283.521 Sure-Vue Serum-Urine hCG STAT Waived for CBOC

Copy of version 1.0 (approved and current)

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Comments for version 1.0
Edited main lab version to have waived testing version only for CBOC

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/7/2024	1.0	yahyaelshimali JohnYahya Elshimali	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	3/7/2024	3/7/2024	Indefinite

Sure-Vue Serum/Urine hCG STAT
West Texas V A Health Care System Laboratory

Tis kit has waived and non-waived methods. The CBOC's will use the waived method only. This has only the waived method.

A rapid one step test for the qualitative detection of human chorionic gonadotropin 9hCG) in serum or urine.

INTENDED USE

SURE-VUE™ Serum/Urine hCG-STAT is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in serum or urine to aid in the early detection of pregnancy.

Summary

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In nornal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception.([14]) hCG levels continue to rise very rapidly, frequently exceeding 100 mlU/mL by the first missed menstrual period and peaking in the 100,000-200,000 mlU/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.
SUREVUE™ Serum/Urine hCG-STAT is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 10 mlU/mL in serum and 20 mlU/mL in urine. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in serum or urine. At the level of claimed sensitivity, the SURE-VUE™ Serum/U1ine hCG-STAT shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

Principle

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. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Reagents

The test device contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.

Precautions:

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouches until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.
- The test device should not be reused.

Sure-Vue Serum/Urine hCG STAT
West Texas V A Health Care System Laboratory

Storage and Stability

Store as packaged in the sealed pouch at 2-30 ^{0}C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8 ^{0} C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 ^{0} C. Frozen specimens should be thawed and mixed before testing.

Materials Provided

Kit with pipets and package insert

Needed Materials Not provided

1. Timer Calibrated to NIST
2. Specimen collection container
3. Two levels of QC material

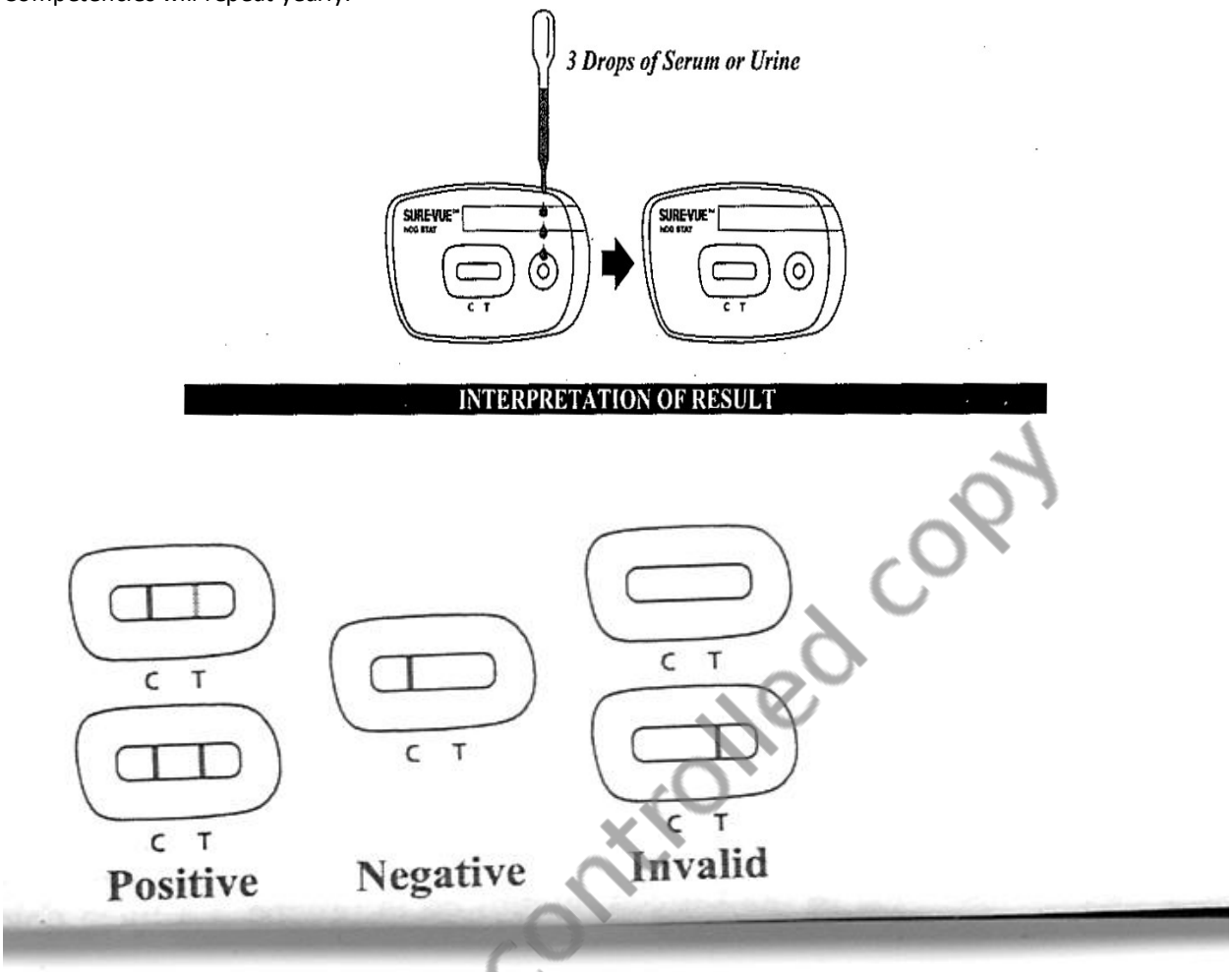
Directions for Use:

Use Standard precautions. Wear gloves.

1. Allow the- test device, urine specimen and/or controls to equilibrate to room temperature (15-30 ^{0} C) prior to testing.
2. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
3. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or urine (approx. 100µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
4. Wait for the red - line(s) to appear. Read the result at 3-4 minutes when testing a urine specimen. Do not interpret results after the appropriate read time. It is important that the background is clear before the result is read.

Sure-Vue Serum/Urine hCG STAT
West Texas V A Health Care System Laboratory

This is what I assigned to home health. They are not pushing back.
Competencies will repeat yearly.



Interpretation of results:

(please refer to the illustration)

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).

NOTE: A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. A line in the test region (T) seen after the read time could be indicative of a low hCG level in the sample. If such results are seen, it is recommended that the test be repeated with a new sample in 48-72 hours or that an alternate confirmation method is used.

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

Sure-Vue Serum/Urine hCG STAT
West Texas V A Health Care System Laboratory

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 1-866-216-0094 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.

Quality Control

Internal procedural controls are included in the test. 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.

External liquid controls:

Quidel hCG Control set containing negative and positive samples.

DO NOT USE THE DROPPER ON THE BOTTLE.

1. Remove dropper tip from bottle.
2. Run test as you would a urine sample.
3. Record your results in your Accuchek system.
4. Replace the dropper tip to reduce leaking when capped.

When to run QC:

1. When a new kit is delivered even if it is the same lot.
2. Monthly thereafter. If the test volume is low and it has been a month since the last time QC was run, you may run the next set of QC with the next patient.

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 48 hours later and tested.
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 serum or urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50mIU/mL) are present in urine and serum specimen shortly after implantation. However, because a significant number of first trimester pregnancy terminate for natural reasons, a test result that is weakly positive should be confirmed retesting with a first morning serum or urine specimen collected 48 hours later.

4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG m; detect hCG degradation products and therefore may disagree with the results of this rapid test.
5. A number of conditions other than pregnancy, including trophoblastic disease •and certain no 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 serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. 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 receiving preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may-cause false positive or false negative results.
7. This 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.

EXPECTED VALUES

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.

SURE-VUE™ Serum/Urine hCG-STAT has a sensitivity of 10 mlU/mL in serum and 20 mlU/mL in urine and is capable of detecting pregnancy as early as 1 day after the first missed menses.

Performance Characteristics

Method Comparison
A multi-center clinical evaluation was conducted comparing the results obtained using SURE-VUE™ Serum/Urine hCG-STAT and another commercially available serum/urine membrane hCG test. The urine study included 100 specimens and both assays identified 50 negative and 50 positive -results; The serum study included 100 specimens and both assays identified 50 negative and 50 positive results.

Analytical Sensitivity and Specificity
SURE-WE™ Serum/Urine hCG-STAT detects hCG at concentrations of 10 mlU/mL or greater in serum and 20 mlU/mL or greater in urine. The test has been standardized to the W.H.O. Fourth International Standard (75/589). The addition of LH (300 mlU/mL), FSH (1,000 mlU/mL), and TSH (1,000 mlU/mL) to negative (0 mlU/mL hCG) and positive (10 mlU/mL hCG in serum/ 20 mlU/mL hCG in urige) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

All substances listed in mg/dLunless otherwise noted.

Acetaminophen 20	Cocaine 10	Ibuprofen 20
Acetone 1,000	Codeine 10	Methadone 10

Sure-Vue Serum/Urine hCG STAT
West Texas V A Health Care System Laboratory

Acetylsalicylic Acid 20	Cholesterol 500	Methamphetamine 10
Acetoacetic Acid 2,000	Creatine 20	Methanol 10%
Ampicillin 20	Dextromethorphan 20	Morphine 0.6
Ascorbic Acid 20	DMSO 5%	Oxalic Acid 40
Atropine 20	EDTA 80	Phenothiazine 20
Albumin 2,000	Ephedrine 20	Phenylpropanolamine 20
ß-Hydroxybutyrate salt 2,000	Ethanol 1%	Pregnanediol 2
Benzoylecgonine 10	Estriol 2	Salicylic Acid 20
Bilirubin 20	Estrone 3-Sulfate 10	Tetracycline 20
Brompheniramine 20	Gentisic Acid 20	Triglycerides 1,200
Caffeine. 20	Glucose 2,000	Theophylline 20
Cannabinol 10	Hemoglobin 1,000	Urea 2,000
Clomiphene 100	Heroin 1	Uric Acid 20
None of the substances at the concentration tested interfered in the assay.		

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