□ SAFH □ SAH □ SDH □ SMCS ■ SRMC □ SMF □ SSMC	SHSSR Laboratory Service Procedure	Section/#: Urinalysis UA.ANA.10.01-/-RV.02
	Title: **Performing a Urine Pregnancy Test Using Sure-Vue hCG-STAT Kit**	Owned by: SRMC Laboratory Director/ Supervisor
	Effective Date: 10/19/17	Next Review Date: 03/2018

Purpose

This procedure describes how to perform a qualitative urine pregnancy test using the Sure-Vue hCG-STAT test kit. The Sure-Vue hCG-STAT test is a rapid, chromatographic immunoassay for the qualitative detection of human gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

Policy

- Sure-Vue hCG-STAT test will be used for pregnancy testing on urine specimens only.
- Serum pregnancy tests (qualitative or quantitative) will be run on the automated chemistry analyzer.

Equipment

Timer

Reagents

Reagents	Storage & Stability
Sure-Vue Serum/Urine hCG-STAT Test Kit *(Each test packet contains a test device and disposable dropper)*	• Store at 2-30ºC. Do not freeze. Test device must remain sealed in pouch until time of use. • Stable until manufacturer's expiration.
MAS UA Control Level 2 (Positive external control)	• Store refrigerated 2-8ºC. • Open stability: 3 months or until stated expiration.
Deionized water (Negative external control)	• Store at room temperature. • Replace daily.

Specimen Requirements

- Urine collected in a clean, dry container. A first morning urine specimen is preferred, however specimens collected at any time of day may be used.
- Specimen is stable for up to 48 hours when stored refrigerated (2-8ºC).
- For prolonged storage, specimen may be frozen and stored at -20ºC.

Continued on next page

Performing a Urine Pregnancy Test Using Sure-Vue hCG-STAT Kit, Continued

Quality Control

- External controls (positive/negative) must be performed once per month, with each new operator, and upon each new lot # or shipment of test kits.
    - Positive Control: MAS UA Control Level 2
    - Negative Control: Deionized water
    - Record QC results on the Immunology Quality Control Log. Also include:
        - Test Kit Lot # and expiration date
        - Control Lot #s and expiration dates
        - Date QC performed
    - Lots/Shipments that fail external QC will not be used for patient testing. Contact technical assistance and notify supervisor.
- Internal controls are contained within each test device. Internal QC reactions are viewed and recorded on the Manual Test Patient Log for every patient result.

Procedure

Follow the steps below to perform Sure-Vue hCG-STAT testing.

Step	Action
1	Allow specimen or control to warm to room temperature before testing if needed. *Note: Specimens exhibiting visible precipitates should be centrifuged prior to testing.*
2	Open a test packet and label the test device with patient or control identification. Do not open until ready for use.
3	Place test device on clean level surface.
4	Remove cap from specimen or control bottle.
5	Using the dropper included in the test packet, hold the dropper vertically and transfer 3 drops of urine or control to the specimen well of appropriate test device. *Avoid trapping air bubbles in the specimen well.*
6	Read results at 3 – 4 minutes. **Note: Do not interpret results after the appropriate read time.**
7	Record result on Urine hCG log. Also record: • Date performed. • Patient ID or control ID. • Results of internal positive and negative controls. • Tech code/initials.

Performing a Urine Pregnancy Test Using Sure-Vue hCG-STAT Kit, Continued

8	Discard used test device and dropper in appropriate biohazard container.
9	Recap specimen or control bottle and retain in designated location.

Evaluating Results

Evaluate the test device internal controls to verify proper procedural technique and ensure the test result is valid.

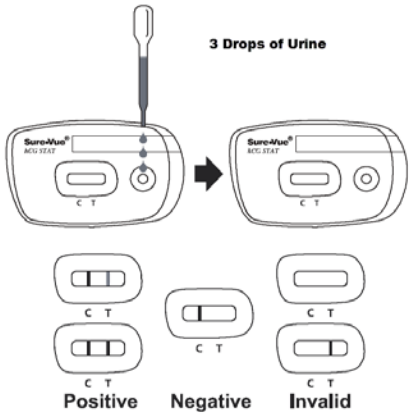
- Positive internal control = Control region (C).
- Negative internal control = Clear background (white to light pink).

If ...	Then the internal controls are...
• Red colored line appears in control region (C), and • Background is clear.	• Acceptable and test result is valid. • Proceed to *Interpreting Results*.
• NO line appears in control region (C), and/or • Background fails to clear, interfering with ability to read test result.	• NOT acceptable and test result is invalid. • Repeat test using new test device.

Interpreting Results

When performance of internal controls is acceptable, interpret the test result as follows:

Test Region (T) Display	Test Interpretation
Red colored line	Positive
No line	Negative



Note: The intensity of the red colored line in the Test region (T) will vary depending on the concentration of hCG present in the specimen.

Continued on next page

Performing a Urine Pregnancy Test Using Sure-Vue hCG-STAT Kit, Continued

Reference Range

Negative

Reporting Results

Follow the steps below to enter results in SunQuest. Note: Default <Enter> at any prompt not included in table below.

Step	Prompt	Action
1	Function	Enter **MEM**
2	Worksheet	Enter **RVPREG**
3	CAP Method Accept/ Modify	Enter **A** to accept.
4	Acc. No.	Enter the patient's accession number.
5	UPREG	Enter the patient result as follows: **If test is...** / **Then enter...** Negative / **NEG** Positive / **POS**
6	Accept/ Modify/ Display/ Prelim/ Reject	Enter: • **A** to accept the result, • **M** to modify the result, • **D** to display prior results, or • **R** to reject the result.
7	Verify the accuracy of result entry by using function WO to review result on a completed worksheet. **Confirm by writing RVS and your initials on the log entry.**	

Limitations:

- This method reliably detects intact hCG up to 500,000 mlU/ml. It does not reliably detect 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.
- Very dilute urine, as indicated by a low urine specific gravity, may not contain representative levels of hCG. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- Very low levels of hCG (less than 50mIU/ml) are present shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a result that is weakly positive should be confirmed by retesting with a first morning serum or urine specimen collected 48 hours later.

Performing a Urine Pregnancy Test Using Sure-Vue hCG-STAT Kit, Continued

- False negative results may occur when the levels of hCG are below the sensitivity level of the test (20 mIU/mL). If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- 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. Therefore, the presence of hCG in serum or urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
- As with any assay employing mouse antibodies, the possibility exists for interference by human 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.
- 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.

Supporting Documents

Immunology Quality Control Log
Form A:Manual Test Patient Log
Detecting and Correcting Data Entry Errors

References

Sure-Vue Serum/Urine hCG-STAT Package Insert, Eff. Date 05/27/2014

End