



V1.3a

NHS REQUIREMENT

**FOR THE PROVISION OF A MANAGED SERVICE CONTRACT FOR
PRIMARY HIGH-RISK HPV (hr-HPV) TESTING AND CYTOLOGY-BASED
TRIAGE (NHS SCOTLAND)**

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MANAGED SERVICE SPECIFICATION

INTRODUCTION

This specification sets out the requirements for the implementation of primary high risk human papillomavirus (Hr-HPV) testing for Cytology based triage to a re-configured Scottish Cytology Screening Programme. The proposed pathway for primary screening has been agreed by a stakeholder group and follows closely that used in the English pilot of HPV primary screening.

The aims of the service are:

- Provide clinically effective screening services, maintaining high quality, performance and specificity to ensure effective detection of significant disease and retain public confidence in the programme, while mitigating the anticipated deterioration of the sensitivity of cervical cytology.
- To improve the patient experience by introducing a testing method of a sensitivity and specificity that will produce results that better reflect patients' individual risk, will reduce reporting time and has the potential to be less intrusive and improve uptake. Please refer to Appendix A for the detailed pathway.
- Building the new reconfigured service on successful existing IT processes, which will retain patient safety and ensure effective communication.

CURRENT SERVICE CONFIGURATION

The Scottish Cervical Screening Programme (SCSP) laboratory service is currently provided from seven laboratories throughout Scotland. A map indicating the location of all the Scottish laboratories is contained in Appendix B.

In 2013, a Managed Service Contract was implemented in the following "Participating Boards": -

- Tayside Health Board
- Grampian Health Board
- Lothian Health Board
- Lanarkshire Health Board
- Forth Valley Health Board
- Fife Health Board
- Highland Health Board
- Ayrshire & Arran Health Board

Note: The current Managed Service Contract involves all Health Boards in Scotland apart from Greater Glasgow Health Board who currently have a separate managed service provision.

Note: In 2014, the laboratory in Highland Health Board was closed and the workload transferred to Grampian Health Board.

Note: In 2017, the laboratory in Ayrshire & Arran Health Board was closed and the workload transferred to Lanarkshire Health Board.

Details of the 2016-17 workload in the Participating Boards' laboratories can be located in Appendix C.

Currently the seven laboratories use Image Assisted Screening (IAS). Four laboratories image only their own workload and one laboratory images their own slides and the workload of the other two labs in a hub and spoke basis. All laboratories have liquid based cytology (LBC) processing equipment and process and stain their own workload.

IMPLEMENTATION OF A PRIMARY HIGH-RISK HPV (Hr-HPV) TESTING AND CYTOLOGY-BASED TRIAGE IN NHS SCOTLAND

Hr-HPV testing will replace cervical cytology as the primary screening method. Liquid-based cytology will be used for triage of women testing positive for Hr-HPV, and combined with HPV testing in certain clinical circumstances, for example Test of Cure of treated Cervical Intra-epithelial Neoplasia (CIN). This implementation will require the current national cytology service delivery to be re-configured. The Scottish Government has supported a business case for the implementation of an Hr-HPV Primary Screening national service to be delivered from two hospital laboratory sites in Scotland (the 'Processing Laboratories'). Both Processing Laboratories will deliver both cervical cytology and Hr-HPV testing for triage and test of cure.

After a national selection process the following Processing Laboratories have been selected to deliver the new configured service. The sites are:

- University Hospital Monklands (UHM) within Lanarkshire Health Board
- Queen Elizabeth University Hospital within Greater Glasgow Health Board

Both Processing Laboratories currently provide UKAS accredited (compliant with ISO15189) Cytology Screening services.

The operational service vision for the primary Hr-HPV testing and cytology-based triage service is one which includes supply and provision of all liquid-based cytology consumables including the logistics of transferring the sample to the Processing Laboratories. The workflow will be managed electronically from test requesting to reporting through laboratory test result algorithms, with the Hr-HPV testing analyses performed on automated equipment. The Hr-HPV equipment will transfer test results via a uni-directional interface and Middleware to the Scottish Cervical Call Recall System (SCCRS)). Barcode labelling and primary tube sampling will be used for positive sample identification, sample traceability and archiving, minimising transcription and sample handling errors. Following Hr-HPV testing, selected samples will then undergo Cytology based triage with the eventual provision of a definitive result and recommended management in the format of an electronic report.

MANAGED SERVICE CONTRACT

NHS National Services Scotland are tendering on behalf of Lanarkshire Health Board and Greater Glasgow Health Board (the 'Health Boards') for a Managed Service Contract (the 'Contract') for a single Contractor for the provision of primary Hr-HPV testing and cervical cytology at the Processing Laboratories and associated transport of samples to ensure a

managed service is delivered for Scotland. Each Health Board will enter into its own Contract with the successful Contractor.

NSS will work with the successful Contractor to achieve as smooth a transition as possible to the new managed service with an anticipated implementation date of January 2020.

The Contractor will be expected to assume responsibility for the guaranteed availability of the managed service solution, encompassing the provision, management and supply of liquid-based cytology consumables, the logistics of transfer of samples to the Processing Laboratories, all requisite equipment and associated reagents/kits/consumables. The Contractor will provide proven equipment (CE marked) and validated (CE marked) kits and reagents to support the Hr-HPV primary screening and cytology services. The Contractor will assume responsibility for the disposal of the used vials, daughter tubes and used reagents, and plastic consumables.

It is expected the Contractor will be able to demonstrate considerable expertise in the field of Liquid Based Cytology and Hr-HPV detection. The contract will be awarded to a Contractor that can provide evidence of experience in supporting managed service contracts. This document specifies the requirements for a managed service solution.

The managed service solution proposed will enable NHS Scotland to make the most effective use of financial resources and efficient use of the available staff resource.

The Contractor will provide evidence on how their equipment will enable flexible throughput options, to ensure the quality of generated results and improve workflow efficiency, which will contribute to improved turnaround times.

WORKLOAD FLUCTUATIONS

Large fluctuations in workload activity are predicted to occur within both the primary Hr-HPV testing service and the cervical cytology screening services over the next 10 years. The fluctuation will occur on a recurring basis over the Term of the proposed Contract. This fluctuation is a consequence of changes in screening frequency of individuals on routine follow-up, the effects of the high take up of the HPV immunisation programme, and changes in age range and frequency (CARAF) recently implemented. Activity levels will be significantly higher in Years 1-3 and Years 6-8 (refer to Appendix E).

There may be a 4-fold difference between the projected numbers of screening specimens referred for cytology in year 3 and in year 5 of the cycle following introduction of Hr-HPV primary. The initial 3 years between 2020 and 2023 demonstrate significant peaks in service activity and then activity declines with further, smaller, peaks within the remaining 10-year period.

However, a 10-year average has been calculated to provide a means of comparison with current activity levels. It is indicated that:

Hr-HPV testing will increase from minimal activity related to test of cure to average annual activity of circa 290,000 tests.

There will be a significant reduction in the number of cytology tests from circa 395,000 to an average of circa 45,000 p.a., representing a reduction of 89%.

Such major fluctuations will require active management of the Managed Service Contract throughout the Term of the Contract.

The Contractor must provide evidence on how their equipment will enable flexible throughput options, to ensure the quality of generated results and improve workflow efficiency, which will contribute to improved turnaround times.

It is essential the equipment is customised to the operational and clinical requirements of the service with a logistic service to each Processing Laboratory that supports the pattern of work required locally. The majority of work is currently processed between the working hours of 9am to 5pm, but systems must be available, with minimum start up times, to support extended day working of 8am to 8pm. All equipment must meet peak demands and required turnaround times throughout the Term of the Contract.

The potential Contractor must be willing to work with the National Services Division (NSD) and the Processing Laboratories, regarding the choice of equipment, assays, reagents and consumables and to propose solutions to accommodate the specimen workflow.

This NHS Requirement provides a specification for the managed service which covers laboratory equipment and consumables, sample takers consumables, logistics, service and support including semi-automated screening to process all cervical cytology samples for the SCSP in the two selected Processing Laboratories.

The Contract will comprise of 1 lot, divided into the following areas, and potential contractors will be invited to tender for the total Contract:

- Liquid Based Cytology (the sample collection method): supply and provision of sample taker consumables to distribution points as detailed in Appendix "D" (the 'Distribution Points')
- Logistics: transfer of all LBC samples to the Processing Laboratories from the designated collection centres as detailed in Appendix B (the 'Collection Centres')
- HPV testing equipment and associated reagents and consumables
- Cytology triage equipment / technology with associated consumables
- Disposal of all waste from the Liquid based Cytology process

The Contracts will be managed as a single managed service and will follow the restricted procedure procurement route to enable the construction of a fully tailored service to meet the needs of the Screening Programme and that enables flexibility in terms of the pace at which Scotland moves towards introducing HPV testing as the primary assay. The Contracts will be for an Initial Term of 5 years, with available extensions for a possible further 5 years.

Contractors should respond to this statement of requirement (NHS Requirement) with their proposed Solution for meeting NHS Scotland's vision which assumes that activity will continue at each of the two Processing Laboratories at the level detailed in Appendix E.

PART A

PART A: GENERIC SPECIFICATION RELATED TO THE REQUIREMENTS OF THE MANAGED SERVICE CONTRACT

A.1 Dedicated or Nominated Staff provided by the Contractor to support the Managed Service Contract

- a. The Contractor **SHOULD** indicate how they will provide appropriate dedicated staff to manage and support this managed service in compliance with HM Tax requirements for VAT recovery.

A.1.a	RESPONSE: E
Please note your response below:	

- b. The Contractor **SHOULD** indicate in detail the on-site and off-site support staff i.e. job roles, responsibilities, skills available that will be dedicated to the contract during the implementation of the service. Please provide details of the proposed Implementation Plan, the staffing resource, the proportion of staff time dedicated to each Processing Laboratory to support this plan.

A.1.b	RESPONSE: E
Please note your response below:	

- c. The Contractor **SHOULD** provide details of on-site and off-site support staff allocations and indicate how these dedicated staff will provide the managed service throughout the Term of the Contract. Please provide details of the proposal, the staffing resource and proportion of staff time dedicated to each Processing Laboratory.

A.1.c	RESPONSE: E
Please note your response below:	

A.2 Supply Chain and Inventory Management

- a. The Contractor **MUST** be responsible for the stock of all reagents and consumables required for the performance of all tests. This includes, but is not limited to, responsibility for maintaining minimum agreed stock levels, responsibility for the monitoring of stock levels, the on-site storage of stock, the ordering of stock, the management of stock issues and ensuring proper rotation of stock. Minimum stock levels **MUST** be agreed with each Health Board.

The Contractor **MUST** describe how the proposed Inventory Management System (IMS) solution would operate and how they will deliver the reagent and consumable management requirements for all components of the managed service and any third party products supplied by the Contractor under the Contract. Contractors **MUST** indicate how the reagent inventory management and storage system enables compliance with ISO 15189:2012 requirements.

The Contractor **MUST** liaise with the procurement departments in both Health Boards to manage changes e.g. actively updating standing order and product listings when products are discontinued or product codes change.

A.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **MUST** facilitate the proposed inventory management storage facilities required to cope with the Contractors delivery schedules. It is envisaged that the Contractor will provide a solution which controls the re-ordering of sample taking consumables and laboratory reagent and consumable packs for the equipment. The Contractor **MUST** provide and install appropriate hardware to deliver an effective local solution at each storage location.

A.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **MUST**:

- c. Indicate how they will distribute the LBC sample taking consumables to the Distribution Points to ensure service provision, as noted in Appendix D.

A.2.c	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- d. Indicate how they will distribute laboratory reagents and consumables to each Processing Laboratory to ensure service provision.

A.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. How they will promptly notify the Health Board of any changes to their products or any safety alerts issued for its products (including but not limited to MHRA product alerts). This would also include any changes in either reagent (composition, stability, packaging etc) or any other item that may affect the analytical performance of equipment, assays and associated methodology.

A.2.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

A.3 Disaster Recovery & Contingency Arrangements

- a. The Contractor **MUST** provide detailed protocols and procedures on the Disaster Recovery and Contingency arrangements for all components of the managed service. The requirements and detailed protocols and procedures will be agreed with the Processing Laboratories prior to the commencement of the Contract. This shall include:
- Provision of all LBC sample taking consumables and the reagent/consumables used on equipment in the provision of the managed service.
 - Availability and reliability of provision of logistics involved in the delivery of LBC sample taking consumables
 - Availability and reliability of provision of logistics delivery of LBC samples from Collection Centres to Processing Laboratory

- Provision of the pre-analytical and analytical Hr-HPV service including test methodology Middleware and Interface support
- Provision of the cytology service

A.3.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Managed Service Solution for the provision of the analytical service **MUST** provide the following minimum requirements:

- b. The Contractor **MUST** offer equipment that has the capacity to handle the current workload and associated peaks in activity, along with capacity to cope with increased demand and satisfy the required test turnaround times (as appropriate) during the Term of the Contract. Activity levels will be significantly higher in Years 1 – 3 and Years 6 – 8 (refer to Appendix E). Please provide a detailed plan for the optimal configuration of the service to meet Service Levels over the Term of the Contract.

A.3.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. There **MUST** be adequate service continuity for both planned and unplanned equipment downtime. Contractors **MUST** specify how test availability will be maintained for all assays and procedures in the event of any equipment breakdown which results in a failure to meet the Health Boards Service Levels including all 3rd party equipment.

A.3.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Resilience of the Contract **MUST** be the responsibility of the Contractor by ensuring that any failure in the equipment will be resolved within 2 working days. Failure to achieve this will result in LBC samples being transported to the other Processing Laboratory or an external laboratory with all contingency arrangements and associated costs being met by the Contractor.

A.3.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. The Contractor **MUST** indicate clearly what will happen in the event of failure of each item of equipment (including third party providers) within the Contract, including the Middleware, to ensure continuity of operation.

A.3.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- f. The Contractor **SHOULD** provide further detailed information on resilience of manufacture and supply of reagents and consumables required to deliver the managed service:

- Contingency arrangements to ensure availability and reliability of manufacture and supply of reagents/consumables for the service. It is anticipated there will be more than one manufacturing site for reagents/consumables. The Contractor **SHOULD** describe their contingency arrangements for all reagents/consumables used in the Contract and, if there is only one site for manufacture, provide details of how such increased risk is addressed.
- Evidence that all reagents/consumables including Hr-HPV assay kits are available to be supplied at all times i.e. provide evidence of no failure or supply for longer than 1 month in the last 2 years.
- Evidence how reserved stock management can be organised to accommodate call-off/just in time ordering and supply.
- The mean time and range taken from placing an ordering to delivery to Distribution Point / Processing Laboratory of use.

A.3.f	RESPONSE: E
Please note your response below:	

A.4 Service Levels

The Contractor **MUST** meet the service levels identified in Appendix F (the 'Service Levels') and validate how they intend to do so with supporting evidence. Contractor response **MUST** include independent validated data.

A.4	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

A.5 Contract Management: Production of Contract Monitoring Reports

The Contractor **MUST**:

- Describe how they propose to manage all aspects of the Contract including the purchase of equipment and procurement of services from other suppliers ('Third Party Providers') in order to undertake the required tests. The Contractor is fully responsible for the performance of all Third Party Suppliers and/ or Sub-Contractors.
- Provide regular management information relating to the operation of the Managed Service Contract. Maintain up-to-date management information in an electronic format on the performance of the service including details of the numbers of tests, Turnaround Times (TATs), supplies of reagents, availability of equipment and calls to the Helpdesk.
- Provide examples of performance management reports.

For strategic Contract Monitoring this **MUST** include (for each Processing Laboratory) but not be limited to:

- Regular meetings with Primary Contractor nominated individual to discuss operational aspects of the contract including all 3rd party providers.
- Review of monthly Hr-HPV workload activity
- Achievement of required Test Turnaround Time targets as specified in the Service Levels
- Financial reports including trending of current and previous reagent/consumable spend
- Formal notification of complaints & compliments
- Contract performance review of delivery of LBC sample taking consumables and delivery of LBC samples to each Processing Laboratory.
- Forecast versus actual usage comparisons including the reagent, QA material, consumable efficiency rates.
- Inventory Management System reports i.e. including the provision of "bespoke" reporting for each Health Board and reporting on the provision of LBC sample taking consumables to Distribution Points.
- Equipment performance statistics such as service calls, engineer response time and equipment availability i.e. uptime (including 3rd party equipment). Service, repair and breakdown information, trend analysis of faults/problems, this should include downtime where NHS staff are able to effect repair

- Service Points applicable during each contract monitoring/reporting period for each Health Board
- Overview of equipment refresh schedules
- Value-added proposals
- Contract Change notifications
- There should be an audit trail of all communication, orders and transactions between Processing Laboratories and the Contractor

Contractors **MUST** give details of how this information will be provided by the Contractor.

A.5	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

A.6 Managed Service Contract: Flexibility

Contractors **SHOULD** indicate how their Solution would incorporate possible future changes such as:

- The inclusion of further services to the Contract.
- The inclusion of new test methodology.
- Any significant increase or reduction in a specific test or overall test workload.
- The relocation of equipment within the Processing Laboratories in line with any future reorganisation of services (currently unknown) or any unplanned event. Provide any costs attributable to such possible future reorganisation.

A.6	RESPONSE: E
Please note your response below:	

A.7 Added Value

The Contractor **SHOULD** add value to the Managed Service through commercial insight and experience of service redesign. Contractors **SHOULD** outline the impact of their proposed solution on current processes and where appropriate, illustrate their response with examples following previous installations in similar sized locations.

Contractors are invited to explain how their proposal will contribute to the operational delivery, efficiency and quality of the Hr-HPV service. The Contractor **SHOULD** identify service improvement opportunities throughout the Term of the Contract. Areas which **SHOULD** be covered include:

- a. Developments to the Hr-HPV workflow to remove potential bottlenecks in laboratory processes by further streamlining the pre-analytical, analytical and post-analytical process to enhance throughput and remove all possible risks i.e. reduce the number of failed/error samples. For example, this should include, but not limited to delivery of LBC sample taking consumables, logistics delivering to the Processing Laboratories, improved patient data entry, specimen handling, equipment consolidation, reduced equipment maintenance, sample filing, retrieval and archiving.

A.7.a	RESPONSE: E
Please note your response below:	

- b. Improved quality of the clinical service. Provide better assay performance leading to improved clinical interpretation and standardising work processes resulting in less variation of clinical results across both Processing Laboratories.

A.7.b	RESPONSE: E
Please note your response below:	

- c. Improved information intelligence on logistics, sample workflow, resources and equipment performance from a single integrated (data management) monitoring system, to allow improved service planning and efficiency on each Processing Laboratories.

A.7.c	RESPONSE: E
Please note your response below:	

- d. Maximising 'pre-failure' monitoring of equipment and scheduled preventative maintenance visits to maximise equipment up-time on each Processing Laboratory.

A.7.d	RESPONSE: E
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Please note your response below:

- e. Internal Quality Control (IQC) which should be displayed and managed centrally on each Processing Laboratory and should be visible from the other Processing Laboratory.

A.7.e	RESPONSE: E
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Please note your response below:

- f. Meeting the educational needs of the service by enabling compliance with ISO 15189 requirements for staff training and competency assessment for all Managed Service analytical components on each Processing Laboratory.

A.7.f	RESPONSE: E
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Please note your response below:

- g. Simplification, consolidation and reduction in Processing Laboratory staff/managers time in reagent stock management on each Processing Laboratory.

A.7.g	RESPONSE: E
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Please note your response below:

- h. Changes required to the layout of the department which enable the implementation of a lean workflow from LBC sample receipt to archive improvements in the working environment on each Processing Laboratory.

A.7.h	RESPONSE: E
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Please note your response below:

- i. A reduction in the administrative burden required to meet UKAS accreditation ISO 15189 e.g. reagent stock management and traceability, SOP preparation, IQC monitoring, compliance with ISO 15189 competency training, uncertainty of measurement, reagent batch acceptance compliance.

A.7.i	RESPONSE: E
Please note your response below:	

- j. A reduction in the administrative burden in relation to management time required for performance and contract monitoring of the Managed Service at each Processing Laboratory i.e. costing performance, reagent management, logistics.

A.7.j	RESPONSE: E
Please note your response below:	

- k. Delivery of process improvements and operational efficiencies that in turn facilitate more efficient workforce planning and working on each Processing Laboratory.

A.7.k	RESPONSE: E
Please note your response below:	

- l. Any added value proposition that can be offered as part of the managed service that can provide a more effective service.

A.7.l	RESPONSE: E
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Please note your response below:

A.8 Innovation and Equipment / Middleware Refresh

It is anticipated that innovative products or services or new technology may become available during the Term of the Contract. Due to the Term of the Contract the Health Boards would expect that all equipment / Middleware which exceed their operational life or breach Service Levels would be replaced with similar or updated versions to maintain the level of clinical service.

For all equipment in the proposed solution Contractors **SHOULD** provide the following:

- a. Expected operational lifetime of proposed installed equipment, with evidence from equipment already in use in the field.

A.8.a	RESPONSE: E
Please note your response below:	

- b. Proposed Equipment Refresh programme within the Term of the Contract including any extension period of installed equipment as detailed in Appendix I. This **SHOULD** include information on whether this is a “like for like” upgrade to existing equipment or an enhanced offering. Please provide detailed programme.

A.8.b	RESPONSE: I
Please note your response below:	

- c. Timeline and implementation strategy (including financial implications) for innovative products which may become available during the Term of the Contract, for information only.

A.8.c	RESPONSE: I
Please note your response below:	

- d. Contractors **MUST** confirm that all equipment supplied as part of their solution, be it for the original installation or part of any proposed Equipment Refresh programme, will be supplied as NEW equipment and not refurbished, recycled, or re-used in any way.

A.8.d	RESPONSE: M (pass/fail/assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

A.9 Timetable for Reconfiguration/ Implementation of the Hr-HPV Primary Screening Service

The delivery and implementation of the service including laboratory equipment **SHOULD** take place in 2019-20 and consist of the following steps. All necessary preparation and installation steps **SHOULD** be executed in 2019. Commissioning of the equipment **SHOULD** be finished in time to allow for staff training and Operational Readiness Testing (ORT). ORT is expected to take place from September 2019. ORT and all staff training should be completed in advance of the full implementation of the service in January 2020. Please provide evidence of how the following will be delivered:

- Ensure current level of service will be maintained during installation and commissioning of new equipment within the service i.e. logistics.
- Indicate how the Contractor will relocate/reconfigure existing equipment/hardware any new equipment which **SHOULD** be with minimum disruption to service provision at mutually agreed times, which may be outside normal working hours.
- Planning workshop and provision of detailed timelines for equipment and Middleware installation, implementation, training and go-live. This will also include the implementation of arrangements for delivery of LBC sample taking consumables and logistic services.
- Installation of the Middleware onsite including installation and operational qualification of the software package including all preconfigured features and workflows.
- Implementation of any customised solutions
- Support the interfacing requirements to the existing IT system e.g. SCCRS
- Training of all users

Installation and commissioning **SHOULD** be within a reasonably short time frame but providing sufficient time for evaluation and training and Contractors **SHOULD** submit a detailed Implementation Plan and provide evidence of implementation in situations where reconfiguration of services has taken place in other commissioning projects.

A.9	RESPONSE: E
Please note your response below:	

A.10 Transportation of Specimens from Collection Centres to Processing Laboratories

The Contractor **MUST** provide:

- a. Appropriate storage and timely transport of LBC samples to Processing Laboratories. This is a requirement for maximising workflow. It is essential that LBC samples are sent to the Processing Laboratory within two working days of uplift from Collection Centre. Please provide details.

A.10.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **MUST** ensure all specimens are transported in accordance with the European Agreement Concerning the International Carriage of Dangerous Goods by Road (2007) (ADR).

A.10.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. LBC samples **MUST** be dispatched to the Processing Laboratories in transport containers which comply with UN3373 requirements.

A.10.c	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- d. Supply sufficient quantities of transport containers to meet the delivery schedule.

A.10.d	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- e. Transportation of LBC samples between Processing Laboratories **MUST** comply with the guidance laid down in this document and **MUST** adhere to NHS Code of Practice for BAC | Recommended Code of Practice for Cytology Laboratories Participating in the UK Cervical Screening Programmes (October 2015 v1)

A.10.e	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- f. The Contractor **MUST** undertake a risk assessment for vehicles used for transporting LBC samples.

A.10.f	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Contractor **SHOULD**:

- g. Optimise the LBC sample collection from each Collection Centre to allow delivery to the Processing Laboratories within two working days. Please provide detailed delivery schedule to each Processing Laboratory. Please provide evidence of previous implementation of logistics services.

A.10.g	RESPONSE: E
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Please note your response below:

- h. The Contractor **SHOULD** provide the logistics delivery schedule and Logistics reports and analysis to meet Service Levels specified by the Processing Laboratories for monitoring and modelling purposes or actual use, at no additional charge.

A.10.h **RESPONSE: E**

Please note your response below:

- i. The Contractor **SHOULD** provide a process and procedure on how they will communicate with each Processing Laboratory regarding non-compliance with the delivery schedule on a real-time basis.

A.10.i **RESPONSE: E**

Please note your response below:

- j. LBC vials **SHOULD** be stored at manufacturer's recommended temperature range during transport to Distribution Points and between Collection Centres and Processing Laboratories. Contractors **SHOULD** state how they will achieve this during distribution to the Distribution Points and also from the Collection Centres for transport to the Processing Laboratories. The Contractor **SHOULD** provide data for monitoring of routine transport temperatures and transit times on a monthly basis.

A.10.j **RESPONSE: E**

Please note your response below:

- k. Traceability of LBC sample consignments from Collection Centre to Processing Laboratory **SHOULD** be provided.

A.10.k **RESPONSE: E**

Please note your response below:

- l. Written procedures for the transportation of LBC samples **SHOULD** be provided and **SHOULD** ensure compliance with the guidance given above.

A.10.l	RESPONSE: E
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Please note your response below:

- m. Disaster Recovery Contingency **SHOULD** be provided and include details of how each Processing Laboratory can maintain service in respect of a Contractor solution failure of the logistics service.

A.10.m	RESPONSE: E
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Please note your response below:

A.10.2 Incident reporting

Any incident during transportation that may affect the quality of the specimen or the safety of personnel **MUST** be brought to the attention of the Processing Laboratory who will investigate and advise on the appropriate action.

A.10.2	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

A.10.3 Logistics Staff Training

The Contractor **MUST** provide and cover all costs for initial and continuing key operator and basic user training.

The Contractor **MUST** ensure all of the Contractor's logistics staff are trained appropriately providing evidence of training and competency documentation including the Model Rules for Transport Drivers.

A.10.3	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

A.11 Waste Management

The Contractor **MUST** make recommendations for safe and confidential methods of waste removal for the vials, their contents and other reagents after completion of the test. Any disposal costs associated with the uplift of the waste will be the responsibility of the Contractor.

A.11	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

There are four waste streams generated with the LBC process.

The first waste stream is the excess preservative solution that is left in the LBC vial. The vials each contain 10-20 ml of an alcohol-based solution.

The second waste stream is the preservative solution remaining in the daughter aliquot tubes processed for molecular HPV testing.

The third waste stream is the preservative waste that comes out of the Cytology slide preparation processor, pre-analytical and analytical equipment. This is the alcohol-based solution. All waste streams need to be collected and managed as an ignitable hazardous waste.

The fourth waste stream relates to disposable/recyclable plastics.

The Contractor **SHOULD** provide details of:

- a. Waste generated by the equipment. The Contractor **SHOULD** state the typical liquid /solid waste volume generated per day and the required disposal method. For liquid waste generated by equipment, details **SHOULD** be included on whether disposal is plumbed to waste or directed to a waste container.

A.11.a	RESPONSE: E
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Please note your response below:

- b. How the Contractor's solution complies with all relevant Environmental Protection legislation, including the National Guidance for Healthcare Waste Water Discharges; which both Health Boards are required to comply with

A.11.b	RESPONSE: E
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Please note your response below:

- c. All storage containers required for waste awaiting collection.

A.11.c	RESPONSE: E
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Please note your response below:

- d. A collection schedule, which will be finalised in consultation with the two Processing Laboratories.

A.11.d	RESPONSE: E
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Please note your response below:

PART B

PART B: EQUIPMENT SOLUTION FOR THE Hr-HPV TESTING SERVICE

B.1 Equipment Solution

- a. The Contractor **MUST** provide all equipment and consumables necessary for the Health Boards to undertake all Hr-HPV testing including calibration and internal and external quality control. The potential throughput for each Processing Laboratory will be in the order of 800 liquid cytology samples for molecular Hr-HPV testing within a typical 8 hour working day (Monday to Friday) (processing and reporting to completed Hr-HPV result). Workload figures are approximations only and may fluctuate due to changes to the screening programme (please refer to annual workload figures in Appendix E).

The Contractor **MUST** provide separate equipment solutions for both Health Boards to meet workload activity on each Processing Laboratory. The Contractor **MUST** provide an equipment solution which delivers the baseline workload capacity whilst being operated at less than capacity during peak times as provided in the annual workload figures in Appendix E.

The equipment **MUST** be capable of being accommodated within the designated footprint of the Processing Laboratories (as provided by the Health Boards) and **MUST** be capable of delivering a flexible and variable test output with efficient workflow at both low and high volume workloads. A visual display of workflows/process maps that indicate the operational equipment solutions, including Middleware **MUST** be provided.

B.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **MUST** provide a daily/weekly workflow schedule for the pre-analytical and analytical equipment that enables compliance with an expected turn-around time of 48h from acceptance of the LBC sample by the Processing Laboratory and allocation of the laboratory number to receipt of Hr-HPV result in SCCRS as specified in Appendix C & E.

B.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.2 Description of Equipment

- a. For each item of equipment including any pre-and post-analysis equipment, the Contractor **MUST** provide a full technical specification including any Middleware

requirement. Pre-analytical equipment for this specification is defined as equipment built specifically for preparing the LBC samples prior to the extraction, amplification and detection steps of the process.

This **MUST** include the name and model of the pre-analytical / analytical equipment providing liquid handling, sample extraction, and amplification and detection. . The Contractor **MUST** list the equipment and reagents required to perform the Hr-HPV test. Equipment / methodologies which will be obtained from Third Party Suppliers **MUST** be specified.

B.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **MUST** provide the following:

- b. The overall dimensions and weight and floor or bench loading, including detail on any special requirements/ restrictions i.e. the amount of space required (footprint plus any additional area, for example for lid/drawer opening, air circulation or waste disposal). The Contractor **MUST** configure the equipment to ensure sufficient space to enable Health Board staff to undertake any associated activities, i.e. preparation of samples and authorisation of test results. The weight of the equipment **MUST** fall within the load limits of the buildings in which they are sited, which can be established during site visits.

B.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. If the equipment is benchtop (benches will need to be able to support the weight of the equipment), suitable benching **MUST** be provided by Contractor if a suitable existing location cannot be agreed between the Contractor and the Processing Laboratory.

B.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. The operational noise levels, the electrical / power / data connection requirements, the heat output of each item of equipment. Noise levels and control **MUST** be within acceptable limits and not exceed any published guidance.

B.2.d	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- e. Describe safety measures associated with each item of equipment to mitigate staff health & safety risks, including arrangements for the handling of Category 3 Pathogens ("High Risk" samples) and any in-built safeguards which prevent or minimise the risk of aerosol formation or minimise splashing / spillage of samples and reagents. Material Safety Data Sheets **MUST** be supplied.

B.2.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- f. A description of the principles / methodologies used for sample handling, sample extraction, amplification and detection **MUST** be provided including any relevant independent evaluation reports worldwide.

B.2.f	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- g. Provide details of any pre-processing and manual techniques that are not fully/semi-automated encompassing the entire sample test pathway. There **SHOULD** be no requirement for complimentary analytical equipment outwith the solution to complete certain analytical steps of molecular testing e.g. the extraction and amplification.

B.2.g	RESPONSE: E
Please note your response below:	

- h. The equipment **SHOULD** have on board automatic processes to prevent cross contamination of samples.

B.2.h	RESPONSE: E
Please note your response below:	

- i. The range of operational ambient temperature and humidity including any air conditioning requirements **SHOULD** be provided, together with information on whether the equipment will continue to operate out with these conditions and the time to recover full functionality once these conditions are met again.

B.2.i	RESPONSE: E
Please note your response below:	

- j. Details of all reagents and consumables **SHOULD** be provided, together with their storage requirements

B.2. j	RESPONSE: E
Please note your response below:	

B.3 Profile of Equipment in the Market place

- a. Contractors **SHOULD** identify existing laboratory site(s) where a similar workload can be demonstrated and viewed. The number, location and contact details of placements in diagnostic laboratories **SHOULD** be supplied. If the Contractor is unable to supply details of a suitable UK placement then a non-UK placement can be provided.

B.3.a	RESPONSE: E
Please note your response below:	

- b. User satisfaction feedback with respect to scientific performance, cost effectiveness and reliability of the Contractor and any third party suppliers **SHOULD** be provided.

B.3.b	RESPONSE: E
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Please note your response below:

B.4 Laboratory Accommodation and Environmental Requirements of the Equipment Solution

The Contractor **MUST** provide the following:

- a. Indicative equipment layouts for the Processing Laboratories. Details of the available laboratory space will be made available by the Health Boards (as detailed in Appendix H) and solutions **MUST** be configured to those structural restrictions. This **MUST** include all equipment with sufficient benching to allow for sample preparation and short-term storage. Requirements for reagent and consumable laboratory storage **MUST** also be indicated i.e. freezer, cold and room temperature storage. A full narrative that explains the proposal **MUST** be provided alongside any room layouts.

B.4.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Prior to the installation of any equipment, the Contractor **MUST** outline a commitment to detailed process mapping including data management by facilitating a series of events to indicate to staff operational solutions for the optimisation of sample flow through the Processing Laboratory.

B.4.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. confirm whether existing services i.e. power, network data points, environmental lighting, temperature control, humidity, vibration, water, drainage etc. are adequate for installation and full operation of the proposed solution.

B.4.c	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- d. Detail any additional works required. Alterations to the building **MUST** be undertaken by the Contractor (or its sub-contractor) in full negotiation and agreement with the Cellular Pathology departments in the Health Boards. The Contractor will be responsible for the entire cost of any installation of new services, or upgraded services required to prepare the Processing Laboratory for installation and/or accommodate the new equipment. For the avoidance of doubt, this will include the cost of relocating existing equipment to temporary accommodation within Health Board premises to allow installation to take place.

B.4.d	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- e. Each component of the equipment solution listed **MUST** be protected by UPS (uninterruptible power supply)/power protection system for the full life of the equipment. Contractors **MUST** indicate the time limit the UPS will support the equipment. Please detail the solution

B.4.e	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Contractor **SHOULD** provide:

- f. The proposed equipment layout arranged to ensure Lean specimen processing and workflow. Describe how the solution addresses this requirement and submit workflow diagrams and room layouts that are to scale and that also provide ergonomic solutions.

B.4.f	RESPONSE: E
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Please note your response below:

- g. The annual workload activity is expected to change over the lifetime of the service, as stated in Appendix D. This may result in re-location of equipment and

their services. The Contractor **SHOULD** facilitate the transfer of equipment. Please confirm how this would be supported.

B.4.g	RESPONSE: E
Please note your response below:	

B.5 Standard, Directive, Legislative Requirements

The Contractor **MUST** ensure that the equipment complies with industry standards, best practice guidelines and all Legislation, including waste disposal, containment of pathological material and electrical safety. The Contractor **MUST** indicate how the solution will ensure compliance with the following:

STANDARD / CERTIFICATION
Hold BS, EN, ISO 9000 or equivalent.
Comply to IEC 60601-1:1990 (BS 5724-1:1989) Medical Electrical Equipment: General Requirements for Safety
Comply to EC Medical Devices Directive 93/42/EC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993) as amended (OJ L 331, 7.12.1998)
Conform to IVD Directive (98/79/EC) (of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998)
Approved for use in the UK Cervical Screening Programme by Public Health England.
Comply with COSHH (Control of Substances Hazardous to Health) Regulations 2002. Safety data sheets in English MUST be available.
Subscribe to the practices and principles of MHRA (Medicines and Healthcare products Regulatory Agency) DB2006 (02) for reporting adverse incidents related to in vitro medical devices. Comply with any additional and relevant, regulations for electrical, mechanical and biological safety. Enables the laboratory to comply with the ISO 15189 (2012) standard
UK Standards for Microbiology Investigations Good Laboratory Practice when Performing Molecular Amplification Assays (Dec 2013,

under review)

B.5	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

B.6 Equipment / Assay Methodology: Clinical Performance Requirements

In a cervical cancer screening setting Hr-HPV tests should exhibit specific requirements to assure high clinical sensitivity for detection of cervical pre-cancer and cancer and at the same time high clinical specificity to limit unnecessary procedures and follow-up of HPV test-positive women.

- a. Contractors **MUST** state the performance of the assay in relation to Meijer et al (2009) in detail providing all relevant data with respect to clinical sensitivity which **MUST** be >90% and clinical specificity >98% in high grade lesions. Assessment by the VALGENT protocols is acceptable if the Meijer criteria are not appropriate.

B.6.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

Contractors **SHOULD** provide the following for their assay:

- b. Details of the compatibility of their Hr-HPV assay and equipment with the LBC technologies approved for use in the UK cervical screening programmes.

B.6.b	RESPONSE: E
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Please note your response below:

- c. Display intra-laboratory reproducibility (i.e. agreement of Hr-HPV test result when the same samples are tested more than once) and inter-laboratory agreement with a lower confidence bound not less than 87%.

B.6.c	RESPONSE: E
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Please note your response below:

- d. Where possible indicate the longitudinal clinical performance data of the proposed assay in a cervical cancer screening setting over at least one screening round between 1 and 5 years.

B.6.d **RESPONSE: E**

Please note your response below:

- e. State where possible the clinical sensitivity of the equipment/assay solution for CIN2+ and CIN3+.

B.6.e **RESPONSE: E**

Please note your response below:

- f. State where possible the clinical specificity of the equipment/assay solution for CIN2+ and CIN3+.

B.6.f **RESPONSE: E**

Please note your response below:

- g. The clinical performance data of the equipment/assay solution for indication of treatment success i.e. “test of cure”.

B.6.g **RESPONSE: E**

Please note your response below:

- h. Describe short and long-term plans for their assay in non-LBC media physician taking kits and self-sampling kits. (Information only)

B.6.h **RESPONSE: I**

Please note your response below:

- i. Acknowledge the Health Boards delivering this service may also operate many clinical trials and that consistency of methodology and threshold levels is important to the continuity of these trials. Please provide details of how this will be provided and evidenced.

B.6.i	RESPONSE: E
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Please note your response below:

B.7 Equipment /Assay Methodology: Analytical Performance Requirements

- a. In addition to existing approved equipment/assay methodology, Contractors can include assays which are in development, with a planned availability date, but **MUST** be clearly indicated as not currently available (give expected availability date).

B.7.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Contractor **MUST** provide the following:

- b. The analytical equipment **MUST** be capable of detecting high risk Hr-HPV types. The HPV test is designed to detect high-risk HPV types, typically including HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. The Contractor **MUST** specify the range of types identified, including individual or 'cocktail' results.

B.7.b	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Hr-HPV assay on the molecular analytical equipment **SHOULD** provide the following:

- c. The Contractor **SHOULD** have been offered NHSCSP/PHE approval or will provide a commitment to undergo NHSCSP/PHE approval. Please provide details of all assay methodology including evidence from peer reviewed published literature, clinical trials and reports.

B.7.c	RESPONSE: E
Please note your response below:	

- d. Provide data on the nature of the targeted sequence including which part, length of sequence, nature of the primers used in the assay.

B.7.d	RESPONSE: E
Please note your response below:	

- e. Details on assay *in vitro* analytical specificity, any known cross-reactions and interferences, limitations of reagents and probes used in the testing assay/solution **SHOULD** be provided. Details **SHOULD** be provided on the level of cross-reactivity with HPV types outside the defined analytical range or other pathogens and selected species of the normal microbiological Human flora.

B.7.e	RESPONSE: E
Please note your response below:	

- f. Any collection media limitations **SHOULD** be identified that might affect changes in sampling or triage methodologies. (Information only)

B.7.f	RESPONSE: I
Please note your response below:	

- g. Include package inserts for each method offered in the tender submission documentation. These **SHOULD** indicate the nature of the assay measurement.

B.7.g	RESPONSE: E
Please note your response below:	

- h. If the HPV type specific genotyping is a concurrent or reflex option.

B.7.h	RESPONSE: E
Please note your response below:	

- i. Provide detailed information on the calculation for the cut-off threshold.

B.7.i	RESPONSE: E
Please note your response below:	

- j. Any Field Safety Notices been issued by MHRA regarding the performance of any proposed equipment or assay in the last year? If yes, please provide details.

B.7.j	RESPONSE: E
Please note your response below:	

The Contractor **MUST** provide the following:

- k. Ensure all equipment methodology **MUST** undergo acceptance testing in line with ISO 15189 Standard (Section 5.5.1.2, 5.5.1.3, 5.5.14, 5.5.2, 5.6.4) requirements and will only be accepted once this process has been successfully completed at each Processing Laboratory. This **MUST** include equipment comparability data for equipment within the same Processing Laboratory and across both Processing Laboratories.

B.7.k	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- l. All Reagents/Kits/Consumables/IQC/calibration material required for validation **MUST** be provided free of charge. The Contractor **MUST** provide staff and supply reagents with all necessary consumables to process LBC samples via an agreed protocol for the evaluation of each item of equipment within the solution and the Hr-HPV methodology.

B.7.l	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- m. A validation report for the equipment including required statistical analysis under direction of the nominated scientific representatives. Acceptable performance of validation/verification will be based on matching the performance of equipment / assays to manufacturer's performance criteria and laboratory acceptance criteria.

The basic protocol will include a minimum of 100 comparisons, confirmation of imprecision at threshold levels and confirmation of published carryover figures. This **MUST** be provided for each Processing Laboratory. Contractors **MUST** provide a protocol on how this is going to be achieved.

B.7.m	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.8 Performance in External Quality Assessment Schemes

Assessment and scoring of methods will be based on the performance in External Quality Assessment (EQA) Schemes including UKNEQAS and QCMD, IMSTAD, "in house" data and intra-laboratory data, methodological principles and the experience of other recognised users. Other information available in the scientific literature may also be used in the evaluation. Documentation required for the assay/equipment solution includes proven EQA performance, where appropriate, on all relevant schemes including UKNEQAS.

Contractors **MUST** supply information on performance in EQA schemes, including UKNEQAS and QCMD, IMSTAD, "in house" data and intra-laboratory data for the assay including third party solutions. Any known indicators of apparent bias or poor performance **MUST** be given.

B.8.	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.9 Reserved Rights on Change

Once procured the Contractor **MUST** not change any analytical aspect (changes to the assay or clinical cut off point) of their testing system without consultation and approval of these potential changes by the Quality Assurance Framework of the Scottish Cervical Screening Programme (SCSP) in place at the time.

If the SCSP agrees in principle, the Contractor **MUST** then agree a timescale of “notice of change” in reagent formulation and allow an appropriate evaluation of the new product at their expense. The process of notification and agreement of timescales will be governed in the Service Levels.

The SCSP reserves the right to request the purchase of equipment/reagents from another source in the event that a method proves to be, or becomes, unreliable, or insufficiently accurate, or insufficiently precise as judged from data from an accredited EQA scheme, or if the supply of reagents becomes unreliable. The Contractor will be responsible for any additional costs incurred.

The SCSP undertakes to make such a change only after discussion with the Contractor, and 3rd party providers where appropriate.

Provide details of proposed management of any equipment/reagent changes that are known at the time of the submission of this tender.

B.9.	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.10 Calibration and Quality Control

Contractors **SHOULD** define any calibration curve verification procedures for equipment permitting accurate determination of the assay cut-off value and include any non-QC/control reason for re-calibration. This **SHOULD** be compatible with Standard Operating Procedures.

The Contractor **SHOULD** indicate:

- a. The recommended methodology for calibrating the pre-analytical and analytical equipment and the actual frequency of any calibration procedure for the Hr-HPV assay (for information only).

B.10.a	RESPONSE: I
Please note your response below:	

- b. Provide details of any calibration material which is of demonstrably high quality and has full metrological traceability (for information only).

B.10.b	RESPONSE: I
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Please note your response below:

- c. How the Contractor will ensure comparability of equipment performance across both Processing Laboratories in relation to assay cut-off values (for information only).

B.10.c **RESPONSE: I**

Please note your response below:

B.11 Quality Control Solution

B.11.1 Quality Control

- a. The proposed Quality control (QC) solution **MUST** comply with ISO 15189:2012 (Section 5.6.2) standard. The Contractor **MUST** indicate how this will be achieved for Hr-HPV testing including third party provision.

B.11.1.a **RESPONSE: M (pass/fail assessment)**

Please describe and evidence how the proposed solution achieves the specification stated above.

- b. There **SHOULD** be a system for providing real-time molecular quality control including internal PCR controls and standard curves in an integrated package with operator selectable Westgard rules, graphical and tabular presentation, warning messages and capability of storing QC data for auditing purposes for the lifetime of the equipment.

B.11.1.b **RESPONSE: E**

Please describe and evidence how the proposed solution achieves the specification stated above.

- c. The Contractor **SHOULD** indicate how they will provide cost-effective Quality control strategies and ease of use for the equipment solution at both Processing Laboratories. Quality control testing protocols to ensure validity of test results through the pre-analytic, analytic, and post-analytic processes **SHOULD** be stated.

B.11.1.c	RESPONSE: E
Please note your response below:	

B.11.2 Internal Controls

Contractors **SHOULD** provide details of how their system controls:

- sample adequacy
- sample extraction
- sample amplification

in order to check for possible inhibition and monitor target recovery.

B.11.2	RESPONSE: E
Please note your response below:	

B.11.3 Number of IQCs and Frequency of Testing

Contractors **SHOULD** state:

- The maximum number of controls recognised by the equipment. Indicate how each is identified by the equipment.

B.11.3.a	RESPONSE: E
Please note your response below:	

- If there is a specific compartment/position for IQC, state the temperature of this compartment and the number of positions available.

B.11.3.b	RESPONSE: E
Please note your response below:	

- If the frequency of running IQC is user definable, by specifying either a number of samples or an elapsed time.

B.11.3.c	RESPONSE: E
Please note your response below:	

- d. If it is possible to define IQC levels/profiles for each IQC sample type (specifically to prevent unwanted analysis on IQC samples)

B.11.3.d	RESPONSE: E
Please note your response below:	

- e. The recommended frequency of running IQC material and the actual frequency of running IQC at sites with similar workloads to the UK laboratories.

B.11.3.e	RESPONSE: E
Please note your response below:	

- f. How the contractor will ensure comparability between equipment on the same Processing Laboratory but also between equipment on both Processing Laboratories across clinical decision levels.

B.11.3.f	RESPONSE: E
Please note your response below:	

B.11.4 Equipment Solution IQC Data Handling

In a single or multiple analytical equipment solution the Contractor **SHOULD**:

- a. Indicate how information relating to IQC is available at the point of analysis on the equipment and also on the Middleware.

B.11.4.a	RESPONSE: E
Please note your response below:	

- b. Allow for multiple lot numbers of QC material to be analysed and compared at the same time.

B.11.4.b	RESPONSE: E
Please note your response below:	

- c. Indicate the number of data points for each IQC that are held on the equipment and the Middleware.

B.11.4.c	RESPONSE: E
Please note your response below:	

- d. Describe the graphical representations of daily and cumulative QC data available (e.g. Levy-Jennings,) and if these are printable or can be exported to data handling IQC software.

B.11.4.d	RESPONSE: E
Please note your response below:	

- e. Indicate, where relevant, the user definable functionality available on the equipment and Middleware that permits allowable limits for IQC material (e.g. Westgard Rules) to be defined. Contractors **SHOULD** describe the process on assigning the values.

B.11.4.e	RESPONSE: E
Please note your response below:	

- f. Indicate how IQC results out-with allowable limits are flagged to the operator in real time.

B.11.4.f	RESPONSE: E
Please note your response below:	

- g. Indicate the process to denote an IQC result as an “outlier” such that it makes no contribution to statistical analysis whilst remaining visible on graphical representations. If this function is not available, then Contractor **SHOULD** clearly state this fact.

B.11.4.g	RESPONSE: E
Please note your response below:	

- h. The IQC software **SHOULD** allow external IQC material (e.g. NIBSC, WHO, other commercial contractors) to be used and subjected to the same recording and analysis as the Contractor’s own IQC.

B.11.4.h	RESPONSE: E
Please note your response below:	

- i. Ensure all IQC results and equipment performance data are available to the Processing Laboratory. Please describe how this will be achieved and the procedures that will ensure equipment backup is deployed to minimise data loss.

B.11.4.i	RESPONSE: E
Please note your response below:	

B.12 Pre-analytical and Analytical Equipment

B.12.1 Operational Functionality

- a. The pre and post analytical equipment **MUST** be capable of providing the workload activity. The majority of work is currently processed between the working hours of 9am to 5pm, but equipment **MUST** be available, with minimum start up times, to support extended day working of 8am to 8pm.

B.12.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Contractors **SHOULD** fully describe their operational solution (including their Middleware proposals) for each Processing Laboratory for the pre- and post-analytical equipment.

B.12.1.b	RESPONSE: E
Please note your response below:	

- c. Pre-analytical equipment for the purpose of this specification is defined as equipment built specifically for preparing the samples prior to the extraction, amplification and detection steps of the process. Pre-analytical equipment **SHOULD** support decapping, vortexing, aliquoting and re-capping. Please provide details of the solution.

B.12.1.c	RESPONSE: E
Please note your response below:	

- d. Any equipment **SHOULD** be an open system operating in random access mode with continuous sample loading and a “STAT” facility and be capable of independent operation in the event of a SCCRS failure. The equipment solution **SHOULD** not create bottlenecks. Please describe your solution.

B.12.1.d	RESPONSE: E
Please note your response below:	

- e. Capacity calculations **SHOULD** take into account when the equipment is not available to process LBC samples. The up-time **SHOULD** include but is not limited to an allowance for predicted equipment downtime for service/maintenance procedures, onboard reagent/consumable renewal and quality assurance procedures. The Contractor **SHOULD** provide realistic capacity throughput data for solutions suggested.

B.12.1.e	RESPONSE: E
Please note your response below:	

- f. The solution needs to be scalable in order to meet the future needs of the service. This **SHOULD** include increasing capacity and decreasing capacity for both pre analytics and post analytics. The Contractor **SHOULD** tabulate the proposed provision of equipment against the workload stated in Appendix E.

B.12.1.f	RESPONSE: E
Please note your response below:	

- g. Please provide the time from loading of the sample to first result, Start up from switch on to ready status and Start up from standby to ready status. Please define the time from stand-by to the pre-analytics being available to run samples.

B.12.1.g	RESPONSE: E
Please note your response below:	

- h. Define the daily, weekly, monthly and any other maintenance procedures which will be evaluated. An estimate of the time needed for maintenance will be evaluated indicating how these might impact on 8hr operation. This will be based on current user information. Times and procedures involved for the replacement of user serviceable parts (e.g. syringes and probes) will be considered.

B.12.1.h	RESPONSE: E
Please note your response below:	

- i. Shut down the equipment, including any special washes. State if the equipment solution has a power saving mode which is engaged after an agreed period of inactivity.

B.12.1.i	RESPONSE: E
Please note your response below:	

- j. State the analysis rates (i.e. samples per hour) in routine operation for the equipment (fully automated, partially automated or standalone) offered to complete the analysis.

B.12.1.j	RESPONSE: E
Please note your response below:	

- k. Please demonstrate, using the workload provided and core working hours, that the pre-analytical solution can cope with the workload.

B.12.1.k	RESPONSE: E
Please note your response below:	

- l. Describe how the analytical equipment will have the ability and capacity to operate in the event of a pre-analytical equipment failure.

B.12.1.l	RESPONSE: E
Please note your response below:	

- m. See below proposed daughter tube label and please detail how your proposed equipment will support this.

The Barcode format should be 128C and include the following data items - barcode, barcode in clear, plus another identifier, such as name or laboratory number.

B.12.1.m	RESPONSE: E
Please note your response below:	

B.12.2 Equipment Status Information

- a. For all components of the equipment solution there **SHOULD** be a visual display capable of indicating equipment status, quality control and patient results, with a hard copy obtainable if required.

The data **SHOULD** be retained on board for a user definable period of not less than six months and/or be downloadable to an appropriate storage medium. The data stored **SHOULD** be in a reviewable format. Graphical representation of QC data (Contractors' and Third Party Suppliers) **SHOULD** be possible.

B.12.2.a	RESPONSE: E
Please note your response below:	

For all equipment in the solution, there **MUST** be real-time “live” access to:

- b. Sample status monitoring: work in progress/completed, onboard/offboard/sampled, and estimated result time. Please provide details.

B.12.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. IQC status, Reagent status.

B.12.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Result storage (number of results, length of storage time).

B.12.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. An event and/or error log and is this accessible during operation. Please provide details, and describe storage or backup for the log.

B.12.2.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- f. Allow interruption of an assay in real time in the event of problems.

B.12.2.f	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- g. Describe equipment backup procedures for the storage of patient data with a facility to view this data.

B.12.2.g	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- h. Provision of user manuals and in what format i.e. on-board documentation or hard copy.

B.12.2.h	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.12.3 Sample Loading

- a. Describe the sampling mechanisms for each equipment in the solution. The consumables used in sample aspiration/pipetting (e.g. tips and reaction vessels) **MUST** be disposable.

B.12.3.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The equipment solution or agreed components **SHOULD** include:

- b. De-capping: On-line de-capping **SHOULD** be capable of dealing with a variety of tube size and cap types. As a minimum the de-capper **SHOULD** cope with ThinPrep and SurePath LBC vials. The Contractor **SHOULD** state any limitation of the de-capping solution(s) including tube type & size limitations

B.12.3.b	RESPONSE: E
Please note your response below:	

- c. State the operational throughput for the equipment offered (8 hour working day), including any factors that will affect the optimal throughput i.e. equipment availability during reagent and consumable top up, maintenance and equipment bottle necks (e.g. varied sample type).

B.12.3.c	RESPONSE: E
Please note your response below:	

- d. Allow for continuous loading or batch processing of samples. Please provide details. State the maximum number of samples (excluding IQC or calibrators) which can be processed continuously or in a single batch. State how test priority can be changed during operation. Describe the processes, from sample presentation to result analysis, available to achieve this.

B.12.3.d	RESPONSE: E
Please note your response below:	

- e. Be capable of independent operation in the event of a failure of SCCRS and/or any associated Middleware. Please provide details.

B.12.3.e	RESPONSE: E
Please note your response below:	

- f. State the methods by which each item of analytical equipment facilitates detection of all of the potential errors below that may affect the result and how this is flagged in the software:
- Liquid level sensing, clot detection, insufficient volume detection, bubble error, pipetting error/ aspiration error, probe crash protection.

B.12.3.f	RESPONSE: E
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Please note your response below:

- g. Describe how the reanalysis of individual flagged samples is performed and identified in the middleware so that the correct result is transferred to SCCRS.

B.12.3.g **RESPONSE: E**

Please note your response below:

- h. State if there are any restrictions to the number of aliquot tubes that can be produced per primary sample.

B.12.3.h **RESPONSE: E**

Please note your response below:

B.12.4 Sample Type and Volume Requirements

The Contractor **SHOULD** provide detailed information on LBC sample types that are UK approved and validated for testing on the proposed main molecular equipment. In addition to:

- a. The sample aspiration volumes for pre-analytical and analytical equipment.

B.12.4.a **RESPONSE: E**

Please note your response below:

- b. Any fixed volume pre-dilution step.

B.12.4.b **RESPONSE: E**

Please note your response below:

- c. Sample “dead” volumes for pre-analytical and analytical equipment.

B.12.4.c	RESPONSE: E
Please note your response below:	

d. Indicate the required sample extraction volume

B.12.4.d	RESPONSE: E
Please note your response below:	

B.12.5 Sample Identification

Sample Identification: Contractors should be aware that all requests for Hr-HPV testing are electronically requested. The SCCRS number is a non-sequential number and will be the primary identifier used as the barcode number on the specimen tube and all associated daughter tubes. The SCCRS Number is a ten digit number that includes check digits. The barcode label will also include an eye-readable SCCRS number.

The label will also include a sequential Laboratory Number in eye-readable format. There will also be additional identifiers on the label

The equipment solution or agreed components **MUST** demonstrate the following attributes/functionality:

- a. All equipment **MUST** have a positive sample identification facility and have the ability to identify any configuration of bar code format of variable size.

B.12.5.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **MUST** provide details of the optical specifications of each of their barcode readers.

B.12.5.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. The equipment **MUST** be compatible with all industry standard barcode systems (including a variety of sizes and dimensions). Provide details of the barcode solution in terms of:

- barcode label size
- barcode positional constraints

B.12.5.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Describe how any sample with a barcode misread and/or an 'undetectable' barcode will be identified and appropriately handled. (e.g. tube detected but barcode misread). Provide evidence of percentage barcode read failures/misreads from a similar site in the field.

B.12.5.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.12.6 Sample Tracking and Archiving

The Contractor **SHOULD** clearly state how:

- a. The solution will ensure the quality of test results by mandating verification of the patient sample from pre-analytic processes to reporting e.g. comprehensive audit trail of each LBC sample/test on any equipment including all associated calibration, QC, reagent lot number and any associated analytical and system flags. Describe the solution for monitoring of the progress of samples in the end to end process to flag parameters such as faults and TATs outside user defined limits.

B.12.6.a	RESPONSE: E
Please note your response below:	

- b. The solution **SHOULD** support the archiving and storage of all sample types in compliance with the ISO 15189 standard with full indexing and retrieval. Please provide details of how this will be achieved.

B.12.6.b	RESPONSE: E
Please note your response below:	

- c. Identify how error messages generated by the equipment can be transmissible to the Middleware. The user **SHOULD** be able to select which messages or flags will block auto-transmission of test results to SCCRS.

B.12.6.c	RESPONSE: E
Please note your response below:	

B.13 IT, Data Management and Connectivity

B.13.1 Data Management and Connectivity

- a. The Contractor **MUST** supply and install all IT Equipment, infrastructure, programmes and licences necessary to deliver the service at both Processing Laboratories and to enable the Contractor's equipment to interface with the Health Board IT system.

A unidirectional interface will be developed between the Middleware to SCCRS based on HL7 messaging stated in the NHS Scotland SCCRS HR-HPV Interface, Interface control document (ICD) (Appendix G)

B.13.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. A key component of the Managed Service is the ability to process patient test samples on the pre-analytical and analytical platforms (including third party equipment) without any interrogation of SCCRS. To achieve this, the solution **MUST** be capable of processing a sample when it is presented to the pre-analytical and analytical platforms and send the result and specified information in the ICD to SCCRS via a unidirectional interface. The Middleware application **MUST** only archive sample results when all processing and testing has been completed.

B.13.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. The Contractor **MUST** provide a Middleware application configured to suit the needs of the Health Boards, which **MUST** be secure and have appropriate resilience. The Contractor **MUST** describe how the solution meets this

requirement inclusive of third party services and all equipment provided as part of the managed service.

The Contractor **MUST** provide specifications of any hardware and software to be supplied. The Contractor **MUST** ensure that all server and PC architecture is configured to meet any e-health policies and procedures and any regulatory requirements that apply on both Processing Laboratories. The specifications **MUST** be discussed in collaboration and communication with local e-Health Departments at each Health Board. e-health security protocols (Appendix G) are embedded at the end of this document. The Middleware and all IT connectivity **MUST** comply with NSS IT security policies and regulations (Appendix G)

B.13.1.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. The Contractor **MUST** guarantee that, at the date of implementation, all analytical equipment will have the capability of being interfaced to SCCRS as identified by ATOS staff. This **MUST** include all equipment and the Middleware supplied as part of the service but may also include other equipment interfaces required by the Health Boards to be integrated for service requirements. Implementation of the interface **MUST** cause no detriment to the existing NHS IT Network.

B.13.1.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. The Middleware **MUST** be able to retransmit results either as a batch, part-batch, individual results to SCCRS. Administrators **MUST** be informed when a test result cannot be delivered to SCCRS in a given timeframe.

B.13.1.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- f. The Middleware at both Processing Laboratories **MUST** be resilient with regards to connectivity to the SCCRS system and **MUST** auto-reconnect upon detection of a connection failure.

B.13.1.f	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- g. The Middleware **MUST** alert when error conditions are detected (e.g. communications failure with equipment or SCCRS). A full list of alert conditions **MUST** be provided.

B.13.1.g	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- h. Any IT hardware associated with the Middleware supplied **MUST** have a declared lifespan, after which new upgraded hardware **MUST** be installed by the Contractor as part of this contract.

B.13.1.h	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- i. The Contractor **SHOULD** state how the pre-analytical and analytical equipment can continue to work during any host computer, Middleware application interface or network failure/inability to receive results and for how long equipment can operate autonomously to provide a screening service. This will include any 3rd party Middleware. Describe the resilience solution for any Middleware software failure. Describe procedures when communications are restored, including resending “live” or archived data without effect on routine analysis following SCCRS or Middleware recovery.

B.13.1.i	RESPONSE: E
Please note your response below:	

- j. The Contractor **MUST** identify the responsibilities for the design, implementation, testing and acceptance of the interface from the Middleware into the SCCRS system. This **MUST** be via a separate “Test” Middleware environment. Specify the test requirements for the interface required to complete “end to end” testing of results into the SCCRS UAT Environment.

B.13.1.j	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- k. Remote support services for server and PC architectures or support of any analytic devices **MUST** be across a secure Scottish Wide Area Network (SWAN) connection. Contractor support facilities **MUST** comply and subscribe to a suitable SWAN connection. Contractors **MUST** liaise with e-health services at both Processing Laboratories in establishing of remote secure connections (e.g. VPNs and firewall policies, WebEx).

B.13.1.k	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- l. The Middleware **MUST** have the ability to store and forward results with user-defined parameters.

B.13.1.l	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- m. The Managed Service Solution **MUST** allow the Processing Laboratories to readily transfer samples between Processing Laboratories for testing without the need to re-number specimens.

B.13.1.m	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- n. The e-health departments at the Health Boards will install virus protection software. There **MUST** be no compatibility issues between this software and the software supplied by the Contractor. Details are available from the e-health Services Department with each Health Board.

B.13.1.n	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- o. The Contractor **MUST** indicate where SCCRS may be a limiting factor in achieving full integration with the Middleware combination and indicate how they would work with ATOS to address these limiting factors.

B.13.1.o	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- p. The Contractor **MUST** include all installation and maintenance costs of a uni-directional interface. NSS, the Health Boards will commission the SCCRS end of the interface. The Contractor **MUST** act as prime contractor and liaise and support ATOS with the installation, testing and commissioning of the interface.

B.13.1.p	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- q. The Contractor **MUST** indicate any on-site ICT requirements that the solution may require, e.g. server space, number of connections, remote access channels, etc. Any PCs or servers requiring connection to the NHS Greater Glasgow & Clyde and NHS Lanarkshire network **MUST** be capable of operating within the

Health Board's I.T. infrastructure. Describe your solution. The Contractor **MUST** state any environmental or physical limits with respect to Middleware associated hardware.

The Contractor **MUST** indicate/detail of any sub-contractors required for implementation or support.

B.13.1.q	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- r. The Contractor **SHOULD** summarise tasks for implementing and managing the Middleware including "backup" procedures.

B.13.1.r	RESPONSE: E
Please note your response below:	

- s. All critical peripheral systems **SHOULD** be protected by UPS (Uninterruptible Power Supply) to ensure the integrity of the system / data is maintained in the event of power failure. Detail how this will be provided and supported. Contractors **MUST** indicate which components will be protected and **MUST** indicate the time range that the UPS will support the component.

B.13.1.s	RESPONSE: E
Please note your response below:	

- t. The Contractor **SHOULD** supply and maintain any software license costs or cost per connection to the Middleware solution. Any cost associated with interfacing the solution, including any Middleware if appropriate, and any costs associated with the service and support arrangements **SHOULD** be included in the Contract.

B.13.1.t	RESPONSE: E
Please note your response below:	

- u. Evidence of up to three prior implementations of IT connectivity of equipment within the NHS, and success in achieving the above aim, **SHOULD** be provided along with contact details for local health board personnel where this has been achieved previously.

B.13.1.u	RESPONSE: E
Please note your response below:	

B.13.2 System Management

Contractors **MUST** provide the following:

- a. Detailed information on how the Middleware can ensure the effective management of sample batches. The Contractor **MUST** provide evidence of the ability of the system to configure variable batch sizes to match variations in workload and to allocate these as appropriate.

B.13.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Indicate how the Middleware allows for technical authorisation and controlled release of results.

B.13.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Indicate how the Middleware will hold an audit trail of all test transactions performed on a patient sample but users are always presented with the current view. The Contractor **MUST** evidence how they will comply with user-defined audit requirements.

B.13.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Indicate the maximum number of patient records that can be stored on the Middleware. It **MUST** be possible to display Quality Control and any Calibration performance data on either the equipment or the Middleware.

B.13.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. Indicate how the Middleware has the ability to re-run failed batches (or part) with the ability to rerun failed batches, part batches or individual samples.

B.13.2.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

Contractors **SHOULD** provide the following information:

- f. Describe, in respect of the managed service solution the generic levels of validation, authorisation and super-user error correction are available and whether these are password protected. Detail how you will provide a Security and user management system to maintain accreditation details and roles based access to the systems.

B.13.2.f	RESPONSE: E
Please note your response below:	

- g. Describe the data management capability for the equipment and Middleware. There **SHOULD** be VDUs capable of demonstrating all stages of the status of the automation and dashboards.

B.13.2.g	RESPONSE: E
Please note your response below:	

- h. The Middleware **SHOULD** have the ability to schedule equipment maintenance and take equipment off-line. The Middleware **SHOULD** also have the ability to record details of maintenance.

B.13.2.h	RESPONSE: E
Please note your response below:	

B.13.3 Middleware Support and Software Updates

The Contractor **MUST**:

- a. Supply and support the interface solution, its software and hardware and supply the service with timely synchronised updates of software, for all components of the equipment, with appropriate training. Software upgrades shall be part of the managed service. The service and support arrangements for the solution **MUST** be comprehensive and in line with the clinical service requirements.

B.13.3.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. User manuals **MUST** be provided either as hard copies **or** onboard the equipment **and** as pdf files.

B.13.3.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Provide a method of producing an audit trail of any changes to software, equipment or other settings. This **MUST** be compliant with ISO 15189 standards. This **MUST** include details of any software TEST environment. Please provide details on the solution.

B.13.3.c	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Contractor **SHOULD** provide the following:

- d. Indicate how the equipment software and the Middleware solution provide a user friendly format (e.g. touch screen). Please provide details on the solution.

B.13.3.d	RESPONSE: E
Please note your response below:	

- e. Undertake to re-install previous hardware or software when an upgrade results in detriment to performance and a procedure and documentation for the process. Please provide details on the solution.

B.13.3.e	RESPONSE: E
Please note your response below:	

- f. Continued development of the software **SHOULD** be demonstrated by the Contractor. Software updates **SHOULD** be free of charge during the contract period. The Contractor **SHOULD** indicate how often software is upgraded and provide a procedure and staffing resource for all software upgrades.

B.13.3.f	RESPONSE: E
Please note your response below:	

B.13.4 Data Management, Storage and QC Analysis

The Contractors **MUST** describe, in respect of the managed service solution on the equipment and Middleware;

- a. What facility exists for the recording of operator training? This **MUST** be compliant with ISO 15189 standards.

B.13.4.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- g. The method of producing an audit trail of any changes to software, equipment or other settings. This **MUST** be compliant with ISO 15189 standards.

B.13.4.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractors **SHOULD** describe, in respect of the managed service solution on the equipment and Middleware:

- c. Detail how you will provide a Security and user management system to support role-based access to the systems.

B.13.4.c	RESPONSE: E
Please note your response below:	

- d. A brief description of Middleware validation options. Results with user definable flags and sample comments to be identified (e.g. colour coded) and held for validation.

Ensure users can identify the confirmation status of a test request. This **SHOULD** include but not be limited to: successful transmission to any processing firmware/software, test queued for processing, test processed, test resulted, test complete, test manually or auto validated/ test failed auto validation, successful test result transmitted to SCCRS/error & warning flags associated with test request. Detail how this will be supported.

B.13.4.d	RESPONSE: E
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Please note your response below:

- e. How operator ID functionality can be provided for a variety of staff groups. This **SHOULD** include but not be limited to password protected levels for support workers, registered staff, process managers and super-users. Detail how this will be supported.

B.13.4.e	RESPONSE: E
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Please note your response below:

- f. The method of performing real time configuration changes and the impact this will have on patient sample processing. Detail how this will be supported.

B.13.4.f	RESPONSE: E
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Please note your response below:

- g. The Middleware **SHOULD** have the ability to identify and allocate quality control material across batches and record and present quality control results to support authorisation of results

B.13.4.g	RESPONSE: E
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Please note your response below:

- h. Viewing and comparison of QC data between multiple items of analytical equipment (if appropriate). The Contractor **SHOULD** describe how this will be achieved by their Solution.

B.13.4.h	RESPONSE: E
Please note your response below:	

- i. Full graphical display of QC data at all levels for each item of analytical equipment. Detail how this will be supported.

B.13.4.i	RESPONSE: E
Please note your response below:	

- j. How data (e.g. IQC) can be archived to an electronic medium in an easily retrievable format e.g. Excel, Access. Detail how this will be supported.

B.13.4.j	RESPONSE: E
Please note your response below:	

- k. Ability to schedule work across multiple analytical equipment and manage reporting from multiple analytical items of equipment. Also, identify scheduled work on all equipment. Detail how this will be supported.

B.13.4.k	RESPONSE: E
Please note your response below:	

- l. Identify, on a multi-equipment solution which item of equipment performed each assay on each individual sample. Detail how this will be supported.

B.13.4.l	RESPONSE: E
Please note your response below:	

- m. A user-definable rule-based auto validation procedure, including fields such as qualitative result and IQC parameters. Detail how this will be supported.

B.13.4.m	RESPONSE: E
Please note your response below:	

B.14 Reagents and Consumables

B.14.1 Reagents and Consumables Environmental Proposal

It is expected Contractors will engage in an environmentally sensitive manner and where possible recover and reuse packaging materials. Reagent management is integral to contract management and Contractors **SHOULD** provide the specification for the proposed reagent management system.

B.14.1	RESPONSE: E
Please note your response below:	

B.14.2 Reagents and Consumables Inventory Management

The Contractor **MUST** describe and evidence how the proposed solution will achieve the following:

- a. Guarantee the supply of high quality CE marked reagents preferably through remotely managed inventory control. Contractors **MUST** indicate how inventory control will be managed to reduce reagent and consumable wastage profiles. Indicate those reagents, including third party reagents, which will be supplied as part of the Contract and those to be supplied by the Processing Laboratory. Using the workload statistics provided, indicate those reagents, which will be supplied including the reagent and kit pack physical sizes/weights.

Contractors **MUST** provide details of:

- i. Reagent pack size / no of tests / expected Reagent and Consumable Efficiency Rate (RCER)

- ii. Reagent preparation (manual / ready to use)
- iii. CE marking
- iv. Shelf life
- v. Storage requirements - on-board and off-board
- vi. Minimal lot number changes
- vii. Open vial stability
- viii. Facility for lot number reservation

B.14.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. All assay/equipment related consumables (e.g. racks, carousels, cuvettes etc.) to be included in the costs. There will be no additional charges.

B.14.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Supply reagents/consumables in volumes appropriate to use, which comply with ISO standards (Section 5.3.2.7), bar coded to show lot number, container number and expiry date.

B.14.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Supply reagents with an appropriate expiry date (at least 3 months, preferably 6 months) later than the date of delivery. The Contractor will (at its cost) be

required to replace any reagent unused at the expiry date. Indicate the minimum storage area required to accommodate 2 months supply of reagents.

B.14.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **SHOULD** provide the following:

- e. Reagent traceability, preferably by barcode, such that all results can be traced back to specific reagent lots. Please provide details.

B.14.2.e	RESPONSE: E
Please note your response below:	

- f. How the equipment stores and displays data of onboard reagent test capacity and number of tests available/remaining.

B.14.2.f	RESPONSE: E
Please note your response below:	

- g. Validation of batches will be required prior to acceptance to meet ISO 15189 (Section 5.3.2.3) standard. Contractors **SHOULD** clearly indicate how this will be achieved.

B.14.2.g	RESPONSE: E
Please note your response below:	

- h. Indicate any additional arrangements each Processing Laboratory would be expected to undertake to facilitate the proposed reagent supply system. (e.g. Temperature controlled storage, FIFO management, meeting agreed wastage targets).

B.14.2.h	RESPONSE: E
Please note your response below:	

- i. Clarify the number of days' worth of reagents required to be stored at each Processing Laboratory to achieve uninterrupted sample processing with minimal wastage profiles. Indicate the space required at the each Processing Laboratory for storage of:
 - i. Reagents/kits requiring refrigerated / frozen storage
 - ii. Reagents/kits which may be stored at room temperature.
 - iii. Consumables

B.14.2.i	RESPONSE: E
Please note your response below:	

- j. Ensure that only reagents and consumables of an appropriate industry standard are used for the delivery of the service and **SHOULD** undertake prompt action when reagents or consumables or equipment fail to achieve an appropriate standard, including but not limited to the persistent failure of equipment, the persistent failure of internal and/or external quality control tests and the issue of any medical device alerts or safety warning broadcasts from the Medicines and Healthcare Products Regulatory Agency (or replacement body) or similar such warning notices. Please state how the Contractor will promptly alert the Health Boards when they become aware of any performance issues.

B.14.2.j	RESPONSE: E
Please note your response below:	

B.14.3 Reagent / Consumable Loading, Capacity and Positioning of Reagents

Contractors **SHOULD** provide details on the following:

- a. State the minimum number of reagents/ consumables slots required on the equipment to perform each analysis.

B.14.3.a	RESPONSE: E
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Please note your response below:

- b. Indicate whether it is possible to replenish reagents while the equipment is in use. If this is not possible, indicate the processing time lost in replacing the depleted reagent packs.

B.14.3.b RESPONSE: E

Please note your response below:

- c. Indicate how the system deals with test requests when reagent or consumable exhaustion occurs. Contractor **SHOULD** describe the on-board reagent management system.

B.14.3.c RESPONSE: E

Please note your response below:

- d. Indicate the total number of tests available without a reagents/ consumables change.

B.14.3.d RESPONSE: E

Please note your response below:

- e. How the equipment stores reagents/test kits on-board. Please provide details on kit and test capacity, and kit shelf life (open and unopened).

B.14.3.e RESPONSE: E

Please note your response below:

- f. How the equipment provides and stores data on reagent usage. Please provide details.

B.14.3.f	RESPONSE: E
Please note your response below:	

- g. How the equipment stores and displays data on reagent/pack expiry dates.

B.14.3.g	RESPONSE: E
Please note your response below:	

- h. If there is automated pack switching with user definable options for running IQC or calibration at change over and holding results.

B.14.3.h	RESPONSE: E
Please note your response below:	

- i. Reagent and consumable wastage **SHOULD** be minimal. Please provide details of wastage for all reagents/consumables/kits/packs, and if any specialist disposal system is required. Note, any specialist disposal costs will be borne by the Contractor.

B.14.3.i	RESPONSE: E
Please note your response below:	

- j. If there is any reagent priming. This **SHOULD** be identified and included in the costings.

B.14.3.j	RESPONSE: E
Please note your response below:	

- k. The reagent sense system for on-board reagents, this **SHOULD** include details covering whether reagent level sense indicators operate by count back, level sensing or other mechanism including availability of on-board reserve reagent reservoir. Contractor **SHOULD** indicate how users will be informed of reagent or consumable depletion but as a minimum the system alarms **SHOULD** occur simultaneously on the equipment and Middleware.

B.14.3.k	RESPONSE: E
Please note your response below:	

- l. Whether the equipment can compare reagent inventory with potential daily workload to assist operator in inventory management.

B.14.3.l	RESPONSE: E
Please note your response below:	

B.14.4 Reagent / Consumable Contingency Arrangements

- a. The Contractor **MUST** guarantee the delivery of all HPV consumables direct to the Processing Laboratories and demonstrate clearly defined contingencies in the event of a supply failure or performance problem of any consumables. If there is only one site for manufacture, provide details of how such increased risk is addressed.

B.14.4.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **SHOULD**:

- b. Demonstrate clearly defined contingency arrangements in place to ensure availability and reliability of supply of HPV reagents in the event of a supply failure or performance problem of any reagent/ Quality Control /Calibrator/ consumables.

B.14.4.b	RESPONSE: E
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Please note your response below:

- c. List any molecular assay kit/reagent which was unavailable to supply for longer than 1 month in the last 2 years (including sub-contractors).

B.14.4.c **RESPONSE: E**

Please note your response below:

B.15 Result and Report Output

- a. The equipment software and Middleware **SHOULD** be capable of reporting qualitative results as positive, negative or inhibitory/invalid (or other appropriate interchangeable terms e.g. reactive, non-reactive, detected, not detected). Describe reporting categories.

B.15.a **RESPONSE: E**

Please note your response below:

- b. Equipment **SHOULD** produce minimal numbers of unreportable results. The Contractor **SHOULD** provide data from reference sites on the numbers of unreportable samples.

B.15.b **RESPONSE: E**

Please note your response below:

- c. It **SHOULD** be possible to view amplification curves onboard the proposed equipment and ensure that all test results are immediately accessible to both Processing Laboratories. Describe how this is achieved.

B.15.c **RESPONSE: E**

Please note your response below:

- d. The Middleware **SHOULD** have the ability to produce reports as specified by users.

B.15.d	RESPONSE: E
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Please note your response below:

- e. The Middleware **SHOULD** have the ability to export data in a range of user-defined formats.

B.15.e	RESPONSE: E
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Please note your response below:

B.16 Contracted, Scheduled, Preventative Maintenance and Support

B.16.1 Contracted Maintenance

- a. The Contractor **MUST** provide comprehensive maintenance and management support for all equipment comprising the managed service solution, including those supplied by third parties including software / Middleware supplied.

B.16.1.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- b. The Contractor **MUST** ensure compliance with the Service Level requirement.

B.16.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. There **MUST** be no single point of failure for any proposed solution located at each Processing Laboratory except where individual equipment has in-built resilience.

B.16.1.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. The Contractor **MUST** provide service continuity for both planned and unplanned downtime. Proposals **MUST** permit the continuation of essential analyses during any equipment downtime and there **MUST** be sufficient resilience in the system, such that the operation of the equipment is not dependent on the functioning of a single piece of ancillary equipment.

B.16.1.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. Resilience **MUST** be the responsibility of the Contractor by ensuring that any failure in any component of the solution will be resolved within 2 working days. Failure to achieve this will result in samples being transported to the other Processing Laboratory with all associated transport and testing costs having to be met by the Contractor.

B.16.1.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- f. Uptime details **MUST** be accompanied with confirmatory data from current users of the system. Please provide evidence to support this.

B.16.1.f	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **MUST** provide concise details of the maintenance support provision including:

- g. The ability to demonstrate the competency of its support services for hardware, software and equipment applications and future support of hardware/software upgrades. This **MUST** be compatible with the legislative requirements of laboratory accreditation including but not limited to ISO 15189. The Contractor is required to provide this information for inclusion in the Quality Management System (Q-Pulse) to allow compliance with ISO 15189 standards.

B.16.1.g	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- h. The equipment **MUST** have decontamination procedures which are easy to perform without impact on surrounding equipment or operations.

B.16.1.h	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- i. Provide details of the proposed engineering establishment, their geographic distribution and the support that will be delivered to both Processing Laboratories.

B.16.1.i	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- j. Indicate which, if any, maintenance routines will be performed by the Contractor and those which will be devolved to Processing Laboratory staff trained by the Contractor.

B.16.1.j	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- k. Provide training to Processing Laboratory staff in all aspects of devolved equipment maintenance. This **MUST** include all new staff throughout the Term of the Contract. This **MUST** also include a competency review process for all staff, by the Contractor in accordance with laboratory ISO 15189 (Section 5.1.6) compliance. Contractors **MUST** indicate how this will be achieved.

B.16.1.k	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- l. Provide a draft breakdown log. This will be agreed prior to installation to include time from reported fault to equipment, test methodology or process being available to staff for clinical work processing. This Contractor **SHOULD** include the time for any calibration and/or internal quality control processes required before patient samples can be processed.

B.16.1.l	RESPONSE: E
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Please note your response below:

The Contractor **SHOULD**:

- m. Provide an escalation procedure tailored to each Processing Laboratory. This will be agreed prior to installation.

B.16.1.m	RESPONSE: E
Please note your response below:	

The Contractor **SHOULD**:

- n. Arrange all scheduled maintenance visits by engineers in advance which **SHOULD** minimally disrupt normal working.

B.16.1.n	RESPONSE: E
Please note your response below:	

- o. Provide the following information on scheduled maintenance:

- The frequency of these visits
- The times at which these visits can be scheduled
- The expected equipment unavailability for each of these visits including software upgrades.

B.16.1.o	RESPONSE: E
Please note your response below:	

The Contractor **MUST** provide the following:

- p. The performance checks that will be carried out by the Contractor's engineer after a scheduled preventative maintenance visit prior to leaving the Processing Laboratory which **MUST** meet the appropriate ISO 15189 (Section 5.3.1.2) standard.

B.16.1.p	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- q. All service reports and data relating to routine performance, planned and unplanned maintenance, and fault rectification **MUST** be provided by the Contractor.

B.16.1.q	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- r. Include options to replace “old for new” equipment where equipment persistently fails to maintain 98% uptime and/or failure to maintain turnaround times. Please explain.

B.16.1.r	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- s. Explain procedures for removal of equipment and any impact on fixed costs.

B.16.1.s	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.16.2 Remote support for engineering & middleware associated with equipment function

The Contractor **MUST** provide information on how the following will be achieved:

- a. A single point of contact is required for inquiries and for reporting problems in respect of:
- Hardware (equipment)
 - Software (including 3rd party connection to Contractor software and software SCCRS interfaces)
 - Applications & test methodology

The Contractor **MUST** provide a Helpdesk facility with a single number which operates to support the Core Hours of the Health Boards accessible by telephone and email, and staffed with engineers or knowledgeable individuals able to provide technical support and log faults. The Helpdesk facility **MUST** log all calls made to the Helpdesk whether answered by an operator, by a call answering

facility or unanswered and must accurately record the call answering time for each call.

B.16.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Contractors **MUST** state how engineering support (i.e. attendance at Processing Laboratory) will be offered (e.g. extended 5 days, Public Holiday cover).

B.16.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Where proposed equipment, Middleware or IT support is not provided Monday – Sunday 8am – 8pm the Contractor **MUST** indicate how their Solution will meet clinical service requirements.

B.16.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Indicate how support provided by an appropriate accredited method acceptable to the Health Boards' IT Security (e.g. SWAN).

B.16.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **SHOULD**:

- e. Provide equipment which utilise real-time remote self-diagnostics sensors or troubleshooting software that is available on the equipment, Middleware to identify issues with the performance of their equipment or software. Contractors **SHOULD** supply relevant information on any of their current preventative systems.

If Remote diagnostics and support is available, the Contractor **SHOULD** supply details of how this will operate.

B.16.2.e	RESPONSE: E
Please note your response below:	

- f. Indicate how the equipment, both Contractor and third party, can be connected to the Contractor for support, preventative diagnostics and inventory management.

B.16.2.f	RESPONSE: E
Please note your response below:	

B.16.3 Engineer response (inclusive of third party services)

- a. For all equipment offered, Contractors **SHOULD** provide evidence of the average number of service calls for UK and worldwide installations by years installed.

B.16.3.a	RESPONSE: E
Please note your response below:	

- b. Contractors **SHOULD** state the guaranteed response time, in terms of attendance at Processing Laboratory by an engineer, for equipment. Contractors **SHOULD** supply independently validated data of equipment and pre/post analytical hardware mean-time-between-failures, predicted up-time, downtime and average time between engineer call-outs.

The Contractor **SHOULD** detail options for back-up/loan systems for unanticipated long-term down-time for equipment.

B.16.3.b	RESPONSE: E
Please note your response below:	

- c. List the performance checks that will be carried out by the Contractor's engineer after a visit in response to equipment malfunction prior to leaving the Processing Laboratory. Downtime logs **SHOULD** be signed off by Contractor and staff.

B.16.3.c	RESPONSE: E
Please note your response below:	

- d. Contractors **SHOULD** define how they would ensure timely and appropriate provision of spare parts in order to meet contractual requirements and Service Levels.

B.16.3.d	RESPONSE: E
Please note your response below:	

B.17 TRAINING

B17.1 Training

- a. There is a requirement to ensure competency training for all staff at each Processing Laboratory prior to go-live and for all appropriate staff to complete basic competency training within an agreed period. The Contractor **MUST** describe the proposed timelines and how the proposed solution will allow compliance with ISO15189 (Section 5.1.5) standard.

B.17.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **SHOULD** provide details of their proposed training plan (own equipment & third party) both on-site and off-site. There is an expectation that sufficient key operator staff training will be delivered prior to live operation at a given Processing Laboratory (It is anticipated that this will be at least 4 key staff for the main equipment and Middleware from each Processing Laboratory.).

B.17.1.b	RESPONSE: E
Please note your response below:	

- c. The training **SHOULD** be accredited for continuing professional development (CPD) in a recognised scheme and records provided (e.g. IBMS), where appropriate. Please describe how this will be achieved.

B.17.1.c	RESPONSE: E
Please note your response below:	

- d. The Contractor **SHOULD** provide electronic training tools where applicable.

B.17.1.d	RESPONSE: E
Please note your response below:	

B.17.2 Initial staff training

- a. The Contractor **MUST** commit staff full time to provide sufficient training to enable the staff in both Health Boards to use all the equipment provided.

Full training and comprehensive operator manuals (online or CD) in English **MUST** be provided. As a minimum the operator manual **MUST** include details of start-up and shut-down procedures; calibration, sample processing, decontamination and fault recognition and handling.

B.17.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **MUST** clearly indicate the full specification of the training for all equipment and state for the key operators
 - Whether this is on or off site
 - Proposals **MUST** provide details of pre and post installation training. Numbers of staff who will receive advanced training
 - Numbers of staff who will receive basic training and duration of training
 - Details of training packages to include attendance at / provision of national / international user group meetings.

B.17.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.17.3 Update/Continued training

In the order to manage the service and allow both Processing Laboratories to comply with ISO 15189 standards the Contractor **MUST** indicate the means by which training and staff competency will be handled throughout the Term of the Contract. This will include:

- a. On-going maintenance of (all) staff training to ISO 15189 (Section 5.1.6) standard for staff competency.

B.17.3.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. On-going advanced training to reflect staff changes / advances / improvements to the level of service provision.

B.17.3.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. All costs attributable to both Processing Laboratories for all elements of training for the Term of the Contract.

B.17.3.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.17.4 “User” Groups

The Contractor **SHOULD** provide:

- a. Details of any “user” group which meets to discuss topics relevant to the equipment solution being offered including third party solutions.

B.17.4.a	RESPONSE: E
Please note your response below:	

- b. Cover the costs involved in attendance at “user” group meetings for the Term of the Contract for a mutually agreed number of staff from both Processing Laboratories.

B.17.4.b	RESPONSE: E
Please note your response below:	

- c. Indicate any generic training credit system offered as part of the solution. This **SHOULD** include 3rd Party solutions.

B.17.4.c	RESPONSE: E
Please note your response below:	

B.18 INSTALLATION AND CONTINUITY EVALUATION OF EQUIPMENT

B.18.1 Installation and Commissioning

The Contractor **SHOULD**:

- a. Guarantee installation procedures that provide a safe working environment for all staff.

B.18.1.a	RESPONSE: E
Please note your response below:	

- b. Submit the survey report for the Processing Laboratory performed in conjunction with the Health Board Estates staff with a view to determining any additional requirements to accommodate the proposed equipment. Identify the need for remedial works required to install equipment.

B.18.1.b	RESPONSE: E
Please note your response below:	

- c. Guarantee that the proposed equipment will fit into the space available and indicate in their Tender submission how they propose to achieve that, and how they intend to deliver, install and commission each item of equipment while maintaining required service level.

B.18.1.c	RESPONSE: E
Please note your response below:	

- d. Detail the installation plan and timeline that ensures service continuity and operation which will be maintained during installation and commissioning of new equipment. The Contractor **SHOULD** submit a timetable showing how installation of their solution will be achieved at both Processing Laboratories.

B.18.1.d	RESPONSE: E
Please note your response below:	

The Contractor **MUST**:

- e. Indicate how advice and support will be provided in the event that the equipment has to be moved after installation including a decommissioning document.

B.18.1.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- f. Commit to facilitate the re-siting, transfer or disposal of equipment if required. The Contractor will meet all decommissioning costs whether at the interim stage of “replacement” of equipment or at the end of the Contract. Please provide a detailed Decommissioning Plans for each scenario.

B.18.1.f	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

B.18.2 Compliance Evaluation: Installation and Commissioning

The Contractor **MUST** provide evidence of compliance to the following:

- a. At installation and before the formal handover the Contractor **MUST** satisfactorily demonstrate and supply either; a commissioning document, statement; handover document to show that the equipment is fully functional and capable of performing an Hr- HPV test.

B.18.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Meet all ISO 15189 standards on validation equipment installation. Where appropriate, the Contractor will be required to staff equipment and supply reagents and all necessary consumables for an agreed protocol for the evaluation of each method.

B.18.2.b	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- c. Produce a validation report for the equipment including required statistical analysis under direction of the nominated scientific representatives. Reagents/Kits/Consumables required for validation **MUST** be provided free of charge.

Where appropriate, the basic protocol will include a minimum of 100 comparisons, confirmation of imprecision at threshold levels and confirmation of published carryover figures. Contractors **SHOULD** provide a protocol on how this is going to be achieved. (Please refer to B.7.j).

B.18.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Provide suitable commissioning documentation for the installation of the equipment. This **MUST** include Installation and Operational documentation.

B.18.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. Indicate how post-installation performance checks **MUST** meet the requirements to the satisfaction of the department. Documentation required for all equipment, which includes the following:

- Operator/Equipment manuals
- Technical specification documentation
- Installation qualification documentation
- Basic troubleshooting
- EN Electrical Safety Certification
- Factory Acceptance Testing

- Calibration Documentation
- Certificates of accreditation for manufacturer's Quality Management system
- Waste Analysis
- Full available reagent and consumable list, with cleaning reagents and consumables required for complete and proper functioning.

B.18.2.e	RESPONSE: M (pass/fail assessment)
	Please describe and evidence how the proposed solution achieves the specification stated above.

PART C

PART C: EQUIPMENT SOLUTION FOR THE CYTOLOGY TRIAGE SERVICE

C.1 Equipment Solution

C.1.1 Equipment Solution (slide preparation system, staining, coverslipping & scanning)

The equipment solution **MUST** be capable of being accommodated within the designated footprint of the Processing Laboratories (as provided by the Processing Laboratories) and **MUST** be capable of delivering a flexible and variable test output with efficient testing of both low and high volume workloads.

a. **Description of Equipment** : For each piece of equipment, the Contractor **MUST** state:

i. The name and model

C.1.1.a.i	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

ii. The overall dimensions and weights

C.1.1.a.ii	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

iii. The operational noise levels

C.1.1.a.iii	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

iv. The electrical / power requirements

C.1.1.a.iv	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- v. The heat output of each unit and associated piece of equipment

C.1.1.a.v	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- vi. The range of operating ambient temperature and humidity with air conditioning requirements, together with information on whether the equipment will continue to operate out with these conditions.

C.1.1.a.vi	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- vii. The water supply and drainage requirements needed per hour at peak usage and the likely water supply system required to meet the demand for each Processing Laboratory

C.1.1.a.vii	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- viii. Provide details of all consumables and reagents to be provided, together with their storage requirements

C.1.1.a.viii	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- ix. Describe safety measures associated with each equipment item to mitigate staff health & safety risks, including arrangements for the handling of Category 3 Pathogens ("High Risk" samples) and any safeguards which prevent or minimise the risk of aerosol formation or minimise splashing / spillage of samples and reagents.

C.1.1.a.ix	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

b. Profile of Equipment in the Market place

For each component of the system listed above the Contractor **MUST** provide details of:

- i. Worldwide and UK launch dates

C.1.1.b.i	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- ii. The number of placements

C.1.1.b.ii	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- iii. The location and contact details of UK placements, if applicable.

C.1.1.b.iii	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- iv. Any independent evaluation in any country.

C.1.1.b.iv	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.1.2 Laboratory Accommodation and Environmental Requirements of the Equipment Solution

- a. Indicative equipment layouts for the Processing Laboratories. Details of the available laboratory space will be made available and solutions **MUST** be configured to those structural restrictions. Provision of adequate space for benching/specimen preparation and short-term storage **MUST** be included.

C.1.2.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- b. Contractors **MUST** confirm whether existing services i.e. power, network data points, environmental lighting, temperature control, humidity, vibration, water, drainage etc. are adequate for installation and full operation of proposed solution.

C.1.2.b **RESPONSE: M (pass/fail assessment)**

Please describe and evidence how the proposed solution achieves the specification stated above.

- c. Contractors **MUST** detail any additional works required. Alterations to the building **MUST** be undertaken by the contractor (or its sub-contractor) in full negotiation and agreement with the Health Boards. The Contractor will be responsible for the entire cost of any installation of new services, or upgraded services required to prepare the Processing Laboratory for installation. For the avoidance of doubt, this will include the cost of relocating existing equipment to temporary accommodation within the Health Board premises to allow installation to take place.

C.1.2.c **RESPONSE: M (pass/fail assessment)**

Please describe and evidence how the proposed solution achieves the specification stated above.

- d. It is expected that important components of the equipment solution will be protected by a UPS. Contractors **MUST** indicate which components will be protected and **MUST** indicate the time range that the UPS will support the component.

C.1.2.d **RESPONSE: M (pass/fail assessment)**

Please note your response below:

- e. The annual workload activity is expected to change over the lifetime of the service, as stated in Appendix E. This may result in re-location of equipment and their services. The Contractor **SHOULD** confirm how this would be supported.

C.1.2.e **RESPONSE: E**

Please note your response below:

- f. Equipment layout **SHOULD** be arranged to ensure Lean specimen processing and workflow. Describe how your solution addresses this requirement.

C.1.2.f **RESPONSE: E**

Please note your response below:

- g. A visual display of workflows/process maps that indicate the operational solutions, including Middleware **MUST** be provided.

C.1.2.g **RESPONSE: M (pass/fail assessment)**

Please note your response below:

C.1.3 Standard, Directive, Legislative Requirements

The Contractor **MUST** ensure that the equipment complies with industry standards, best practice guidelines and all Legislation, including waste disposal, containment of pathological material and electrical safety. The Contractor **MUST** indicate how the Solution will ensure compliance with the following:

STANDARD / CERTIFICATION
Hold BS, EN, ISO 9000 or equivalent.
Comply with IEC 60601-1:1990 (BS 5724-1:1989) Medical Electrical Equipment: General Requirements for Safety
Comply with EC Medical Devices Directive 93/42/EC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993) as amended (OJ L 331, 7.12.1998)
Conform to IVD Directive (98/79/EC) (of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998)

Be approved for use for cervical screening by Public Health England or the Scottish Cervical Screening Programme.
Comply with COSHH (Control of Substances Hazardous to Health) Regulations 2002. Safety data sheets in English MUST be available.
- Subscribe to the practices and principles of MHRA (Medicines and Healthcare products Regulatory Agency) DB2006 (02) for reporting adverse incidents related to in vitro medical devices. - Comply with any additional and relevant, regulations for electrical, mechanical and biological safety. - Enables the Processing Laboratories to comply with the ISO 15189 (2012) standard

C.1.3	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.1.4 Cytology Slide Preparation and Scanning

C.1.4.1 Operational Functionality

- a. The Contractor **MUST** fully describe their solution and data management for the Cytology triage solution.

The majority of work is currently processed between the working hours of 9am to 5pm, but the Solution **MUST** be available, with minimum start up times, to support extended day working of 8am to 8pm.

C.1.4.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Any equipment **SHOULD** be an open system operating in random access mode with continuous sample loading. Please describe how your solution meets this requirement.

C.1.4.1.b	RESPONSE: E
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Contractor **SHOULD** state:

- c. Start up from switch on to ready status and Start up from standby to ready status.
Please provide the time from loading of the sample to first slide available.

C.1.4.1.c	RESPONSE: E
Please note your response below:	

- d. Performance of daily, weekly and monthly maintenance and any other maintenance procedures indicating how these might impact on 8hr operation.

C.1.4.1.d	RESPONSE: E
Please note your response below:	

- e. Shut down the equipment, including any special washes.

C.1.4.1.e	RESPONSE: E
Please note your response below:	

- f. State the throughput rates (i.e. slides per hour) in routine operation for the equipment offered (fully automated, partially automated or standalone) including any factors that will affect the optimal throughput i.e. equipment availability during reagent & consumable top up, maintenance and equipment bottle necks.

C.1.4.1.f	RESPONSE: E
Please note your response below:	

- g. Provide sufficient Core Hours capacity to meet routine test workload.

C.1.4.1.g	RESPONSE: E
Please note your response below:	

C.1.4.2 Equipment Availability

- a. It is expected that the Solution will be capable of functioning 24/7. The Contractor **MUST** provide details of expected uptime for each component of the Solution.

C.1.4.2.a	RESPONSE: M (pass/fail assessment)
Please note your response below:	

- b. The Contractor **MUST** indicate clearly what will happen in the event of failure of each component of the Solution, including the Middleware, to ensure continuity of operation.

C.1.4.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.1.5 Equipment Status Information

For all components of the equipment solution there should be a visual display capable of indicating equipment status and test status as appropriate, with a hard copy obtainable if required. Data including image analysis/scanning data for scanned slides for tests and for calibration samples should be retained on board for a user definable period of not less than six months and/or be downloadable to an appropriate storage medium. The data stored should be in a reviewable format.

For all Slide processing systems and scanners in the solution, there **MUST** be real-time “live” access to:

- a. Sample status monitoring (for example, work in progress/completed, sampled, and estimated processing time). Please provide details.

C.1.5.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Onboard test information storage (for example, number of tests processed, length of storage time).

C.1.5.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. An event and/or error log and is this accessible during operation. Please provide details, and describe storage or backup for the log.

C.1.5.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Allow interruption of sample processing in real time in the event of problems.

C.1.5.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- e. Provision of user manuals and state in what format i.e. on-board documentation or hard copy.

C.1.5.e	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.1.6 Slide Preparation

The Equipment solution or agreed components **SHOULD**:

- a. Describe the sampling mechanisms for each item of equipment in the solution. Consumables used in slide preparation must be disposable.

C.1.6.a	RESPONSE: E
Please note your response below:	

- b. State the methods by which the equipment facilitates detection of all of the potential errors below that may affect the result and how this is flagged in the software:
- Liquid level sensing, insufficient volume detection, pipetting error/ aspiration error, slide and internal consumable handling errors.
 - Describe how the reanalysis of individual samples that have been flagged is performed.

C.1.6.b	RESPONSE: E
Please note your response below:	

- c. The slide preparation system **MUST** include de-capping and recapping of sample vials. The Contractor **MUST** state any limitation of the de-capping solution(s) including tube type & size limitations.

C.1.6.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above	

C.1.7 Sample Type and Volume Requirements

The Contractor **SHOULD** provide detailed information on LBC sample types that are UK approved and validated for testing on the proposed equipment platform and the sample volume required.

C.1.7	RESPONSE: E
Please note your response below:	

C.1.8 Sample Identification

Contractors should be aware that all tests are electronically requested. The SCCRS number is a non-sequential number and will be the primary identifier used as the barcode number on the specimen container and all associated daughter tubes. The SCCRS Number is a ten digit number that includes check digits. The barcode label will also include an eye-readable SCCRS number.

The label will also include a sequential Laboratory Number in eye-readable format. There will also be additional identifiers on the label

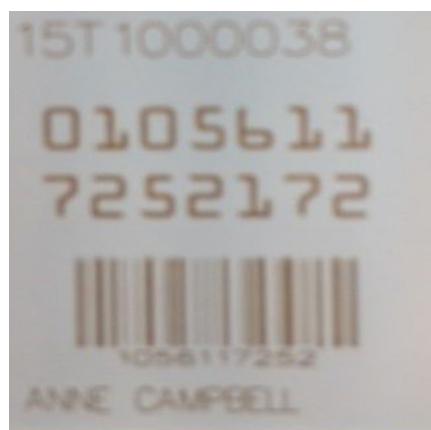
The equipment or agreed components **SHOULD** demonstrate the following attributes/functionality:

- a. All equipment **SHOULD** have a positive sample identification facility. The Contractor **SHOULD** detail the requirements of the proposed equipment in terms of:
 - i. barcode type
 - ii. barcode label size
 - iii. barcode positional constraints
 - iv. optical specification of barcode readers

C.1.8.a	RESPONSE: E
Please note your response below:	

- b. The Contractor **SHOULD** fully describe how patient demographics and unique identifiers are printed on the slide in the processing solution. Examples of the printed format **SHOULD** be provided.

A copy of the current labelling can be seen here, below, for reference:



C.1.8.b	RESPONSE: E
Please note your response below:	

- c. The Contractor **MUST** detail how any sample with a barcode misread and/or an 'undetectable' barcode will be identified and appropriately handled. (e.g. tube/vial detected but barcode misread).

C.1.8.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.1.9 Sample Tracking and Archiving

The Contractor **SHOULD** clearly state how the solution will ensure the quality of specimen processing by mandating verification of the patient sample from pre-analytic processes to slide availability e.g. complete audit trail of each specimen on any equipment including all associated calibration, QC, reagent lot number and any associated analytical and system flags.

C.1.9	RESPONSE: E
Please note your response below:	

C.1.10 IT, Data Management and Connectivity

The Contractor **MUST**

- a. describe how the Cytology solution offered will interface with SCCRS

C.1.10.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Provide a full technical specification of the interface.

C.1.10.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Identify the responsibilities for the design, implementation, testing and acceptance of the interface.

C.1.10.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Specify the test requirements for the interface(s).

C.1.10.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **SHOULD**

- e. describe how their Solution would operate in the event of an SCCRS failure (for information only.)

C.1.10.e	RESPONSE: I
Please note your response below:	

C.2

C.2.1 Reagents and Consumables Inventory Management

The Contractor **MUST**:

- a. Ensure all related reagents and consumables (e.g. racks, carousels etc.) are included in the costs. There will be no additional charges.

C.2.1.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- b. Supply reagents/consumables in volumes appropriate to use which comply with ISO standards (Section 5.3.2.7), bar coded to show lot number, container number and expiry date.

C.2.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Validate reagents and consumable batches prior to acceptance for delivery and use, to meet ISO 15189 (Section 5.3.2.3) standard. The Contractor **MUST** clearly indicate how this will be achieved.

C.2.1.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **SHOULD** describe and evidence how the proposed solution will achieve the following:

- d. Guarantee the uninterrupted supply of high quality CE marked reagents preferably through remotely managed inventory control. Contractors **SHOULD** indicate how inventory control will be managed to reduce reagent and consumable wastage profiles. Indicate those reagents and consumables, including third party reagents and consumables which will be supplied as part of the Contract and those to be supplied by the Processing Laboratory.

C.2.1.d	RESPONSE: E
Please note your response below:	

- e. Supply reagents with an appropriate expiry date (at least 3 months, preferably 6 months) later than the date of delivery. The Contractor will (at its cost) be

required to replace any reagent unused at the expiry date. Indicate the minimum storage area required to accommodate 2 months' supply of reagents.

C.2.1.e	RESPONSE: E
Please note your response below:	

- f. The solution **SHOULD** have reagent and consumable traceability, preferably by barcode, such that all results can be traced back to specific lots. Please provide details.

C.2.1.f	RESPONSE: E
Please note your response below:	

- g. How the equipment stores and displays data of onboard reagent status and number of tests available/remaining.

C.2.1.g	RESPONSE: E
Please note your response below:	

- h. Using the workload statistics provided, indicate those reagents, which will be supplied – including the reagent and kit pack physical sizes/weights.

C.2.1.h	RESPONSE: E
Please note your response below:	

- i. Indicate any additional arrangements each site would be expected to undertake to facilitate the proposed reagent supply system. (e.g. Temperature controlled storage, FIFO management, meeting agreed wastage targets).

C.2.1.i	RESPONSE: E
Please note your response below:	

- j. Clarify the number of days' worth of reagents required to be stored at each Processing Laboratory to achieve uninterrupted sample processing with minimal wastage profiles. Indicate the space required at each Processing Laboratory for storage of:

- Reagents/kits requiring refrigerated / frozen storage
- Reagents/kits which may be stored at room temperature.
- Consumables

C.2.1.j	RESPONSE: E
Please note your response below:	

- k. How the Contractor will promptly alert NSS and Health Boards when they become aware of any performance issues. Describe how this will be achieved.

C.2.1.k	RESPONSE: E
Please note your response below:	

C.2.2 Reagent / Consumable Loading, Capacity and Positioning of Reagents

Contractors **SHOULD** provide details on the following:

- a. The total number of tests available without a reagents/ consumables change.

C.2.2.a	RESPONSE: E
Please note your response below:	

- b. Whether it is possible to replenish reagents while the equipment is in use. If this is not possible, indicate the processing time lost in replacing the depleted reagent packs.

C.2.2.b	RESPONSE: E
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Please note your response below:

- c. How the Solution deals with test requests when reagent or consumable exhaustion occurs. Contractor **SHOULD** describe the on-board reagent management system.

C.2.2.c **RESPONSE: E**

Please note your response below:

- d. How the equipment stores reagents/consumables on-board. Please provide details on kit and test capacity, and kit shelf life (open and unopened).

C.2.2.d **RESPONSE: E**

Please note your response below:

- e. How the equipment provides and stores data on reagent usage. Please provide details.

C.2.2.e **RESPONSE: E**

Please note your response below:

- f. How the equipment ensures any reagent/consumable batches are within expiry dates.

C.2.2.f **RESPONSE: E**

Please note your response below:

- g. How reagent and consumable wastage is minimised. Details of wastage for all reagents/consumables/kits/packs **SHOULD** be provided.

C.2.2.g **RESPONSE: E**

Please note your response below:

- h. If there is any reagent priming. This **SHOULD** be identified and included in the reagent requirements.

C.2.2.h **RESPONSE: E**

Please note your response below:

- i. Describe the on-board reagent/consumable monitoring system and how users will be informed of reagent or consumable depletion.

C.2.2.i **RESPONSE: E**

Please note your response below:

- j. Whether the equipment can compare reagent inventory with potential daily workload to assist operator in inventory management.

C.2.2.j **RESPONSE: E**

Please note your response below:

C.2.3 Reserved Rights on Change

Once procured the Contractor **MUST** not change any aspect of their testing system without consultation and approval of these potential changes by the Quality Assurance Framework of the Scottish Cervical Screening Programme (SCSP) in place at the time.

If the SCSP agrees in principle, the Contractor **MUST** then agree a timescale of “notice of changes” in reagent formulation and allow an appropriate evaluation of the new product at their expense. The process of notification and agreement of timescales will be governed by the Service Levels.

The SCSP reserves the right to request the purchase of equipment/reagents from another source in the event that a method proves to be, or becomes, unreliable, or insufficiently accurate, or insufficiently precise as judged from data from an accredited

EQA scheme, or if the supply of reagents becomes unreliable. The Contractor will be responsible for any additional costs incurred.

The SCSP undertakes to make such a change only after discussion with the Contractor.

Provide details of proposed management of equipment/reagent changes.

C.2.3.	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.3 INSTALLATION AND CONTINUITY EVALUATION OF EQUIPMENT

C.3.1 Installation and Commissioning

The Contractor **MUST** provide:

- a. Advice and support **MUST** be provided in the event that the equipment has to be moved after installation including a decommissioning document. Describe how this will be provided.

C.3.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Guarantee installation procedures that provide a safe working environment for all staff.

C.3.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor **SHOULD**:

- c. Submit the survey report for the Processing Laboratory performed in conjunction with the Health Board Estates staff with a view to determining any additional requirements to accommodate the proposed equipment.

C.3.1.c	RESPONSE: E
Please note your response below:	

- d. Include a Plan proposing any phased installation and indicate how the current level of service will be maintained during installation and commissioning of new equipment.

C.3.1.d	RESPONSE: E
Please note your response below:	

C.3.2 Compliance Evaluation: Installation and Commissioning

The Contractor **MUST** provide the following:

- a. At installation and before the formal handover the Contractor **MUST** satisfactorily demonstrate and supply a commissioning document, to show that the equipment is fully functional and capable of providing a robust cervical cytology service. This **MUST** include slide processing, staining, coverslipping and automated screening solutions.

C.3.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- a. The Contractor will be required to meet all ISO 15189 standards on validation equipment installation. Where appropriate, the Contractor will be required to provide staff and supply reagents and all necessary consumables to process samples for an agreed protocol for the evaluation of each method.

Contractor **MUST** produce a validation report for the equipment under direction of the nominated scientific representatives. Reagents/Kits/Consumables required for validation **MUST** be provided free of charge

Where appropriate, the basic protocol will include a minimum of 100 comparisons between the output of the equipment and that in use in the Processing Laboratories at the time of implementation. The quality of the prepared slides **MUST** be assessed by the nominated lab representative. The automated screening solution **MUST** be validated by comparison with manual screening on the same slides.

Contractors **MUST** provide a protocol on how this is going to be achieved.

C.3.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. The Contractor **MUST** provide suitable installation and Operational documentation for the Equipment.

C.3.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Post installation performance checks **MUST** meet the requirements of the Processing Laboratory. Documentation required for all equipment includes the following:
- Operator/Equipment manuals
 - Technical specification documentation
 - Installation qualification documentation
 - Basic troubleshooting
 - EN Electrical Safety Certification
 - Factory Acceptance Testing
 - Calibration Documentation
 - Certificates of accreditation for manufacturer's Quality Management system
 - Waste Analysis
 - Full available reagent and consumable list, with cleaning reagents and consumables required for complete and proper functioning.

C.3.2.d	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.4 RESILIENCE AND CONTINGENCY ARRANGEMENTS

C.4.1 Reagent / Consumable Contingency Arrangements

The Contractor **MUST**:

- a. Demonstrate clearly defined contingency arrangements in place to ensure availability and reliability of supply of Cytology reagents in the event of a supply failure or performance problem of any reagent/ Quality Control /Calibrator/ consumables. The Contractor **MUST** guarantee the delivery of all Cytology consumables direct to the Processing Laboratory and Distribution Points and demonstrate clearly defined contingencies in the event of a supply failure or performance problem of any consumables. If there is only one site for manufacture, provide details of how such increased risk is addressed.

C.4.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. List any Cytology reagent/consumable which were unavailable to supply for longer than 1 month in the last 2 years (including sub – contractors).

C.4.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.4.2 Equipment Capacity and resilience

It is expected that each of the Processing Laboratories, though linked in terms of IT, will retain the ability to operate as an independent unit.

The Contractor **MUST** clearly show that their proposals will provide:

- a. The capacity to meet projected activity, including peak and trough demands. A variation in projected workload of +/-5% pa **MUST** be assumed.

C.4.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. Adequate service continuity for both planned and unplanned downtime.

C.4.2.b	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- c. Resilience of manufacture and supply of equipment, reagents and consumables.

C.4.2.c	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- d. A robust response to equipment failure or interruption of supply of reagents and consumables.

C.4.2.d	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

C.4.3 Contracted, Scheduled, Preventative Maintenance and Support

C.4.3.1 Contracted Maintenance

- a. The Contractor **MUST** provide comprehensive maintenance and management support for all equipment comprising the managed service solution, including those supplied by third parties. The Contractor **MUST** ensure compliance with the Service Level requirements.

The Contractor **MUST** provide service continuity for both planned and unplanned downtime. Proposals **MUST** permit the continuation of essential processes during any equipment downtime

Resilience will be the responsibility of the Contractor by ensuring that any failure in any component of the solution will be resolved within 48 hours. Failure to achieve this will result in samples being transported to an external laboratory with all associated transport and testing costs met by the Contractor.

C.4.3.1.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

The Contractor **MUST** provide concise details of the maintenance support provision including:

- b. Demonstrating the competency of its support services for hardware, software and equipment applications and future support of hardware/software upgrades. This **MUST** be compatible with the legislative requirements of laboratory accreditation including but not limited to ISO 15189. Contractors are required to provide this information for inclusion in the Laboratory Quality Management System (Q-Pulse) to allow compliance with ISO 15189 standards.

C.4.3.1.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

The Contractor:

- c. **SHOULD** provide details of the proposed engineering establishment, their geographic distribution and the support that will be delivered to both Processing Laboratories.

C.4.3.1.c	RESPONSE: E
Please note your response below:	

- d. **SHOULD** indicate which, if any, maintenance routines will be performed by themselves and those which will be devolved to Processing Laboratory staff trained by the Contractor.

C.4.3.1.d	RESPONSE: E
Please note your response below:	

- e. Provide training to Processing Laboratory staff in all aspects of devolved equipment maintenance. This **SHOULD** include all new staff throughout the Term of the Contract. This **SHOULD** also include a competency review process for all staff, by the Contractor in accordance with ISO 15189 (Section 5.1.6) compliance. Indicate how this will be achieved.

C.4.3.1.e	RESPONSE: E
Please note your response below:	

- f. **SHOULD** provide an example of a breakdown log. This will be agreed prior to installation.

C.4.3.1.f	RESPONSE: E
Please note your response below:	

- g. **SHOULD** provide an escalation procedure tailored to the clinical service provided by each Processing Laboratory. This will be agreed prior to installation.

C.4.3.1.g	RESPONSE: E
Please note your response below:	

- h. Scheduled visits by engineers **SHOULD** be arranged in advance and **SHOULD** minimally disrupt normal working. Detail the frequency, day of the week and times for these visits.

C.4.3.1.h	RESPONSE: E
Please note your response below:	

- i. **SHOULD** provide the following information on scheduled maintenance:

- i. The expected equipment unavailability for each of these visits including software upgrades.

C.4.3.1.i.i	RESPONSE: E
Please note your response below:	

- ii. The performance checks that will be carried out by the Contractor's engineer after a scheduled preventative maintenance visit prior to leaving the Processing Laboratory which **MUST** meet the appropriate ISO 15189 (Section 5.3.1.2) standard.

C.4.3.1.i.ii	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- iii. All service reports and data relating to routine performance, planned and unplanned maintenance, and fault rectification **MUST** be provided by the Contractor and its service agent.

C.4.3.1.i.iii	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- iv. Decontamination procedures **MUST** be stated/described. Please provide details.

C.4.3.1.i.iv	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

C.4.3.2 Remote support for equipment solution and any associated middleware

The Contractor **MUST** provide information on how the following will be achieved:

- a. A single point of contact is required for reporting problems in respect of:
- hardware (all equipment including third party supplied equipment)
 - software (including 3rd party connection to Contractor software and SCCRS interfaces)
 - scanners / image analysis equipment, including microscopes.

C.4.3.2.a	RESPONSE: M (pass/fail assessment)
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Please describe and evidence how the proposed solution achieves the specification stated above.

- b. Contractors **MUST** detail when engineering support (i.e. fault logging and telephone advice) will be offered (e.g. extended days, weekends and Public Holiday cover as per the Contract).

C.4.3.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- c. Where proposed equipment, Middleware or IT support is not provided Monday - Friday (including 3rd Party proposals) the Contractor **MUST** indicate how their proposal will meet clinical service requirements.

C.4.3.2.c	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- d. Remote support utilising real-time self-diagnostics sensors or troubleshooting software that is available on the equipment, middleware or on-line diagnostics. Contractors **SHOULD** supply relevant information on any of their current preventative systems.

C.4.3.2.d	RESPONSE: E
Please note your response below:	

- e. **SHOULD** detail equipment, both Contractor and third party, that can be connected to the Contractor for remote support, preventative diagnostics and inventory management.

C.4.3.2.e	RESPONSE: E
Please note your response below:	

C.4.3.3 Engineer response (inclusive of third party services)

- a. For all equipment offered, Contractors **SHOULD** provide evidence of the average number of service calls for UK and worldwide installations by years installed.

C.4.3.3.a	RESPONSE: E
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Please note your response below:

- b. Contractors **SHOULD** state the guaranteed response time, in terms of attendance at the Processing Laboratory by an engineer, for equipment taking into account weekends and public holidays. Contractors **SHOULD** supply independently validated data on equipment mean-time-between-failures, predicted up-time, downtime and average time between engineer call-outs.

C.4.3.3.b RESPONSE: E

Please note your response below:

- c. The Contractor **SHOULD** detail options for back-up/loan systems for unanticipated long-term down-time for each item of equipment.

C.4.3.3.c RESPONSE: E

Please note your response below:

- d. The performance checks that will be carried out by the Contractor's engineer after a visit in response to equipment malfunction prior to leaving the Processing Laboratory **SHOULD** be listed. Downtime logs **SHOULD** be signed off by Contractor and Processing Laboratory's staff.

C.4.3.3.d RESPONSE: E

Please note your response below:

- e. Contractors **SHOULD** define how they would ensure timely and appropriate provision of spare parts in order to meet contractual requirements and the Service Levels.

C.4.3.3.e RESPONSE: E

Please note your response below:

C.5 TRAINING

Contractor **MUST** provide details of their proposed training plan (own equipment & third party) both on-site and off-site. There is an expectation that sufficient key operator staff training will be delivered prior to live operation at a given site/discipline (It is anticipated that this will be at least two key staff per equipment or data manager/hospital).

There is a requirement to ensure competency training for all staff at each Processing Laboratory prior to go-live and for all appropriate staff to complete basic competency training within an agreed period. The Contractor **MUST** describe the proposed timelines and how the proposed solution will allow compliance with ISO15189 (Section 5.1.5) standard.

C.5	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.5.1 Initial staff training

- a. The Contractor will be expected to commit staff full time to this exercise.

Full training and comprehensive operator manuals (online or cd) in English **MUST** be provided. As a minimum the operator manual **MUST** include details of start-up and shut-down procedures; calibration, sample processing, decontamination and fault recognition and handling.

C.5.1.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The Contractor **SHOULD** clearly indicate the full specification of the training equipment and state for the key operators

- Whether this is on or off site
- Whether this is pre or post installation
- Numbers of staff who will receive advanced training
- Numbers of staff who will receive basic training and duration of training

C.5.1.b	RESPONSE: E
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Please note your response below:

C.5.2 Update/Continued training

In the order to manage the service and allow both Processing Laboratories to comply with ISO 15189 standards the Contractor **SHOULD** indicate the means by which training and staff competency will be maintained throughout the Term of the Contract. This will include:

- a. On-going maintenance of (all) staff training to ISO 15189 (Section 5.1.6) standard for staff competency.

C.5.2.a	RESPONSE: E
Please note your response below:	

- b. On-going advanced training to reflect staff changes / advances / improvements to the level of service provision.

C.5.2.b	RESPONSE: E
Please note your response below:	

- c. All costs attributable to both Processing Laboratories for all elements of training for the Term of the Contract.

C.5.2.c	RESPONSE: E
Please note your response below:	

C.5.3 "User" Groups

The Contractor **SHOULD** provide:

- a. Details of any “user” group which meets to discuss topics relevant to the equipment solution being offered.

C.5.3.a	RESPONSE: E
Please note your response below:	

- b. Cover the costs involved in attendance at “user” group meetings for the Term of the Contract for a mutually agreed number of staff.

C.5.3.b	RESPONSE: E
Please note your response below:	

- c. Indicate any generic training credit system offered as part of the solution. This **SHOULD** include 3rd Party solutions.

C.5.3.c	RESPONSE: E
Please note your response below:	

C.6 Service Management

C.6.1 Service Reporting

The Contractor **MUST** provide details of how they propose to interact with the Processing Laboratories, including submission of performance reports, performance review meetings etc.

C.6.1	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

C.6.2 Service Changes Over the Term of the Contract

The Contractor **MUST** describe:

- a. The change process which will apply to any unplanned event or reconfiguration of laboratory services in one or both of the two Processing Laboratories.

C.6.2.a	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

- b. The change process associated with the advent of new technology arising during the Term of the Contract.

C.6.2.b	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

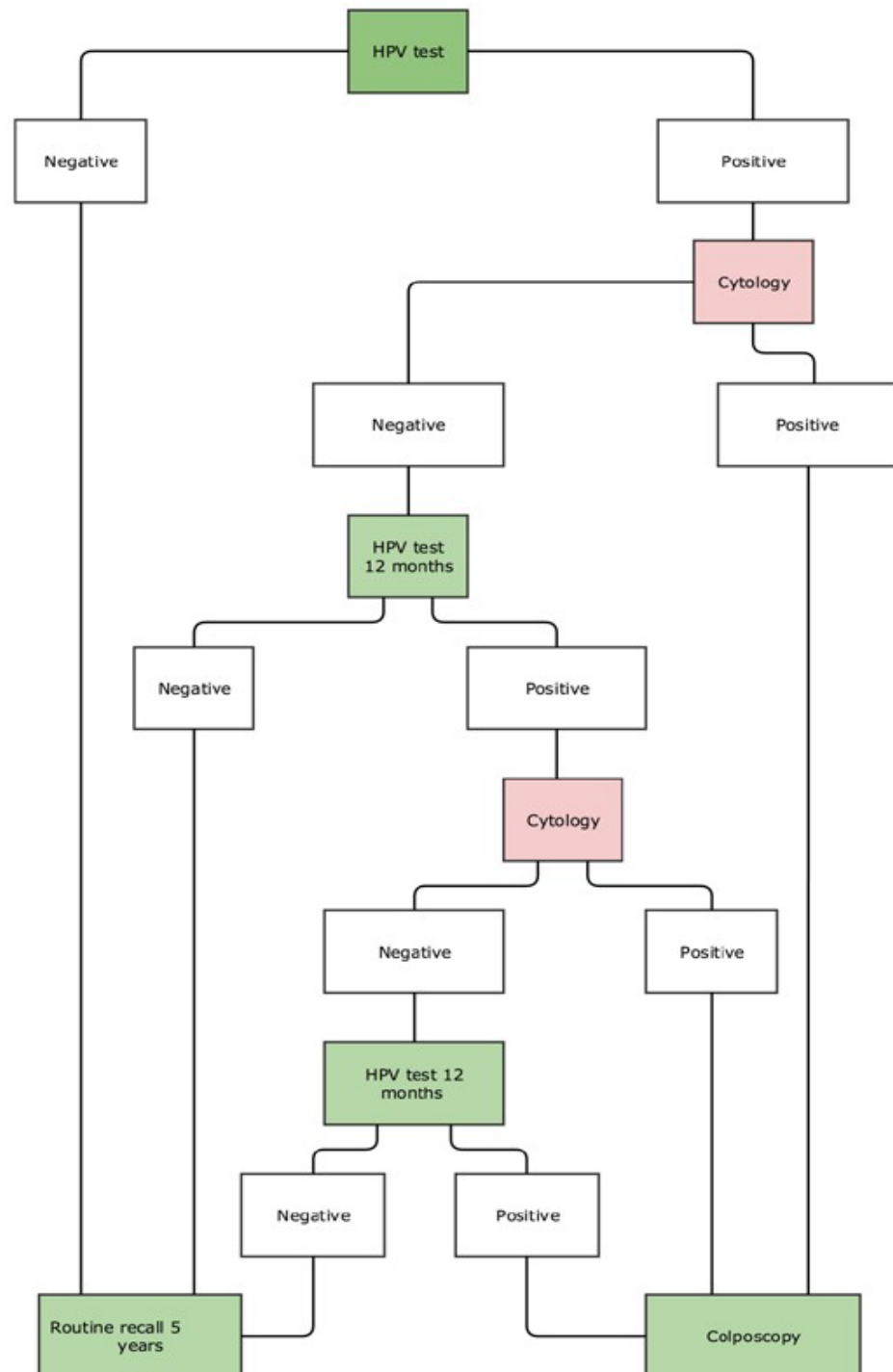
C.7 Performance in External Quality Assessment Schemes

The Contractor **MUST** supply information on performance in EQA schemes, “in house” data and intra-laboratory data for the assay including third party solutions. Any known indicators of apparent poor performance **MUST** be given.

C.7	RESPONSE: M (pass/fail assessment)
Please describe and evidence how the proposed solution achieves the specification stated above.	

APPENDICES

Appendix A: Hr-HPV Primary Screening Pathway



Processing laboratory

Collection centre

NSS Procurement Hr-HPV Managed Service Contract Page 130

Appendix C: DETAILS OF THE PARTICIPATING BOARD 2016-17 WORKLOAD **CONFIDENTIAL**

Cervical smears processed at NHS laboratories: Scotland, 1st April 2003 to 30th September 2017

Number by quarter and NHS board performing analysis

Year/ quarter	Scotland	(Former) Argyll & Clyde ¹	Ayrshire & Arran	Fife	Forth Valley	Grampian	(Former) Greater Glasgow ¹	Greater Glasgow & Clyde ^{1,3}	Highland ⁴	Lanarkshire ³	Lothian	Tayside
2017/2018												
Q2	91,590	x	5,584	5,868	5,174	14,717	x	23,316	x	12,325	17,762	6,844
Q1	97,015	x	5,920	6,109	5,584	16,076	x	24,434	x	12,992	19,072	6,828
2016/2017												
		x					x		x			
Q4	107,520	x	6,760	6,610	6,324	16,880	x	27,752	x	14,478	20,482	8,234
Q3	95,256	x	6,120	6,097	5,393	16,397	x	23,400	x	12,501	18,556	6,792
Q2	116,414	x	7,840	7,497	7,016	18,873	x	28,719	x	15,549	21,798	9,122
Q1	98,077	x	6,360	6,150	5,980	16,760	x	23,917	x	12,726	19,095	7,089
Q1 - Q4	417,267	x	27,080	26,354	24,713	68,910	x	103,788	x	55,254	79,931	31,237
2015/2016												
Q4	104,811	x	6,600	6,711	6,257	16,438	x	26,599	x	14,093	20,205	7,908
Q3	91,501	x	5,720	5,738	5,391	15,596	x	22,799	x	11,851	17,600	6,806
Q2	98,859	x	6,600	6,496	5,631	16,316	x	24,199	x	12,831	19,281	7,505
Q1	103,979	x	6,839	6,543	5,957	17,335	x	25,440	x	13,790	20,322	7,753
Q1 - Q4	399,150	x	25,759	25,488	23,236	65,685	x	99,037	x	52,565	77,408	29,972
2014/2015												
Q4	106,557	x	6,840	6,641	6,166	16,936	x	27,640	x	13,973	20,401	7,960
Q3	95,040	x	6,000	5,723	5,314	16,118	x	24,000	x	12,032	18,917	6,936
Q2	95,514	x	6,120	6,171	5,571	14,553	x	24,040	59	12,852	19,004	7,144
Q1	100,562	x	6,359	6,287	5,707	12,099	x	25,320	4,539	12,936	19,841	7,474
Q1 - Q4	397,673	x	25,319	24,822	22,758	59,706	x	101,000	4,598	51,793	78,163	29,514

Appendix D: Liquid Based Cytology (the sample collection method): supply and provision of Sample Taker consumables to Distribution Points

Health Board	Distribution Point for smear taker consumables (Address)	Specimen uplift/collection centre (if different from distribution point) (Address)
NHS Ayrshire & Arran	Pathology Department Crosshouse Hospital Kilmarnock	
NHS Borders	Central Stores Borders General Hospital Huntleyburn Melrose TD6 9BS	
NHS Dumfries & Galloway	Supplies Dept Dumfries & Galloway Royal Infirmary Cargenbridge, Dumfries, DG2 8RX	Laboratory reception Dumfries & Galloway Royal Infirmary Cargenbridge, Dumfries, DG2 8RX
NHS Fife	Department of Cellular Pathology North Laboratory Block Hayfield Road Kirkcaldy Fife KY2 5AH	
NHS Forth Valley	NHS Forth Valley Central Supplies Department, Unit 2, Colquhoun Street, Stirling, FK7 7PX	Laboratory Central Reception, 2nd Floor, N Block, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR
NHS Grampian	Sciamed Unit 3-5 Mart Industrial Estate Mart Road Alford Aberdeenshire AB33 8BZ United Kingdom	Pathology Dept Link Building Aberdeen Royal infirmary Foresterhill Aberdeen AB25 2ZD

Health Board	Distribution Point for smear taker consumables (Address)	Specimen uplift/collection centre (if different from distribution point) (Address)
NHS Greater Glasgow & Clyde	Sciamed Unit 3-5 Mart Industrial Estate Mart Road Alford Aberdeenshire AB33 8BZ United Kingdom	
NHS Highland	The Cellular Pathology Department Raigmore Hospital Old Perth Road Inverness IV2 3UJ	
NHS Lanarkshire	Pathology department Monklands Hospital Monkscourt Avenue Airdrie ML6 0JS	
NHS Lothian	Unit Distribution Centre Astley Ainslie Hosp 133 Grange Loan Edinburgh EH9 2HL	Central stores RIE 51 little France Crescent Edinburgh EH16 4SA
NHS Orkney	Sciamed Unit 3-5 Mart Industrial Estate Mart Road Alford Aberdeenshire AB33 8BZ United Kingdom	Pathology Dept Link Building Aberdeen Royal infirmary Foresterhill Aberdeen AB25 2ZD
NHS Shetland	Sciamed Unit 3-5 Mart Industrial Estate Mart Road Alford Aberdeenshire AB33 8BZ United Kingdom	Pathology Dept Link Building Aberdeen Royal infirmary Foresterhill Aberdeen AB25 2ZD
NHS Tayside	Sciamed Unit 3-5 Mart Industrial Estate Mart Road Alford Aberdeenshire AB33 8BZ United Kingdom	Microbiology Dept Ninewells Hospital Dundee DD1 9SY

Health Board	Distribution Point for smear taker consumables (Address)	Specimen uplift/collection centre (if different from distribution point) (Address)
NHS Western Isles	The Cellular Pathology Department Raigmore Hospital Old Perth Road Inverness IV2 3UJ	

Appendix E: Service Specifications: - Activity Levels per the Business Case

This future model of care will result in changes to activity figures. A best estimate of figures over the initial ten years following implementation are provided below.

Year		Hr-HPV tests	Cytology tests
Baseline		4,842	395,078
Year 1	2020-21	260,379	50,679
Year 2	2020-22	404,772	74,660
Year 3	2022-23	418,938	76,848
Year 4	2023-24	166,561	34,342
Year 5	2024-25	52,548	15,803
Year 6	2025-26	238,978	26,392
Year 7	2026-27	327,089	35,537
Year 8	2027-28	336,268	38,724
Year 9	2028-29	144,022	23,511
Year 10	2029-30	81,906	15,738
10- year average		243,146	39,223

Appendix F: Service Levels

Refer to Managed Service Contract for Laboratory Services Schedule: Part 11 Service Levels and Service Deductions

Appendix G: Specification for SCCRS Hr-HPV HL7 Interface and IT Security

Refer to the following separate documents:

CPC-DSID-001 SCCRS HR-HPV HL7 ICD.docx

NHSGGC IT Security Policy.pdf

Information Security Policy.doc (NHS Lanarkshire)

Appendix H: Processing Laboratory Room Layout Drawings

Refer to the following separate documents:

GGC HPV Current lab set up – Screening room.pdf

GGC HPV Current lab set up.pdf

NHSL Floorplan (2).PNG

NHSL Processing Screening (2).PNG

Appendix I: Equipment Refresh Programme

**Refer to Managed Service Contract for Laboratory Services Schedule: Part 15
Equipment Refresh Programme**