hCG Rapid Urine test

* READ POLICY PRIOR TO STARTING TUTORIAL
Before Testing a Patient

• ORIENT YOURSELF TO YOUR WORKING AREA:

• Locate the pregnancy test

• Locate testing supplies:
  – Disposable specimen droppers
  – Package insert
  – Specimen collection container
  – Timer (or clock)
  – Daily Temperature Log
  – IDA Page for your testing location
Qualified Personnel

- Testing personnel are required to take this Initial Orientation and Training, the Initial Competency Exam, and a second Competency Exam within the first year.

- Competency Exams are then required annually thereafter.
hCG Rapid Urine Test

- Using the hCG Rapid Urine Test is considered **WAIVED** in complexity by the FDA.

- **PURPOSE**: To aid in the early detection of pregnancy at the point of care.

- The hCG Rapid Urine Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gondadotropin (hCG) in urine.

- The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines, as the specimen migrates via capillary action along the membrane to the test area.
hCG Rapid Test Cassette

- **hCG Rapid Test cassettes** contain anti-hCG gold conjugate and anti-hCG coated on the membrane.

- Store as packaged in the sealed pouch at 2-30º C.

- Test only at room temperature.

- Test cassette is stable through the expiration date printed.

- The test cassette must remain in the sealed pouch until use.

- **DO NOT FREEZE.**
Specimen

- First morning urine specimen is preferred (this sample contains the highest concentration of hCG hormone).

- Urine collection container should be clean and dry, and must not contain any preservatives.

- Stability: up to 48 hours refrigerated at 2-8°C.

- Test only at room temperature.
Quality Control Testing

- Obtain the test cassette and remove the test cassette from the sealed pouch and use it as soon as possible.

- **Internal Quality Controls:**
  - Internal quality controls are included in the test. A line appearing in the control region (C) is the **positive internal quality control**.
  - It confirms sufficient specimen volume and correct procedural technique.
  - A clear background is an internal **negative quality control**. If working properly, it should be white to light pink and not interfere with the ability to read the test results.
Quality Control Testing

• **External Quality Controls:**

• Positive and negative controls are run on all new lot numbers or shipments of test cassettes and as needed by the Clinical Laboratory prior to distribution.
Patient Testing

- Using two patient identifiers (patients full name and date of birth), verify the patient’s identity, and explain the procedure to patient and/or family.

- Observe universal precautions; wear gloves and other personal protective equipment as appropriate.

- Label a urine cup with the patient’s name and Medical Record Number and hand it to the patient for urine collection.
Patient Testing

• The test device should be at room temperature before it is removed from its protective pouch.

• Remove the test cassette from the sealed pouch and use it as soon as possible.

• **Label the test cassette** with the patient’s name and Medical Record Number.
Patient Testing

- Place the test cassette on a clean and level surface.

- Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well of the test cassette.

- Start the timer. The result should be read at 3 minutes – no longer than 5 minutes.
Patient Testing

INTERPRETATION OF TEST RESULTS:

• **POSITIVE**: Two distinct lines appear. One line should be in the control region (C) and another line should be in the test region (T) – even if faint.

• **NEGATIVE**: One line appears in the control region (C). No apparent line appears in the test region (T).

• **INVALID**: Control line fails to appear or background is other than white or light pink. Repeat test.

POSITIVE = 2 Lines
1 in Control and 1 in Test

NEGATIVE = 1 Line
1 in Control and 0 in Test
Patient Testing

- Record date, Medical Record Number, & test result on the log maintained in the nursing unit.

- Chart the patient’s results in their medical record.

- Discard the test cassette in a proper biohazard container after testing.
Confirmatory Testing

• If the clinical impression does not agree with the hCG Rapid Test result, and repeat testing on a fresh first morning urine sample collected 48 hours after the initial sample is not an appropriate option, a blood sample may be submitted to the Clinical Laboratory for quantitative serum hCG hormone measurement.
Limitations

- This test cassette is for professional in vitro diagnostic use only. **Do not use after the expiration date.** The test cassette should remain in the sealed pouch until use.

- Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG and give a negative result.

- If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. The test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
Limitations

– Gross hematuria may prevent an accurate reading of the test result by masking a positive line.

– A number of conditions other than pregnancy may cause elevated hCG – including: trophoblastic disease and certain non-trophoblastic neoplasms including breast cancer tumors and lung cancer tumors.

MSDS – Located on the SFGH-POCT.org website under “Urine Pregnancy”
For Further Questions or Information
Contact POCT Services

SFGH-POCT.org