Pregnancy Test Using SureStep One Step Pregnancy Test

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Changes from last version of this document

First entry to Q-pulse

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1 Purpose and Principle

Human chorionic gonadotrophin (hCG) is a glycoprotein hormone, which is produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The hCG One Step Pregnancy Test Device (urine) is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. AT the level of claimed sensitivity, the hCG One Step Pregnancy Test Device (urine) shows no cross-reactivity interference from the structurally related glycoprotein hormone hFSH, hLH and hTSH at high physiological levels.

The hCG One Step Pregnancy Test Device (urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotrophin in urine to aid in the detection of early pregnancy.

2 Patient Preparation & Sample Requirements

The urine sample must be collected into a clean dry container without preservatives. Specimens collected at any time of day may be used, but the first urine sample of the day usually contains the highest concentration of hCG and is therefore the sample of choice. Urine specimens exhibiting visible precipitants should not be used.

If the test is not to be done immediately the sample should be labeled with the patient's full name, DOB and NHS number and stored at 2-8 C for up to 48 hours. Before analysis the sample must be bought to room temperature.

3 Abbreviations and Definitions

Definition/ Abbreviation	Expansion/ Meaning
SHYPS	Scarborough, Hull, York Pathology Services
hCG	Human Chorionic Gonadotrophin
hFSH	Human Follicle-stimulating Hormone
hLH	Human Luteinizing Hormone
hTSH	Human Thyroid Stimulating Hormone
POCT	Point of Care Testing
EQA	External Quality Assurance

4 Tasks, Responsibilities and Authorisations

Tasks	Responsible	Authorised By
Patient Test	Trained Clinical Staff	POCT Senior
Analysis of External Quality Assurance Samples (EQA)	Trained Clinical Staff	POCT Senior
Troubleshooting	Trained Clinical Staff	POCT Senior

5 Equipment

Abbott SureStep pregnancy test kits are supplied by:

Abbott Rapid Diagnostics Limited
Pepper Road
Hazel Grove
Stockport
Cheshire
SK7 5BW
UK
+44 (0)161 483 5884

POCT supply kits to end users in the Trust upon receipt of completed SureStep audit sheets.

6 Chemicals and Reagents

The SureStep test strip comes in a sealed foil pouch and is stable until the expiry date when stored at 2-30°C. The Pouches **MUST NOT BE FROZEN.**

The test strips are obtained from POCT on production of a completed audit sheet. If any area has any issues with the test strips, please contact the POCT team on:

- York 772 5890
- Scarborough 771 2659
- Bridlington 771 3321

7 Risk Assessment (Environmental and Safety Controls)

For a full risk assessment please see PC-RA-YS-24

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be always followed during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk is mitigated as far as possible and or monitored with health surveillance to ensure health and safety for all those affected by this procedure.

8 Calibration

N/A

9 Quality Control

A procedural control line is included in the test. A coloured line appearing in the control line region (C) is considered an internal control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background colour appears in the result window and interferes with the ability to read the test result, the result may be invalid.

If the control line is missing the assay should be repeated with a fresh test strip, if the control fails to appear on repeat do not report the patients result. Contact the Point of Care Team on ext. 5890.

10 External Quality Assurance (EQA)

All areas are registered with WEQAS EQA scheme for urine hCG and samples are distributed every two months. The samples should be analysed immediately or stored at 4-8 C until analysed. The results should be recorded on the audit sheet and the return slip provided with the samples. Please return the results to the POCT office in York, Scarborough or Bridlington as soon as possible.

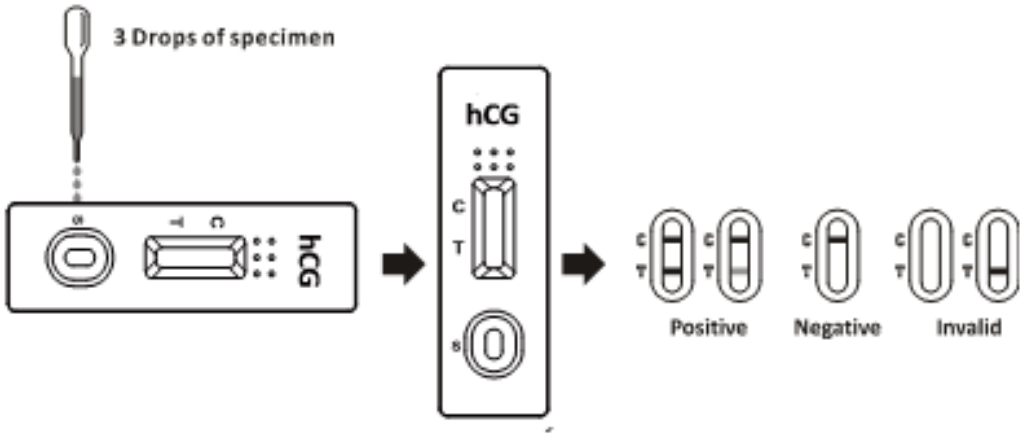
11 Procedural Steps

1. Collect a fresh urine sample in a universal container labelled with patient details and ensure it is at room temperature. Also collect a pregnancy test kit, timer and the audit sheet to fill in (PC/FOR/YS-10).
2. Remove the pregnancy test strip and dropper from the foil wrapper and place on a flat surface. Label the strip with the patient's name/NHS number.
3. Using the dropper provided dispense three full drops of urine into the round sample well
4. Set the timer for **three minutes**. Interpret the results between **3-4 minutes**.

   Do not interpret the results after four minutes.

12 Reporting of Results

To interpret the results please ensure that you are in good light. See below for interpretation guidance:



Ask a colleague to confirm your interpretation if you are in any doubt.

Please remember that a blood hCG sample to the laboratory can also be requested to confirm results.

All results (including invalid results) must be recorded in the patients' notes and on the Audit sheet provided (PC/FOR/YS-10). Failure to do so will result in the test kits being withdrawn.

Please note: This pregnancy test kit is particularly sensitive, therefore positive/equivocal results can appear as a very faint test line between 3-4 minutes. Please see the example External Quality Assurance sample below for a very faint positive/equivocal result:

13 Reference Intervals

The SureStep test for pregnancy can detect hCG concentrations of 25mIU/mL and greater

14 Performance Characteristics

See Section 15 below and the kit insert for additional details and performance characteristics (PC/IFU/YS-28).

15 Known Limitations

A few other conditions other than pregnancy can cause elevated levels of hCG, therefore the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.

- Trophoblastic disease
- Non-trophoblastic neoplasms
- Breast cancer
- Lung cancer

Normal pregnancy cannot be distinguished from an ectopic pregnancy and confusing results may be obtained in cases of spontaneous miscarriage.

hCG levels may remain detectable in patients several weeks post-delivery, spontaneous abortion, therapeutic abortion or hCG injections.

A faint-coloured line in the specimen zone indicates a positive result; however the result must be looked at in light of the possible clinical and physiological conditions, which may cause slightly elevated hCG levels. If such conditions exist, the patient should be retested 48 hours later.

Negative Results may be obtained if the urine sample is too dilute or hCG levels are below the sensitivity level of the test. If pregnancy is still suspected a second test should be carried out on an early morning urine 48 hours later or a blood sample should be taken (Brown topped gel tube) and sent to Clinical Biochemistry for a serum hCG.

For information on the accuracy and precision of these test kits please refer to the manufacturers insert One step Pregnancy test procedure provided with the test kits.

16 Related Forms/Templates and Documents

PC/RA/YS-24
PC/COM/YS-35
PC/COM/YS-36
PC/VV/YS-26
PC/FOR/YS-10

17 References

Abbott SureStep One Step hCG Pregnancy Test Kit Insert