1.0 Purpose

1.1 Sure-Vue Serum/Urine hCG is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. This test is CLIA-Waived for urine testing.

1.1.1 Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal preganancy, hCG can be detected as early as 7-10 days after conception.

1.1.2 hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy.

1.1.3 The appearance of hCG 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.

1.2 The test utilizes a combination of antibodies including mouse monoclonal anti-hCG and goat polyclonal anti-hCG to selectively detect elevated levels of hCG. The urine is added into the specimen well of the test device and the operator observes formation of colored lines.

1.2.1 Positive specimens react with specific colored antibody conjugates and form a colored line in the TEST region of the membrane. Absence of this colored line suggests a negative result.

1.2.2 To serve as a procedural control, a colored line should always appear at the CONTROL region if the test is performed properly and device storage has been adequate.

1.3 The sensitivity of the Sure-Vue Serum/Urine device is 25 mIU/mL.

2.0 Sample – Only Urine samples will be accepted for Point-of-Care (POC) testing.

2.1 Urine samples

2.1.1 Urine should be collected in a clean and dry container and properly labeled with proper patient identification per policy.

2.1.2 A first morning urine is preferred because it generally contains the highest concentration of hCG; however, urine specimens from any time of day may be used.

2.1.3 Urine specimens with gross hematuria may prevent an accurate reading of test results by masking the positive line.

2.1.4 Urine specimens with visible precipitates should be allowed to settle to obtain a clear specimen for testing.

2.2 Urine storage

2.2.1 For POC analysis, urines are intended to be tested immediately.

3.0 Materials

Reagents and Supplies	Storage	Stability
In Kit:		
Sure-Vue test device	2-30°C	Expiration date on pouch
Disposable pipettes		
Not included in kit:		

Positive and Negative Controls (QC)	2-8°C	See 6.2

4.0 Safety Precautions

4.1 For in-vitro diagnostic use only.

4.2 Personal Protective Equipment (PPE)

4.2.1 All specimens should be considered potentially hazardous. Use appropriate PPE, e.g. gloves.

5.0 Calibration – none required

6.0 Quality Control (QC)

6.1 INTERNAL CONTROL

6.1.1 Positive: The appearance of a red control line in the control region (C) of the test device is a positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

6.1.2 Negative: A clear background after the sample absorbs through the device is the internal negative 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.

6.1.3 All internal QC results will be recorded on the POC Urine Pregnancy Result Form with each test analysis.

6.1.4 If QC does not perform as expected, do not report patient results. See procedure.

6.2 EXTERNAL CONTROL

6.2.1 Performed by main laboratory and trained clinic personnel.

6.2.2 A positive and negative control must be run with each new lot number of devices *and* each new shipment of devices to the lab or clinic site at the minimum, while others prefer more frequent testing.

6.2.3 Urine pregnancy controls

Urine QC Product	Storage	Open Stability
MAS UA Controls Level 1 and Level 2 Dropper Bottles	2-8ºC Do Not Freeze	Unopened bottles are stable until the expiration date on the label. Once opened, bottles are stable 3 months 2-8ºC, cap tightly.
UA	2-8°C Do Not Freeze	30 days at 2-8°C, redate, cap tightly
UAB	2-8°C Do Not Freeze	3 months at 2-8°C, redate, cap tightly 6 weeks at 18-25°C, redate, cap tightly

6.2.4 All external control results will be recorded on a POC Urine Pregnancy Quality Control Log and retained by the laboratory or Ancillary Testing Coordinator (ATC) after their use.

7.0 Procedure

Step	Action
7.1	• Allow test device (in sealed pouch), to equilibrate to room temperature (15-30°C) prior to testing.
7.2	• Remove the test device from the protective pouch and place it on a clean and level surface. Label the device with patient identification.
7.3	• Hold the dropper pipette vertically and dispense 3 full drops (approx. 100uL) of urine to the specimen well of the test device. Avoid trapping air bubbles in the specimen well.
7.4	• Do not walk away from test.
7.5	• Wait for the red line(s) to appear. It is important the sample has migrated through the test

	device and the background is clear before the result is read. ***The reaction time/read time for this test is <u>at</u> 3 minutes.***
7.6	• Interpret results (see 8.0) and record per your sites training on an approved sheet/form.
7.7	• Results <u>must be</u> entered into Vista Laboratory Package in a timely manner.

8.0 Interpretation

8.1 Negative Results – One red line appears in the Control Region (C). No apparent red or pink line appears in the Test Region (T). Background does not interfere with result reading.

8.2 Positive Results: Two distinct red lines appear**;** one line should be in the Control Region (C) and another in the Test Region (T).

> **NOTE:** The intensity of the red color in the Test 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.

8.3 Invalid Results: Control Region (C) 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 the Ancillary Testing Coordinator in the laboratory for technical assistance.

> **NOTE:** Detection level (sensitivity) of this test is 25 mIU/mL hCG.

9.0 Procedural Notes

9.1 Very dilute 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.

9.2 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.

9.3 Weakly positive urine Sure-Vue pregnancy test results should be repeated with first morning urine 48 hours later if clinically desired.

9.4 This Qualitative test does not reliably detect hCG degradation products as compared with some Quantitative assays offered in clinical laboratories. Therefore, results from both qualitative and quantitative systems may disagree.

9.5 A number of conditions other than pregnancy, including hCG diet regimen, 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 the specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

9.6 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 received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.

9.7 This is a screening test that can provide 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.

9.8 The following potentially interfering substances were added to hCG negative and positive specimens and did not interfere in the assay at the concentrations tested: Bilirubin up to 20 mg/dL, Cholesterol up to 500 mg/dL, Hemoglobin up to 1000 mg/dL and Triglycerides up to 1200 mg/dL.

NOTE: See package insert for a full list of other potentially interfering substance that were tested.

10.0 References

10.1 Sure-Vue Serum/Urine hCG Package Insert, (current edition)
10.2 Urine Pregnancy Control Package Insert, (current edition)
10.3 VHA Handbook 1330.01, Health Care Services for Women Veterans