Safety Action Notice

Reference **SAN2111** Issued **25 October 2021**

Clinical governance and correct use of urine pregnancy tests (UPT)

Summary

Incorrect use of urine pregnancy tests (UPT) may result in misdiagnoses which adversely affect treatment and health outcomes. Governance and practice should be reviewed.

Background

1. The urine pregnancy test (UPT) is a qualitative diagnostic point of care test (POCT) used by clinical teams to determine appropriate treatment pathways for women who may be pregnant. It detects the presence of human chorionic gonadotropin (hCG) in urine during the early stages of pregnancy.

2. Local policy varies and either urine pregnancy tests (UPTs) or serum hCG measurement may be used as a first line test. In some circumstances, serum hCG measurement may be used in addition to UPT when there is clear clinical justification, e.g. if any patient results are unexpected or do not fit the clinical profile.

3. This alert provides guidance to ensure UPT is used effectively. The appropriate use of any POCT within a clinical service requires an evaluation of the clinical effectiveness of the test[1]. In order to prevent misdiagnosis, users of any POCT are required to understand the limitations of use, analytical principles, quality assurance issues, and factors affecting quality of results[2].

4. False positive, false negative and invalid test results have been reported following UPT procedures. These results can adversely affect clinical decision making leading to inappropriate treatment pathways and negatively impacting the health outcomes of both the patient and their unborn fetus.

5. Investigation of reports of invalid test results have found examples of incorrect use of the UPT including: misinterpretation of the test result (no visible control line present); incorrect procedures being followed and unfamiliarity with the limitations of use described in the instructions for use (IFU). Anecdotally, reading the result at the incorrect time is also an issue.

6. Reliable performance and effective management of risks associated with use of a UPT requires the relevant clinical laboratory to have a key role in the support, organization and management of this POCT device.

Action

7. This notice should be brought to the attention of managers responsible for the provision and use of UPT, and staff that require to use a UPT in their role.
8. Suitable governance arrangements should be in place for each clinical area conducting the Urine Pregnancy Tests (UPT). Clinical governance arrangements should include the following:
    - Definition of all healthcare roles authorised to conduct UPT with their health board's point of care test (POCT) co-ordinator
    - Implementation of standard operating procedure for use of UPT
    - Define scope of clinical experience or healthcare role required to verify results to confirm a diagnosis of pregnancy.
    - Maintenance of ongoing and up-to-date staff training and competency records
    - Systems which ensure the accurate recording of results
    - Ensure a protocol of internal and external quality controls is completed regularly for UPT
    - Maintain up to date adherence with agreed national and local clinical protocols, which are based on peer-reviewed best evidence
    - Ensure quality management systems in place to report and mitigate any incidents
9. Evaluation of the UPT result should be carried out in consideration with other clinical information.
10. Incidents and near misses associated with the use of a UPT and any inaccurate results should be reported to the following:
    - local adverse event reporting system e.g. Datix, Ullyses, etc.
    - clinical management team for the department where this inaccuracy occurred
    - health board's POCT co-ordinator.
    - Incident Reporting & Investigation Centre (IRIC).

References

1. Guidance, In vitro diagnostic medical devices: procurement, safety, quality and performance, issued by Medicines and Healthcare products Regulatory Agency (MHRA) on 28 January 2021.
2. Guidance, In vitro diagnostic point-of-care test devices, issued by Medicines and Healthcare products Regulatory Agency (MHRA) on 22 July 2005.

Equipment Details

The following UPT kits are supplied by the National Distribution Centre in Scotland.

NDC SKU	Description	Supplier	Product Code
141791	Pregnancy Test Kit Alere hCG Easy Dip Test	Alere Ltd	UPK009A
231379	Pregnancy Test Kit Alere hCG	Alere Ltd	CV506788C
157358	Pregnancy Test Dip Test Medicheck 50	Pasante Healthcare	8625B
194872	Pregnancy Test hCG Cassette	Pasante Healthcare	8615B

Suggested onward distribution

Assisted Conception
Clinical Chemistry
Emergency Department
Family Planning
General Medical Practitioners
Gynaecology
Health & Safety
Maternity
Medical Admissions
Nursing
Practice Nurses
Risk Management
Supplies/Procurement
Surgical
Wards

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.