed Service in accordance with (i) the Specification; (ii) the Reagent Specifications; and (iii) the applicable Quality Systems and cGMP Requirements. The Contractor agrees to comply with all of the applicable requirements of the Regulations and all Legal Requirements and undertakes to ensure that manufacture of the Reagents is in conformity in all material respects with the applicable requirements of the Regulations and all Legal Requirements.

11.1.2 The Parties shall have the following responsibilities with respect to the Regulations:

- (i) the Contractor shall provide the Board (if requested) with a copy of the “Certificate of Compliance” and “Declaration of Conformity” for the Reagents;
- (ii) the Contractor shall be responsible for ensuring that the Reagents meet the essential requirements of the Regulations and comply with the “Declarations of Conformity”;
- (iii) the Contractor shall be responsible for the design and content of the labelling, including the CE mark, and for the conformity of the packaging of

the Reagents with the Regulations;

- (iv) if either Party receives a complaint from any Competent Authority in relation to any of the Reagents supplied to the Board, the relevant Party will immediately inform the other Party. The Contractor shall have the responsibility of corresponding with the Competent Authority and the Contractor will procure and ensure that such correspondence takes place. The Contractor shall, and shall (if appropriate) procure that the relevant Third Party Supplier affected shall, report all Serious Incidents relating to the Reagents to the relevant Competent Authority.

#### 11.2 Shelf Life and Stability

Reagents supplied to the Board shall have a shelf-life of at least a similar term to substantially similar products supplied by the Contractor to other laboratories in the United Kingdom, or six months, whichever is the longer. Where required by the Board, the Contractor shall provide or procure the provision of data and information to the Board to demonstrate compliance with claimed stability specification.

#### 11.3 Reagents to be supplied as part of the Managed Service

All Reagents and other goods supplied in the course of provision of the Managed Services that customarily bear any mark, tab, brand, label or other device indicating place of origin, inspection by any government or other body or standard of quality must be delivered with all the said marks, tabs, brands, labels or other devices intact.

#### 11.4 Inventory Management

11.4.1 Where requested by the Board (acting reasonably), the Contractor will agree to hold sufficient quantities of a single batch of any Reagent to ensure consistency of supply for at least six (6) months, and will allow the Board to perform confirmatory testing to ensure continuity of results;

11.4.2 Reagents will be ordered through an agreed mechanism established with the Contractor, the principal elements of which are set out below.

11.4.3 The Contractor will manage and take responsibility for all aspects of Reagent ordering and supply and the Board will not be required to have contact with Third Party Suppliers for ordering purposes other than in exceptional circumstances. An Automated Reagent Inventory and Management System will be provided and maintained by the Contractor.

11.4.4 The Automated Reagent Inventory Management System will provide the Board with the following functionalities:

- (i) It will hold a complete catalogue of Reagents supplied to the Board, both those of the Contractor and all Third Party Suppliers;
- (ii) It will provide a stock management function i.e. optimum stock levels with re-ordering triggers providing the basis for electronic purchase orders;
- (iii) A checking mechanism that randomly selects, from the full catalogue of Reagents, a number of products for checking on a weekly basis. This should randomly select 1/52 of the total stock holding every week and should enable the entire Reagent catalogue to be checked over the course of a year. This functionality must facilitate continuous stock checking and must negate the requirement for a full inventory check.

## 11.5 Packaging

11.5.1 The Contractor shall ensure that Reagents shall be securely packed in trade packages of a type normally used for commercial deliveries of the same or similar goods either in retail or in bulk quantities within the United Kingdom.

11.5.2 The Contractor shall ensure that the following details shall be shown on the outside of every package unless otherwise specified in this Agreement:

- (i) a description of the goods;
- (ii) the quantity in the package;

- (iii) any special directions for storage and the expiry date of the contents (where applicable);
- (iv) the batch number;
- (v) the name of the manufacturer; and
- (vi) container and pallet details.

#### 11.6 Reagent Issues

The Contractor shall immediately notify the Board of any Reagent failure, manufacturing or delivery problems, or similar issues that may, to the Contractor's knowledge, impact upon the Contractor's ability to supply the Managed Services to the Board. Within three (3) Working Days following notice from the Contractor that a technical problem has developed with a Reagent, the Contractor shall provide a detailed written response to the Board outlining a plan to resolve the problem in a manner satisfactory to the Board. Notwithstanding the foregoing if the problem identified results in the Reagent or Reagents in question being unavailable for use by the Board at either Site, the provisions of Schedule Part 11 shall apply.

#### 11.7 Reagent Recall – Single Batch

11.7.1 In the event of a recall by the Contractor of a particular batch of any Reagent (other than for regulatory reasons), and without prejudice to the application of Service Deductions, which may apply in respect of the non-availability of any aspect of the Managed Services should the Reagent in question become unavailable for use at either Site, then the Contractor shall forthwith replace, at its cost, the Reagent which is the subject of the recall with a replacement supply, or an alternative Reagent acceptable to the Board if appropriate.

11.7.2 In the event of a failure to supply which continues beyond five (5) Working Days the Contractor must, if necessary, source the service or similar product from an alternative third party approved by the Board. If the Reagent which is the subject

of the recall requires to be replaced either on a temporary or permanent basis with one which is more expensive, the Contractor will for the remainder of the Term (or shorter time in the case of a temporary replacement) charge the Board only for the price of the Reagent which was the subject of the recall.

11.7.3 In the event that a Reagent remains unavailable beyond five (5) Working Days the Board may, if it wishes, itself source a similar product from its own alternative source and in such event the Contractor shall indemnify, subject to the limit of liability in Clause 20.2, and hold the Board harmless against and reimburse the Board on demand in respect of any expenses, liabilities, damages, costs (including legal costs) and claims arising out of such action including, without limitation, Direct Costs, provided that the Board shall use its reasonable endeavours to pay the best achievable price given constraints of time and volume.

11.7.4 Recalls and Product Actions will be dealt with in accordance with Clause 12.3.

## 11.8 Reagent Safety

11.8.1 To the extent that the Reagents and Equipment are used in accordance with all written instructions provided to the Board, and to the extent that the Reagents and Equipment have only been used for their intended purposes, and other than where and to the extent damage (if any) is caused by Equipment being moved or relocated by the Board without the knowledge of the Contractor, the Contractor shall be liable for all issues relating to Reagent safety and Equipment safety and shall, subject to Clause 20.2, be liable for any losses, claims, damages, expenses suffered or incurred by the Board arising from the possession or use (or inability to use) the Equipment and/or Reagents.

## 11.9 Failure to Supply Reagents

11.9.1 If the Contractor fails to timeously deliver or procure the delivery of any Reagent/Consumables in accordance with the provisions of this Agreement the

provisions of Clause 9, this Clause 11, and Schedule Part 11, will apply.

## **12. REGULATORY MATTERS**

### **12.1 Regulatory Approvals**

12.1.1 The Contractor will be responsible for, bear the cost of, and own, any CE mark and registration necessary under the Regulations in order for the Contractor to supply and procure the supply of the Reagents.

### **12.2 Regulatory Inquiry**

12.2.1 Each Party shall promptly and, in any event, within five (5) Working Days of receipt of notice of such an inquiry, inform the other in writing of any formal or informal inquiry by any regulatory agency relating to any Reagent supplied to the Board.

### **12.3 Product Action**

12.3.1 Subject to the limit of liability in Clause 20.2 if any Reagent defect, or operation issues arising in respect of any Component of the Solution, or any governmental or court action or other event results in (i) the formal recall, destruction or withholding from the market of any Reagent or Equipment provided under this Agreement (“**Recall**”); or (ii) the institution of a field correction of any Reagent sold or Equipment or other Component of the Solution provided under this Agreement; or (iii) any similar steps in relation to the Reagents or Equipment or other Component of the Solution (collectively, “**Product Action**”), the Contractor shall:-

- (i) bear all costs and expenses of and shall be responsible for all corrective actions associated with such Product Action;
- (ii) indemnify and hold the Board harmless against any claims, loss, expenses, liabilities, damages, costs (including legal costs) arising out of such Product Action and/or the use of a Reagent or Equipment which is

then the subject of a Product Action including, without limitation, Direct Costs;

- (iii) provide, at the Contractor's cost, all assistance reasonably required by any Third Party Supplier;
- (iv) be responsible for communication to the Competent Authorities regarding such Product Action as well as communicating any Product Action to senior staff at the Board's Sites.

12.3.2 In the event that a failure to supply a Reagent or an inability to operate an any aspect of the Solution due to a Product Action continues beyond a period of three (3) Working Days and the Contractor is unable to supply the required quantities of such Reagent, or source and commission an alternative aspect of the Solution acceptable to the Board, then without prejudice to its rights and remedies hereunder and at law, the Board may, at its discretion and upon written notice to the Contractor, request that the Contractor sources the Reagent or relevant aspect of the Solution from an alternative Third Party, and the provisions of Clause 10 and Schedule Part 11 shall apply.

12.3.3 During any such period the Board shall also be entitled (but not obliged) to itself source and purchase necessary Reagents and/or any relevant Component of the Solution to allow continued performance of all tests affected by the Product Action and in such event the Contractor shall, subject to the limit of liability in Clause 20.2, indemnify and hold the Board harmless against, and reimburse the Board, on demand, in respect of, any expenses, liabilities, damages, costs (including legal costs) and claims arising out of such action including, without limitation, Direct Costs.

12.3.4 If a Reagent or any Component of the Solution which is the subject of the Product Action requires to be replaced either on a temporary or permanent basis with a Reagent or aspect of the Solution which is more expensive, there

shall be no adjustment to the Charges payable in accordance with the Financial Schedule and any additional cost associated with providing such replacement shall be borne by the Contractor regardless of the period for which the replacement is provided.

#### 12.4 Medical Device Reports

12.4.1 Each Party shall immediately (within three (3) Working Days) notify the other Party in writing of any incident or complaint that may affect any part of the Managed Services that gives rise or could give rise to the need to file a Medical Device Vigilance Report (a “**MDVR**”) within the meaning of the Regulations with respect to any Reagent or Equipment, or the manufacture, distribution or use thereof in accordance with the Regulations. Each such written notice shall be treated as “Confidential Information” under this Agreement. If, as a result of any corrective action or any governmental, regulatory or court action, a MDVR is required to be issued for any Reagent or item of Equipment used as part of the Managed Services, the Contractor shall bear the costs and expenses of, and shall be responsible for all corrective actions associated with, such MDVR and if there is a failure to supply a Reagent or an inability to operate an item of Equipment or any other aspect of the Solution as a result of the incident which gave rise to the MDVR then the provisions of Clause 10 and Schedule Part 11 shall apply.

#### 12.5 Compliance with Laws

In performing this Agreement, each Party shall comply with all Legal Requirements treaties, laws and regulations, and shall not be required to perform or omit to perform any act as required or permitted under this Agreement if such performance or omission would violate any Legal Requirements.

### 13. **CUSTOMER SUPPORT, COMPLAINTS AND RETURNS**

#### 13.1 General

The following provisions of this Clause 13 are without prejudice to the application of the provisions of Schedule Part 11 in the event that the Board suffers non-availability of any aspect of the Managed Services at the Sites. If applicable, Service Deductions shall be applied notwithstanding the steps taken by the Contractor pursuant to this Clause 13.

## 13.2 Rejections or Shortages

13.2.1 In the event of rejection of any Reagent/Consumables by the Board or shortage of any Reagent/Consumables or any aspect of the Managed Services the Contractor shall arrange for the immediate replacement or supplementing (in the case of shortage) of the relevant Reagent/Consumables or aspect of the Managed Services.

13.2.2 The Contractor shall then investigate such rejection or shortage and, within ten (10) days, subject to the limit of liability in Clause 20.2, ensure the Board is reimbursed for any and all expenses, liabilities, damages, costs (including legal costs) including, without limitation, Direct Costs, incurred by the Board as a result of the rejection/shortage.

13.2.3 All replacements, making up of shortfalls and removal of rejected Reagents/Consumables shall be at the Contractor's cost. If any such Reagent/Consumable requires to be replaced either on a temporary or permanent basis with one which is more expensive, the Contractor will charge the Board only the price of the originally supplied Reagent for the duration during which the replacement is provided.

## 13.3 Returned Reagent

13.3.1 In the event that the Board notifies the Contractor it wishes to return Reagents/Consumables as a result of performance problems that are a result of non-compliance of any Reagent/Consumable with the relevant aspect of the Specification, the Contractor shall, at its own cost, forthwith replace such Reagent/Consumable with a replacement supply of the same

Reagent/Consumable or, at the Board's request, with an equivalent product to the Reagent/Consumable, sourced from an alternative supplier.

13.3.2 If any such Reagent/Consumable requires to be replaced either on a temporary or permanent basis with one which is more expensive, the Contractor will charge the Board only the price of the originally supplied Reagent/Consumable for the duration during which the replacement is provided.

#### 13.4 Remedying Performance Issues with any Component of the Solution

Managed Service Failures (as such term is defined in Schedule Part 11) caused by issues with any aspects of the Solution shall be resolved in accordance with Schedule Part 11 and the provisions of Clause 13.5 below.

#### 13.5 Problems

13.5.1 In the event of any failures in the performance and/or timely availability of Reagents/Consumables and/or any Component of the Solution the Contractor shall take, and ensure that any relevant Third Party Suppliers take, such appropriate steps as are required to address and remedy the issue forthwith.

13.5.2 In the event of any persistent or prolonged performance or availability issue (as determined by the clinical requirements of the services operated by the Board) in respect of a Reagent/Consumable or any Component of the Solution, the Board shall be entitled, at its discretion and without prejudice to its other remedies hereunder and at law, to require that the Contractor replace the Reagent/Consumable or any aspects of the Solution in question with a replacement of at least equivalent functionality. Subject to the limit of liability in Clause 20.2, any such replacement shall be at the Contractor's cost and the Contractor shall be responsible for all corrective actions associated with such replacement and shall indemnify and hold the Board harmless against any claims, loss, expenses, liabilities, damages, costs (including legal costs) arising in respect of, or as a result of, such replacement including, without limitation,

Direct Costs. Any dispute regarding whether a persistent or prolonged performance or availability issue has arisen in respect of a Reagent or any aspect of the Solution shall be resolved in accordance with Clause 25.

#### **14. INTELLECTUAL PROPERTY INDEMNITY**

- 14.1 The Contractor shall indemnify and hold harmless, on demand, the Board, its chief executive, board members, representatives, agents, distributors and customers, from and against any liabilities, damages, judgements, costs, expenses (including reasonable legal fees and expenses necessary to consider, advise and defend) arising out of or from any suit, proceeding or claim made or brought against the Board, or any of the indemnified parties referred to above alleging that the method of manufacturing, and/or the provision to the Board and/or the use and/or contemplated use hereunder of any Reagent and/or any aspect of the Solution, constitutes an infringement of any third party patent or other third party intellectual property right.

#### **15. REPRESENTATIONS AND WARRANTIES**

15.1 By the Contractor:

The Contractor hereby represents and warrants to the Board that:

- 15.1.1 the Contractor has the full right, power and corporate authority to enter into this Agreement and to make the promises set forth in this Agreement and to grant the rights herein;
- 15.1.2 to the best of its knowledge and belief, having made all due, diligent and appropriate enquiry as at the date hereof, no actions are threatened or pending before any court or governmental agency or other tribunal relating to any Reagent or any part or all of the Solution;
- 15.1.3 All aspects of the Solution and the Reagents/Consumables provided to the Board hereunder shall:-

- (i) be in accordance with, and shall function and perform in accordance with,

the Specification, the relevant Reagent Specifications, the Performance Specifications and with the Quality Systems and cGMP Requirements;

(ii) function and perform as required by the Regulations;

(iii) function and perform in accordance with all Legal Requirements regulations, and guidelines; and

(iv) shall be capable of handling the volumes and types of Processes detailed in the Specification, including any increases in volume during the term of this Agreement referred to in the Specification,

and shall be fit for their purpose, be of satisfactory quality, and comply in all respects and at all times with the Specification;

15.1.4 in respect of each lot of Reagent delivered to the Sites, at the time of delivery, have the applicable shelf life set forth in Clause 11.2 and shall continue, until the applicable expiration date, to conform to the Quality Systems and cGMP Requirements and to the Reagent Specifications, and shall be free from defects in materials and workmanship.

15.2 The Contractor further represents and warrants to the Board that:-

15.2.1 there have been no claims or assertions, written or oral, that the making, having made, using, offering for sale, having sold, selling, or importing of one or more of the Reagents/Consumables and/or any Component of the Solution and/or services received by the Board hereunder infringes the patents, trademarks, or other Intellectual Property Rights of any third party;

15.2.2 to the best of its knowledge and belief, having made all due, diligent and appropriate enquiry as at the date hereof, there are no third party Intellectual Property Rights which are valid and which would be infringed by making, having made, using, offering for sale, having sold, selling, or importing Reagents/Consumables and/or any Component of the Solution in accordance

with the terms of this Agreement;

- 15.2.3 to the best of its knowledge and belief, having made all due, diligent and appropriate enquiry as at the date hereof to the extent any third party owns any Intellectual Property Rights relating to the making, having made, using, offering for sale, having sold, selling, or importing of Reagents/Consumables and/or any Component of the Solution and any software required for the operation thereof and/or for interfacing with the Board's systems, the Contractor has obtained valid license rights from such third party under which the Contractor may provide Reagents/Consumables and/or provide all Components of the Solution to the Board in the course of providing the Managed Services for use by the Board in accordance with the terms of this Agreement;
- 15.2.4 that it will comply, and continue to comply, with the requirements of the Board as specified in the Specification, and that it can, and will be able to, deliver the quality and quantity of the Managed Services required by the Board during the Term;
- 15.2.5 the Managed Services shall be supplied and rendered by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;
- 15.2.6 to the best of its knowledge and belief, any representation made by the Contractor as to staffing levels required by the Boards to operate the Solution in accordance with the Specification are true and accurate;
- 15.2.7 It shall not create or allow to be created any floating charge or any other charge or item capable of attaching to the Equipment;
- 15.2.8 it shall discharge its obligations hereunder with all due skill, care and diligence including, but not limited to, good industry practice;
- 15.2.9 it shall not create or allow to be created any floating charge or any other charge or lien capable of attaching to any Component of the Solution provided always

that this Clause 15.2.9 shall not be construed as preventing or restricting the Contractor from acquiring any Component of the Solution by operational or financial lease;

15.2.10 all statements and representations made to the Board in response to the ITT including without limitation those made in the Specification are true and accurate in all respects and not misleading and that it will advise the Board of any fact, matter or circumstance of which it may become aware which would render any such statement or representation to be false or misleading; and

15.2.11 the Board will, for the duration of this Agreement, enjoy quiet uninterrupted possession and use of all aspects of the Solution and all Reagents/Consumables, and that no third parties will repossess, or attempt to repossess any aspect of the Solution or Reagents/Consumables, or otherwise prevent, hinder or affect the Board's use thereof.

## **16. SUPPORT AND TRAINING**

### **16.1 Information**

Upon the Board's reasonable request, the Contractor shall and shall procure that its Third Party Suppliers shall, respond to any reasonable technical questions posed by staff or others working for the Board, and shall review for technical accuracy and provide comments to the Board regarding any guidelines, promotion aids, reference material, training and sales documentation, or similar information which may be provided to the Board in connection with the Managed Services. Such review and comment shall take place in English within ten (10) Working Days of receipt of the material by the Contractor.

### **16.2 Training**

The Contractor shall provide such training as is detailed in the Specification, required to enable the Board's staff to demonstrate agreed core competences in the operation, use and maintenance of the Equipment, the Solution Management Systems and the use of the Reagents/Consumables.

## **17. CONFIDENTIALITY**

### **17.1 Non-Disclosure**

Subject to Clause 17.2.2 and the following provisions of this Clause 17, each Party will, for the Term (i) keep confidential and not disclose to others, all Confidential Information of the other Party; and (ii) not use any of the other Party's Confidential Information for its own direct or indirect benefit, or the direct or indirect benefit of any third party, except that each of the Contractor and the Board may use the other Party's Confidential Information to the extent necessary to perform its duties and obligations, or to enforce such Party's rights, under this Agreement.

### **17.2 Disclosure**

17.2.1 Notwithstanding the above, nothing contained in this Agreement shall preclude the Board or the Contractor from utilising or disclosing to others its own Confidential Information. In addition, either Party may disclose Confidential Information received from the other Party as required by law and pursuant to this Agreement, provided that the disclosing Party shall, where practicable, not make such disclosure unless it has first advised the proposed disclosure of Confidential Information to the other Party and has given the other Party reasonable opportunity for prior review of and comment regarding the proposed disclosure.

17.2.2 No term of this Agreement, whether express or implied, shall preclude the Board from making public under the Freedom of Information (Scotland) Act 2002, and any Codes applicable from time to time relating to access to public authorities' information, details of all matters relating to this Agreement unless such details constitute a trade secret, the disclosure of such details would or would be likely to substantially prejudice the commercial interest of any person (including but not limited to the Contractor or the Board) or such details fall within such other exemption as may be applicable at the discretion of the Board in terms of the

said Act. The Contractor will facilitate the Board's compliance with the Board's obligations under these provisions and promptly comply with any request from the Board in connection therewith. The Board will consider any representations made by the Contractor in relation to the disclosure or possible disclosure of such details.

17.3 Employees

Each Party represents to the other that its employees, sub-distributors, agents and contractors are or will be governed by internal regulations or appropriate arms length agreements which prohibit the disclosure of Confidential Information, which may belong to the other Party, and that such internal regulations and agreements will enable it to comply with all of the provisions of this Clause.

17.4 Third Party Suppliers

The Contractor will procure that all Third Party Suppliers will, prior to being in a position whereby they may be able to access information and data proprietary to the Board and/or any Confidential Information of the Board, enter into such form of confidentiality undertaking in favour of the Board as is satisfactory to the Board.

17.5 Publicity

17.5.1 Except with the written consent of the other party which shall not be unreasonably withheld or delayed, neither the Contractor nor the Board shall make any press announcements or (subject to Clause 17.2) publicise this Agreement including but not limited to any disputes or default by either party in any way.

17.5.2 Both parties shall (subject to Clause 17.2) take all reasonable steps to ensure the observance of the provisions of Clause 17.5.1 by all its servants, employees, agents, consultants and sub-contractors. The Contractor shall procure that the Third Party Suppliers comply with this Clause 17.5.

## **18. DATA PROTECTION**

### ***Controller/Processor and Personal Data***

18.1 Where for the purposes of the Data Protection Legislation:

18.1.1 the Board is the Controller and the Contractor is the Processor, to the extent that the Parties have these roles in terms of the Data Protection Legislation, this Clause 18 shall apply with the exception of Clauses 18.27 and 18.28 and Schedule Part 15 (Processing Information) shall only apply insofar as it relates to the Purpose;

18.1.2 the Board and the Contractor are Joint Controllers, to the extent that the Parties have these roles in terms of the Data Protection Legislation, this Clause 18 shall apply with the exception of Clauses 18.5, 18.6 and 18.28 and Schedule Part 15 (Processing Information) shall only apply insofar as it relates to the Purpose;

18.1.3 the Contractor is a Controller because it requires to Process Personal Data for the Additional Permitted Purpose, to the extent that in terms of the Data Protection Legislation, the Contractor is a Controller for the Additional Permitted Purpose, this Clause 18 shall apply, subject to the amendments set out in Clause 18.28 and Schedule Part 15 (Processing Information) shall only apply insofar as it relates to the Additional Permitted Purpose,

and the Parties acknowledge that in connection with the Contractor's performance of its obligations pursuant to or under this Agreement, including but not limited to the performance of the Services, the Contractor may, in terms of the Data Protection Legislation, have more than one of the roles described in this Clause 18. This Clause 18.1 describes what provisions of this Clause 18 and Schedule Part 15 (Processing Information) apply in relation to each role.

18.2 For the avoidance of doubt, references in this Clause 18 to the term "Personal Data" shall only apply to Personal Data Processed in the course of the performance of the obligations imposed on the Contractor pursuant to or under this Agreement, including but

not limited to the performance of the Services and where, and to the extent that, the Contractor is a Controller as described in Clause 18.1 above, shall only apply to such of this Personal Data which the Contractor Processes for the Additional Permitted Purpose.

### ***Compliance with Data Protection Legislation***

18.3 The Contractor warrants that it will, and will procure that any and all Sub-processors will, at all times throughout the Term, Process Personal Data in compliance with the Data Protection Legislation.

### ***Processing Instructions***

18.4 The only Processing that the Contractor is authorised to undertake in connection with the performance of the obligations imposed on the Contractor pursuant to or under this Agreement, including but not limited to the performance of the Services is listed in this Clause 18.4 and in Schedule Part 15 (Processing Information), as the same may be amended from time to time by written agreement between the Parties (together, the “**Processing Instructions**”). In addition, the Contractor warrants that it will, and will procure that any and all Sub-processors will, at all times throughout the Term, only Process the Personal Data for the purposes of the performance of the obligations imposed on the Contractor pursuant to or under this Agreement, including but not limited to the performance of the Services (the “**Purpose**”).

18.5 The Contractor shall promptly comply with any written request from the Board requiring the Contractor to amend, transfer or delete the Personal Data.

18.6 The Contractor shall notify the Board immediately if it considers that any of the Board’s instructions infringe the Data Protection Legislation and will provide the Board with a written explanation of the reasons why it considers any of the Board’s instructions to be so infringing.

### ***Assistance to the Board***

18.7 The Contractor shall, as part of the Services and at no additional cost or expense to the Board, provide all reasonable assistance to the Board in ensuring compliance with the

Board's obligations under the Data Protection Legislation in relation to:

- 18.7.1 ensuring the security of the Personal Data;
- 18.7.2 any notifications, communications and remedial action that may be required to be made or taken following any Data Loss Event, including notifications to the relevant Supervisory Authority following a Data Loss Event and communications to affected or potentially affected Data Subjects;
- 18.7.3 responding to Data Subject Access Requests within the timescale set out in the Data Protection Legislation;
- 18.7.4 responding to any other requests, complaints or communications relating to either Party's obligations under the Data Protection Legislation;
- 18.7.5 responding to any request from any third party for disclosure of Personal Data;
- 18.7.6 any communication from a Supervisory Authority or any other regulatory authority or any consultation by the Board with a Supervisory Authority or any other regulatory authority, to the extent that such communication or consultation relates to or involves the Processing undertaken by the Contractor and/or any Sub-processor under or in connection with this Agreement; and
- 18.7.7 the preparation of any Data Protection Impact Assessment prior to commencing any new Processing that has been agreed between the Parties pursuant to Clause 18.4. Such assistance may, at the discretion of the Board, include:
  - (i) a systematic description of the envisaged Processing operations and the purpose of the Processing;
  - (ii) an assessment of the necessity and proportionality of the Processing operations in relation to the performance of the obligations imposed on the Contractor pursuant to or under this Agreement, including but not limited to the performance of the Services;
  - (iii) an assessment of the risks to the rights and freedoms of Data Subjects;

and

- (iv) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

18.8 At any time throughout the Term, or following the date of termination, at the request of the Board, the Contractor shall provide to the Board a copy of all Personal Data held by the Contractor in the format and on the media reasonably specified by the Board. If the Contractor fails to provide the Board with a copy of such requested Personal Data the Board may, without limiting its other rights or remedies, enter the Contractor's premises and take a copy of such Personal Data.

### ***Technical and Organisational Measures***

18.9 The Contractor shall:

18.9.1 Process the Personal Data only in accordance with Schedule Part 15 (Processing Information), unless the Contractor is required to do otherwise by Law, in which case the provisions of Clause 18.6 shall apply;

18.9.2 ensure that it has in place Protective Measures, which the Contractor shall maintain throughout the Term at its cost and expense, and which are appropriate to protect against a Data Loss Event, having taken account of:

- (i) the nature of the Personal Data to be protected;
- (ii) the harm that might result from a Data Loss Event;
- (iii) the state of technological development; and
- (iv) the cost of implementing any measures.

### ***Contractor Personnel***

18.10 The Contractor shall ensure that it takes all reasonable steps to ensure the reliability and integrity of any Contractor Personnel who have access to the Personal Data and ensure

that they:

18.10.1 are aware of and comply with the Contractor's duties under this Agreement, in particular those obligations set out in this Clause 18;

18.10.2 are subject to appropriate confidentiality undertakings with the Contractor or any Sub-processor, as the case may be, which confidentiality undertakings require the Contractor Personnel to keep the Personal Data confidential and to only Process the Personal Data for the Purpose;

18.10.3 are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third Party unless directed in writing to do so by the Board or as otherwise permitted by this Agreement; and

18.10.4 have undergone adequate training in the use, care, protection and handling of Personal Data and on the Data Protection Legislation insofar as it relates to Processing.

#### ***International Transfers of Personal Data***

18.11 The Contractor shall not transfer Personal Data outside of the United Kingdom without the prior written consent of the Board.

18.12 Where the Contractor wishes to transfer Personal Data to a country within the EEA, the Board's consent shall not be unreasonably withheld or delayed.

18.13 If the Board gives its written consent to a transfer of Personal Data outside of the EEA, the Contractor shall ensure that:

18.13.1 the Contractor has Appropriate Safeguards in place in respect of such transfer and, where practicable, the particular Appropriate Safeguards to be used by the Contractor for such transfer shall be subject to the Board's prior written approval, which approval shall not be unreasonably withheld or delayed;

18.13.2 the transfer and any Processing of Personal Data following such transfer complies at all times with Clause 18.4; and

18.13.3 the transfer otherwise complies with Data Protection Legislation.

***Notifications required to be given by the Contractor to the Board***

18.14 The Contractor shall, at its own cost and expense, notify the Board immediately (and within three (3) Business Days of receipt of the relevant communication at the latest) if it:

18.14.1 receives a Data Subject Request (or purported Data Subject Request);

18.14.2 receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

18.14.3 receives any communication from any Supervisory Authority, including from the Information Commissioner's Office, or any other regulatory authority in connection with Personal Data processed under or in connection with this Agreement; or

18.14.4 receives a request from any third party for disclosure of Personal Data where compliance with such request is required or permitted by Law,

and the Contractor will provide the Board with a copy of the relevant Data Subject Access Request, request, complaint or communication, as the case may be and such further information regarding the same as the Board may request from time to time.

18.15 Taking into account the nature of the Processing, the Contractor shall provide the Board with all reasonable assistance in relation to any complaint, communication or request notified to the Board pursuant to Clause 18.14 (and insofar as possible within the timescales reasonably required by the Board).

18.16 The Contractor shall, at its own cost and expense:

18.16.1 notify the Board of any Data Loss Event of which it becomes aware within twenty four (24) hours of becoming aware of such Data Loss Event; and

18.16.2 provide the Board, as soon as practicable and wherever possible within twenty four (24) hours of becoming aware of such Data Loss Event, with such information regarding the Data Loss Event as the Board may reasonably

require, including but not limited to:

- (i) the nature of the Data Loss Event, including, where possible the categories and approximate number of Data Subjects and Personal Data records affected by the Data Loss Event;
- (ii) the likely consequences of the Data Loss Event; and
- (iii) where the Data Loss Event involves the Contractor and/or any Sub-processor, the measures taken or proposed to be taken by the Contractor and/or any Sub-processor to address the Data Loss Event, including those to mitigate the possible adverse effects of the Data Loss Event.

18.17 If the Contractor cannot provide all of the information set out in Clause 18.16 within the timescale specified, the Contractor shall, within such timescale advise the Board of the delay and of the reasons for the same and advise the Board when the Contractor expects to be able to provide the relevant outstanding information, which information may be provided in phases without undue delay, as details become available.

## **Records**

18.18 The Contractor shall maintain complete, accurate and up-to-date written records of all Processing carried out under or in connection with this Agreement. Such records shall contain the following information:

18.18.1 the name and contact details of the Contractor's Representative (if any) and of the Contractor's Data Protection Officer (if any);

18.18.2 the categories of Processing carried out in connection with the Purpose;

18.18.3 where applicable, details of any transfers of Personal Data pursuant to Clause 18.13, including the identity of the recipient of such transferred Personal Data and the countries to which such Personal Data is transferred, together with details of the Appropriate Safeguards used; and

18.18.4 a general description of the Protective Measures implemented by the Contractor

pursuant to Clause 18.9.

### ***Use of Sub-processors***

18.19 The Contractor shall not allow any Sub-processor to Process any Personal Data unless the Contractor has:

18.19.1 notified the Board in writing of the intended Sub-processor and the Processing activity that the Contractor wishes the Sub-processor to undertake on the Contractor's behalf;

18.19.2 obtained the prior written consent of the Board in respect of the use of such Sub-processor in connection with the Processing undertaken pursuant to this Agreement;

18.19.3 entered into a binding written agreement with the Sub-processor, which agreement sets out enforceable data protection obligations on the same terms as set out in this Clause 18 such that they apply to the Sub-processor, in particular such binding written agreement must provide:

- (i) sufficient guarantees that the Sub-processor will adopt Protective Measures such that the Processing undertaken by the Sub-processor will meet the requirements of the Data Protection Legislation; and
- (ii) details of the Processing that is to be undertaken by the Sub-processor, which Processing shall only involve activity that is set out in Schedule Part 15 (Processing Information) of this Agreement; and

18.19.4 provide the Board with such other information regarding the Sub-processor as the Board may reasonably require from time to time.

18.20 The Contractor shall cease using a Sub-processor to undertake any Processing of Personal Data pursuant to or in connection with this Agreement immediately upon receipt of a written request from the Board requesting that such Sub-processor ceases Processing the Personal Data, in circumstances where the Board has reasonable

grounds for concern about the Sub-processor's ability to carry out the Processing in accordance with the Data Protection Legislation.

18.21 The Contractor shall remain fully liable for all acts or omissions of any Sub-processor.

***Audit Right***

18.22 The Contractor shall, and shall procure that any and all Sub-processors shall, make available to the Board, at no cost or expense to the Board, all information necessary to demonstrate the Contractor's compliance with its obligations under this Clause 18 and the Data Protection Legislation.

18.23 The Contractor shall, and shall procure that any and all Sub-processors shall, allow for and contribute to audits, including inspections, conducted by the Board or by another auditor mandated by the Board, for the purpose of reviewing and assessing the Contractor's compliance with its obligations under this Clause 18 and the Data Protection Legislation, provided that the Board shall, where possible:

18.23.1 provide the Contractor with reasonable prior notice of such audit or inspection;

18.23.2 ensure that such audit is carried out during normal business hours; and

18.23.3 ensure that each such audit and inspection is carried out so as to cause minimal disruption to the Contractor's business and other customers.

18.24 The Parties agree that they shall bear their own respective costs and expenses incurred in respect of compliance with their obligations under Clause 18.23, unless the audit identifies a breach of the Contractor's obligations under this Clause 18 and/or the Data Protection Legislation, in which case the Contractor shall reimburse the Board for all of the Board's reasonable costs incurred in the course of the audit.

18.25 If an audit identifies that the Contractor has failed to perform its obligations under this Agreement in any material manner, the Board may, at its sole discretion:

18.25.1 treat such failure as a material breach of the Agreement; or

18.25.2 agree with the Contractor a remedial plan to resolve such failure, which

remedial plan the Contractor shall implement at its sole cost and expense.

***Deletion or Return of Personal Data***

18.26 Within one (1) month following the date of termination of this Agreement, or if earlier, the date of the cessation of those Services pursuant to or in connection with which the Processing of Personal Data by the Contractor on behalf of the Board was undertaken, the Contractor shall, at the written direction of the Board, securely delete or securely return to the Board all affected Personal Data (and any copies of it) and the Contractor shall certify in writing to the Board that to the best of the Contractor's knowledge and belief all Personal Data (and any copies of it) have been securely deleted or securely returned to the Board, unless the Contractor is required by Law to retain the Personal Data. If the Contractor is required by Law to retain the Personal Data, the Contractor shall advise the Board of such requirement in writing.

***Additional Considerations for Joint Controllers***

18.27 Where the Parties are Joint Controllers:

18.27.1 Without prejudice to Clauses 18.7 and 18.14:

- (i) the Parties agree that the Board shall handle all Data Subject Requests and all requests from third parties for disclosure of Personal Data;
- (ii) the Parties agree that the Board shall be responsible for co-ordinating the notifications, communications and remedial action that may be required to be made or taken following any Data Loss Event;
- (iii) each Party shall be responsible for responding to communications addressed to that Party from any Supervisory Authority or other regulatory authority and for participating in consultations with any Supervisory Authority or other regulatory authority at their instance relating to the Processing of any Personal Data but that Party shall keep the other Party informed in relation to same; and
- (iv) any Processing Instructions which, in terms of the Data Protection Legislation, are inconsistent with the Contractor's role as Joint Controller with the Board, shall not apply to the Contractor.

### ***Controller for Additional Permitted Purposes***

18.28 Where, and to the extent that, the Contractor is a Controller pursuant to Clause 18.1.3:

18.28.1 Clauses 18.5, 18.7, 18.8, 18.15, 18.18-18.27 inclusive shall not apply;

18.28.2 Clause 18.4 shall apply but shall be amended such that all words in Clause 18.4 following "for the purposes of the" where they appear in the last sentence shall be deleted and replaced with the words "Additional Permitted Purpose";

18.28.3 in Clause 18.9.2, the words "Protective Measures" shall be deleted and replaced with the words "appropriate technical and organisational measures";

18.28.4 Clause 18.10 shall apply but shall be amended such that:

- (i) in Clause 18.10.2 the words "Additional Permitted" shall be inserted prior to the word "Purpose"; and

- (ii) in Clause 18.10.3, the words “directed in writing to do so by the Board” shall be deleted and replaced with the words “required or permitted by Law in connection with the Additional Permitted Purpose”;
- (iii) and the Contractor requires to transfer Personal Data outside of the UK, the Contractor shall advise the Board in writing and shall ensure that the transfer complies with the Data Protection Legislation;
- (iv) and the Contractor receives a Data Subject Request, the Contractor shall action the same.

### ***Liability***

- 18.29 Whether the Contractor is a Processor, Joint Controller and/or Controller, the Contractor shall indemnify and keep indemnified and defend at its own expense the Board from and against any and all DP Losses incurred by the Board or for which the Board may become liable arising from or in connection with any failure by the Contractor or any Sub-processor or any of their employees or agents to comply with any of the Contractor’s obligations under this Clause 18. The indemnity set out in this Clause 18 shall not be subject to any limit of liability in terms of Clause 20.2 (Limits of Liability).
- 18.30 The Board shall indemnify and keep indemnified and defend at its own expense the Contractor from and against any and all DP Losses incurred by the Contractor or for which the Contractor may become liable whether the Contractor is a Processor, Joint Controller and/or Controller arising solely from or in connection with any failure by the Board or its employees or agents to comply with any of the Board’s obligations under this Clause 18. The aggregate liability of the Board in respect of the indemnity set out in this Clause 18.30 shall be subject to the limits of liability in terms of Clause 20.2(Limits of Liability).”
- 18.31 The provisions of Clauses 18.29 and 18.30 shall not affect the liability of either Party to any Data Subject.

## 19. **PAYMENT**

Subject to performance by the Contractor of its obligations under this Agreement, the Board shall make payment to the Contractor in accordance with the Financial Schedule.

## 20. **INDEMNIFICATION, LIABILITY AND INSURANCE**

### 20.1 Indemnification by the Contractor

20.1.1 The Contractor shall defend, indemnify and hold the Board, its chief executive, directors, employees, representatives and agents harmless from and against any liability, damage, loss, cost or expense, including reasonable legal fees, including where such arise as a result of third party claims against the Board, arising out of or resulting from: (i) the Contractor's breach of any representation, certification or warranty given pursuant to or set forth in this Agreement; (ii) the Contractor's default, negligence, or wilful misconduct in the performance of its obligations under this Agreement or otherwise; and (iii) any fault or defect in any Reagent, any or all Components of the Solution or related product or service supplied by the Contractor.

### 20.2 Limitation of Liability

20.2.1 Subject to Clause 20.2.2 below, the liability of the Contractor for breach of contract and in respect of the indemnity and/or payment obligations in Clauses 10.3, 11.7.3, 12.3.1(ii), 12.3.3, 13.2.2, 13.5.2 and 20.7 will be limited, in any Contract Year, to a sum equal to Ten Million Pounds (£10,000,000) Sterling or twice the amount payable to the Contractor in that Contract Year, whichever is the greater

20.2.2 Nothing in this Agreement shall operate or be construed as to limit or exclude the Contractor's liability for death or personal injury caused by negligence or breach of duty, or for fraud or fraudulent misrepresentation.

### 20.3 Insurance

The Contractor throughout the duration of this Agreement, commencing on the Commencement Date, in respect of claims relating to events or incidents arising or beginning during the Term, whether or not a claim is made after expiry or termination of this Agreement maintain appropriate insurance with a reputable insurance company notified to the Board the following:-

20.3.1 Public liability insurance in not less than the sum of Ten Million Pounds (£10,000,000) Sterling in respect of any one incident;

20.3.2 Employers liability insurance in not less than Five Million Pounds (£5,000,000) Sterling;

20.3.3 Insurance in respect of all Component parts of the Solution against any normal insurance risk;

20.3.4 Product liability insurance in not less than the sum of Ten Million Pounds (£10,000,000) Sterling in respect of any one incident;

20.3.5 Such other insurances of a type and to a level of cover appropriate and commensurate with the Contractor's obligations hereunder and the nature and type of the Managed Services, the Reagents/Consumables, and the Solution.

20.4 The Contractor shall at the request of the Board exhibit appropriate evidence of the policy or policies of insurance taken out in respect of this Clause 20 together with a confirmation of payment of the latest premiums invoiced by the insurer.

20.5 The Contractor shall procure that the Board's interest shall be noted against all policies of insurance taken out and maintained in respect of this Clause 20 to the effect that the Board shall be advised by the insurers of:-

20.5.1 any claim submitted by the Contractor against any policy in respect of this Agreement;

20.5.2 any monies paid or to be paid by the insurers to the Contractor pursuant to such claim; and

20.5.3 if any policy is permitted to lapse for any reason or is cancelled by the Contractor.

20.6 The Contractor shall not knowingly do or permit to be done anything which may result in any policy or policies of insurance required in terms of this Clause 20 becoming void or voidable.

20.7 If the Contractor shall default in taking out and maintaining insurance as required by this Clause 20 the Board may itself take out such insurances as the Contractor is required to take out and maintain pursuant to this Clause 20 and, subject to the limit of liability in Clause 20.2, may charge the cost of such insurance (together with its reasonable costs in taking out and maintaining such insurance) to the Contractor and such sum shall be a debt due and payable by the Contractor to the Board upon demand which may be set off against future payments due to be paid by the Board to the Contractor.

## **21. TERM/TERMINATION**

### **21.1 Term and Expiration**

This Agreement shall commence on the Commencement Date and, unless terminated or extended as provided in this Agreement, shall continue in effect until expiry of the Term. The Board shall be entitled, at its sole discretion, to extend the Term beyond the initial five (5) year period. Such right may be exercised on one (1) or more occasions and the extension or extensions may be for a period of up to five (5) years in total. If the Board elects to exercise such right, it shall provide the Contractor with at least six (6) months' written notice of its requirement to do so prior to expiry of the initial five (5) year period. During such extension, the Board shall make payment for the Semi Fixed Charge and the Annual Test/Variable Costs. Any fixed charge and the Service Levels shall be amended by agreement between the Parties, acting reasonably, to reflect the age of Equipment then being used to deliver the Managed Services.

### **21.2 Contractor Default**

For the purposes of this Agreement, "**Contractor Default**" means any of the following

events or circumstances:

21.2.1 the occurrence of any of the following events in respect of the Contractor, namely:

- (i) any arrangement or composition with or for the benefit of creditors (including any voluntary arrangement as defined in the Insolvency Act 1986) being entered into by or in relation to the Contractor, or a petition being presented to the court in respect of the same;
- (ii) a receiver, administrator, administrative receiver or other encumbrancer taking possession of or being appointed over, or any distress, execution or other process being levied or enforced (and not being discharged within ten (10) Working Days) upon, the whole or any material part of the assets of the Contractor, or a petition being presented to the court in respect of the same;
- (iii) the Contractor ceasing or threatening to cease to carry on business;
- (iv) a petition being presented (and not being discharged within twenty (20) Working Days), or a resolution being passed or an order being made for the administration or the winding-up, bankruptcy or dissolution of the Contractor, provided always that no Replacement Supplier has been approved by the Board in which event the Board shall not be entitled to terminate this Agreement on the grounds of the Contractor's insolvency;
- (v) the Contractor is unable to meet its debts as they fall due;
- (vi) if the Contractor shall suffer any event analogous to the events set out in Clauses (i) to (v) above in any jurisdiction in which it is incorporated or resident; or
- (vii) the Board reasonably anticipates that any of the events set out in Clauses

21.2.1(i) to 21.2.1(vi) is about to occur.

- 21.2.2 the Contractor failing to achieve Final Acceptance by the Longstop Date;
- 21.2.3 six hundred (600) or more Service Points in total have been accrued in any two (2) consecutive Quarterly Periods;
- 21.2.4 the Contractor committing a material breach of its obligations under this Agreement, or a series of breaches which, when taken together, constitute a material breach;
- 21.2.5 Two and hundred and fifty (250) or more Service Points have been accrued for any System in a Quarterly Period in any period of two (2) consecutive Quarterly Periods;
- 21.2.6 any criminal investigation, prosecution and/or conviction (whether or not subject to appeal or further judicial process) of the Contractor under the relevant legislative regime which shall be deemed to include individual directors, or officers of the Contractor (all referred to herein as a "Conviction");
- 21.2.7 the Contractor, whether by its own act or omission, or the act or omission of any Third Party Supplier, breaching the provisions of Schedule Part 8 (Corrupt Gifts and Payments);
- 21.2.8 the occurrence of any Change in Control or any other act which is prohibited by Clause 28 (Assignment, Sub-Contracting and Changes in Control);
- 21.2.9 the Contractor failing to comply with the provisions of Clause 28 (Assignment, Sub-Contracting and Changes in Control); and/or

**CLO NOTE: Other ground to constitute default may be required dependent on the terms of tenders submitted.**

- 21.3 The Contractor shall notify the Board of the occurrence, and details, of any event which gives rise to a Contractor Default and of any event or circumstance which is likely, with the passage of time or otherwise, to constitute or give rise to a Contractor Default, in

either case promptly on the Contractor becoming aware of its occurrence.

21.4 On the occurrence of a Contractor Default, or within a reasonable time after the Board becomes aware of the same, or while the same is subsisting, the Board may:

21.4.1 in the case of Contractor Default referred to in Clause 21.2.1, 21.2.2 and/or 21.2.3 terminate this Agreement in its entirety by notice in writing having immediate effect;

21.4.2 in the case of any Contractor Default referred to in Clause 21.2.4 to 21.2.9 which is capable of remedy, serve notice of default on the Contractor requiring the Contractor at the Contractor's option either:

- (i) to remedy the Contractor Default referred to in such notice of default (if the same is continuing) within twenty (20) Working Days of such notice of default; or
- (ii) to put forward within twenty (20) Working Days of such notice of default a reasonable programme (set out, if appropriate, in stages) for remedying the Contractor Default. The programme shall specify in reasonable detail the manner in, and the latest date by, which such the Contractor Default is proposed to be remedied (the Contractor shall only have the option of putting forward a programme in accordance with this paragraph if it first notifies the Board within ten (10) Working Days of such notice of default that it proposes to do so).

21.5 Where the Contractor puts forward a programme in accordance with Clause 21.4, the Board shall have twenty (20) Working Days from receipt of the same within which to notify the Contractor (acting reasonably) that it does not accept the programme, failing which the Board shall be deemed to have accepted the programme. Where the Board notifies the Contractor that it does not accept the programme as being reasonable, the parties shall endeavour within the following five (5) Working Days to agree any necessary amendments to the programme put forward. In the absence of agreement

within five (5) Working Days, the question of whether the programme (as the same may have been amended by agreement) will remedy the Contractor Default in a reasonable manner and within a reasonable time period (and, if not, what would be a reasonable programme) may be referred by either party for resolution in accordance with the Dispute Resolution Procedure.

21.6 If:

21.6.1 the Contractor Default notified in a notice of default served under Clause 21.4.2(i) is not remedied before the expiry of the period referred to in that Clause; or

21.6.2 where the Contractor puts forward a programme pursuant to Clause 21.4.2(ii) which has been accepted by the Board or has been determined to be reasonable and the Contractor fails to achieve any element of the programme or the end date for the programme (as the case may be); or

21.6.3 any programme put forward by the Contractor pursuant to Clause 21.4.2(ii) is rejected by the Board as not being reasonable, and the Dispute Resolution Procedure does not find against that rejection,

21.6.4 the Board considers that procurement of a new agreement is required as a result of a substantial modification, or a series of modifications which, taken together, constitute a substantial modification, being, or having been, effected to the Agreement; or

21.6.5 the Board becomes aware that the Contractor and/or any Relevant Person has been convicted of any of the offences listed in Regulation 58(1) of the Public Contracts (Scotland) Regulations 2015; or

21.6.6 the ECJ makes a declaration that the Agreement should not have been awarded to the Contractor in view of a serious infringement of the obligations under the Treaty and Directive; or

21.6.7 proceedings are served on the Board in connection with or related to:-

- (i) any substitution of the Contractor with a Replacement Supplier or any Transfer of the Agreement in whole or in part approved by the Board pursuant to Clause 28; and/or
- (ii) the Agreement between the Board and the Replacement Supplier or the Transferee;

then the Board may terminate this Agreement in its entirety by written notice to the Contractor with immediate effect. Provided that for the purposes of this Clause 21.6 if the Contractor's performance of the programme is adversely affected by the occurrence of Force Majeure, subject to the Contractor complying with the mitigation and other requirements in this Agreement concerning Force Majeure the time for performance of the programme or any relevant element of it shall be deemed to be extended by a period equal to the delay caused by Force Majeure which is agreed by the parties or determined in accordance with the Dispute Resolution Procedure.

- 21.7 Subject to Clause 20.2 the Contractor shall reimburse the Board for all costs incurred by the Board in tendering for services to replace the Managed Services in the event that the Board exercises any of its rights under this Clause 21 (including, without limitation, legal and administrative expenses).
- 21.8 The rights of the Board (to terminate or otherwise) under this Clause 21 are in addition (and without prejudice) to any other right which the Board may have to claim the amount of loss or damage suffered by the Board on account of the acts or omissions of the Contractor (or to take any action other than termination of this Agreement).
- 21.9 For the purposes of this Agreement "**Board Default**" means any failure by the Board to pay any sum or sums due to the Contractor under this Agreement (which sums are not in dispute) which, either singly or in aggregate, exceed an amount equal to two (2) unpaid invoices submitted by the Contractor and such failure continues for thirty (30) Working Days from the date of receipt by the Board of a notice of non payment from the Contractor.

- 21.10 On the occurrence of a Board Default or within a reasonable time after the Contractor becomes aware of the same, the Contractor may, at its option, serve written notice on the Board of the occurrence (and specifying details) of the Board Default. If the Board Default has not been rectified or remedied by the Board (or otherwise) within thirty (30) Working Days of such notice the Contractor may serve a further written notice on the Board terminating this Agreement within immediate effect.
- 21.11 The Contractor shall not exercise or purport to exercise any right to terminate this Agreement except as expressly set out in this Agreement.
- 21.12 Subject to the limit of liability in Clause 20.2, the Board shall reimburse the Contractor for all costs (including the costs of legal and professional services, legal costs being paid on a client paying basis and any other sums due to the Contractor) incurred by the Contractor exercising its rights to terminate this Agreement in accordance with Clause 21.10 (including any relevant administrative expenses). The Contractor shall take reasonable steps to mitigate such costs.

21.13 Consequences of Expiration or Termination

21.13.1 In the event of termination or expiry of this Agreement for whatever reason:

- (i) the Contractor shall on request repay forthwith to the Board any payments made by the Board relating to any Managed Services not properly performed or Reagents/Consumables not properly delivered by the Contractor in accordance with the Agreement;
- (ii) subject to paragraph (g) below the Contractor shall immediately cease to use all Board Data and shall procure that all Third Party Suppliers so cease;
- (iii) the Contractor shall provide to the Board (or a New Contractor nominated by the Board) all Board Data in its possession or in the possession of any

Third Party Suppliers (including without limitation any Board Data residing on/in any Component parts of the Solution) in a format nominated by the Board (acting reasonably), together with all training manuals and other related documentation, and all copies thereof;

- (iv) the Contractor shall return to the Board all items in its possession or in the possession of any Third Party Suppliers provided to it or to them (as the case may be) by the Board in the course of this Agreement or otherwise including Board Property but excluding Board assets purchased by the Contractor;
- (v) The Board shall be entitled to witness the physical removal by the Contractor of all Board Data from all Component parts of the Solution and shall be entitled to perform its own independent checks to verify that the Contractor has complied with its obligations under this Clause 21.13;
- (vi) the Contractor shall render reasonable assistance to the Board, if requested, to the extent necessary to effect an orderly assumption by a New Contractor of the services performed by the Contractor hereunder;
- (vii) the Contractor shall at the request of the Board continue to provide the Managed Services for a period of up to twenty four (24) months (or longer if requested by the Board) beyond the date of expiry or termination. For this period the Board shall continue to pay the Charges (or an agreed appropriate pro-related percentage thereof if not all of the Managed Services are to be provided) for services properly performed and Reagents/Consumables properly delivered as if this Agreement had not been terminated.

21.13.2 Termination, expiration, cancellation or abandonment of this Agreement through any means and for any reason shall not relieve the Parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies

of either Party with respect to any antecedent breach of any of the provisions of this Agreement, or which are either expressed, or by implication, required to survive termination or expiry of this Agreement.

21.13.3 All invoices properly due and outstanding shall be issued and paid in accordance with Schedule Part 3 and all orders for Reagents/Consumables submitted until the date of termination shall be fulfilled unless the Board request otherwise.

21.14 All provisions under Clause 17 relating to Confidential Information shall survive in force for a period of ten (10) years following the termination, expiration, cancellation or abandonment of this Agreement excepting in respect of patient information, in respect of which event the obligations to maintain such information in confidence shall continue in perpetuity.

21.15 On the expiry or earlier termination of this Agreement, the parties agree that whether TUPE shall apply in respect of the provision thereafter of any service equivalent to the Managed Services shall be determined in accordance with the Legal Requirements at the date of such expiry or termination, and the provisions of Schedule Part 4 shall apply without prejudice to such determination.

21.16 During the period referred to above prior to termination the Contractor shall also comply, and act in such a way as to ensure the Board can comply, with TUPE in respect of any employees who may be Affected Employees including without limitation complying with regulation 11 of TUPE. Without limitation the Contractor shall within fourteen (14) days of receiving such request provide all information regarding such employees as the Board shall reasonably request.

21.17 The Contractor undertakes that in the twelve (12) months preceding any transfer possibility or once it receives notice of any potential transfer of Affected Employees it shall not (a) materially vary the terms and conditions of any Affected Employee affected or potentially affected by such transfer and/or (b) terminate the employment of any of the

Affected Employees affected or potentially affected by the transfer on or before the date

of the transfer, without the prior written consent of the Board.

- 21.18 The Contractor agrees to ensure that there will not be in existence on the date of any transfer, any written or unwritten contract of employment with any Affected Employee affected by that transfer which cannot be terminated by three month's notice or less without giving rise to a claim for damages or compensation.
- 21.19 The Contractor will maintain complete personnel records in the format normally adopted by it regarding the service of each Affected Employee including all personnel records required to be maintained by law. The Contractor further undertakes to deliver the personnel records of any Affected Employee affected by any transfer, to the Board (or such other person as the Board may direct), on the date of that transfer.
- 21.20 The Contractor shall notify the Board not later than one (1) month before any transfer (or as soon as reasonably practicable after it becomes aware of the same) of any outstanding disputes of a material nature between any Affected Employee affected by that transfer and the Contractor.

## **22. LIAISON AND PROVISION OF INFORMATION AT TERMINATION**

- 22.1 Upon termination of this Agreement the Contractor shall subject to prior compliance with Clause 21.13 remove all Component parts of the Solution from all Sites, at the Contractor's sole expense. In so doing and, more generally, whenever any Components of the Solution are being removed from Sites the Contractor shall cause as little damage to the Site and interruption to the Board's business as possible and make good, to the reasonable satisfaction of the Board, any damage which is thereby caused.
- 22.2 In anticipation of termination of this Agreement (either within twenty four (24) months prior to natural expiry, or as soon as possible prior to earlier termination in accordance with its terms) the Board may require the Contractor to deliver up to the Board such information held by the Contractor as is specified in the Specification and/or as the Board may reasonably require, and in the format specified by the Board (in the Specification or otherwise), in relation to the use of all Component parts of the Solution during the period

of this Agreement including, without prejudice to the foregoing generality, information regarding the volume of Reagents/Consumables provided by the Contractor during the period of this Agreement. The Contractor will positively assist the Board in ensuring a smooth, timely, transition of services to a New Contractor following the end of the Agreement.

22.3 Upon notification that it has been unsuccessful in being awarded a contract for provision of the Managed Services (or equivalent services) for a further period at expiry of the period of this Agreement, or in the event that the Contractor chooses not to compete for subsequent service provision, the Contractor will:-

22.3.1 appoint a project manager for a period of two (2) months prior to the termination of this Agreement and for any period following termination when the Managed Services may be being delivered pursuant to Clause 21.13.1, to plan and manage the transfer of activities in relation to the Managed Services;

22.3.2 meet with the New Contractor and representatives of the Board to agree a transition plan, timescales, responsibilities and detailed transfer activities;

22.3.3 draw up a project plan, showing milestones, timescales, responsibilities and the Contractor specific activities necessary to effect the handover of responsibility for delivery of the Managed Services to the New Contractor.

## **23. ALTERNATIVE PRODUCTS AND/OR EQUIPMENT**

### **23.1 Improved Reagents**

If the Contractor or a Third Party Supplier wishes to provide the Board with, or the Board wishes to use, an improved or modified version of a Reagent for use under this Agreement, which when compared to the relevant Reagent has improved performance characteristics (e.g. sensitivity, stability, linearity, etc.) or more favourable pricing, or is more user friendly (collectively an **“Improved Reagent”**), the Party wishing to include the Reagent within the Managed Services shall give the other at least three (3) months’ notice in writing of such Improved Reagent and the Parties may at the Board’s option

enter into discussions in accordance with the Change Control Procedure.

## 23.2 Changes in Reagents

If the Contractor or a Third Party Supplier wishes to change the formulation or any aspect of a Reagent including pack sizes, and/or the discontinuation of batch continuity, they must provide the Board with at least three (3) months notice in writing, and allow the Board to carry out an appropriate evaluation of the amended Reagent and its performance characteristics (including without limitation, sensitivity, stability, linearity). If the Board does not accept the proposed changes to the Reagent, including as to pack sizes and/or batch continuity discontinuation, the Contractor will ensure the continued supply of the unchanged Reagent or if that is not possible, the Contractor shall give appropriate recognition, in assessing any wastage levels in respect of that Reagent, to the changes introduced.

## 23.3 Changes in Equipment

23.3.1 If at any time subsequent to the Commencement Date, and notwithstanding the purchase by the Contractor of all Nominated Existing Items, the Board wishes for the Contractor to include, within the scope of the Managed Services, any additional or alternative equipment, the Change Control Procedure shall govern the communications and process between the Parties in relation to any such new/alternative equipment.

23.3.2 If the new/alternative equipment which the Board wishes the Contractor to include within the scope of the Managed Services is already being used by the Board ("**Adopted Equipment**"), then the following sub-clauses will also apply. These sub-clauses will not apply either to new equipment purchased by the Contractor, nor to Nominated Existing Items.

23.3.3 The performance of the Adopted Equipment shall be monitored and measured by the Contractor for a period of three (3) months. During such three (3) month period, the performance of the Adopted Equipment will not be considered in

connection with any assessment of the Contractor's performance of the Managed Services.

23.3.4 The Contractor will work pro-actively and in cooperation with the Board, to improve the performance of the Adopted Equipment.

23.3.5 If, at the end of such three (3) month period the Board considers that the Adopted Equipment is performing at a standard which is acceptable to it, the Board and the Contractor will agree, with reference to the performance data collected by the Contractor during that three (3) month period, and taking into account any improvements and alterations to be implemented by the Contractor, the Performance Specifications in respect of such Adopted Equipment.

## **24. EQUIPMENT REFRESH AND GAIN SHARING**

24.1 The Contractor shall update the Equipment Refresh Programme throughout the Term in accordance with the provisions of Clause 24.5 to include, as a minimum, proposals:

24.1.1 that ensure that the Solution necessary for the provision of the Managed Services is refreshed (by replacement, addition, modification or otherwise) on an ongoing basis throughout the Term to the extent necessary so as to enable the Contractor to provide the Managed Services in accordance with the Service Levels;

24.1.2 that ensure that any software necessary for the provision of the Managed Services is a currently supported version of that software;

24.1.3 to apply to the Managed Services proven tools and methodologies that may be of financial, clinical or operational benefit to the Board; and

24.1.4 to prepare and implement procedures to ensure that the Managed Services are, at all times, provided in accordance with Good Industry Practice.

24.2 The Contractor shall ensure that the Equipment Refresh Programme delivers refresh and replacement of Equipment on the basis anticipated in the Financial Model and is at least comparable with the level of technological change and innovation generally being used

by similar service providers providing services similar to the Managed Services and associated services to the healthcare sector.

24.3 The Contractor shall use all reasonable endeavours to ensure that the Equipment Refresh Programme is conducted in a manner which complements the timing and content of any internal Board programme of technology refresh and/or continuous improvement as notified by the Board to the Contractor from time to time or of which the Contractor should reasonably be aware.

24.4 The Contractor shall provide the Board in writing on a quarterly basis:

24.4.1 an update of the Equipment Refresh Programme for review by the Board;

24.4.2 details of any improvement developed in accordance with the Equipment Refresh Programme;

24.4.3 details of any upgrades to software required to deliver the Managed Services ("**Upgrades**"), providing details of the functionality and features of the Upgrades (but always providing that such Upgrades will be available as part of the Managed Services without any additional cost to the Board if such Upgrades are required to ensure the software required to deliver the Managed Services is a supported version or if the Upgrade is provided free of charge by the Contractor or licensor of the same and can be provided free of charge to the Board); and

24.4.4 information on any ancillary changes to the Solution that are required, the anticipated impact (if any) upon the Managed Services, the Service Levels, and Charges and the achievement of any benefit which may result from the incorporation of any improvement, Upgrade or their use in the provision of the Managed Services and the reasons for such recommendation.

24.5 In the event that the Board considers that the Equipment Refresh Programme proposed by the Contractor should be implemented, the Board will advise the Contractor accordingly and any implementation of the same shall be undertaken by means of the Change Control Procedure. Nothing contained in this Agreement shall oblige the Board

to implement any aspect of the Equipment Refresh Programme to the extent such implementation would give rise to: (i) an increase in the Charges payable to the Contractor; or (ii) the Board incurring any cost or expense in addition to the Charges or any other charge payable to the Contractor as a direct result of implementation of the Equipment Refresh Programme, in both cases except to the extent necessarily incurred to permit the Contractor to deliver the Managed Services.

24.6 Net Gain will be calculated at the end of each Contract Year and the Contractor shall submit reports to the Board within ten (10) Working Days of the end of each Contract Year providing full details of the Net Gain in that Contract Year.

24.7 Where there has been a Net Gain the Parties shall, acting reasonably, agree through the Change Control Procedure any Changes to the Charges required to deliver the Gain to the Board with effect from the expiry of that Contract Year. If the Parties are unable to agree a resolution within ten (10) Working Days of the matter first being raised for discussion, either Party may refer the matter to the Dispute Resolution Procedure.

24.8 In the event that there is no Net Gain there shall be no adjustment to the Charges and, to avoid doubt, where the Loss exceeds the Gain there shall be no increase to the Charges.

## **25. DISPUTE RESOLUTION**

25.1 All disputes or differences which shall at any time hereafter arise between the Contractor and the Board in respect of the construction or effect of this Agreement or the rights, duties and liabilities of the parties hereunder or any matter or event connected with or arising out of this Agreement (“**Dispute**”) shall first be referred to Director of Finance for the Board and **CLO NOTE: Please advise** for the Contractor for resolution.

25.2 If the Dispute has not been resolved within ten (10) Working Days of it being referred under Clause 25.1 above either party may by notice to the other refer the Dispute to an expert named by the parties to act as Expert in resolution of the Dispute. If the parties fail to agree the appointment of the Expert within five (5) Working Days of such notice, the Expert shall be appointed upon application of either party by the President of the Law

Society of Scotland.

- 25.3 The Expert shall at his discretion hear oral evidence from the parties or require written submissions. Each party shall have a period of ten (10) Working Days from the date of appointment of the Expert to submit their representations and the Expert shall intimate his decision no later than four (4) weeks after his appointment.
- 25.4 The Expert shall act as an expert and not as an arbiter and shall act fairly and impartially.
- 25.5 The Expert shall make an award of expenses.
- 25.6 The decision of the Expert shall be final and binding on the parties.

## **26. AUDITS**

- 26.1 The Contractor shall provide the Board with a written report, on a monthly basis, prior to Final Acceptance and on a quarterly basis thereafter giving details of:-
- 26.1.1 (prior to Final Acceptance) progress in relation to the Implementation Plan (or Detailed Implementation Plan, once agreed);
- 26.1.2 details of any problems encountered in the provision of the Managed Services; and
- 26.1.3 details of any failure to meet the Service Levels during the relevant month.
- 26.2 The Contractor shall keep or cause to be kept full and accurate records (“**the Records**”) of all Managed Services performed in connection with this Agreement, together with all materials used in connection therewith. The Contractor shall also comply with the requirements of Schedule Part 11 in relation to performance monitoring.
- 26.3 The Contractor hereby grants to Board, and any statutory auditors of the Board and their respective authorised agents, the right of reasonable access to the Records and agrees to provide all reasonable assistance at all times during the currency of this Agreement for the purposes of carrying out an audit of the Contractor’s compliance with this Agreement including all activities, the calculation of Charges in accordance with the terms of this Agreement, performance, security and integrity in connection therewith. The Contractor

shall procure that the Board shall enjoy unhindered access to the premises and/or staff, documents used in connection with performance of the Managed Services including those of any Third Party Supplier.

- 26.4 Without prejudice to the foregoing, in the event of an investigation into suspected fraudulent activity or other impropriety by the Contractor or any third party the Board reserves for itself any statutory auditors of the Board and their respective authorised agents the rights of immediate access to the Records described in Clause 26.3 above and the Contractor agrees to render and procure all Third Party Suppliers render all necessary assistance to the conduct of such investigation at all times during the currency of this Contract or at any time thereafter. For the avoidance of doubt, the Contractor shall only be repaid all its expenses incurred in giving assistance pursuant to this Clause 26.4 in the event that the result of such investigation reveals no fraudulent activity or other impropriety by the Contractor, its servants, agents or sub-contractors.

## **27. NOTICES**

- 27.1 All notices, requests or other communications required or permitted to be given under this Agreement to any Party shall be in writing, although can be sent by email, provided immediately followed by one of the methods specified below. Notices, requests or other communications shall be deemed to have been sufficiently given when delivered by personal service or sent by registered mail or a recognised private mail carrier service or by email or facsimile with a written confirmation copy, to the recipient addressed as follows:

If to the Contractor: marked for the attention of [ • ]

**CLO NOTE: Address to be inserted**

If to the Board: marked for the attention of [ • ]

**CLO NOTE: Address to be inserted**

- 27.2 All such communications shall be deemed to be effective on the Working Day on which personally served or on the next following Working Day if personally served after 4pm or on a Saturday or Sunday or Public Holiday recognised by the Board, or, if sent by

registered mail, on the fourth Working Day following the date presented to the postal authorities for delivery to the other Party (the date stamped on the envelope being evidence of the date of such presentation) or the next Working Day if such a day falls on a Saturday or Sunday or Public Holiday recognised by the Board, or if by private mail carrier service, the date of the carrier receipt or the next Working Day is received after 4:00pm or on a Saturday or Sunday or Public Holiday recognised by the Board, or if by e-mail or facsimile, on the email/facsimile date if sent before 4:00pm, or the next Working Day if sent after 4:00pm or on a Saturday, Sunday or Public Holiday recognised by the Board. Either Party may give to the other written notice of a change of address, in which event any communication shall thereafter be given to such Party as above provided at such changed address.

## **28. ASSIGNATION, SUB-CONTRACTING AND CHANGES IN CONTROL**

- 28.1 This Agreement is personal to the Contractor. The Contractor shall not assign, novate, or otherwise dispose of this Agreement or any part thereof without the previous consent in writing of the Board provided that this Agreement shall transfer automatically to any Replacement Supplier or Transferee approved by the Board. The Contractor may not sub-contract or delegate any of its obligations to any party other than an agreed Third Party Supplier without the prior written consent of the Board. Specific Third Party Suppliers must be approved in respect of specific aspects of the Managed Services. No changes to a Third Party Supplier's delegated responsibilities may be made without the prior written consent of the Board. No Change in Control (at any time) in the Contractor (or any company of which the Contractor is a subsidiary) shall be permitted without the prior written approval of the Board where the person acquiring control is a Restricted Person, is controlled by a Restricted Person, or is acquiring control on behalf of a Restricted Person or on behalf of a person controlled by a Restricted Person.
- 28.2 The Board shall be entitled to assign its rights and obligations under this Agreement without restriction.

## **29. RELATIONSHIP OF PARTIES**

The relationship of the Parties under this Agreement is that of independent contractors. Nothing contained in this Agreement is intended or is to be construed so as to constitute the Parties as partners, joint venturers, agent and principal, or either Party as employee or employer of the other.

## **30. FORCE MAJEURE**

30.1 Neither Party shall be held in breach of this Agreement for failure to perform any of its obligations hereunder and the time required for performance shall be extended for a period equal to the period of such delay, provided that such delay has been caused by or is a result of any acts of God, acts of the public enemy, civil strife, wars declared or undeclared, embargoes, labour disputes, including strikes, lockouts, job actions or boycotts (but provided that such disputes must affect more people than just the relevant Party's employees) fires, explosions, floods, or by any other supervening unforeseeable circumstances beyond the reasonable control of the Party so affected provided that a failure in the performance of a Third Party Supplier or the occurrence of an event listed at Clause 21.2.1 in relation to a Third Party Supplier shall not be considered to be an event of force majeure.

30.2 The Party so affected shall: (a) give prompt written notice to the other Party of the nature and date of commencement of the force majeure event and its expected duration; and (b) use its commercially reasonable efforts to relieve the effect of such cause as rapidly as possible and to work around the event of force majeure notwithstanding its occurrence. Notwithstanding the above, if an event of force majeure prevents or will prevent performance of a material provision of this Agreement by one Party for more than three (3) months, then the other Party may terminate this Agreement upon providing ten (10) Working Days written notice to the non-performing Party.

## **31. SEVERABILITY**

If any provision of this Agreement is held to be invalid, illegal or unenforceable by a court

or agency of competent jurisdiction, that provision shall be severed or shall be modified by the Parties so as to be legally enforceable (and to the extent modified, it shall be modified so as to reflect, to the extent possible, the intent of the Parties) and the validity, legality and enforceability of the remaining provisions shall not be affected or impaired in any way.

## **32. ENTIRE AGREEMENT**

This Agreement is the sole understanding and agreement of the Parties hereto with respect to the subject matter hereof and supersedes all other prior agreements and understandings which may exist, provided that nothing herein shall operate or be construed as to limit or exclude either party's liability for fraud or for fraudulent misrepresentation.

## **33. CORRUPT GIFTS AND PAYMENTS**

The provisions of Schedule Part 8 shall apply to this Agreement.

## **34. WAIVER**

34.1 The failure of either party to seek redress for breaches or to insist on strict performance of any provision of the Agreement or the failure of either party to exercise any right or remedy to which it is entitled under the Agreement shall not constitute a waiver thereof and shall not cause diminution of the obligations under the Agreement.

34.2 No waiver of any provision of the Agreement shall be effective unless it is agreed by both parties in writing.

34.3 No waiver of any default shall constitute a waiver of any subsequent default.

## **35. EQUAL OPPORTUNITIES COMPLIANCE**

The Contractor shall not unlawfully discriminate either directly or indirectly on such grounds as race, colour, ethnic or national origin, disability, sex or sexual orientation, religion or belief, or age and without prejudice to the generality of the foregoing the Contractor shall not unlawfully discriminate within the meaning and scope of the Equality

Act 2010, the Human Rights Act 1998 or other relevant or equivalent legislation, or any statutory modification or re-enactment thereof. The Contractor shall take all reasonable steps to secure the observance of this clause by all employees and representatives of the Contractor employed in the performance of the Agreement.

## **36. RELIEF EVENT**

36.1 For the purpose of this Clause 36, a “**Relief Event**” means:

36.1.1 any breach of any express provision of this Agreement by the Board or any Board Party (unless, and to the extent, caused or contributed to by the Contractor or any Third Party Supplier); or

36.1.2 wilful or negligent damage to Reagents, any Equipment, the SMS and other equipment and laboratory materials provided by the Contractor which is caused by the Board or a Board Party whilst on the Board's premises save where (and to the extent) caused or contributed to by the Contractor or any Third Party Supplier and/or the Board (or relevant Board Party) is acting in accordance with a recommendation or instruction of the Contractor or any Third Party Supplier;

36.1.3 any negligent act or omission of the Board or any Board Party, save where:

(i) (and to the extent) caused or contributed to by the Contractor or any Third Party Supplier;

(ii) the Board (or relevant Board Party) is acting in accordance with a recommendation or instruction of the Contractor or any Third Party Supplier;

(iii) any such act or omission giving rise to such failure was provided for in this Agreement or otherwise necessary to ensure compliance by the Board with its obligations under this Agreement; or

(iv) the consequences of any such deliberate act or omission or failure by the Board (or relevant Board Party) giving rise to such failure would have

been prevented by the proper performance of the Contractor's obligations under this Agreement.

36.2 If:

36.2.1 a Relief Event causes a material adverse interference with, or causes a material failure by the Contractor to successfully complete the Milestone Acceptance Procedure in accordance with, the timescales set out in the Implementation Plan or Detailed Implementation Plan, once agreed; and

36.2.2 provided that the Relief Event and the likely effects of it are notified to the Board by the Contractor in writing within ten (10) Working Days of the date on which the Contractor or any Third Party Supplier became aware (or ought reasonably to have become so aware) of the occurrence of the Relief Event;

then (subject to Clauses 36.4 and 36.5) to the extent such failure or interference arises as a result of such Relief Event such failure by the Contractor to successfully complete the Acceptance Procedure shall not constitute a breach of this Agreement by the Contractor. Such interference shall be taken account of in assessing completion of the Acceptance Procedure so that, provided that the Contractor can show to the reasonable satisfaction of the Board that, but for the occurrence of the Relief Event it would have successfully completed the Milestone Acceptance Procedure by the date specified in the Implementation Plan or the Detailed Implementation Plan, once agreed the Contractor shall be entitled to an extension of time equal to the delay.

36.3 If a Relief Event causes a material adverse interference with, or causes a material failure of performance of this Agreement by the Contractor (as determined by the facts and circumstances in each case) and provided that the Relief Event and the likely effects of it are notified to the Board by the Contractor in writing within ten (10) Working Days of the date on which the Contractor or any Third Party Supplier became aware (or ought reasonably to have become so aware) of the occurrence of the Relief Event, then (subject to Clauses 36.4 and 36.5) to the extent such failure or interference arises as a result of such Relief Event:

36.3.1 such failure by the Contractor to perform this Agreement, shall not constitute a breach of the provisions of this Agreement by the Contractor; and

36.3.2 such interference shall be taken account of in measuring performance of the Managed Services, which shall be operated as though the Agreement had been performed free from such adverse interference,

so that, provided that the Contractor can show to the reasonable satisfaction of the Board that but for the occurrence of the Relief Event it would have performed in accordance with this Agreement, the Contractor shall be entitled to payment under this Agreement as if the Relief Event had not occurred and the Board shall not be entitled to apply any Service Deductions in respect of poor performance of the Solution (or any part of it) or failure to perform the Managed Services if and to the extent that the Relief Event is the direct cause of such poor performance or failure.

36.4 The rights and remedies of the Contractor under this Clause 36 shall be the only rights and remedies of the Contractor in respect of the occurrence of a Relief Event and the Contractor hereby waives all and any other rights, and agrees that it shall not be entitled to exercise any other right or remedy in respect of the occurrence of that Relief Event.

36.5 The Contractor shall take all reasonable steps to mitigate the consequences of a Relief Event insofar as it affects the Contractor's ability to perform its obligations under this Agreement. To the extent that the Contractor does not take such steps, the Contractor shall not be entitled to, and shall not receive, the relief specified in Clauses 36.2 and 36.3. To avoid doubt, Clause 36.1.3(ii) shall not impose a general obligation on the Board to take such steps and shall apply (and be construed) solely for the purpose of establishing whether a Relief Event has occurred.

## **37. SOCIAL BENEFITS**

The Contractor shall implement and perform the social and environmental benefits detailed in Schedule Part 13 .

### **38. RELATIONSHIP WITH NHS SCOTLAND BOARDS**

38.1 The Board and the Contractor hereby agree that the Board is entering into this Agreement on its own behalf and on behalf of and for the benefit of NHS Scotland Health Boards to which the Board provides Screening Services. The Contractor acknowledges that the provision of the Managed Services, by the Contractor pursuant to the terms of this Agreement shall be deemed to be for the benefit of the Board and such NHS Scotland Health Boards and the Contractor shall owe a duty of care to such NHS Scotland Health Boards in respect of provision of Managed Services in accordance with the terms of this Agreement.

38.2 The Contractor warrants that (i) any warranty, representation, undertaking or indemnity given or made to the Board by the Contractor in terms of this Agreement shall be deemed, for the purpose of this Agreement, to have been made to the NHS Scotland Health Boards to which the Board provides Screening Services and (ii) for the purpose of calculating any loss, injury, damages, costs or expenses due from the Contractor, subject to the terms of this Agreement, arising directly or indirectly from performance of the Managed Services or otherwise arising out of or in connection with this Agreement and/or its termination or in respect of any indemnity, warranty, representation or undertaking in terms of this Agreement, there shall be deemed to be included by way of addition within such loss, injury, damages, costs or expenses any or all loss, injury, damages, costs or expenses suffered or incurred by the NHS Scotland Health Boards to which the Board provides Screening Services and as if such NHS Scotland Health Boards were a party to this Agreement in the stead of the Board and such obligations were due directly to such NHS Scotland Health Boards. To avoid doubt any claims which arise between the Contractor and any NHS Scotland Health Board for loss, injury, damages, costs or expenses suffered or incurred by the Contractor or any NHS Scotland Health Board may only be raised by:-

38.2.1 the Contractor against the Board; or

38.2.2 the Board (on behalf of a NHS Scotland Health Board) against the Contractor.

### 39. GOVERNING LAW

The parties hereby accept, subject to Clause 24, the exclusive jurisdiction of the Scottish courts, and agree that this Agreement is to be governed and construed according to Scots law. IN WITNESS WHEREOF, these presents consisting of this and the preceding [ • ] pages and the Schedule are executed in duplicate as follows:-

For and on behalf of [ • ] Health Board

|                   |                    |
|-------------------|--------------------|
| Place .....       | Date .....         |
| Signed by .....   | Witnessed by ..... |
| Print Name .....  | Print Name .....   |
| Designation ..... | Designation .....  |
|                   | Address .....      |
|                   | .....              |

For and on behalf of [ • ] Limited

|                   |                    |
|-------------------|--------------------|
| Place .....       | Date .....         |
| Signed by .....   | Witnessed by ..... |
| Print Name .....  | Print Name .....   |
| Designation ..... | Designation .....  |
|                   | Address .....      |
|                   | .....              |

This is the Schedule referred to in the foregoing Agreement between [ • ] Health Board and [ • ] Limited

## **SCHEDULE: PART 1**

### **EQUIPMENT INCLUDED IN THE MANAGED SERVICES, AND THEIR LOCATIONS**

**[TO BE COMPLETED BY INSERTION OF TABLE]**

## SCHEDULE: PART 2

### REAGENTS

**[TO BE COMPLETED BY INSERTION OF TABLE]**

## SCHEDULE: PART 3

### FINANCIAL SCHEDULE

#### 1. General

Subject to the terms and conditions of this Agreement, and in consideration for the satisfactory performance of the Managed Services, the Board shall pay the Unitary Charge.

#### 2. Unitary Charge

2.1 Following Final Acceptance, the Contractor shall charge the Unitary Charge to the Board for the Managed Services as ordered by the Board calculated on the basis detailed below and in the Appendix to this Schedule Part 3. The Unitary Charge shall be payable by the Board in twelve instalments monthly in arrears.

2.2 The annual Unitary Charge shall be the total of:

- The annual Fixed Charge;
- The annual Semi-Fixed Charge (as indexed); and
- The Actual Variable Costs (in accordance with paragraphs 3 and 4 below).

#### 3. The Actual Variable Costs

3.1 In this paragraph 3:

- **“Assumed Volume”** shall be based on the total number of tests forecaster by the public health population testing predictions to be undertaken each year as detailed in Appendix 2 of Schedule Part 3;
- **“Assumed Charge”** shall be the Cost per Test multiplied by the Assumed Volume;
- **“Actual Volume”** shall be the actual number of tests undertaken by the Board in each of the Contract Years;
- **“Actual Variable Costs”** shall be the Cost per Test multiplied by the Actual Volume;
- **“Cost per Test”** means the cost per test detailed in Appendix 1 of Schedule Part 3.

3.2 The Contractor shall identify the amount of equipment required for the Assumed Volume of the Board and specify the amount of reagents and consumables required on an annual basis to meet the workload figures. This shall take into account any dead volumes, expiry dates on packs, their Quality Control regime, plus planned preventative maintenance requirement for the equipment and details of anticipated spare parts.

#### 4. Indexation

On the second anniversary of the date of Final Acceptance Date and annually at the end of each Contract Year thereafter the Contractor may vary the Semi-Fixed Charges and the Annual Test Cost by the change in the Index from the date of Final Acceptance Date to the second anniversary of that date and thereafter by the change in the Index during any subsequent Contract Years. The Fixed Charges are not subject to indexation except through Change Control Procedure.

#### 5. Costs Included in Unitary Charge

The Contractor hereby confirms that the following is included in the Unitary Charge:-

- Equipment supplied and any associated solution to provide an uninterruptible power supply (UPS). This MUST include the cost of all Equipment which the Contractor plans to replace throughout the Term in accordance with a rolling replacement programme or otherwise (see Clause 24 and Schedule Part 12 relating to refresh costs of Equipment);
- Any costs associated with any remedial or enabling works associated with the initial installation of all Components of the Solution (including, without limitation, new network connections, benching alterations, air conditioning, changes to power supplies, layout changes, etc.).
- All cost associated with the installation, qualification and validation of new equipment at the Site (including delivery and any storage).
- All costs associated with the commissioning, decommissioning and relocation of each analyser, tracking and pre / post analytical systems during the reconfiguration process and the duration of the Term.
- Any costs associated with the decommissioning and removal of any equipment made redundant or superseded by introduction of the Solution or at any time during the Term.
- Any costs associated with the current planned service reconfiguration for any Components of the Solution.
- Clear identification and inclusion of all costs of any associated IT requirements, hardware and software. This must include Middleware, inventory management and temperature monitoring systems.
- Licensing costs including workstations.
- Interfacing of equipment to SCCRS and its ongoing support.
- All costs associated with the operation of all analysers included in the Solution. Including, without limitation:
  - reagents, chemicals and consumables associated with the Equipment and processes (analysers and any pre- and post- analytical processes);
  - any “spare parts” taking account of anticipated frequency of replacement;
  - maintenance;
  - calibration;
  - QC material;
  - carriage costs;
  - any other costs, including special washes / treatment, repeat samples, dilutions (pre-programmed or otherwise);
  - wastage (through, for example, requirement for recalibrations, priming);
  - any reagent costs attached to existing equipment associated with any phased introduction of new equipment as part of Equipment Refresh;
  - transport costs in delivering the sample taker test kits to the Health Board Distribution Points (as defined in the NHS Requirement) and the uplift of samples to the Processing Laboratory;
  - the waste uplift/disposal costs generated within the LBC process;

- attendance at user group meetings; and
  - staff training.
- Reimbursement to the Board for reagents and consumables in stock for any equipment removed from the Site as part of the installation of new analysers.
  - Initial training including travel and accommodation costs.
  - On going training including travel and accommodation costs. The training by 3<sup>rd</sup> party suppliers must be of a comparable standard and frequency to that provided by the Contractor.
  - All costs involved in attendance at “user” group meetings and other educational meetings for an agreed number of staff for during the Term.
  - Freight and/or delivery charges and any applicable taxes, duties, clearance and or levies.
  - Costs associated with delivering the social, environmental and added value requirements set out in Clause 38 Schedule Part 14.
  - The management fee to be applied for provisions of the Managed Services.

## 6. Invoices

- 6.1 At the end of each month the Board will receive from the Contractor one invoice with the total amount payable to the Contractor expressed in pounds sterling. The invoice will detail the Managed Services provided in that month and any Service Deductions applied.
- 6.2 The invoice shall set out separately the Fixed Charges, Semi Fixed Charges and the Actual Variable Costs for Reagent and Consumables costs incurred.
- 6.3 The Contractor must ensure:
- 6.3.1 all deliveries are required to arrive with unique delivery note numbers with the delivery note number recorded on the monthly invoice to ensure that the Board is only paying for goods actually received;
- 6.3.2 any deliveries that have not been invoiced shall be detailed on the monthly statement by delivery note number for Board accrual purposes.

## 7. Value Added Tax

- 7.1 All prices are exclusive of VAT.
- 7.2 It is anticipated by the Board that this Agreement will, as a contract for managed services, entitle it to claim, and be reimbursed by HMRC for, VAT paid by it in respect of the Unitary Charge. The Contractor agrees, if and when requested to do so, to make any reasonable adjustments to the mechanism and/or methodology of applying the Unitary Charge and to provide such other co-operation and assistance to the Board as may be necessary to ensure that the Board is able to receive such reimbursement providing such adjustments or other reasonable co-operation puts the Contractor in no worse a position than it would have otherwise been with HMRC.

## 8. Price Variations due to Efficiency

The Reagent and Consumable efficiency rate (“**RCER**”) for each Process, as stated within the Contractor’s Response. If there is a deviation of less than five per cent (5%) below the RCER for any Process, (measured across a Quarterly Period) this will be considered to be within an acceptable level. In the event of a deviation of five per cent (5%) or greater when measured across a Quarterly Period the following will apply:-

- 8.1.1 The Contractor will immediately investigate the cause of the efficiency failure, and shall report to the Board on its findings;

- 8.1.2 If the cause of the failure to achieve the RCER stated within the Contractor's Response is not attributable to the Board then the Contractor will reimburse the Board in respect of all additional Reagent it has been required to use to achieve the required number of Reportable Results, by reference to the RCER stated within the Contractor's Response;

9. Orders

- 9.1 The Contractor will ensure that the correct Reagents/Consumables are always available in sufficient quantities at the Site, through the Automated Reagent Inventory Management System or, in the event of failure of the Automated Reagent Inventory Management System, through manual processes deployed and paid for by the Contractor. [Note: to be updated post tender reflecting Contractor's Response]

10. Delivery and Invoicing

- 10.1 Unless otherwise directed by the Board, the Contractor will ensure that all Managed Services and Reagents/Consumables ordered by the Board are delivered to the Sites and in accordance with the quantities, delivery dates and delivery instructions specified through the Automated Reagent Inventory Management System. The Contractor shall be responsible for freight and/or delivery charges and for any applicable taxes, duties, clearance and or levies.
- 10.2 The Contractor will send an invoice following the last working day of the month for the Unitary Charge. The Board shall pay the Contractor within sixty (60) days of the date of the invoice. Failure to do so will entitle the Contractor to charge interest on the amount outstanding under the invoice at the rate of two per cent (2%) per year above the base rate of the Bank of England from time to time in respect of any sums properly due, to be invoiced in the subsequent month. The Contractor will receive and pay directly all invoices from Third Party Suppliers in respect of their respective aspects of the Managed Services including provision of Reagents/Consumables. To avoid doubt, the Board shall have no responsibility for payments to Third Party Suppliers.
- 10.3 In the event that discrepancies and variations between invoices from the Contractor and orders by the Board or delivery notes occur, and other than in the case of material or manifest error, the Board agrees to pay the non-disputed elements of the invoice, then contact the Contractor Facility Manager who shall investigate the discrepancy and/or variation and report to the Board within seven (7) Working Days. Any credit or debit will be applied to invoices in the subsequent month.
- 10.4 Unless the Parties expressly agree in writing to use a different currency, all invoices under this Agreement shall be expressed and paid in UK Pounds Sterling.

# **APPENDIX 1**

## **FINANCIAL MODEL**

## **APPENDIX 2**

### **PUBLIC HEALTH POPULATION TESTING PREDICTIONS TO BE UNDERTAKEN EACH YEAR**

## SCHEDULE: PART 4

### TUPE PROVISIONS

Where there is a transfer pursuant to TUPE of the contracts of employment of any the Contractor staff (such group of employees being referred to herein as “**Affected Employees**”) to the Board or a New Contractor on expiry or termination of this Agreement then the following shall apply:-

1. All obligations in respect of the Affected Employees including without limitation those which arise prior to the date of transfer shall be borne by the Contractor and the Contractor shall indemnify the Board and any New Contractor and hold them harmless from and against all such obligations and any and all claims, costs, damages expenses, liabilities relating thereto.
2. The Contractor shall have ensured it has complied, and shall ensure that the Board is in a position to comply, with all requirements of TUPE in respect of the Affected Employees, and shall indemnify the Board and any New Contractor in respect of any losses, claims, damages, demands, actions, fines, penalties, awards, liabilities and expenses (including reasonable legal expenses) suffered by them as a result of the Contractor’s failure to so comply and to ensure the Board is able to comply, with all the requirements of TUPE.
3. The Contractor shall indemnify and hold the Board and any New Contractor appointed by the Board to perform the Services harmless in respect of any losses, claims, damages, demands, actions, fines, penalties, awards, liabilities and expenses (including reasonable legal expenses) incurred or suffered by either or both of the Board and any New Contractor arising as a result of or in connection with a TUPE transfer as a result of or in connection with:-
  - (a) The termination by the Contractor of the employment of any of the Affected Employees affected by the transfer occurring on or before the date of transfer;
  - (b) Any claim from any individual that their employment should have transferred to the Board or the New Contractor or any third party as a result of any transfer pursuant to the operation of TUPE or otherwise.
4. The terms of this Schedule Part 4 shall survive the expiry or earlier termination of this Agreement.

**SCHEDULE: PART 5**

**ENVIRONMENTAL REQUIREMENTS**

**[TO BE INSERTED POST TENDER]**

**CLO NOTE: The NHS Requirement must ask bidders as part of their tender to detail the environmental considerations required for their solution.**

## **SCHEDULE: PART 6**

### **IMPLEMENTATION PLAN AND IMPLEMENTATION SERVICES**

#### **A. IMPLEMENTATION PLAN**

**[TO BE INSERTED POST TENDER]**

#### **Milestones:- Key dates to be inserted**

Final Acceptance must occur no later than **[TO BE INSERTED]** following the Commencement Date

#### **B. IMPLEMENTATION SERVICES**

**[TO BE INSERTED POST TENDER]**

#### **C. ACCEPTANCE CHECKLIST**

**[TO BE INSERTED POST TENDER]**

## **SCHEDULE: PART 7**

### **LIQUIDATED DAMAGES**

1. If Milestone Acceptance of any part of the Implementation Plan including in respect of all Systems has not occurred by the relevant milestone date specified in the Implementation Plan for such completion and for such Milestone Acceptance to occur, the Contractor shall pay to the Board, as liquidated damages for each day of delay in respect of that aspect of the Implementation Services, the sum of £750 for each delayed milestone
2. The parties agree that the sum specified above represent a genuine pre-estimate of the losses which the Board would suffer in the event of a failure to achieve Milestone Acceptance of each part of the Implementation Services in accordance with the Implementation Plan.

## SCHEDULE: PART 8

### CORRUPT GIFTS AND PAYMENTS

#### **Prohibition on Corruption**

1. The term “**Prohibited Act**” means:
  - (a) offering, giving or agreeing to give to the Board or any other public body or to any person employed by or on behalf of the Board or any other public body any gift or consideration of any kind as an inducement or reward:
    - (i) for doing or not doing (or for having done or not having done) any act in relation to the obtaining or performance of this Agreement or any other agreement with the Board or any other public body; or
    - (ii) for showing or not showing favour or disfavour to any person in relation to this Agreement or any other agreement with the Board or any other public body;
  - (b) entering into this Agreement or any other agreement with the Board or any other public body in connection with which commission has been paid or has been agreed to be paid by the Contractor or on its behalf, or to its knowledge, unless before the relevant agreement is entered into particulars of any such commission and of the terms and conditions of any such agreement for the payment of such commission have been disclosed in writing to the Board;
  - (c) committing any offence:
    - (i) under the Bribery Act 2010;
    - (ii) under any Law creating offences in respect of fraudulent acts; or
    - (iii) at common law, in respect of fraudulent acts in relation to this Agreement or any other agreement with the Board or any other public body; or
    - (iv) defrauding or attempting to defraud or conspiring to defraud the Board or any other public body.

#### **Warranty**

2. The Contractor warrants that in entering into this Agreement it has not committed any Prohibited Act.

#### **Remedies**

3. If the Contractor (or anyone employed by or acting on behalf of them) commits any Prohibited Act, then the Board shall be entitled to act in accordance with paragraphs (a) to (c) below:
  - (a) if a Prohibited Act is committed by the Contractor or by an employee not acting independently of the Contractor, then the Board may terminate the Agreement with immediate effect by giving written notice to the Contractor, and no compensation or payment shall be due to the Contractor in respect of such termination;
  - (b) if the Prohibited Act is committed by an employee of the Contractor or a sub-Agreement or acting independently of the Contractor, then the Board may give written notice to the Contractor of termination and the Agreement will terminate, unless within twenty (20) Working Days of receipt of such notice the Contractor terminates the employee's employment or sub-contractors Agreement (as the case may be) and (if necessary) procures the performance of the relevant part of the Services by another person;
  - (c) any notice of termination under this Schedule Part 8 shall specify:
    - (i) the nature of the Prohibited Act;

- (ii) the identity of the party who the Board believes has committed the Prohibited Act; and
  - (iii) the date on which the Agreement will terminate in accordance with the applicable provisions of this Schedule Part 8.
- 4. Without prejudice to its other rights or remedies under this Clause, the Board shall be entitled to recover from the Contractor:
  - (a) the amount or value of any such gift, consideration or commission; and
  - (b) any other loss sustained in consequence of any breach of this Schedule Part 8.

#### **Permitted Payments**

- 5. Nothing contained in this Schedule Part 9 shall prevent the Contractor from paying any proper commission or bonus to its employees within the agreed terms of their employment.

#### **Notification**

- 6. The Contractor shall notify the Board on the occurrence (and details) of any Prohibited Act promptly on the Contractor becoming aware of its occurrence.

## SCHEDULE: PART 9

### CHANGE CONTROL PROCEDURE

#### 1. DEFINITIONS

- 1.1 Without prejudice to Clause 1 (Interpretation), in this Schedule Part 9, unless the context requires otherwise, the following expressions have the following meanings:

**“Change”** means a change in the volume (beyond the volume parameters detailed in the Specification) and/or scope of the Managed Services or any other aspect of the Managed Services or any change to this Agreement, including without limitation the location, type, and/or functionality of Equipment and any change relating to Reagents/Consumables as requested by either of the parties in accordance with this Schedule Part 9;

**“Change Confirmation”** has the meaning given in paragraph 6.3 of this Schedule Part 9;

**“Change Enquiry”** means a request for change containing the information set out in paragraph 3.1 of this Schedule Part 9;

**“Objection Notice”** means a notice served by the Contractor objecting to a Change Enquiry on one of the grounds set out in paragraph 4.2 of this Schedule Part 9;

**“Response Notice”** means a notice served by the Contractor setting out the paragraph 5.2 of this Schedule Part 9;

**“Qualifying Change”** means a Change for which a Change Confirmation has been issued and the Supplementary Agreement has become unconditional in all respects;

**“Service Change”** means a change in the manner of provision of the Services; and

**“Supplementary Agreement”** means an agreement which sets out all the amendments to this Agreement required as a result of a Qualifying Change which Supplementary Agreement shall so vary this Agreement.

#### 2. GENERAL

- 2.1 Subject to:

2.1.1 receiving a Change Confirmation issued in accordance with the terms of this Schedule Part 9;

2.1.2 the other provisions of this Schedule Part 9;

the Contractor shall be under a duty to implement a Change requested by the Board.

#### 3. BOARD CHANGE ENQUIRIES

- 3.1 The Board may serve on the Contractor a Change Enquiry which states on its face that it is a Change Enquiry and specifies the nature of the Service Change and which of the provisions of this Agreement and/or the Specification it considers may require to be amended to accommodate the proposed Service Change.

#### 4. CONTRACTOR OBJECTION TO CHANGE ENQUIRY

- 4.1 Within ten (10) Working Days of receipt of a Change Enquiry the Contractor may serve an Objection Notice and the Board may either:

4.1.1 accept such Objection Notice and confirm in writing that the Change Enquiry is withdrawn; or

4.1.2 refer the matter to the Dispute Resolution Procedure on the grounds that none of the grounds set out in paragraph 4.2 exists.

- 4.2 The Contractor may only object to a Change Enquiry on one or more of the following grounds:

4.2.1 that implementation of the Change would materially and adversely affect the health and safety of any person;

4.2.2 the implementation of the Change would infringe any Legal Requirement;

## 5. **CONTRACTOR RESPONSE NOTICE**

5.1 If the Contractor does not serve an Objection Notice pursuant to paragraph 4.1 or an Objection Notice is determined to be invalid, then within ten (10) Working Days of receipt of a Change Enquiry the Contractor shall, serve a Response Notice on the Board.

5.2 The Response Notice shall set out:

5.2.1 the steps which the Contractor proposes to take to implement the Change giving such level of detail as is reasonable and appropriate in all the circumstances;

5.2.2 The Contractor's estimated expenditure or estimated savings in respect of the Change (if any) and whether there will be any increase in the Charges pursuant to paragraph 8 below;

5.2.3 a schedule of amendments to this Agreement (including in particular the provisions of the Financial Schedule which are necessary and appropriate as a consequence of the Change.

## 6. **CHANGE CONFIRMATION**

6.1 Within ten (10) Working Days of receipt of the Response Notice the Board and the Contractor shall meet and seek to discuss and find a solution to the contents of the Response Notice and all matters relating to the Change. The Board or the Contractor may refer any matter not agreed for determination in accordance with the Dispute Resolution Procedure.

6.2 The Board shall by notice (a "**Change Confirmation**") confirm the Change upon the agreement or determination of all the matters referred to in paragraph 6.1 above and upon the issue of the Change Confirmation, the parties shall enter into a Supplementary Agreement.

6.3 Upon the Change Confirmation being issued and the Supplementary Agreement becoming unconditional in all respects:

6.3.1 the relevant Change shall be a Qualifying Change; and

6.3.2 the rights and liabilities of the parties under this Agreement shall thereafter be construed accordingly.

## 7. **WITHDRAWAL OF A CHANGE**

7.1 The Board may withdraw a Change Enquiry at any time prior to the issue of a Change Confirmation.

## 8. **VALUATION OF CHANGES**

8.1 The Contractor may charge for certain Changes. In assessing whether a change to the Charges will be appropriate and if so the extent of any variation in the Charges the following principles shall be applied. No increase shall be permitted:-

8.1.1 where Equipment and/or Reagents/Consumables require to be substituted and/or supplemented due to performance issues, to enable the Specification to be met, and/or to meet increased volume requirements as specified in the Specification;

8.1.2 due to increases in the Contractor's costs due to compliance with Legal Requirements;

8.1.3 where due to a Change, the Board's Reagent and/or Equipment usage requirements may be less than anticipated

8.2 Increases in the Charges associated with an increase in the Board's Reagent and/or Equipment usage requirements (beyond the volume parameters detailed in the Specification) shall be consistent with the figures provided by the Contractor in the Specification. In

addition, the Contractor shall take all reasonable steps:

8.2.1 to minimise any increase in cost arising from any Qualifying Change;

8.2.2 to maximise any reduction in costs arising from any Qualifying Change;

8.2.3 to take advantage of any positive or of any beneficial effects of any Qualifying Change.

8.3 To avoid doubt the Contractor shall not be entitled to payment of any sums (whether by way of payment of a capital sum or otherwise) where such costs could have been extinguished or reduced by the Contractor taking such reasonable steps.

8.4 The Board shall be entitled to challenge any Service Change valuation if it does not believe that the Contractor has given due and proper consideration to all relevant valuation factors. Any dispute regarding the valuation of a Service Change shall be referred to the Dispute Resolution Procedure.

## 9. **CONTRACTOR CHANGE**

9.1 The Contractor may request a Change by serving a Change Enquiry on the Board which shall contain the information set out in paragraph 3.1.

9.2 Within ten (10) Working Days of receipt of a Change Enquiry from the Contractor, the Board shall serve written notice on the Contractor either:

9.2.1 objecting to such Change Enquiry and the Contractor shall not be entitled to challenge any such objection by the Board, or

9.2.2 stating that it has no objection in principle to the Change Enquiry and requiring that the Contractor submits to the Board a Response Notice which sets out all the information required by Paragraph 5.2.

9.3 The Board shall consider the Response Notice in good faith and if so required by the Contractor, shall meet with the Contractor to discuss the contents of such Response Notice. Within a reasonable time (or within ten (10) Working Days of receipt of a notice from the Contractor requiring that a decision be made in respect of a Response Notice) the Board shall either:

9.3.1 issue a Change Confirmation which shall confirm the Change (as amended by agreement with the Contractor); or

9.3.2 state in writing that the Change is rejected

and the parties acknowledge that the Board shall be entitled in its sole discretion to reject any request by the Contractor for a Change without giving any reason for such rejection.

9.4 If the Board:

9.4.1 rejects any Change Enquiry submitted by the Contractor then such Change Enquiry shall be deemed to be withdrawn;

9.4.2 accepts a Change Enquiry then it shall issue a Change Confirmation setting out the agreed change which shall, to avoid doubt, include a draft Supplementary Agreement.

## **SCHEDULE: PART 10**

### **BOARD RESPONSIBILITIES**

This Schedule shall be completed by inserting any additional of Board Responsibilities proposed by the Contractor in its tender to the extent these are accepted by the Board.

The Board Responsibilities detailed here are an exhaustive list of those matters incumbent on the Board to facilitate performance of the Managed Services by the Contractor.

The Health Board will be responsible for:

1. co-operating with the Contractor to enable it to have access to information reasonably necessary relating to the Managed Services;
2. granting the Contractor and its personnel reasonable access to Board Sites during normal business hours as reasonably required from time to time to the extent necessary for the Contractor to provide the Managed Services and outside normal business hours by prior appointment to the extent necessary to carry out any emergency correction, assistance or upgrade;
3. ensuring that Board personnel co-operate with the Contractor by performing the role required of them in the implementation, co-ordination and delivery of the Agreement;
4. subject always to the Contractor's compliance with the Requirements (including the Contractor's obligation to provide training and assess the competency of personnel), using staff trained and assessed as competent by the Board to operate the Equipment;
5. operating the Equipment in accordance with the operating manuals and guidance issued from time to time or otherwise orally communicated to the Board; and
6. ensuring the supply of electricity, water, telephone and internet access.

## SCHEDULE: PART 11

### SERVICE LEVELS AND SERVICE DEDUCTIONS

#### 1. GENERAL

- 1.1 This Schedule Part 11 sets out the Service Levels to which the Contractor must deliver the Managed Services.
- 1.2 The Service Levels shall apply from the relevant Go-Live Date plus thirty (30) days.
- 1.3 A failure to achieve the Service Level will result in Service Deductions being applied in accordance with this Agreement.
- 1.4 The Service Levels shall be measured at the end of each Quarterly Period.
- 1.5 Within thirty (30) days following the end of each Quarterly Period the Contractor shall deliver a service report in accordance with this Schedule Part 11.
- 1.6 The Contractor shall monitor and measure performance of the Managed Services in accordance with the Service Levels.

#### 2. SOLUTION MAINTENANCE

- 2.1 The Contractor will ensure that all Components of the Solution are maintained and serviced in line with good industry practice to ensure that the Solution operates at all times in accordance with the requirements of the Specification including the performance specification for each Component of the Solution. This will include quality assurance checks and action taken as appropriate to the results, and regular preventative maintenance and replacement of part or all of the Components of the Solution as required. The Contractor, without limitation, and as a minimum, will follow any servicing programmes set out by the manufacturer for each Component of the Solution.
- 2.2 Planned servicing of all Components of the Solution will take place at a frequency set out by the relevant Component manufacturer, or more frequently if provided for in the Specification.
- 2.3 The Contractor shall provide, and ensure all Third Party Suppliers provide, certificates of calibration, which are traceable to a national and/or international standard, for all measuring instruments/devices used in the manufacture and/or service/maintenance of any Component of the Solution.
- 2.4 Maintenance shall be considered to be “**Routine Planned Maintenance**” if it satisfies the following criteria:
  - (a) it shall not exceed six (6) hours per System in any month or a total of seventy five (75) hours in any Contract Year unless otherwise agreed with the Board such consent not to be unreasonably withheld or delayed; and
  - (b) where two (2) or more items of Equipment are available at a Site to perform a Process it shall only be performed on one of the items of Equipment provided to perform the relevant Process at any given time; and
  - (c) the time of occurrence of maintenance must be agreed with the Board at least one (1) month in advance and be within Core Hours unless otherwise agreed; and
- 2.5 Any work which results in Scheduled Downtime must be pre-arranged with the Board, in the same way as Routine Planned Maintenance.

- 2.6 Maintenance in respect of any Component of the Solution other than Routine Planned Maintenance, and which is not otherwise Scheduled Downtime, and which results in the non-availability of any Process will be considered to be Unapproved Downtime.
- 2.7 The Contractor shall reschedule Routine Planned Maintenance and work which otherwise results in Scheduled Downtime (but such rescheduling must be agreed by the Board so that it is not delayed by more than one (1) month from the original scheduled date for the Routine Planned Maintenance or the proposed Scheduled Downtime) where the Board, acting reasonably, requires it to do so due to clinical or operational requirements.
- 2.8 A failure to conduct Routine Planned Maintenance and/or work which otherwise results in Scheduled Downtime in accordance with the requirements of this Section 1 will result in the application of the provisions detailed at Section 7 below.

### 3. **PROBLEM RESOLUTION**

- 3.1 The Contractor will provide the following services in relation to the maintenance of all Components of the Solution, and the resolution of any issues which arise in relation to their performance and/or availability:
  - (a) local engineering support, telephone advice and remote assistance; and
  - (b) the investigation and resolution of all problems, bugs and errors in the Components of the Solution, and/or Reagents/Consumables.
- 3.2 The Contractor shall ensure that once notified to the Contractor or relevant Third Party Supplier (whether automatically by the Component of the Solution in question or by the Board) each Managed Service Failure will have a single point of ownership.
- 3.3 All Managed Service Failures relating to the Solution Management System and the Equipment will be remedied utilising engineering support provided by the Contractor. Other Managed Service Failures must be remedied utilising the most appropriate means, to ensure compliance with the Service Levels.
- 3.4 The Contractor will ensure that any involvement of a relevant Third Party Supplier in the resolution of a Managed Service Failure is supervised by the Contractor. The Contractor undertakes to retain responsibility and an active input and involvement in relation to the Resolution of all Managed Service Failures. If the Contractor and the Board should agree that Managed Service Failures should be notified to a Third Party Supplier then such report shall be considered to be a report, by the Board, to the Contractor, and the Contractor will procure that the Contractor will be made aware of such Managed Service Failure, and in any event the Contractor will be deemed to be aware of such Managed Service Failure from the time it is reported to the relevant Third Party Supplier.
- 3.5 Managed Service Failures reported by the Board to the Contractor shall be reported by telephone, using the number provided for that purpose by the Contractor (the "Helpline"). Subject to paragraph 3.7 below, the time of such call being connected to the Contractor shall be the time from which the Resolution of the Managed Service Failure shall be measured.
- 3.6 The Contractor undertakes that all calls received during Core Hours from the Board will be answered to within thirty (30) seconds, and that remedial action as appropriate will be undertaken forthwith such that the Service Levels required in terms of this Schedule Part 11 are adhered to.
- 3.7 If the Contractor itself becomes aware of a Managed Service Failure prior to receiving notification of that Managed Service Failure by the Board, by means of receiving an automated alert by the relevant Component of the Solution or otherwise, the

Contractor shall immediately notify the Managed Service Failure to the relevant the Board personnel affected by such Managed Service Failure. In such event the time from which the Resolution of the Managed Service Failure shall be measured will be the first minute following the time the Contractor became aware of the Managed Service Failure.

- 3.8 All Components of the Solution with the functionality permitting automated reporting of Managed Service Failures shall be deemed to have made a report forthwith on the happening of a Managed Service Failure and the Contractor shall be deemed to be aware of such Managed Service Failure from that moment (whether the Contractor is actually aware of it, or not).
- 3.9 The Contractor shall ensure that, as a minimum, the following details are recorded by it and provided to the Board in respect of each Managed Service Failure:-
- (a) a unique report number (report numbers shall be applied sequentially);
  - (b) the date and time the Managed Service Failure was reported to the Contractor, whether automatically by the Component of the Solution in question, or by the Board;
  - (c) the nature and location of the Managed Service Failure;
  - (d) if relevant the person making the call;
  - (e) details of any communication with the Board in connection with the Managed Service Failure;
  - (f) the Contractor's plans for remedying the Managed Service Failure including details, where applicable, of the estimated time within which such Managed Service Failure will be remedied;
  - (g) the reasons for any inability of the Contractor to meet the engineer response time specified in Annex 1 to this Schedule Part 11 ("**Engineer Response Time**") for Resolution of the Managed Service Failure, such that Service Points were applied; and
  - (h) the time of resolution of the Managed Service Failure.

#### 4. **SYSTEM DOWNTIME**

4.1 In each Quarterly Period during the Term:

- (a) System Downtime for each individual Band A Component, Band B Component or Band C Component shall not exceed the Permitted System Downtime specified in Annex 1 to this Schedule Part 11. The Unapproved Downtime in respect of each Component within each System shall contribute to aggregate System Downtime within the relevant System. System Downtime shall be measured during Service Hours; and
- (b) Complete System Downtime for each System shall not exceed the Permitted Downtime specified in Annex 1 to this Schedule Part 11. Complete System Downtime shall be measured during Service Hours.

4.2 Downtime shall be calculated in accordance with the following:

- (a) System Downtime shall be measured from the moment the Managed Service Failure is notified to the Contractor (subject to paragraphs 2.5 to 2.8 above) until the moment the Managed Service Failure is Resolved or a Workaround satisfactory to the Board has been implemented. System Downtime shall be

measured during Service Hours.

- (b) Complete System Downtime shall be measured from the moment the Managed Service Failure is notified to the Contractor (subject to paragraphs 2.5 to 2.8 above) and shall cease at the time at which the System is capable of providing Reportable Results. Complete System Downtime shall be measured during Service Hours.
- 4.3 Where the Board agrees that it may do so, the Contractor may implement a Workaround in respect of a Managed Service Failure instead of implementing a Resolution. Where The Contractor has implemented a Workaround such that the Managed Service Failure no longer exists (albeit on a temporary basis) the Contractor shall implement a Resolution within thirty (30) days thereafter.
- 4.4 System Downtime and Complete System Downtime does not include:
  - (a) Routine Planned Maintenance;
  - (b) Downtime caused by Relief Events or events of Force Majeure;
  - (c) any time to implement a Resolution following implementation of a Workaround;
  - (d) any time where the Contractor is not given access to the Systems upon arrival at any of the Sites.
- 4.5 In the event that, at the Board's discretion, a reported Managed Service Failure may not require an immediate remedy or that it may be delayed to a later mutually convenient date, then for the purposes of calculating System Downtime and Complete System Downtime, the relevant time of commencement shall instead be the agreed date and time.

## 5. **ALTERNATIVE ARRANGEMENTS**

- 5.1 In the event of any Complete System Downtime, the Board may require to transport samples to a third party location and have testing of such samples undertaken by such third party. The Contractor agrees to provide all assistance required to the Board in this regard and reimburse the Board fully for all costs and expense incurred by the Board in relation to such alternative arrangements,
- 5.2 The exercise by the Board of its rights under this paragraph 5 shall be without prejudice to any other rights or remedies of the Board.

## 6. **ENGINEER RESPONSE TIMES**

- 6.1 The Contractor shall meet or improve upon the Engineer Response Time.
- 6.2 The Contractor shall as a part of its response to a Managed Service Failure provide:
  - (a) Fault analysis;
  - (b) a timescale for Resolution of the Managed Service Failure; and
  - (c) shall either implement a Resolution remotely or initiate attendance of an appropriately qualified and experienced member of the Contractor's personnel (the "**Engineer**") at the relevant Site.
- 6.3 Engineer Response Time shall be the time taken by the Engineer to attend the relevant Site and location at the Site where the relevant Managed Service Failure has occurred.

- 6.4 The Engineer Response Time shall commence at the moment the Board contacts the Helpline regarding the Managed Service Failure and shall cease at the moment the Engineer attends and signs in at the relevant Site (at an appropriate reception desk) for the purposes of Resolving the Managed Service Failure, provided the Engineer is able to commence work on Resolving the Managed Service Failure at that time. The Contractor shall only be obliged to send Engineers to attend the Site during Core Hours unless otherwise agreed with the Board.

## 7. TEST TURNAROUND TIMES

- 7.1 The Contractor shall meet the Test Turnaround Time as set out in the table headed **“Test Turnaround Time”** in Annex 1 to this Schedule 11.
- 7.2 The Test Turnaround Time for Hr-HPV shall commence from the moment that the sample is received by the laboratory in SCCRS and shall cease when the Reportable Result for Hr-HPV is available at the Middleware software interface and is appropriately formatted and available to be transmitted to SCCRS. Test Turnaround Time shall include any period during which Reagents are not available.
- 7.3 Test Turnaround Time shall be measured during Service Hours.

## 8. SERVICE DEDUCTIONS

- 8.1 Service Deductions shall be calculated using the following for each System:

$$\text{Service Deductions (£)} = (\text{Service Points accrued for each System})^{1.4}$$

This is Service Points “to the power” of 1.4.

- 8.2 Service Points will be applied in the event of any failure to meet the relevant Service Levels in any Quarterly Period, in accordance with the mechanisms specified above.
- 8.3 The maximum Service Deductions which the Contractor will be required to pay/deduct in any month is twenty five per cent (25%) of the total sums payable to the Contractor in respect of the Managed Services for the Quarterly Period in question.
- 8.4 Service Deductions will be payable in addition to the requirement for the Contractor to reimburse the Board for its additional costs in providing manual work-arounds, additional staff, alternative arrangements, overtime, transport etc to attempt to ensure continuity of Services affected by Unapproved Downtime.
- 8.5 Annex 3 of this Schedule sets out the calculation of Service Points in accordance with paragraph 8.1 above. Annex 3 is shown for illustration purposes only and shall not operate as a cap in relation to the calculation of Service Failure Points.
- 8.6 Service Deductions shall be calculated by reference to the Service Level report provided pursuant to the provision in Paragraph 9.1 of this Schedule Part 11.
- 8.7 Where applicable each Managed Service Failure shall accrue the Service Points as specified in Annex 1 to this Schedule Part 11. Service Points shall accrue in respect of each separate System.
- 8.8 Service Deductions shall be calculated for, and calculated immediately following, the expiry of each Quarterly Period. For the avoidance of doubt each Service Level shall be reported on following the end of each Quarterly Period.
- 8.9 The sum of all Service Deductions accrued for each Quarterly Period shall be applied to the value of the next invoice issued following the expiry of the relevant Quarterly Period in which the Service Deductions accrued, and delivery of the service report, and which invoice is issued pursuant to Schedule Part 3 (and accordingly the amount

of such invoice shall be reduced accordingly) or, at the Board's written request, the Contractor shall issue the Board with a credit note for the said amount and such amount shall be due as a debt by the Contractor to the Board.

- 8.10 Where the value of Service Deductions exceeds the value of the next following invoice the Contractor shall in any event issue a credit note to the Board for the value of those Service Deductions which exceed the said invoice. On termination or expiry of this Agreement the Contractor shall pay to the Board the value of any Service Deductions which are accrued in the Quarterly Period (or part thereof) prior to termination or expiry of this Agreement and which have not been applied to the value of any invoice (including where the Contractor has issued any credit notes which have not been used by the Board and applied to invoices issued by the Contractor).
- 8.11 Without prejudice to Paragraph 9.1 of this Schedule Part 11, if the Contractor reasonably believes that the Managed Service Failure is wholly or partly attributable to another third party supplier to the Board or if the Contractor is unable to Resolve the Managed Service Failure without the assistance of another such supplier, the Contractor shall immediately notify the Board of the issue. Upon receipt of notification of a Managed Service Failure under this Paragraph 9.11, the Board will, acting reasonably, allocate responsibility for fixing the Managed Service Failure. Any disputes or issues in relation to the allocation of responsibility for Managed Service Failures shall be dealt with in accordance with Clause 25 (Dispute Resolution Procedure).

## **9. SERVICE LEVEL REPORTING**

- 9.1 Within thirty (30) days of the end of each Quarterly Period the Contractor shall deliver service reports in respect of the immediately previous Quarterly Period which shall specify all of:
- (a) the period to which the report relates;
  - (b) the monitoring which has been performed in accordance with this Schedule Part 11 and a summary of any material issues identified by such monitoring;
  - (c) the performance of each service measure measured against the applicable Service Levels including identifying those service measures (if any) which are operating below the applicable Service Levels;
  - (d) the number of hours of Unapproved Downtime in the Quarter on a System by System basis;
  - (e) any Service Points applicable;
  - (f) Reportable Result work load;
  - (g) Test Turnaround Times, and performance against the relevant Service Level;
  - (h) any problems reported by other users for Reagent lot numbers currently in use or delivered to Board premises; and
  - (i) any ongoing MHRA investigations for any user for any Reportable Results.

## **10. PROBLEM ESCALATION**

- 10.1 The Contractor will keep the Board advised in respect of the steps being taken to resolve each Managed Service Failure, until it is resolved to the satisfaction of the Board.
- 10.2 Separately, in respect of any ongoing failure to resolve an incident, the Contractor

shall escalate matters as follows:

- (a) the Contractor's Principal Contact (*expected to be the Facility Manager*) shall contact the Board's designated Departmental Lead (expected to be the Operational Manager for Cytology or Molecular, depending on the area of failure) if the Managed Service Failure is not resolved within two (2) days;
- (b) the Contractor's [ • ] shall contact the Board's [Service Lead for Molecular or Cytology] (expected to be the Laboratory Manager) if the Managed Service Failure is not resolved within four (4) days;
- (c) the Contractor's [ • ] shall contact the Board's [Head of Laboratory Medicine] (expected to be General Manager/Service Manager) if the Managed Service Failure is not resolved within seven (7) days;
- (d) the Contractor's [ • ] shall contact the Board's [Director of Diagnostics] if the Managed Service Failure is not resolved within ten (10) days.

10.3 In the event of a failure properly to provide Routine Planned Maintenance in respect of any Component of the Solution in accordance with the requirements of paragraph 2 of this Schedule Part 11 (a "**Planned Maintenance Failure**"), the Board shall be entitled to notify the Contractor regarding the Planned Maintenance Failure, and the Contractor shall ensure it is resolved as soon as is reasonably practicable. If the Planned Maintenance Failure is not resolved forthwith then the following shall apply:

- (a) the Contractor's Principal Contact (*expected to be the MSC Liaison Officer*) shall contact the Board's designated Departmental Lead (expected to be the Operational Manager for Cytology or Molecular, depending on the area of failure) if the Planned Maintenance Failure is not resolved within seven (7) days of notification; and
- (b) the Contractor's [Insert role] shall contact the Board's Service Lead for Molecular or Cytology (expected to be the Laboratory Manager) if the Planned Maintenance Failure is not resolved within fourteen (14) days of notification.

10.4 In addition to notifying any of the persons referred to in paragraph 10.3 above, the Board shall be entitled to require the attendance of any such person(s) at a meeting with the Board to discuss the Managed Service Failure and the steps that are being taken by the Contractor to resolve it. Any such meeting shall be at a time and location that the Board shall require.

10.5 Any escalation of an incident that takes place in accordance with paragraph 10.2 of this Schedule Part 11 is without prejudice to any other rights and remedies of the Board under this Agreement.

## ANNEX 1

### Service Levels and Service Points

#### System Downtime and Complete System Downtime

|                                                                                                                                                                                                                   | Band<br>as detailed in<br>Annex 2 of<br>this Schedule<br>Part 11                                   | Permitted System<br>Downtime<br>expressed in hours<br>per Quarterly Period |   | Service Failure Points per<br>Component for each<br>relevant hour above the<br>Permitted System Downtime |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------|--|
| <b>System Downtime –<br/>measured per System during<br/>Service Hours</b>                                                                                                                                         | Band A                                                                                             | 26                                                                         |   | 20                                                                                                       |  |
|                                                                                                                                                                                                                   | Band B                                                                                             | 39                                                                         |   | 10                                                                                                       |  |
|                                                                                                                                                                                                                   | Band C                                                                                             | 52                                                                         |   | 5                                                                                                        |  |
| <b>Complete System Down<br/>Time measured during<br/>Service Hours</b><br><br>Unapproved Downtime<br>resulting in Reportable Results<br>not being reported from the<br>relevant System in respect of<br>HPV Tests | Applies in<br>respect of<br>each and<br>every System<br><br>(i.e. Band A,<br>Band B and<br>Band C) | Band A                                                                     | 4 | 45                                                                                                       |  |
|                                                                                                                                                                                                                   |                                                                                                    | Band B                                                                     | 6 | 25                                                                                                       |  |
|                                                                                                                                                                                                                   |                                                                                                    | Band C                                                                     | 8 | 15                                                                                                       |  |

1. Calculation of System Downtime

$$\text{System Downtime} = \Sigma \text{CDn} / \Sigma \text{Cn}$$

Where:

$\Sigma \text{CDn}$  - is the sum of the Unapproved Downtime for each Component of the relevant System;

$\Sigma \text{Cn}$  - is the number of the same Components in the relevant System as specified in Annex 2 to this Schedule Part 11.

2. Complete System Downtime shall be the total number of hours of Unapproved Downtime in excess of four (4) hours.

## Service Levels and Service Failure Points

### Test Turnaround Time

|                                                                                                                                                                                                                        | Service Level                                          | Service Points                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>Test Turnaround Time.</b><br>Reportable Results must be available for Hr-HPV in 24 hours on 80% of occasions, in 48 hours on 90% of occasions and in 96 hours on 100% of occasions measured over a Quarterly Period | 80% in 24 hours<br>90% in 48 hours<br>100% in 96 hours | Ten (10) Service Failure Points per each zero point one percent (0.1%) below Service Level |

## Service Levels and Service Failure Points

### Telephone Response Time

|                                                                        | Band   | Response time<br>(Telephone support)<br>(Working Hours) |  |  | Service Points for each relevant half hour (30 minutes) above Service Level |
|------------------------------------------------------------------------|--------|---------------------------------------------------------|--|--|-----------------------------------------------------------------------------|
| Telephone Response Time                                                | Band A | 0.5 hours                                               |  |  | 20                                                                          |
| Note – Service Levels to apply in respect of each individual component | Band B | 1 hour                                                  |  |  | 10                                                                          |
|                                                                        | Band C | 1 hour                                                  |  |  | 10                                                                          |

## Service Levels and Service Failure Points

### Engineer Response Time

|  | Band | Response (on site attendance)<br>Working Hours | Resolution time<br>(Working Hours) | Service Points for each relevant hour above Service Level |
|--|------|------------------------------------------------|------------------------------------|-----------------------------------------------------------|
|--|------|------------------------------------------------|------------------------------------|-----------------------------------------------------------|

|                                                                                                      |        |         |                     |    |
|------------------------------------------------------------------------------------------------------|--------|---------|---------------------|----|
| Engineer Response Time<br><br>Note – Service Levels to apply in respect of each individual component | Band A | 4 hours | 48 hours of failure | 20 |
|                                                                                                      | Band B | 8 hours | 48 hours of failure | 10 |
|                                                                                                      | Band C | 8 hours | 48 hours of failure | 10 |

### Service Levels and Service Failure Points

#### Preventative Maintenance - Compliance with Planned Schedule

|                                                                             | Service Level    | Service Points                                                                             |
|-----------------------------------------------------------------------------|------------------|--------------------------------------------------------------------------------------------|
| Preventative maintenance undertaken within 2 working days of scheduled date | 98% of occasions | Ten (10) Service Failure Points per each zero point one percent (0.1%) below Service Level |

### Service Levels and Service Failure Points

#### Provision of Service Reports

|                                                                                       | Service Level    | Service Points                                                                             |
|---------------------------------------------------------------------------------------|------------------|--------------------------------------------------------------------------------------------|
| Service/repair reports are submitted to the laboratory within 48 hours of completion, | 98% of occasions | Ten (10) Service Failure Points per each zero point one percent (0.1%) below Service Level |

### Service Levels and Service Failure Points

#### Invoicing/Finance Reports

|  | Service Level | Service Points |
|--|---------------|----------------|
|--|---------------|----------------|

|                                                                                       |                  |                                                                                          |
|---------------------------------------------------------------------------------------|------------------|------------------------------------------------------------------------------------------|
| Invoices and finance reports are submitted to the Board(s) by the agreed target dates | 95% of occasions | Ten (10) Service Failure Points per each zero point one percent (1%) below Service Level |
|---------------------------------------------------------------------------------------|------------------|------------------------------------------------------------------------------------------|

**Service Levels and Service Failure Points**  
**Transport Time (Compliance with Delivery Schedule)**

|                                                                                                                                                                                                                                              | <b>Service Level</b> | <b>Service Points</b>                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------------------------------------------------------------------------------|
| <b>Compliance with Delivery Schedule</b><br>Specimens must be uplifted from collection hubs and delivered to processing laboratories as per agreed daily schedule.<br>(adjunctments may be agreed during periods of severe weather warnings) | 95% of occasions     | Ten (10) Service Failure Points per each zero point one percent (0.1%) below Service Level |

**Service Levels and Service Failure Points**  
**Provision of Performance Reports**

|                                                                                           | <b>Service Level</b> | <b>Service Points</b>                                                                      |
|-------------------------------------------------------------------------------------------|----------------------|--------------------------------------------------------------------------------------------|
| Agreed performance reports are submitted according to agreed schedule on 95% of occasions | 95% of occasions     | Ten (10) Service Failure Points per each zero point one percent (0.1%) below Service Level |

## **ANNEX 2**

### **Systems**

Pre-analytics – HPV – band A

HPV analytical equipment – Band A

Middleware – Band A

Reagents/IQC – Band A

Cytology processor – Band B

Cytology imager – Band C

Cytology staining – Band C

Archiving system – Band C

## ANNEX 3

### Illustration of Service Failure Points

| Service Failure Points | Service Credits |  | Service Failure Points | Service Credits |  | Service Failure Points | Service Credits |  | Service Failure Points | Service Credits |  | Service Failure Points | Service Credits |
|------------------------|-----------------|--|------------------------|-----------------|--|------------------------|-----------------|--|------------------------|-----------------|--|------------------------|-----------------|
| 1                      | £1.00           |  | 51                     | £245.81         |  | 101                    | £639.81         |  | 151                    | £1,123.49       |  | 201                    | £1,617.98       |
| 2                      | £2.64           |  | 52                     | £252.58         |  | 102                    | £648.69         |  | 152                    | £1,133.92       |  | 202                    | £1,628.42       |
| 3                      | £4.66           |  | 53                     | £259.41         |  | 103                    | £657.62         |  | 153                    | £1,144.37       |  | 203                    | £1,638.86       |
| 4                      | £6.96           |  | 54                     | £266.29         |  | 104                    | £666.57         |  | 154                    | £1,154.86       |  | 204                    | £1,649.30       |
| 5                      | £9.52           |  | 55                     | £273.22         |  | 105                    | £675.56         |  | 155                    | £1,165.37       |  | 205                    | £1,659.74       |
| 6                      | £12.29          |  | 56                     | £280.20         |  | 106                    | £684.59         |  | 156                    | £1,175.91       |  | 206                    | £1,670.18       |
| 7                      | £15.25          |  | 57                     | £287.23         |  | 107                    | £693.65         |  | 157                    | £1,186.48       |  | 207                    | £1,680.62       |
| 8                      | £18.38          |  | 58                     | £294.31         |  | 108                    | £702.74         |  | 158                    | £1,197.07       |  | 208                    | £1,691.06       |
| 9                      | £21.67          |  | 59                     | £301.43         |  | 109                    | £711.86         |  | 159                    | £1,207.69       |  | 209                    | £1,701.50       |
| 10                     | £25.12          |  | 60                     | £308.61         |  | 110                    | £721.02         |  | 160                    | £1,218.34       |  | 210                    | £1,711.94       |
| 11                     | £28.70          |  | 61                     | £315.84         |  | 111                    | £730.22         |  | 161                    | £1,229.01       |  | 211                    | £1,722.38       |
| 12                     | £32.42          |  | 62                     | £323.11         |  | 112                    | £739.44         |  | 162                    | £1,239.71       |  | 212                    | £1,732.82       |
| 13                     | £36.27          |  | 63                     | £330.43         |  | 113                    | £748.70         |  | 163                    | £1,250.44       |  | 213                    | £1,743.26       |
| 14                     | £40.23          |  | 64                     | £337.79         |  | 114                    | £758.00         |  | 164                    | £1,261.19       |  | 214                    | £1,753.70       |
| 15                     | £44.31          |  | 65                     | £345.21         |  | 115                    | £767.32         |  | 165                    | £1,271.97       |  | 215                    | £1,764.14       |
| 16                     | £48.50          |  | 66                     | £352.66         |  | 116                    | £776.68         |  | 166                    | £1,282.78       |  | 216                    | £1,774.58       |
| 17                     | £52.80          |  | 67                     | £360.17         |  | 117                    | £786.07         |  | 167                    | £1,293.61       |  | 217                    | £1,785.02       |
| 18                     | £57.20          |  | 68                     | £367.72         |  | 118                    | £795.49         |  | 168                    | £1,304.47       |  | 218                    | £1,795.46       |
| 19                     | £61.70          |  | 69                     | £375.31         |  | 119                    | £804.94         |  | 169                    | £1,315.35       |  | 219                    | £1,805.90       |
| 20                     | £66.29          |  | 70                     | £382.95         |  | 120                    | £814.43         |  | 170                    | £1,326.26       |  | 220                    | £1,816.34       |
| 21                     | £70.98          |  | 71                     | £390.63         |  | 121                    | £823.95         |  | 171                    | £1,337.19       |  | 221                    | £1,826.78       |
| 22                     | £75.75          |  | 72                     | £398.35         |  | 122                    | £833.50         |  | 172                    | £1,348.15       |  | 222                    | £1,837.22       |
| 23                     | £80.62          |  | 73                     | £406.12         |  | 123                    | £843.08         |  | 173                    | £1,359.14       |  | 223                    | £1,847.66       |
| 24                     | £85.56          |  | 74                     | £413.93         |  | 124                    | £852.69         |  | 174                    | £1,370.15       |  | 224                    | £1,858.10       |
| 25                     | £90.60          |  | 75                     | £421.78         |  | 125                    | £862.33         |  | 175                    | £1,381.19       |  | 225                    | £1,868.54       |
| 26                     | £95.71          |  | 76                     | £429.67         |  | 126                    | £872.00         |  | 176                    | £1,392.25       |  | 226                    | £1,878.98       |
| 27                     | £100.90         |  | 77                     | £437.61         |  | 127                    | £881.71         |  | 177                    | £1,403.34       |  | 227                    | £1,889.42       |
| 28                     | £106.17         |  | 78                     | £445.59         |  | 128                    | £891.44         |  | 178                    | £1,414.45       |  | 228                    | £1,899.86       |
| 29                     | £111.52         |  | 79                     | £453.61         |  | 129                    | £901.21         |  | 179                    | £1,425.59       |  | 229                    | £1,910.30       |
| 30                     | £116.94         |  | 80                     | £461.66         |  | 130                    | £911.00         |  | 180                    | £1,436.75       |  | 230                    | £1,920.74       |
| 31                     | £122.44         |  | 81                     | £469.76         |  | 131                    | £920.83         |  | 181                    | £1,447.94       |  | 231                    | £1,931.18       |
| 32                     | £128.00         |  | 82                     | £477.90         |  | 132                    | £930.69         |  | 182                    | £1,459.15       |  | 232                    | £1,941.62       |
| 33                     | £133.63         |  | 83                     | £486.08         |  | 133                    | £940.57         |  | 183                    | £1,470.39       |  | 233                    | £1,952.06       |
| 34                     | £139.34         |  | 84                     | £494.30         |  | 134                    | £950.49         |  | 184                    | £1,481.65       |  | 234                    | £1,962.50       |
| 35                     | £145.11         |  | 85                     | £502.56         |  | 135                    | £960.43         |  | 185                    | £1,492.93       |  | 235                    | £1,972.94       |
| 36                     | £150.95         |  | 86                     | £510.86         |  | 136                    | £970.41         |  | 186                    | £1,504.24       |  | 236                    | £1,983.38       |
| 37                     | £156.85         |  | 87                     | £519.19         |  | 137                    | £980.41         |  | 187                    | £1,515.58       |  | 237                    | £1,993.82       |
| 38                     | £162.82         |  | 88                     | £527.56         |  | 138                    | £990.45         |  | 188                    | £1,526.94       |  | 238                    | £2,004.26       |
| 39                     | £168.85         |  | 89                     | £535.98         |  | 139                    | £1,000.51       |  | 189                    | £1,538.32       |  | 239                    | £2,014.70       |
| 40                     | £174.94         |  | 90                     | £544.43         |  | 140                    | £1,010.60       |  | 190                    | £1,549.73       |  | 240                    | £2,025.14       |
| 41                     | £181.09         |  | 91                     | £552.91         |  | 141                    | £1,020.72       |  | 191                    | £1,561.16       |  | 241                    | £2,035.58       |
| 42                     | £187.30         |  | 92                     | £561.44         |  | 142                    | £1,030.87       |  | 192                    | £1,572.61       |  | 242                    | £2,046.02       |
| 43                     | £193.58         |  | 93                     | £570.00         |  | 143                    | £1,041.05       |  | 193                    | £1,584.09       |  | 243                    | £2,056.46       |
| 44                     | £199.91         |  | 94                     | £578.60         |  | 144                    | £1,051.25       |  | 194                    | £1,595.59       |  | 244                    | £2,066.90       |
| 45                     | £206.30         |  | 95                     | £587.24         |  | 145                    | £1,061.49       |  | 195                    | £1,607.12       |  | 245                    | £2,077.34       |
| 46                     | £212.75         |  | 96                     | £595.91         |  | 146                    | £1,071.75       |  | 196                    | £1,618.67       |  | 246                    | £2,087.78       |
| 47                     | £219.25         |  | 97                     | £604.62         |  | 147                    | £1,082.04       |  | 197                    | £1,630.24       |  | 247                    | £2,098.22       |
| 48                     | £225.81         |  | 98                     | £613.36         |  | 148                    | £1,092.36       |  | 198                    | £1,641.84       |  | 248                    | £2,108.66       |
| 49                     | £232.42         |  | 99                     | £622.14         |  | 149                    | £1,102.71       |  | 199                    | £1,653.46       |  | 249                    | £2,119.10       |
| 50                     | £239.09         |  | 100                    | £630.96         |  | 150                    | £1,113.08       |  | 200                    | £1,665.11       |  | 250                    | £2,129.54       |

## SCHEDULE: PART 12

### EQUIPMENT REFRESH PROGRAMME

#### 1. Introduction

##### 1.1 Overview

1.1.1 This Schedule Part [x] (Equipment Refresh Programme) sets out the Contractor's initial proposed policy for the refreshing of all elements of the Solution necessary for the provision of the Managed Services and the basis upon which any Net Gain shall be returned to the Board.

1.1.2 In practice, technology refreshes will be performed in a rolling programme, driven by the following factors:

- End of life of Equipment;
- End of warranty;
- Escalating maintenance costs and replacement business case;
- Major application upgrade;
- Operating system upgrade; and
- Consolidation programmes.

#### 2. Refresh Policy

2.1 All technical refresh activities will be effected in accordance with the Change Control Procedure and the following table:

| Technology                                                                | Refresh Period (years) | Notes                               |
|---------------------------------------------------------------------------|------------------------|-------------------------------------|
| [NOTE: To be completed post tender once programme received by Contractor] |                        | [NOTE: detail any assumptions here] |

If any of the Contractor's assumptions set out above prove to be incorrect, all risk in the same shall remain with the Contractor and the Board shall not be obliged to make any

payment to the Contractor in respect of any cost or expense arising as a result of incorrect assumptions.

## SCHEDULE: PART 13

### SPECIFICATION

**CLO NOTE: Insert NHS Requirement, the Contractor's Response and the Clarifications (if any).**

In the event of ambiguity or conflict the undernoted documents shall rank in the order below:

1. The NHS Requirement;
2. The Contractor's Response;
3. Clarifications.

**SCHEDULE: PART 14**  
**SOCIAL AND ENVIRONMENTAL BENEFITS**

This Schedule Part 14 shall be completed by incorporating the information provided by the Contractor in Annex 10 of Contractor's Response (as set out in Annex 10 of the ITT) relating to Social and Environmental Considerations.

## SCHEDULE: PART 15

### PROCESSING INFORMATION [TO BE COMPLETED POST TENDER]

1. The Contractor shall comply with any further written instructions with respect to Processing issued by the Board.
2. Any such further instructions shall be incorporated into this Schedule Part 15.
3. This Schedule Part 15 must be read in conjunction with Clauses **[18.27.1(iv)]**

| Description                          | Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Purpose                                                                                                                                                                                                                                 | Additional Permitted Purpose                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Subject matter of the Processing     | <i>[This should be a high level, short description of what the Processing is about, i.e. its subject matter]</i>                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                          |
| Duration of the Processing           | <i>[Clearly set out the duration of the Processing, including dates. It may be that all of the Processing activities will be undertaken throughout the entire Term, in which case, this should be stated clearly. If, however, the various Processing activities will be required for different periods of time, then this needs to be considered and narrated.]</i>                                                                                                                      |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                          |
| Nature and purpose of the Processing | <p><i>[Please be as specific as possible, but make sure that you cover all intended purposes.]</i></p> <p><i>The nature of the Processing means any operation such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means), etc.</i></p> | <p>The Purpose of the Processing is the performance of the obligations imposed on the Contractor pursuant to or under this Agreement, including, but not limited to, performance of the Services. In summary, this is <b>[ • ]</b>.</p> | <p>The Additional Permitted Purpose is a purpose in addition to the Purpose which the Contractor must implement itself by Law, being <b>[INSERT DETAILS]</b>, [e.g. processing of insurance claims relating to staff as part of insurance services purchased, such processing also being required to be recorded by the Contractor for regulatory purposes given the</p> |

|                                                                                                                                                              |                                                                                                                                                                                                                |  |                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------|
|                                                                                                                                                              |                                                                                                                                                                                                                |  | <i>Contractor's role in providing such services in the marketplace.]</i> |
| Type of Personal Data                                                                                                                                        | <i>[Examples here include: name, address, date of birth, NI number, telephone number, pay, images, biometric data, etc.]</i>                                                                                   |  |                                                                          |
| Categories of Data Subject                                                                                                                                   | <i>[Examples include: Staff (including volunteers, agents, and temporary workers), customers/ clients, suppliers, patients, students / pupils, members of the public, users of a particular Website, etc.]</i> |  |                                                                          |
| Plan for return and destruction of the data once the Processing is complete UNLESS requirement under union or member state law to preserve that type of data | <i>[Describe how long the data will be retained for, how it be returned or destroyed]</i>                                                                                                                      |  | N/A                                                                      |
| Minimum Requirements                                                                                                                                         | <i>[E.g. detail any specific technical and organisational measures that the Contractor must comply with, e.g. ISO 27001, particular NHSS policies, etc.]</i>                                                   |  | N/A                                                                      |
| Additional Information                                                                                                                                       | <i>[E.g. details of any approved Sub-processors; details of any approved transfers outside the EEA, other relevant information, etc.]</i>                                                                      |  |                                                                          |

