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| **hCG in Urine or Serum** | | | | | | | | |
| **Purpose** | This procedure provides instructions for TESTING FOR hCG IN URINE OR SERUM. | | | | | | | |
| **Principle** | The hCG Combo Rapid Test is a rapid chromatograhic immunoassay for the qualitative detection of human Chorionic Gonadatropin (hCG) in serum or urine for the early detection of pregnancy. | | | | | | | |
| **Policy Statements** | * This procedure applies to all laboratory technologists performing urinalysis, section supervisor, and pathologist. | | | | | | | |
| **Materials** | **Equipment** | | | **Reagents** | | | **Supplies** | |
|  | * Timer or stopwatch * Thirty-seven degree waterbath (37°C) | | | * The hCG Combo Rapid Test kit, Cardinal Health cat # B1077-23 contains 30 individually wrapped test cassettes and disposable pipettes:  1. Store kit at room temperature, 2-30°C, out of direct sunlight 2. Stable until expiration date printed on outer 3. DO NOT FREEZE  * Quantify Control System manufactured by Bio-Rad Vendor Item # BR975 (Cardinal Health):  1. Two levels, positive and negative 2. Bulk control vials are stored in refrigerator, stable until date on label 3. Open vials stored at 2-8°C in the dark are stable for 31 days 4. Label opened vials with date and initials 5. Controls should be room temperature before running  * Known Positive and Negative patient (Proficiency testing) control:  1. Aliquoted and stored at –70°C 2. Thaw specimen in 37°C waterbath for three minutes 3. DO NOT REFREEZE. | | | N/A | |
| **Sample** | 1. Urine: 2. Minimum volume 0.5 mL 3. Collection of clean container 4. First morning specimen recommended for early detection 5. Storage:    * 8 hours at 15-30°C (room temperature)  * 48 hours at 2-8°C * Freeze samples at -20°C if testing will be delayed  1. Serum: 2. Minimum requirement 0.5 ml serum 3. No special patient preparation is required 4. Store specimens at 2-8°c up to 48 hours prior to testing 5. Freeze samples at -20°C if testing will be delayed  * DO NOT REFREEZE * DO NOT CHEMICALLY MODIFY THE SERUM IN ANY WAY | | | | | | | |
| **Quality Control** | 1. Internal Control- with each test: 2. Development of a red control line next to the letter “C” is a positive procedural control:  * If this line does not develop, the test is invalid.  1. The absence of interfering background is a negative procedural control.  * Your results may be invalid, if background control appears in the result window that interferes with your ability to read the test result. * Call Technical Services at 1-866-211-7853  1. Record results of the internal controls (+/-) on the patient result form. 2. External Controls- with new kit lot number or shipment or every 31 days: 3. The Quantify® controls are run with the old pregnancy kit and with the new pregnancy kit. 4. Record the results on the Urinalysis Reagent/Control Lot to Lot sheets. 5. Run known positive and negative patient (Proficiency testing) samples with the old and new pregnancy kits. 6. Record the results on the Urinalysis Reagent/Patient Lot to Lot sheets 7. Mark box of the new kit with date checked and initial. 8. If controls do not react as expected, repeat the test. 9. If the controls still do not react as expected, DO NOT USE THE KIT and Technical Services, 1-866-211-7853. | | | | | | | |
| **Procedure** | Follow the activities in the table below for TESTING FOR hCG IN URINE OR SERUM. | | | | | | | |
|  | **Step** | **Action** | | | | | | **Related Document** |
|  | 1 | Open a sufficient number of foil pouches to test all samples. | | | | | |  |
|  | 2 | Place the test cassette on a clean, dry, level surface. | | | | | |  |
|  | 3 | With one of the disposable pipettes supplied:   1. Add three (3) drops of serum or urine to the sample well. 2. Do not pick up cassette. | | | | | |  |
|  | 4 | Read results at the appropriate time for the same time for sample type:   1. Urine: read at 3-4 minutes. 2. Serum: read at 5-6 minutes.   \* Some positive results may be seen earlier, any color development after the  designated read time should be disregarded. | | | | | |  |
|  | 5 | Write results on the 4x6 UA worksheet and enter results in the computer. Record observed internal control results as positive and negative along with the patient result (i.e. QC:+/- or QC Pos/Neg). | | | | | |  |
| **Procedural Notes** | 1. Human chorionic gonadotropin is a hormone produced by the placenta shortly after implantation.  * Since hCG is present in the serum and urine or pregnant women, it is an excellent marker for confirming pregnancy.  1. Very dilute urine specimens, as indicated by low specific gravity, may not contain representative urinary hCG concentrations.  * The presence of hCG in urine or serum as indicated by this test must always be evaluated in conjunction with other clinical and laboratory data available to the physician.  1. A specimen with a low level of hCG may show color development over time. If a negative result is obtained but pregnancy is suspected, hCG levels may be too low. Another specimen should be collected after 48-72 hours and tested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test. 2. Elevated hCG concentrations unrelated to pregnancy have been reported in some patients. hCG may remain detectable for a few days to several weeks after delivery, abortion, or hCG injections.   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.   1. Abnormal pregnancies cannot be diagnosed by qualitative hCG results. 2. The hCG controls are qualitative reagents and are not to be used as quantitative calibrators. | | | | | | | |
| **Interpretation/**  **Results/Alert Values** | 1. Reference Range: Negative 2. Positive: The appearance of any pink to red line next to the letter ”T” in the Result Window, along with a red procedural Control Line next to the letter “C” at 3-4 minutes for urine or at 5-6 minutes for serum. 3. Negative: The appearance of the red procedural Control line next to the letter “C” only and no pink-to red line next to the letter “T” at three (3) minutes for urine or five (5) minutes for serum. 4. No Results: A red procedural Control Line should always appear next to the letter “C” in the Result Window. If no red procedural Control Line appears, the test is invalid, and the specimen must be re-tested. 5. “Broken” or non-continuous test lines: Control or test lines in the result window of the test cassette should go from one side to the other in a complete or continuous line. Any specimens tested that have spaces (gaps) in these lines would be considered to have invalid results and should be retested. If these results persist a new sample should be collected. | | | | | | | |
| **Method Performance Specifications** | The hCG Combo Rapid Test detects hCG concentrations of 10 mIU/ml or greater in serum and  20 mIU/ml or greater in urine.   * In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32 to 48 hours, peaking in excess of 100,000 mIU/mL in approximately ten to twelve weeks. * Levels of 25 mIU mL hCG are reported present in urine and serum as early as two to three days before expected menses. * Serum hCG is rapidly cleared into the urine and the concentration of hCG in serum is approximately equal to the concentration in urine   This test reliably detects hCG up to 500,000 mIU/ml. It does not detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect degradation products and therefore may disagree with the results of this rapid test. | | | | | | | |
| **Result Reporting** | In Sunquest:  Function: MEM <CR>  Worksheet: <CR>  Test-l: URHCG or SEHCG<CR>  Test-2: <CR>  Acc. No.: Enter ####  INTERNAL QC RESULT: Enter IQC (Internal QC verified as acceptable<CR>  URHCG or SEHCG: Enter pos or neg  Accept (A), Modify (M) or Reject (R): A <CR> | | | | | | | |
| **References** | 1. Donhowe, J.M., hCG Testing in Early Pregnancy, CAP Today, January 1996, pp 61-62  2. QuickVue® One-step hCG Controls Package Insert #2372-2, Quidel, San Diego, Ca, 12/95.  3. QuickVue® One-step hCG Combo Test Package Insert #2367-1, Quidel, San Diego, Ca, 1/95.  4. hCG Combo Rapid Test Package Insert Cardinal Health #1155904805, Rev C 9/14. | | | | | | | |
| **Historical Record** | **Version** | | **Written/Revised by:** | | **Effective Date:** | **Summary of Revisions** | | |
| 1 | | Laura Rachford | | 08/30/1996 | Initial Version | | |
| 2 | | Jim Berger | | 10/14/2003 |  | | |
| 3 | | Al Quigley | | 09/21/2009 | Updated post-CAP inspection | | |
| 4 | | Al Quigley | | 06/01/11 | Updated, Reformatted | | |
|  | 5 | | Al Quigley | | 09/29/15 | Revised after CAP inspection to include documentation in Suquest of internal QC results. | | |
|  | 6 | | Al Quigley | | 11/01/17 | New kit ( Combo Rapid Test )  Cardinal Health | | |