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Summary of Significant Changes at this Revision

Update to include new test instructions around dipping time and reading time.
 Plus additional interferences.

<p>Purpose and Scope</p> <p>The One Step Pregnancy Test urine test strip is a rapid chromatographic immunoassay for the qualitative detection of hCG in urine (urine pregnancy test).</p>	<p>Items Required</p> <ol style="list-style-type: none"> 1) One Step Pregnancy Test strip containing a combination of antibodies, including a monoclonal hCG antibody 2) Specimen collection container 3) Timer 4) OneStep Urine Pregnancy Testing Results Log - (see Appendix 1)
<p>Definitions and Abbreviations</p> <p>POCT = Point of care testing hCG = human chorionic gonadotropin QC = Quality Control EQA = External Quality Assurance QMS = Quality Management System</p>	<p>Grade / Qualifications Required</p> <p>Nursing Staff - All trained operators Health Care assistants - All trained operators Medical Staff - All trained operators Biomedical Scientists - All trained operators Supervised Trainee BMS staff</p> <p>Competencies Required Current Version of: FM/POCT/24 – POCT Competence/One Step HCG Urine Pregnancy Test Strip</p>

Risk Assessment:
Current Version of: RA/POCT/20 Urine Pregnancy Testing – this can be found on the POCT intranet page

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This test must **ONLY** be performed by trained and competent staff. Competency sheets can be found on the intranet under:

Pathology > Point of Care Testing (POCT) > SOPs for POCT Users

Completed competencies must be signed by a link trainer and will require renewing every two years.

1. Reagents

Test strips are comprised of colloidal gold coated with anti β -hCG antibody; NC membrane coated with mouse anti α -hCG antibody and rabbit anti mouse IgG. Test strips are supplied by the RUH pharmacy.

2. Reagent Storage

Store kit at 2 – 30°C

The test kits should be kept away from direct sunlight, moisture and heat.

3. Reagent Stability

Test strip stable until the expiration date printed on sealed pouch.

Test strip must remain sealed in foil package until use.

Do not freeze.

4. Quality Control (QC)

A procedural QC is included in the test. A red line appearing in the Control region is the internal procedural QC. It confirms correct urine volume and correct procedure were used.

5. Specimen Collection

Urine must be collected into a clean dry container.

First morning urine preferred as it is most concentrated, but urine collected anytime of the day can be used. Please see **Section 11 - Limitations**.

Urine can be stored at 2 – 8°C up to 48 hours prior to testing. The specimen must be at room temperature before testing.

Urine specimen can be frozen and stored below -20°C. Ensure sample is thawed, at room temperature and mixed before testing.

6. Method

- 1) Ensure urine specimen and test strips are at room temperature (15 – 30°C).
- 2) Remove the test strip from the protective pouch and use the strip immediately.
- 3) Immerse the test strip **tip** vertically, with arrows pointing down, into the urine sample for **at least 15 seconds**.
- 4) **DO NOT** allow the urine level to go above the **MAX** (maximum) level line (marked by arrows) on the test strip.
- 5) Remove the strip from the urine and place the strip on a clean dry surface.
- 6) Set the timer for **3 minutes**.
- 7) Read the strip at 3 minutes. **N.B.** Positive results may be apparent before 3 minutes have elapsed, but a negative result can only be confirmed after 3 minutes, when the background is clear.
- 8) **Do not** read the test strip after 10 minutes as the test will be invalid.
- 9) Discard the test strip and urine sample after testing – treat as biohazard waste.
- 10) **N.B. If insufficient sample has been collected** to carry out the test, then a repeat sample should be collected – and this must be recorded in the patient's notes – and recorded as an incident in Datix if appropriate.
- 11) **If unable to obtain a urine sample for analysis** – a serum sample should be sent to the lab for hCG analysis

7. Interpretation and Reporting of Results

7.1 Positive Result

Two red lines will appear; one in the Control region and one in the Test region. Please refer to the diagrams on the test pouch for an illustration of a positive result.

A very faint line in the Test region must be taken as a positive result.

7.2 Negative Result

A red line on the Control region **only** indicates a negative test.

7.3 Invalid Result

- 1) The absence of any lines indicates the test has failed. Repeat using a new test strip.
- 2) A red line that appears in the Test region only, i.e. there is no control line, indicates the test has failed. Repeat using a new strip.

N.B. Stop using the test strips if the second test also fails.

7.4 Reporting Results

Test results should be written in two places:

1. Patient notes
2. Urine Pregnancy Testing Results Log (Appendix 1)

The following items must accompany the test result:

- 1) QC line observed
- 2) Test strip lot number
- 3) Test strip expiry date
- 4) Signature of person carrying out test and transcribing result

A patient results sticker (Appendix 2) can be filled in and stuck in the patient notes to assist with transcribing all the above information.

8. Sensitivity

The test strip will give a positive result if the hCG concentration in the urine is greater than 25 mIU/mL.

9. Accuracy

Comparison studies on the One Step HCG Urine Pregnancy Test with a legally marketed device were performed by the company and in a clinical reference laboratory. Positive and negative results were compared and the correlation was >99.5%

10. Interferences

Alcohol may interfere with the test result as well as hCG containing drugs (Pregnyl, Profasi, Pergonal, APL).

11. Limitations

- 1) The test strip should be read at exactly 3 minutes.
- 2) Alcohol consumption may interfere with the test result as well as hCG containing drugs (Pregnyl, Profasi, Pergonal, APL).
- 3) False negative results may occur if testing is done too early, (hCG levels may be below the sensitivity levels of the test) – repeat test 48 hours later with an early morning urine sample.
- 4) False negative results may occur if the urine specimen is very dilute (hCG levels are below the sensitivity levels of the test) - repeat test 48 hours later with an early morning urine sample.
- 5) Possible false positive results may be obtained several weeks post normal/caesarean delivery and post spontaneous/therapeutic abortion.
- 6) Very high levels (>500,000 mIU/ml) may give false negative results due to a 'Prozone' effect. If pregnancy is suspected, but the result is negative, a serum sample should be sent to the lab for hCG analysis.
- 7) Elevated levels of hCG are also seen in: trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumours, prostate cancer, breast cancer and lung cancer.

12. External Quality Assurance (EQA)

- EQA samples are distributed to all RUH departments enrolled in the Urine Pregnancy WEQAS EQA scheme (as per SOP/POCT/47 – Urine Pregnancy EQA)
- A set of 3 EQA samples is distributed every 2 months by POCT – along with a results return sheet
- The samples must be analysed as per the patient testing method described in this SOP
- The results should be entered on the return sheet and returned to POCT (B38) as soon as possible
- EQA performance is assessed retrospectively by WEQAS, as the results are not known at the time of distribution.
- The results are compared to those of other hospitals carrying out urine pregnancy testing, (using the same and different methods), and this gives an indication of the accuracy of the RUH performance.

13. C.O.S.H.H

Discard urine and all other test related materials as biohazard - as per the RUH Trust Policy: Policy & Procedure for the Management and Disposal of Waste

14. References

- 1) Package insert: - One Step Pregnancy Test, Hangzhou AllTest Biotech Co., Ltd., China.

Copy number	Location held
1	On the intranet POCT page
2	Children's Ward

PREGNANCY TEST

Time:
Date:
Patient:
MRN:
Consultant:
Strip lot:
Strip Expiry Date:
Test result: NEGATIVE Positive
Quality control Line present:
Signature:

PREGNANCY TEST

Time:
Date:
Patient:
MRN:
Consultant:
Strip lot:
Strip Expiry Date:
Test result: NEGATIVE Positive
Quality control Line present:
Signature:

PREGNANCY TEST

Time:
Date:
Patient:
MRN:
Consultant:
Strip lot:
Strip Expiry Date:
Test result: NEGATIVE Positive
Quality control Line present:
Signature:

PREGNANCY TEST

Time:
Date:
Patient:
MRN:
Consultant:
Strip lot:
Strip Expiry Date:
Test result: NEGATIVE Positive
Quality control Line present:
Signature:

PREGNANCY TEST

Time:
Date:
Patient:
MRN:
Consultant:
Strip lot:
Strip Expiry Date:
Test result: NEGATIVE Positive
Quality control Line present:
Signature:

PREGNANCY TEST

Time:
Date:
Patient:
MRN:
Consultant:
Strip lot:
Strip Expiry Date:
Test result: NEGATIVE Positive
Quality control Line present:
Signature: