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|  | **WORK INSTRUCTION** |
| **R-W-UA-2210-00** |
| hcg pregnancy rapid test | |
| **St. Joseph Medical Center Tacoma, WA**  **St. Clare Hospital Lakewood, WA**  **St. Elizabeth Hospital Enumclaw, WA**  **St. Francis Hospital Federal Way, WA**  **St. Anthony Hospital Gig Harbor, WA**  **PSC** | |

**PURPOSE**

To provide instructions for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine.

**BACKGROUND**

The hCG Combo Rapid Test 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 detects the presence of hCG at the sensitivity of 10 mlU/ml in serum and 20mIU/ml in urine. The assay 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 specimen migrates via capillary action along the membrane to react with the colored conjugate.

**SUPPLIES**

1. Kit contains 30 individually packaged test cassettes and disposable dropper. Store at room temperature, 15-30˚C or refrigerate at 2-8˚C. Do not freeze. Record date opened and tech initials on kit when kit is put into use.

2. Sure-Vue hCG-STAT controls are stored refrigerated at 2-8˚C.

3. Quantimetrix controls for urine. Store at 2-8˚C.

**SPECIMEN COLLECTION**

1. Urine specimen must be collected in a clean and dry container. A first morning specimen is preferred since it may contain higher levels of hCG, however urine specimens collected at any part of the day may be used. Any visible precipitates should be centrifuged, filtered or allowed to settle to obtain a clear specimen prior to testing.

2. Serum is collected from the patient and centrifuged as soon as possible. Avoid hemolysis which may interfere with reading the test lines.

3. Serum or urine may be stored at 2-8˚C for up to 48 hrs prior to testing. For prolonged storage, specimens may be frozen and stored at -20˚C. Thaw and mix thoroughly before testing.

**STEPS**

1. The test cassette must remain in the sealed pouch until ready for use. Do not use the cassette if the package is torn or ripped or the cassette itself is damaged.

2. Allow the test cassette, serum or urine specimen and controls to come to room temperature, 15-30˚C prior to use.

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

4. Place the test cassette on a clean and level surface. Using the enclosed dropper, transfer 3 full drops of urine or serum (approx. 100mcL) to the specimen well of the test cassette. Avoid trapping air bubbles in the specimen well.

5. Set the timer. Read a urine specimen at 4 minutes. Read a serum specimen at 6 minutes. Do not interpret results after the appropriate read time. The background must be clear before the result is read.

**INTERPRETATION OF RESULTS**

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| **Control Line (C)** | **Test Line (T)** | **Result** |
| Red Line | Red Line | Positive |
| Red Line | No red or pink line | Negative |
| No red line | Red line or no line | Inconclusive |

1. The intensity of the red line in the test line region will vary depending on the concentration of hCG present in the sample. Any questions about reading the test line perform a quantitative hCG.

2. A weak red test line or a line seen after the read time could be indicative of a low hCG level. If such results are seen, the test should be repeated in 48-72hrs or perform a quantitative serum hCG.

**QUALITY CONTROL**

1. Internal procedural controls are included with each test. The red line appearing at the control region (C) is the positive procedural control. It confirms that sufficient specimen volume and correct procedural technique has been used.

2. Internal negative control is complete clearing of the background on the cassette. The color is white to slightly pink if the test is performed correctly.

3. External controls, perform lot to lot when a new lot and/or shipment is received **OR** the same QC material  
that was used to QC the previous lot can be used to QC the new lot. If new QC has been received since the old lot then you must do lot to lot testing.

**Serum controls:**

* External controls will be performed on all new lots or shipment of reagents. For the serum controls only, external controls must be performed at least every 30 days.
* Allow controls to come to room temperature prior to testing.
* The serum controls are ready to use and do not need any dilution for testing.
* There are three serum controls: Two positives, one at 10 mIU/ml hCG and one at 250 mIU/ml hCG. There is one negative control.
* Perform testing in place of a specimen following Steps 1-5
* The two positive controls should result as positive, the negative control should result as negative.
* If controls do not perform properly, either the test kit is not performing correctly or the proper  
  steps were not followed performing the test. Any quality control that fails must be investigated prior to entering patient results. Inspect the reaction device and controls for contamination. Check expiration dates and storage requirements. Repeat testing.
* If controls continue to be invalid, remove lot from service and contact the vendor, Fisher, at 1-800-640-0640 for controls or the Cardinal vendor for the kit at 1-866-211-7853.

**Urine controls:**

* Run controls with each new lot and/or shipment and record on the hCG Reagent Verification log. Quantimetrix Urine controls- Level 1 (negative) and 2 (positive). No preparation required. Bring controls to room temperature prior to testing. Controls are stable unopened until expiration date printed on box and an open box is stable for 3 months if stored between 2-8˚C.

**EXPECTED RESULTS**

1. Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. The intensity of the red line in the test line (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.

2. The hCG Combo test has a sensitivity of 10 mIU/ml in serum and 20 mIU/ml in urine and is capable of detecting pregnancy as early as 1 day after the first missed menses.

**LIMITATIONS**

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected in 48 hours and retested.

2. False negative results may occur when the level of hCG is below the sensitivity level of the test. If pregnancy is still suspected, a first morning serum or urine should be collected in 48 hours and retested.

3. Very low levels of hCG are present in serum or urine shortly after implantation. A weakly positive test should be confirmed by retesting in 48 hours or test the serum sample with a quantitative method.

4. This kit does not reliably detect hCG degradation products such as free-beta hCG and beta core fragments. Quantitative tests may detect hCG degradation products and therefore disagree with results of this rapid test.

5. 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 can cause elevated hCG levels. The presence of hCG in a serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

6. Specimens from patients who have received preparations of human anti-mouse antibodies for conditions or therapy, may get a false positive or negative reaction with this kit.

7. This test provides a presumptive diagnosis of pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

**REFERENCES**

1. hCG Combo Rapid test product insert. Cardinal Health, Waukegan, IL. 3/2011

2. Sure-Vue hCG STAT serum controls product insert. Fisher Scientific, 2/2012.

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| **DOCUMENT APPROVAL Purpose of Document / Reason for Change:** | | | |
| New document | | | |
| *No significant change to process in above revision.  Per CAP, this revision does not require further Medical Director approval.* | | | |
| **Committee Approval  Date** | Date:  N/A – revision of department-specific document which is used at only one facility | **Medical Director Approval** *(Electronic Signature)* | H:\Katie\Signature - KEW.jpg1/31/14 |