URINARY PREGNANCY TESTING - CLINICAL GUIDELINE

1. **Aim/Purpose of this Guideline**
   1.1. To ensure that urinary pregnancy testing at the point-of-care is performed safely and consistently.
   1.2. To minimise risk to patients from the errors that may occur from using these devices incorrectly.

2. **The Guidance**

   2.1 **Introduction and Intended Use**

   2.1.1 Human chorionic gonadotrophin (hCG) normally begins to be detected in urine from 7-10 days after conception, reaching a level around 100 mIU/mL on the first day of the missed period. In early pregnancy hCG levels double every 36 - 48 hours.

   2.1.2 The hCG One Step Pregnancy Test Device (SureScreen Diagnostics Ltd) is a rapid chromatographic immunoassay for the qualitative detection of hCG in urine to aid in the early detection of pregnancy.

   2.1.3 A result is obtained at **3 minutes** post sample application and provided the testing procedure is correctly followed then hCG concentrations as low as 25 mIU/mL can be detected in urine. This kit is recommended for use throughout RCHT.

   2.2 **Indications**

   2.2.1 Suspected ectopic pregnancy. It is essential to test in any female of reproductive age who complains of abdominal pain whether or not she has missed a period or had abnormal vaginal bleeding.

   2.2.2 Patients requiring clinical imaging who may be pregnant.

   2.2.3 Prior to laparoscopic sterilisation if the date of the LMP is vague.

   2.2.4 Women attending GUM or contraception clinics where appropriate.

   2.2.5 Before testing, a full history including LMP and current contraceptive history should be taken. Patient informed consent should be obtained with reference to the Trust’s consent policy.

2.3 **Staff Training**

   2.3.1 Staff using pregnancy kits must have received training by the Pregnancy Testing key trainer for the ward, Clinical Chemistry POCT staff.

   2.3.2 An alternative option for training is e-learning on the RCHT Competencies Module [http://etrain.cornwall.nhs.uk/](http://etrain.cornwall.nhs.uk/), select SURESCREEN KIT to run the pregnancy test session.
2.4 Ordering Kits & Storage

2.4.1 Pregnancy kits are ordered through the Pharmacy Department at Treliske.

2.4.2 Store kits in their sealed pouches at room temperature or refrigerated (2-30°C).

2.4.3 If a kit has been refrigerated it must reach room temperature prior to usage.

2.4.4 Kits should not be used after the expiry date printed on the sealed pouch.

2.5 Sample Collection and Storage

2.5.1 A first morning specimen is the sample of choice, however a sample collected at any time of day is suitable.

2.5.2 Collect sample into a dry clean pot containing no preservative and labelled with the patient's identification details.

2.5.3 Samples containing visible precipitates must be allowed to settle before testing.

2.5.4 Samples not to be tested within 2 hours of collection should be stored in the fridge for a maximum of 48 hours. If refrigerate samples must be allowed to reach room temperature prior to testing.

2.6 Test Procedure

2.6.1 Ensure the lighting in the room is sufficient to easily read the device results.

2.6.2 Check that both the sample and kit are at room temperature if have been previously refrigerated.

2.6.3 Check the urine sample is fully labelled with patient identification.

2.6.4 Remove device from the sealed pouch.

2.6.5 Label the device with patient identification information.

2.6.6 Place the device on a clean flat surface.

2.6.7 Using the transfer pipette supplied with the pouch, transfer 3 full drops of urine (100ul) to the sample well (S).

2.6.8 Read test result at 3 minutes after applying the urine sample, not before.
2.7 **Interpretation of Results**

2.7.1 **POSITIVE** Two coloured lines appear, one in the control region (C) and one in the test region (T). *Please note if the test (T) line is faint this is still a positive result.*

2.7.2 **NEGATIVE** One coloured line appears in the control region (C) and no line appears in the test region (T).

2.7.3 **INVALID** No line appears in the control region (C). Discard cassette and retest, regardless of whether a line appears in the test region (T).

2.7.4 *Reading of the result from the device must be done by a trained user AND confirmed by a second trained user.* This is to ensure correct reading and interpretation of the result.

2.7 **Recording Results**

2.7.1 All results are to be recorded in the patient’s notes and the ward HCG log book also be completed (see appendix 1).

2.8 **Sources of Error**

2.8.1 **Sample contaminated** e.g. boric acid collection pot used, bacteria, cleaning agent.

2.8.2 **Incorrect storage**: samples must be tested within 2 hrs of collection, if not, refrigerate sample.

2.8.3 The most likely cause of a **false positive** result is user error by incorrect interpretation of test windows. An evaporation line in the test window can develop if the test is read after the maximum read-time of 10 minutes.

2.8.4 Causes of an analytical **false negative** result include incorrect interpretation of test windows, incorrect timing of test (reading too early), incorrect pipetting procedure, insufficient sample, bubbles in the sampling area, kits expired, kits stored incorrectly

2.9 **Limitations of Test**

2.9.1 Positive results from early pregnancy may later prove negative due to natural termination. Retest weak positive results with a first morning urine 48 – 72 hours later.

2.9.2 A negative result may be obtained if the urine sample is dilute. If pregnancy still suspected then retest with a first morning urine 48 – 72 hours later.

2.9.3 hCG remains elevated for 3 weeks after giving birth and 9 weeks after natural loss or termination. These cases may require further evaluation.

2.9.4 A number of conditions other than pregnancy can cause elevated levels of urinary hCG e.g. menopause, trophoblastic disease and certain non-trophoblastic neoplasms.

2.9.5 False positive/negative results may be observed in patients with abnormal kidney or bladder function.
2.9.6 Inconsistent results may be obtained if the urine sample contains excessive amounts of bacteria.

2.9.7 A negative result does not rule out pregnancy, this is due to the lag between conception and the appearance of hCG in the urine.

2.9.8 Test not intended to detect conditions other than pregnancy, it cannot determine if the pregnancy is viable/ectopic.

2.9.9 If there is any doubt about the validity of a reading, or where the patient's clinical condition does not correspond to the result, then a sample should be sent to the laboratory for analysis.

2.10 Quality Assurance

2.10.1 All staff should be made aware of quality assurance in accordance with Trust’s POCT Guidelines. The scheme is co-ordinated by the Clinical Chemistry POCT team and requires the testing of 3 samples bi-monthly. All results must be returned to the POCT team who will submit the data to the National scheme whereby individual performance can be compared to all users of the same kit.

2.10.2 Performance is reported back to the Ward Manager, with any consistently poor performance resulting in re-training. It is essential for all locations performing pregnancy testing to take part in this scheme and failure to do so will result in kits being removed from the ward.

2.11 References:


- Surescreen Diagnostics Ltd Pregnancy Test Cassette Package Insert Feb 2012


- Royal Cornwall Hospitals Trust (2014), Point of Care Testing policy

- Royal Cornwall Hospitals Trust, (2002), Policy for Consent to examination or Treatment
### Appendix 1: Example of the recommended format for Ward Results Log Sheet

**PREGNANCY (HCG) TESTING RESULT LOG FOR WARD**

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient Name</th>
<th>NHS Number</th>
<th>Kit Batch Number</th>
<th>Expiry Date</th>
<th>Result</th>
<th>Test Operator</th>
<th>Result Checker</th>
</tr>
</thead>
<tbody>
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3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Quality</th>
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<tbody>
<tr>
<td>Lead</td>
<td>Dr Anthea Patterson / Helen Hobba</td>
</tr>
<tr>
<td>Tool</td>
<td>External Quality Assurance Monitoring</td>
</tr>
<tr>
<td>Frequency</td>
<td>Bi-monthly</td>
</tr>
</tbody>
</table>

Reporting arrangements
- Reports will be feedback to Ward Managers
- Persistent poor performance will be feedback to Matrons and Datix

Acting on recommendations and Lead(s)
- Trust’s point-of-care testing committee will monitor performance and undertake subsequent recommendations and action planning.

Change in practice and lessons to be shared
- Practice changes be implemented via training, e-learning, and via communication with all relevant stakeholders

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

4.2. Equality Impact Assessment
The Initial Equality Impact Assessment Screening Form is at Appendix 2.
# Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Urinary Pregnancy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>16th October 2014</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>January 2014</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>January 2017</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Helen Hobba / Clinical Chemistry</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 25 2556</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Operating Instruction for use of Urinary Pregnancy Testing Devices at the point-of-care.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Surescreen, βhCG, Pregnancy test</td>
</tr>
<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Dr Anthea Patterson</td>
</tr>
<tr>
<td>Date revised:</td>
<td>October 2014</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Urinary Pregnancy Testing</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Obstetrics &amp; Gynaecology Directorate Meeting</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Sheena Wallace</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>'Not Required'</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td>Document Library Folder/Sub Folder</td>
<td>e.g. Clinical / Gynaecology</td>
</tr>
<tr>
<td>Links to key external standards</td>
<td>Governance Team can advise</td>
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</table>
Surescreen Diagnostics Ltd Pregnancy Test Cassette Package Insert Feb 2012
Royal Cornwall Hospitals Trust (2014), Point of Care Testing policy
Royal Cornwall Hospitals Trust, (2002), Policy for Consent to examination or Treatment

Training Need Identified? Yes

Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<tr>
<td>14th March 2012</td>
<td>V1</td>
<td>Original Version</td>
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</tr>
<tr>
<td>16th October 2014</td>
<td>V2</td>
<td>Pre Op guideline</td>
<td>Ms Lisa Verity Consulting for Obstetrics and Gynaecology</td>
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All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document
This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.
Appendix 2. Initial Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed (hereafter referred to as policy) (Provide brief description):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate and service area: Obstetrics and Gynaecology</td>
</tr>
<tr>
<td>Name of individual completing assessment: Lorraine Sole</td>
</tr>
<tr>
<td>Telephone: 01872 25 3120</td>
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</tbody>
</table>

1. Policy Aim*  
Who is the strategy / policy / proposal / service function aimed at?  
All clinical staff working in RCHT who will have to undertake urinary pregnancy testing as part of their role

2. Policy Objectives*  
As above

3. Policy – intended Outcomes*  
As above

4. *How will you measure the outcome?  
See section 3

5. Who is intended to benefit from the policy?  
All patients attending RCHT requiring a urinary pregnancy test

6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?  
No

b) If yes, have these groups been consulted?  

C). Please list any groups who have been consulted about this procedure.

7. The Impact  
Please complete the following table.

Are there concerns that the policy could have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Sex (male, female, transgender / gender reassignment)</td>
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<td>X</td>
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</tbody>
</table>

Clinical Guideline Template
### Race / Ethnic communities /groups
- X

### Disability -
- learning disability, physical disability, sensory impairment and mental health problems
- X

### Religion / other beliefs
- X

### Marriage and civil partnership
- X

### Pregnancy and maternity
- X

### Sexual Orientation,
- Bisexual, Gay, heterosexual, Lesbian
- X

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended. Yes No X

9. If you are not recommending a Full Impact assessment please explain why.

<table>
<thead>
<tr>
<th>Signature of policy developer / lead manager / director</th>
<th>Date of completion and submission</th>
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<table>
<thead>
<tr>
<th>Names and signatures of members carrying out the Screening Assessment</th>
<th>1. Lisa Verity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Helen Hobba</td>
</tr>
<tr>
<td></td>
<td>3. Lorraine Sole</td>
</tr>
</tbody>
</table>

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ____________________

Date ____________________