**1.0 Purpose**

Human chorionic gonadotropin (hCG) is a glycoprotein hormone 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.(1-4) hCG levels continue to rise very rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period,(2-4) and peaking in the 100,000-200,000mIU/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.

**2.0 Principle**

# Sure-Vue® Serum/Urine hCG 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. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

**3.0 Specimen**

Urine: The urine specimen must be collected into a clean, dry container, either plastic or glass. Specimens collected at random may be used; however, the first morning urine generally contains the highest concentration of hormone. A urine sample exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle (obtaining clear aliquots) before testing.

 Serum: Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage: Serum or urine specimen may be stored at 2-8ºC for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20ºC. Frozen specimens should be thawed and mixed before testing.

**4.0 Equipment**

4.1 The test device contains anti-hCG particles and anti-hCG coated on the membrane

 4.1.1 Store as packaged in the sealed pouch at 2-30ºC.

 4.1.2 The test device is stable through the expiration date printed on the sealed pouch.

 4.1.3 The test device must remain in the sealed pouch until use.

 4.1.4 Do Not Freeze

 4.1.5 Do not use beyond the expiration date.

4.2 Disposable specimen droppers

4.3 Sure-Vue® Serum and Urine hCG Control Sets include both positive and negative controls

 4.3.1 Sure-Vue® hCG controls are stored refrigerated (2º-8ºC) for the duration of the shelf-life.

 4.3.2 Controls must be equilibrated to room temperature (15º-30ºC) before use.

 4.3.3 Controls are liquid ready to use. No dilution is required.

4.3.4 Do not use controls if they are cloudy or if precipitates are observed in the vials. This may be an indication of reagent instability or deterioration.

4.3.5 Do not use beyond expiration date.

**5.0 Calibration: None**

**6.0 Quality Control**

Internal procedural controls are included in the test. A red line appearing in the control region 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.

Positive (25 mIU/mL) and negative serum and urine controls are performed and recorded for each new box of test kits opened and at least once a month if the same box is still in use to due to low test volume. ~~daily by the day shift. At Elkins Park Quality Control is only performed once daily when a patient specimen is received.~~ Quality Control should be recorded on CH04-002 Form A2 and B2 daily. Positive (25 mIU/mL) and negative urine/serum controls are performed on each new lot number or shipment of test devices.

**7.0 Procedure**

7.1 Remove test device from pouch. Place on flat surface. Label with patient or control identification.

7.2 Hold the dropper vertically and transfer 3 full drops of serum or urine (approximately 100µl) to the specimen well of the test device. Avoid trapping air bubbles in the specimen well.

7.3 Wait for the red line(s) to appear. **Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum specimen. Do not interpret results after the appropriate read time.**  It is important that the background is clear before the result is read.

**8.0 Interpretation of Result**

(Please refer to the illustration above)

**POSITIVE:\* Two distinct red lines appear.** One line should be in the control region ( C ) and another line should be in the test region ( T ).

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

**INVALID: 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 the test kit immediately and call 1-800-637-3717 for Technical Assistance.

**\*NOTE:** 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.

**9.0 Reporting Results**

9.1 Results are entered into the LIS

 9.2 Report as Positive or Negative

 9.3 Patient results should be recorded on CH04-002 Form C1

**10.0 Expected Results**

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 Sure-Vue® Serum/Urine hCG has a sensitivity of 25mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

**11.0 Limitations**

11.1 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 48 hours later and tested.

11.2 False negative results may occur when the 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.

11.3 As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.

* 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.(6-7) Therefore, the presence of hCG in a serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
	2. Detectable levels of hCG may remain following normal pregnancy and delivery, or spontaneous or therapeutic abortion.
	3. Approximately one third of all conceptions end in natural termination. This may produce a positive result when testing early in pregnancy, followed by a negative result after the natural termination.
	4. Gross hematuria may prevent an accurate reading of the test result by masking the positive line. If an intensely red background color appears, it may interfere with the ability to read the test result. Centrifuge the specimen and repeat the test on the supernatant.
	5. A high dose “hook effect” may occur, where the intensity of the sample line decreases as the concentration of hCG increases. If a “hook effect” is suspected, dilution of the specimen may increase color intensity of the test line.

**12.0 Sensitivity and Specificity**

 The Sure-Vue® Serum/Urine hCG detects hCG at concentrations of 25mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL, FSH (1,000 mIU/mL), and TSH (1,000 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

**13.0 References**

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**Approval Signatures:**

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| --- | --- | --- |
| **Date** | **Printed Name** | **Signature** |
| 8/11/2016 | Vanessa RawlingsElkins Park Supervisor |  |
| 8/11/2016 | Jennifer Lore, MFS, MTChemistry Supervisor |  |
| 8/11/2016 | Nancy A. Young, M.D., FCAPMedical Director |  |

**Review History**

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| **Date Reviewed** | **Reviewed By** | **Revisions** |
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