Title: Urine hCG Procedure

Cross References: Urine hCG Training and Competency Record
Urine HCG Quality Control-Test Result Log
MGH POCT QC Storage Ordering and Documentation Guide
Urine HCG job aid

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Written by: Gino Pagnani Date: 5/22/03
Purpose

This document outlines policies and procedures that deal with urine hCG (pregnancy) testing. In an effort to be concise some information may be excluded from the manufacturer’s recommended procedure. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each package.

Scope

Level of Personnel: All RNs, NPs, PCAs, and MAs who have successfully completed initial training and maintained annual competency.

Testing Site: All sites approved and on file with the Pathology Service’s POCT Division

Policy and Procedure Statement

The Sure-Vue kit is utilized for pregnancy screening by qualitative detection of hCG in the urine. The test is only approved for use with urine specimens at the point of care and is considered a waived test.

Test Principle

The Sure-Vue Serum/Urine hCG STAT is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding serum or urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. The rapid test detects the presence of hCG at the sensitivity of 20 mIU/mL.

Regulatory Requirements

1. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

2. All test results must be maintained in patient records with all required information for four years

Required information:
   1. Patient’s name
   2. Medical Record Number
   3. Patient’s gender
   4. Patient’s age or date of birth
   5. Date & time test collected, performed and reported
   6. Ordering Physician
   7. Responsible physician (if not 6)
   8. Reference or Target Range
   9. Test Performed
   10. Test units
   11. Lab name

3. Additional information that must be retained for four years:
   1. Testing personnel records
2. Quality control results
3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
4. QC charts, maintenance sheets, reference and critical ranges

4. Other

1. Universal precautions must be observed when handling any patient specimen.
2. A physician’s order or standing order is required prior to performing test.
3. The Hospital Hand Hygiene policy must be adhered to at all times.

### Test Kits/Supplies

<table>
<thead>
<tr>
<th>Products</th>
<th>Distributor</th>
<th>Manufacturer #</th>
<th>PeopleSoft # or Fisher #</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traceable Instant-Recall Memory Timer</td>
<td>Fisher Scientific</td>
<td></td>
<td>Catalog #:02-401-7</td>
<td></td>
</tr>
<tr>
<td>Sure-Vue Serum/Urine hCG STAT</td>
<td>Owens &amp; Minor or Fisher Healthcare</td>
<td>Fisher 23900530</td>
<td>PS# 177431</td>
<td>Room Temp</td>
</tr>
<tr>
<td>Quantimetrix (Required QC product for Clinitek STATUS users): The Dipper UDC Set 6x15ml (Levels 1 and 2) QC</td>
<td>Fisher Healthcare</td>
<td>Quantimetrix Ref #1440-01</td>
<td>Vendor Item ID: NC9728698 Use Special Request tab to order. Add in comments: Give order to Fisher Onsite to process. Longest outdate please.</td>
<td>2 – 8°C: until manufacturer’s expiration date if unopened. Opened, 3 months or 20 dips. No room temp storage allowed.</td>
</tr>
<tr>
<td>Thermo Fisher Sentry Urine Controls</td>
<td>Fisher Healthcare</td>
<td>#URN5005</td>
<td>Fisher# 23 029-375 On campus testing sites should email MGH POCT Coordinator or page 35058 for controls. ALL OTHER SITES: Use Special Request tab to order. Add in comments: Give order to Fisher Onsite to process. Request the “longest outdate possible”.</td>
<td>2 – 8°C or 6 months at RT</td>
</tr>
</tbody>
</table>

### Critical Elements

1. Do not use kit beyond the expiration date.
2. Dispose of all test-devices in a proper biohazard container after testing.
3. Internal Procedural Controls must be documented with each test.
4. External Quality Controls must be performed and documented with each new box.
5. The test device should remain in the sealed pouch until ready for use.
6. This test has been approved for POCT sites using urine only (not serum) as the sample.
Specimen Collection

Specimens may be collected in any clean, dry, plastic container and labeled with two patient identifiers per hospital policy. The first morning urine specimen usually contains the highest concentration of hCG, and therefore, is the best specimen. Dilute specimens may not contain representative levels of hCG. If the test is to be analyzed within 24 hours after collection, the specimen should be stored in the refrigerator. Stored specimens should be brought to room temperature before analysis.

Test Procedure

1. **Follow hand hygiene protocol and put on gloves.**
2. Remove the test device from the protective pouch and place it on a flat dry surface. *(If a new box is opened, External QC must be performed. See Quality Control Procedure)*
3. Label test device with two patient identifiers.
4. Dispense three drops of specimen (approximately 100ul) into the round sample well. This amount of sample will fill the well. Wait for red lines to appear. Use only the transfer pipette included for each test. They are single use only.
5. Read results after 3 minutes and no later than 5 minutes. Positive results may be observed in as short as 30 seconds depending on the concentration of hCG. **READ UNDER DIRECT LIGHT TO AVOID INTERFERENCE OF SHADOWS IN THE T (TEST) AND C (CONTROL) WINDOWS.**
6. Document patient results and procedural controls on the appropriate chart.

Interpretation of Results

**Negative Results**

One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). The background should be clear and both procedural controls must be documented.

**Positive Results**

Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). Any line in the T (test) window should be considered positive. The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

**Invalid Results**

The test is invalid if a control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using that lot number of kit and call 1-800-637-3717 for technical assistance. Notify the POCT Coordinators at 617-726-1462 or 617-643-5392.

Documentation

The patient's results and the Performance monitor results must be recorded concurrently in one of the following manners:
1. in the patient’s record, or
2. on, urine pregnancy testing Quality Control / Test Result Log or
3. on another approved permanent record.

All records must be retained and retrievable for 4 years.

**Quality Control**

**Internal QC** - Each test device contains built-in procedural controls. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result. Both levels must be interpreted and documented with each test.

**External QC** - A negative and a positive external control must be analyzed whenever a new box of test kits is opened or whenever test pack is questioned. Results are recorded on the QC log along with lot #, expiration date, and operator’s initials. Record the following on the outside of the test kit box that was Quality Controlled: QC was acceptable, the date, and your initials.

**External QC Procedure (Each New Box)**

1. Remove one negative and one positive control vial from the refrigerator. The pair should always be from the same original lot. New vials should be initialed and labeled with the date opened. Allow the controls to reach room temperature before testing (this may take one hour). Note on QC product insert which control is normal or abnormal. Quantimetrix and Sentry controls are different!

2. Remove a test device from the pouch and place on a flat dry surface.

3. Gently swirl the contents of one of the QC vials to assure good mixing.

4. Dispense three drops of the control into the sample well. This should fill the well, but not overflow.

5. Interpret the results following the directions in the Interpretation of Results section above.

6. Repeat steps 2 - 6 with the second QC level.

7. If both the QC vials give expected results, remaining kits may be used for patient samples.

8. If either QC does NOT give expected results, repeat analysis.

9. If QCs again fail, repeat using new box of kits and/or new controls. Contact the manufacturer(s) or laboratory POCT Coordinators for assistance if new kit or controls fail the third time.

**Limitations of the Procedure**

1. A number of conditions other than pregnancy, including trophoblastic disease, and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer,
and lung cancer, cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.

2. False negative results may occur when levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

3. Detectable levels of hCG may remain several weeks following normal pregnancy, delivery by Caesarean section, spontaneous or therapeutic abortion.

4. Approximately one third of all conceptions end in natural termination. This may produce positive results when testing early in the pregnancy followed by negative results after the natural termination. Low positive results may be confirmed by retesting with a fresh first morning urine specimen collected 48 hours later.

5. This test provides a presumptive diagnosis for pregnancy. Clinicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.

6. Review package insert for other limitations and interferences.

**Expected Values**

Negative results are expected in healthy, non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine. The amount will vary with gestational age and between patients. Sure-Vue Serum/Urine hCG -STAT can detect hCG levels as low as 20 mIU/mL in urine.

**Training/Competency Assessment**

Competency is assessed after initial training and annually (within 365 days) using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user’s quality control performance is monitored.
4. Written testing specific to the method.

Operators that have not completed annual competency should not perform patient testing.
Clinical Pathology Laboratory Exercise at Harvard Medical School

Pregnancy Test:
An assay for human Chorionic Gonadotropin (hCG)

What the Test Measures
This test measures the concentration of a placental hormone, human chorionic gonadotropin, which is elevated in pregnancy.

Human chorionic gonadotropin (hCG) is a hormone secreted by the syncytiotrophoblast of the developing placenta. The appearance of a threshold hCG concentration in the urine or serum is used as a marker for pregnancy.

How the Test is Done
The urine hCG test kit used in this exercise is a qualitative (yes/no) assay. It is an immunoassay which utilizes both monoclonal and polyclonal antibodies to hCG.

The test device contains a sample well, a test ("T") window and a control ("C") window. Urine is added to the well, and hCG migrates through a membrane where complexes between hCG (if present) and anti-hCG antibodies are formed. If hCG is present, a line is developed by the dyes in the test kit in the test window. If hCG is not present, no line develops. A line should always develop in the control window, indicating that the reagents in the kit are working properly. Should no line appear in the control window, it is an indication that the testing apparatus or reagents are defective.

Common Clinical Situations in Which the Test is Used
- The urine hCG test serves as a qualitative (yes/no) determination of pregnancy as early as 10 days after a missed menstrual period.
- A positive test may also be an indication of the presence of an hCG-secreting tumor.
- Quantitative tests are also available. When a qualitative test is positive, a quantitative test can be used to measure the hCG level and date the pregnancy.
- hCG production begins within 24 hours of blastocyst implantation, which corresponds to about 8 days after conception or 3 weeks after the last menstrual period. By one day after implantation, the serum hCG is approximately 5 IU/L, which is detectable by most current laboratory-based hCG assays. These assays have greater sensitivity than those used outside the clinical laboratory, which generally use urine as a test sample. In general, urine pregnancy kits have analytical sensitivities of about 20-25 IU/L, and are thus able to detect pregnancies only at the time of the first missed menses when hCG levels exceed 20-25 IU/L.

Limitations/Interferences
- Serum is preferred because of the potential for wide variation in hCG urine concentrations as a result of such factors as fluid intake, hydration status and renal function.
- Dilute urine with low urinary specific gravity (unlike concentrated early morning urine), or specimens with high protein concentration, gross lipemia, and significant turbidity may yield erroneous results.
- Operator interpretation of faint color changes can lead to errors in interpretation of the results.