POCT – Urine Pregnancy Test Policy	**Type: Clinical Guideline** **Register No: 12018** **Status: Public on ratification**

Developed in response to:	Best practice CPA Guidance
Contributes to CQC Outcome:	4

Consulted With	**Post/Committee/Group**	**Date**
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Policy to be followed by (target staff)	All Nursing staff undertaking Pregnancy POCT
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Related Trust Policies (to be read in conjunction with)	

Document Review History

Review No	Reviewed by	Review Date

It is the personal responsibility of the individual referring to this document to ensure that they are viewing the latest version which will always be the document on the intranet

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Appendices

1.0 Purpose of Policy

1.1 The purpose of this policy is to provide guidance to staff to ensure that tests to detect pregnancy are effectively undertaken to facilitate high quality patient care in accordance with the requirements of Clinical Pathology Accreditation, Care Quality Commission and the NHS Litigation Authority.

1.2 It provides information on the initial training required before a member of staff is authorised to perform the test and the subsequent annual competency checks.

1.3 It details the procedure for performing the test and the performance of the External Quality Control [NEQAS] and the electronic returning of the NEQAS results.

1.4 It details the procedure that the laboratory will follow should they receive notification from NEQAS that the user has either returned an incorrect NEQAS result or results has not been submitted for a given distribution

1.5 The hCG One Step Ultra Pregnancy Test Device is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) at a concentration of 10 mlU/ml or above in urine to aid in the detection of pregnancy. The device is suitable for Point of Care Testing (POCT).

2.0 Scope

2.1 This Policy applies to all Pregnancy POCT preformed at any MEHT site.

2.2 All nursing and other healthcare professionals undertaking POCT Pregnancy testing must adhere to the principles described in this Policy.

3.0 Definitions

3.1 Pregnancy test kit

This is a single test kit for urinary pregnancy test supplied in boxes of 40 by the Immunology Department, Broomfield Hospital.

3.2 NEQAS QC material

The National External Quality Assurance Scheme [NEQAS] distributes Quality Control [QC] samples on a monthly cycle. It is a CPA requirement that all examinations are subjected to external quality assurance and the Trust has agreed to conform by registering all POCT sites with this NEQAS scheme. The laboratory is required to provide evidence of compliance and satisfactory performance for each site [Ward or Clinic] undertaking near patient pregnancy testing to the inspection team.

3.3 CPA

Clinical Pathology Accreditation (UK) Ltd - undertakes regular inspection of Pathology Departments against defined standards.

4.0 Roles and Responsibilities

4.1 Chief Executive

The Chief Executive is responsible for ensuring that systems are in place to ensure safe and effective Pregnancy POCT. This responsibility is delegated to the Chief Nurse.

4.2 Chief Nursing Officer

The Chief Nursing Officer is responsible for ensuring that systems are in place to comply and monitor all training, QC and competency assessments to provide a safe and effective Pregnancy POCT service.

4.3 Lead Nurses

The Lead Nurses are responsible for the implementation of this policy within their areas of responsibility and for cascading the training to their teams and ensuring that training records are maintained with competency re-assessed on a 6 monthly basis.

4.4 Immunology Clinical Scientist

The Immunology Clinical Scientist is responsible for the laboratory aspects of the Pregnancy POCT service. The day to day management of this service is delegated to the Immunology Senior Biomedical Scientist.

4.5 Immunology Senior Biomedical Scientist

The Immunology Senior Biomedical Scientist is responsible for the day to day management of the Pregnancy POCT service and ensuring distribution of the NEQAS QC material. All NEQAS reports received are reviewed by the Immunology Senior Biomedical Scientist and the Immunology Clinical Scientist.

4.6 Healthcare Professionals

All Nursing and other Healthcare professionals, who undertake Pregnancy POCT must adhere to this policy.

5.0 Training

5.1 Full training on the performance of the test will be provided for two senior staff members [normally Sister or Staff Nurse] from the ward or clinic by senior staff from the Immunology Department, Broomfield Hospital. The Sister or Staff Nurse will then be expected to cascade the training to other members of their nursing team who will be undertaking testing [Grade: Registered Nurses and above].

5.2 The following key areas will be covered during the training session:

- Levels of hCG vs weeks/months gestation
- How the test works
- Sample required

- Technique for performing the test
- Reading test
- Quality control – Internal and External QC
- Recording of results/log book
- Test limitations
- Shelf life
- Point of contact

5.3 It is essential that any staff member authorised to perform Pregnancy POCT has a regular training refresher/update and a Competency assessment performed every 6-months. Staff will only be authorised to continue performing Pregnancy POCT on successful completion of this competency assessment (see appendix 1)

5.4 Senior Immunology staff will provide a 6-monthly refresher/update/competency assessment session for the designated trainers from each of the clinical areas authorised to perform pregnancy POCT, it will then be the responsibility of the designated trainers to cascade the training refresher/update sessions and perform a competency check for all members of their team authorised to perform pregnancy POCT.

5.5 A signed list of staff authorised to perform the pregnancy testing must be maintained by the clinical area and updated every 6-months following the nursing competency checks. A copy of this 6-monthly updated list must be sent to the Immunology Department as required evidence for the Pathology CPA and Trust CQC and NHSLA inspections.

6.0 Equipment

- Pregnancy test kit
- Electronic timer
- Disposable gloves
- Electronic countdown timer for accurate measurement of 3 minutes

7.0 Urine Pregnancy Test procedure

7.1 Principle of examination

hCG is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in urine as early as 7 to 10 days after conception. This test qualitatively detects the presence of hCG in urine at the sensitivity of 10mIU/mL. The test uses a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The specimen migrates via capillary action along the membrane to react with the coloured conjugate. Positive specimens react with the specific antibody- hCG coloured conjugate to form a coloured line at the test line region of the membrane. Absence of a coloured line suggests a negative result. A procedural control line should appear in the control line region indicating that the proper volume of specimen has been added and the membrane wicking has occurred.

7.2 Hazards and safety precautions

Handle all human and animal products as potentially hazardous.

REAGENTS	Product Number	Data Sheet	COSHH Code	Hazards
Test device	INV-FHC-U102	DOC143	RC-400-003	Non-hazardous
Positive control	DPT-101-5	DOC915	RC-400-030	Non-hazardous

7.3 Specimen requirements and means of identification

- Preferably an early morning concentrated urine.
- Collected into a plain sterile urine bottle, **NOT** one containing Boric Acid or other preservative.
- If sample is not in a laboratory issue plain container it should not be tested.
- If specimen is very turbid or blood stained either allow settling, using only clear urine above any sediment for the test procedure or send specimen to the laboratory for centrifugation and testing.
- Samples for testing should be at Room Temperature (15^0 – 28^0C).

7.4 Calibration

The test has been standardised to the W.H.O 4^{th} international standard (WHO STD.REF 75/589)

7.5 Procedure / instructions for performance of the test

- Bring samples and test device to room temperature.
- Open one sachet per patient
- Set timer for 3 minutes, start the timer when the patient's urine has been dropped onto test device.
- Hold the dropper vertically and transfer 3 drops of patient's urine slowly into sample well of appropriate test cassette, using transfer pipette supplied in each pack (avoid trapping air bubbles in the specimen well)
- Read the test at 3 minutes. Do not interpret after 10 minutes.

7.6 Interpretation of Results

Negative: If one red line appears in the Control (C) line region with no band seen in the Test (T) line region this is a negative.

Positive: If two red lines appear, one in the Control (C) line region and one in the Test (T) line region this is a positive result.

Invalid: If no lines appear, or a Test line appears without a Control line the device reagents may have deteriorated or the test may not have been performed correctly.

The presence of a Control Band is necessary to validate test performance. Repeat the sample with a new device.

7.7 Limitations / pitfalls of the examination

- This test is a qualitative test; therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
- Very dilute urine samples may not contain representative levels of hCG. An early morning urine specimen should be tested
- Very low levels of hCG (<50mIU/mL) are present in urine samples shortly after implantation. However, as a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with an early morning sample 48 hours later.
- False positives may occur in trophoblastic disease and in certain non-trophoblastic neoplasm's including breast cancer, and lung cancer.
- False negatives may occur when the levels of hCG are below the sensitivity level of the test.
- The test provides a presumptive diagnosis for pregnancy. A physician should only make a confirmed pregnancy diagnosis after all clinical and laboratory findings have been evaluated.

7.8 Performance criteria

- Sensitivity: of this test is >99.9% (manufacturers data).
- Specificity: The test has no cross-reactivity with human LH, TSH or FSH (manufacturer data).
- Interference: No interference with the expected results was observed from any of the following substances at the indicated concentrations:

Acetaminophen 20mg/dL
Caffeine 20mg/dL
Ascorbic acid 20mg/dl
Glucose 2g/dL
Atropine 20mg/ml
Ampicillin 20mg/d
Haemoglobin 1mg/dL
Albumin 20 mg/ml
Gentisic Acid 20mg/dL
Acetylsalicylic Acid 20mg/Dl
Tetracycline 20mg/dl

7.9 Recording of results

7.9.1 The patient result should be entered into the Pregnancy Test Logbook completing all the information columns [Date, patients surname, patient's first name, D of B or hospital number, test result, signature of person performing the test, Printed name & kit batch number].

7.9.2 The result should also be recorded in the patient's notes.

7.9.3 Once the test is complete and any required checks undertaken the samples and Pregnancy test devices should be discarded into the Clinical waste bin.

8.0 Quality control procedures

8.1 Test control position

East test cassette has a control line © region – it is important to check that a coloured line has appeared in the control position. If no lines appear, or a Test line appears without a Control line the device reagents may have deteriorated or the test may not have been performed correctly. The presence of a Control line is necessary to validate test performance.

8.2 External quality assessment (NEQAS Samples)

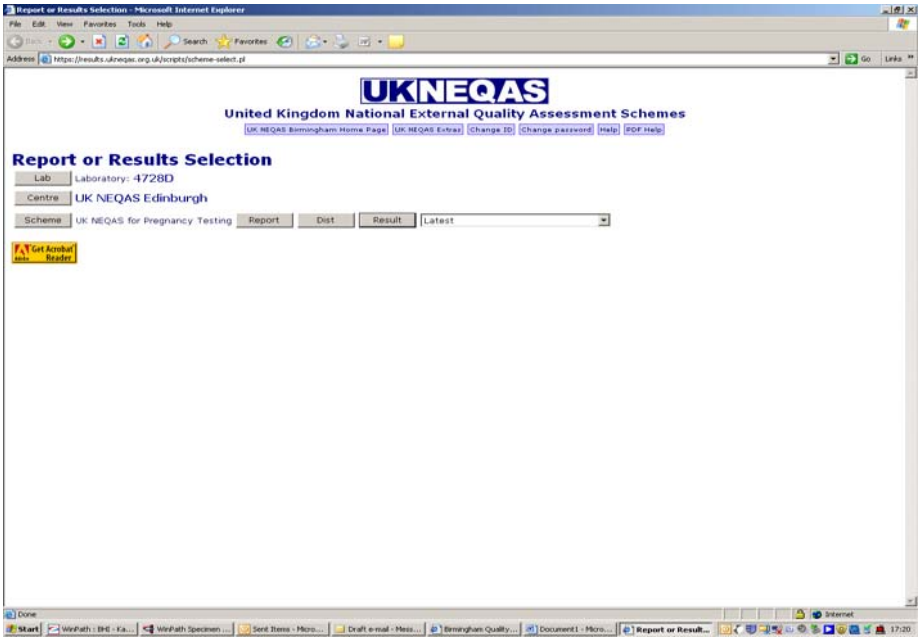
It is a CPA requirement that all examinations are subjected to external quality assessment. The Trust has committed to evidence compliance by registering all POCT testing sites with the UK NEQAS scheme

NEQAS samples for Pregnancy Testing are sent out every month and samples are distributed to the POCT sites by the Immunology Department

The results are returned electronically using the website https://results.ukneqas.org.uk as described in section 9.0.

9.0 Returning/ Entering Results electronically

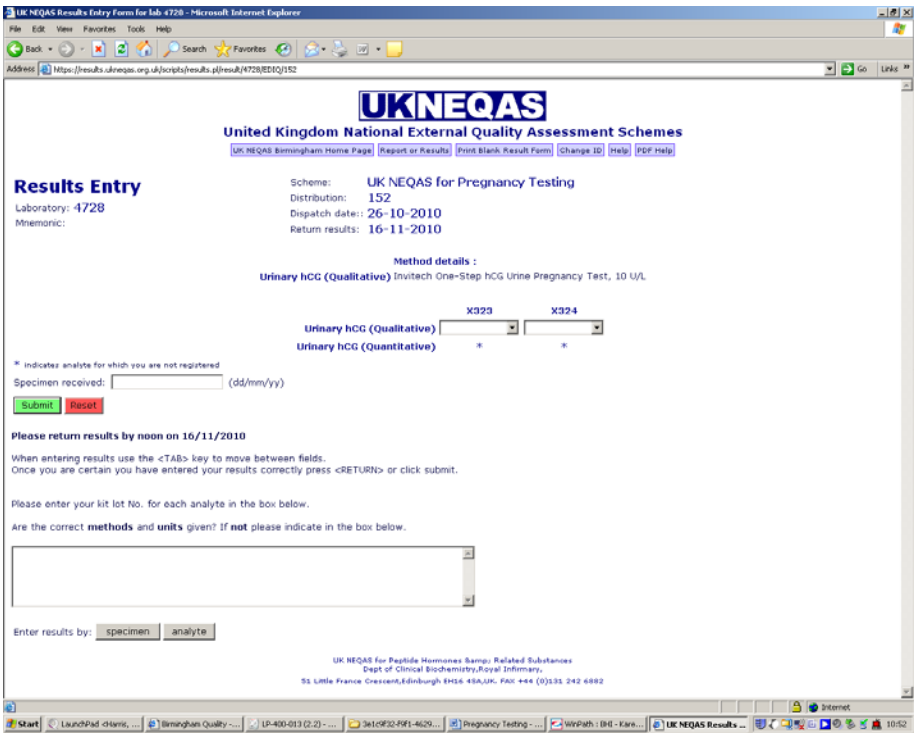
- The website address is https://results.ukneqas.org.uk.
- On the first page you will be asked for your user name and password these have been issued to each POCT site performing pregnancy tests
- Once the lab code and password have been accepted, the first page displayed will be similar to the one shown below



- The report button allows you to download a report from a previous distribution. Select the distribution number first before clicking Report.

- You can now enter results by clicking on the results box for the scheme you require i.e. Pregnancy testing. The distribution selector automatically defaults to latest. Therefore you should not need to change this.

- The next page displayed can be seen below



- Enter each result into the appropriate field using the drop down menu below the sample numbers. Select Positive, Negative or equivocal. To move to the next field click into it using the mouse

- Enter the date of receipt of the specimens in the format dd/mm/yy.

- The comments area can be used to free text a message if required. Enter the kit lot number in this box

- When you are happy with the entries click the submit button. **If you exit the page without submitting using the submit button your results will be lost.**

- If submit is successful you will see a page which confirms the submission.

- Results must be submitted by the closing date. After that date it will not be possible to submit your results.
- If you have any problems you can contact Immunology on ext 4139.

10.0 Audit and Compliance Monitoring

10.1 The following aspects of compliance will be monitored by the Immunology Laboratory on a monthly basis and audited on a yearly basis:

- Performance and result returns of monthly NEQAS samples
- 6-monthly competency checks as detailed under the training section for all designated trainers from each of the clinical areas authorised to perform pregnancy POCT
- Monthly Ward/Clinical area visit to check security of Pregnancy POCT log book, performance/recording of monthly NEQAS and log book records for patient testing.
- Receipt of a copy of the signed list of staff authorised to perform the pregnancy testing following the 6-monthly competency checks as required evidence for the Pathology CPA and Trust CQC and NHSLA inspections.

10.2 **Incorrect NEQAS result returned or non submission of NEQAS result**

If an incorrect NEQAS result is returned or if a NEQAS result has not been submitted the laboratory will initiate the following actions/communication procedures detailed in the flowcharts in Appendices 1 & 2

11.0 Communication & Implementation

11.1 The policy will be available to Healthcare professionals on the Trust's intranet site.

11.2 The policy will be launched in the Trust's Staff Focus newsletter.

11.3 The policy will be sent to all Clinical Directors and Corporate Nursing for information and dissemination amongst their teams.

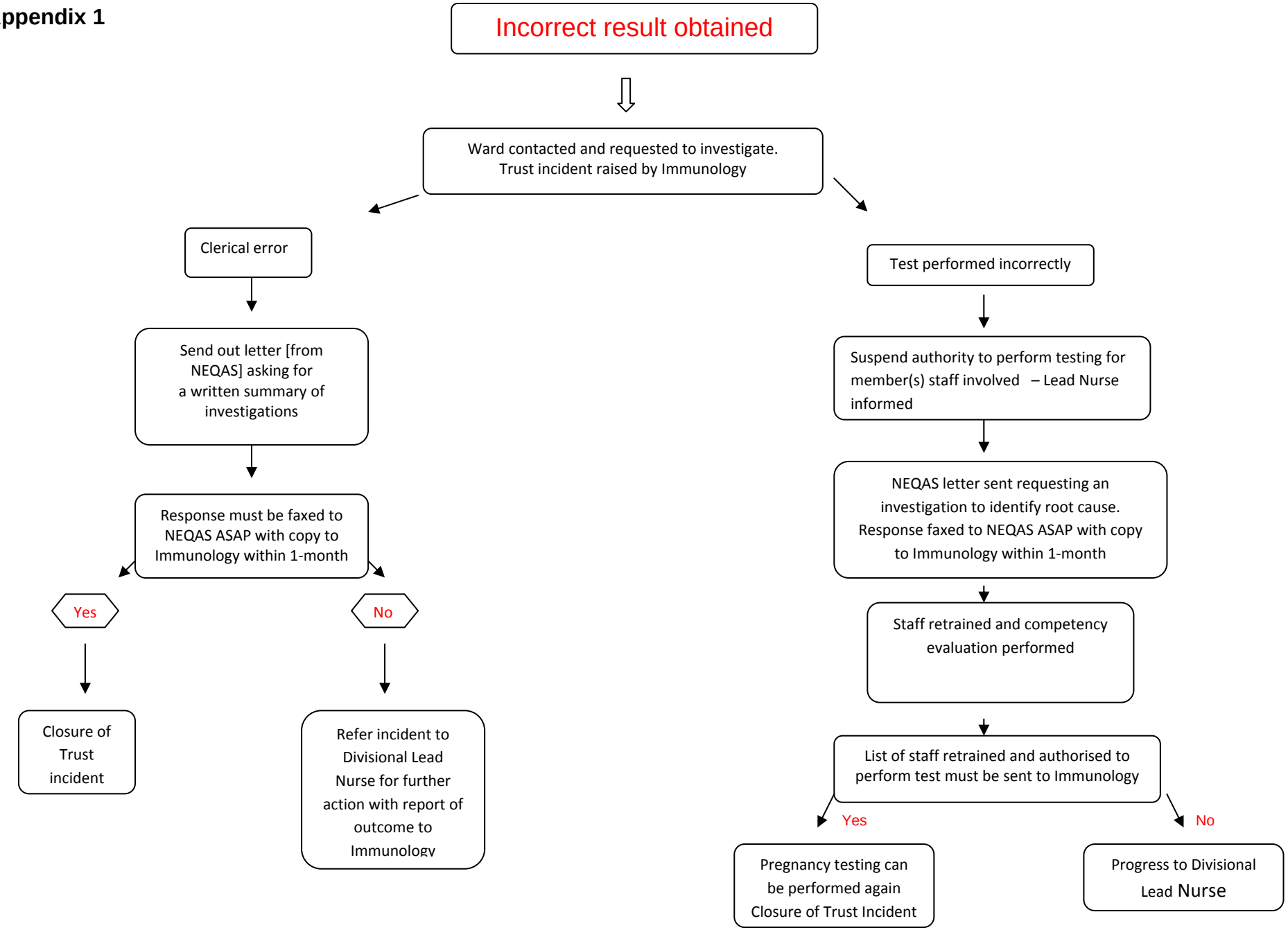
12.0 Review

This policy will be reviewed every two years or earlier in response to incident management, local changes or a change in kit supplier.

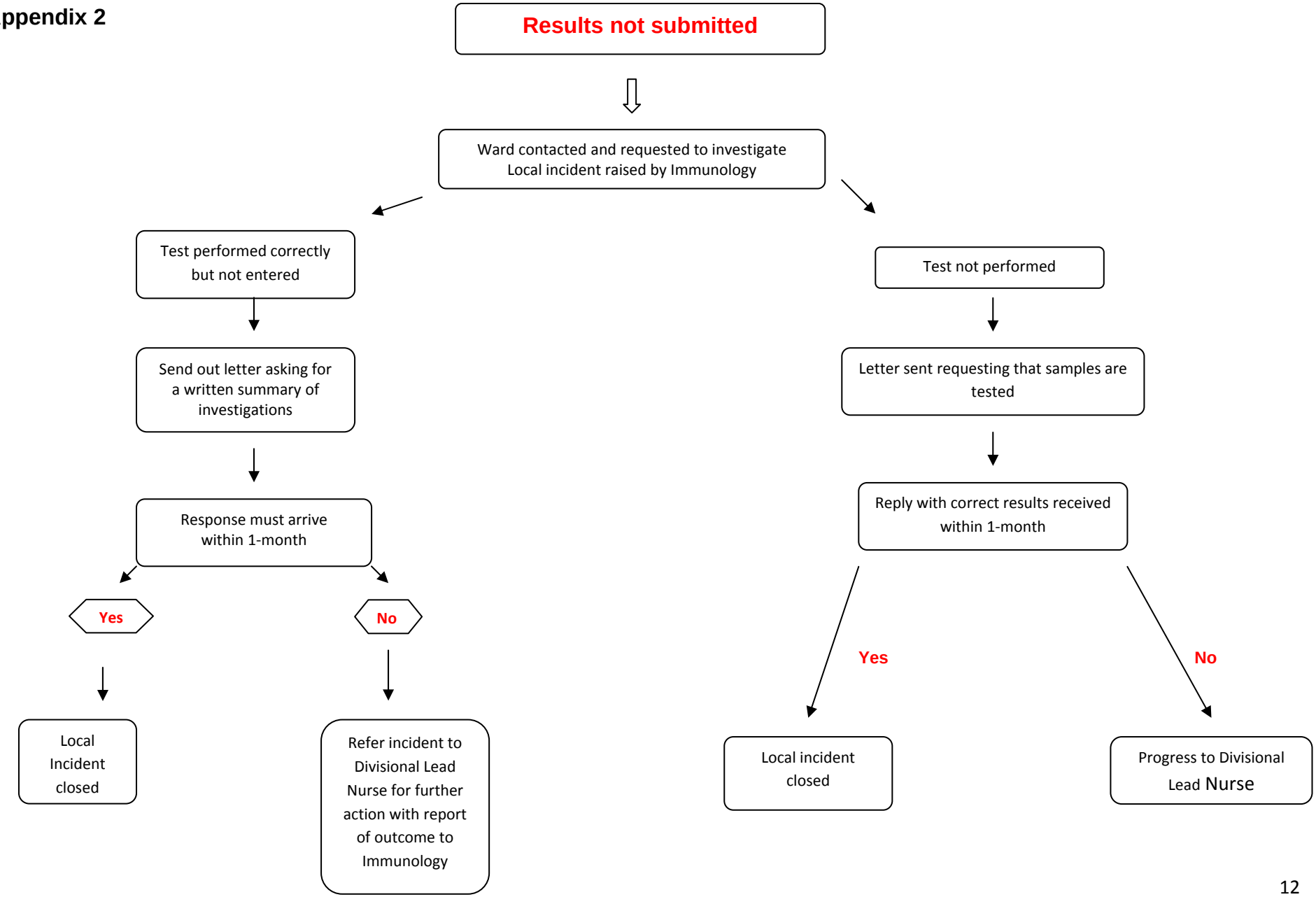
13.0 References

- Batzer FR. Hormonal evaluation of early pregnancy, Fert. Steril. 1980: 34(1): 1-13
- Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross Ectopic production of human chorionic gonadotropin by neoplasm's, Ann. Intern Med. 1973 : 78(1):39-45.
- Serum human chorionic gonadotropin levels throughout normal pregnancy AM. J. Obstet. Gynecol 1976 126 (6): 678-681
- Test instruction booklet – provided in the kit box

Appendix 1


Incorrect result obtained
Ward contacted and requested to investigate.
Trust incident raised by Immunology
Clerical error
Send out letter [from NEQAS] asking for a written summary of investigations
Response must be faxed to NEQAS ASAP with copy to Immunology within 1-month
Yes
No
Closure of Trust incident
Refer incident to Divisional Lead Nurse for further action with report of outcome to Immunology
Test performed incorrectly
Suspend authority to perform testing for member(s) staff involved – Lead Nurse informed
NEQAS letter sent requesting an investigation to identify root cause. Response faxed to NEQAS ASAP with copy to Immunology within 1-month
Staff retrained and competency evaluation performed
List of staff retrained and authorised to perform test must be sent to Immunology
Yes
No
Pregnancy testing can be performed again Closure of Trust Incident
Progress to Divisional Lead Nurse

Appendix 2


Results not submitted
Ward contacted and requested to investigate
Local incident raised by Immunology
Test performed correctly but not entered
Send out letter asking for a written summary of investigations
Response must arrive within 1-month
Yes
No
Local Incident closed
Refer incident to Divisional Lead Nurse for further action with report of outcome to Immunology
Test not performed
Letter sent requesting that samples are tested
Reply with correct results received within 1-month
Yes
No
Local incident closed
Progress to Divisional Lead Nurse

Appendix 3: Nursing Competency for the performance of Pregnancy POCT

Name: **Date:** **Clinical Area:**

POCT: Urinary Pregnancy test	Initial self assessment	Date to be achieved by	Date achieved	Signature of Trainer	Staff member signature
Understands the test principle					
Ensures adherence to infection prevention measures throughout testing procedure					
Obtains a suitable urine sample for testing and is aware of the sample requirements/limitations					
Performs the test to required standard as outlined in the policy					
Understands the importance of quality control and undertakes NEQAS quality control tests on receipt of test samples from laboratory					
Checks that a control line is evident on each test and knows what to do if problems arise.					
Is aware of the logbook requirements and accurately records results in patients notes and logbook					
Is able to enter and return NEQAS results electronically					
Is aware of test of test limitations as outlined in the policy					
Is aware of the communication procedure followed by the laboratory should an incorrect NEQAS result be returned					
Is aware of the communication/procedure followed by the laboratory should a NEQAS result not be returned					