TRAINING UPDATE

Lab Location:	FWMC	**Date Distributed:**	3/22/2022
Department:	Core Lab	**Due Date:**	4/22/2022

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Title: Sure-Vue Serum/Urine HCG Stat Test (FWMC -Lab-Misc-008)

Description of change(s):

Changed QC frequency to weekly and with each new lot number or shipment.

See attached SOP and QC log (AG.FW20.3)

This revised SOP was implemented March of, 2022

Document your compliance with this training update by taking the quiz in the MTS system.

FORT WASHINGTON MEDICAL CENTER
A Nexus Health Company

FWMC-LAB-MISC-0008 Sure-Vue Serum/Urine HCG STAT Test

PRINCIPLE:

The Sure-Vue Serum/Urine hCG-STAT test is a rapid chromogenic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) hormone in serum or urine to aid in the early detection of pregnancy.

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 the100,000-200,000mIU/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. Sure-Vue® Serum/Urine hCG-STAT is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 10mIU/mL in serum and 20mIU/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/Urine hCG-STAT shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels

PRECAUTIONS:

- Urine specimens with low specific gravity (diluted) will not contain representative amounts of hCG. It is recommended testing is repeated using a morning void specimen.
- Very low levels of hCG (50mIU/Ml) will not be detected by this test. A test with a weak positive result should be repeated using a new specimen and within 48hrs

REAGENTS:

The test device contains anti-hCG gold conjugate and anti-hCG coated on the membrane.

EQUIPMENT:

Materials

• Test devices ·
• Package insert
• Disposable specimen droppers

Materials Required But Not Provided

- Specimen collection container
- Timer

STORAGE AND STABILITY:

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

LIS ORDER CODES:

Assay	Test Code
HCG, Qual (Urine)	UHCG
HCG, Qual (Serum)	HCG

SPECIMEN COLLECTION AND STORAGE:

Urine Assay

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.

Serum Assay

Blood should be collected aseptically into a clean tube without anticoagulants. Separate theserum 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 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

TEST PROCEDURE:

Allow the test device, serum or urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. 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.
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. It is important that the background is clear before the result is read.

Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS:

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: 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.

NEGATIVE: One red line appears in 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.

Tests performed by POC staff will document results on the HCG log sheet and entered in the Patient's Flow chart in CPSI.

REPORTING RESULTS:

IF the result is …	THEN…
Negative	Report as NEG
Positive	Report as POS
Invalid	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.

Use LIS function **MEM** to enter results.

Enter Shift: (1, 2, or 3)
Worksheet: FMAN
Test: <Enter>
Enter “A” (Accept)
Enter Accession number
Press <Enter> until Result screen is displayed

Enter Results as listed below:

Result	Report with LIS Result Code
Negative	NEG
Positive	POS
Invalid	INVD

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.

Sure-Vue Serum/Urine hCG STAT 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.

QUALITY CONTROL:

Built-in 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 Quality Control

External Controls are tested and documented once each week and with each new kit lot number or shipment. POC External controls will be performed each time a new box is obtained from the lab.

REFERENCES:

Package Insert: hCG Combo Rapid Test. Cardinal Health. Waukegan, IL, Mar. 2011.

REVISION HISTORY:

All revision dates: 04/2019, 07/2018, 05/2014, 03/2012

12/15/21	Added Reporting Results and Test Code sections	MSabonis
3/8/22	Updated external QC frequency based on IQCP	DCollier

Attachments

Sure-Vue Serum and Urine HCG STAT Test QC Log (AG.FW 20)

Approval Signatures

Approver	Date
Dr. Senda Beltaifa: Medical Director Lab	See electronic signature

Adventist HealthCare

SURE – VUE SERUM and URINE HCG QUALITY CONTROL LOG

Fort Washington Medical Center

1. **External Controls** are tested and documented once each week and with each new kit lot number or shipment.
2. **Internal controls** must be documented each time a patient test is performed.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Date	Sample Type	Patient Name / MR#	Patient Result	Kit	Internal Control	External Positive Control		External Negative Control		Tech Code
				Lot # / Expire	Red Control Line (Y / N)	Lot # / Expire	Result	Lot # / Expire	Result	
	☐ Serum ☐ Urine									
	☐ Serum ☐ Urine									
	☐ Serum ☐ Urine									
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Weekly review:				Weekly review:				Weekly review:		
Weekly review:				Weekly review:				Monthly review:		