

PROCEDURE

Title: Sure-View Signature Mono Test

Procedure #: 2015SEROLOGY01

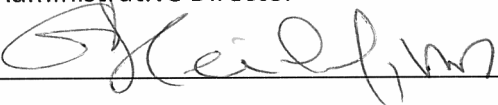
Institution: Highlands Regional Medical Center

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Date: 5/22/2015

Title: Laboratory Administrative Director

Accepted by:  Date: 5-22-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 6/15/15

Review of procedure every two years

Reviewed by: _____ Date: _____

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Discontinued testing date: _____

SURE-VUE® SIGNATURE MONO TEST PROCEDURE

I. TEST NAME

Sure-Vue® *Signature* Mono Test
Waived for Whole Blood.

II. INTENDED USE

The Sure-Vue *Signature* Mono Test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of infectious mononucleosis.

III. SUMMARY AND EXPLANATION OF TEST

The diagnosis of infectious mononucleosis (IM) is suggested on the basis of the clinical symptoms of fever, sore throat and swollen lymph glands. The highest incidence of symptomatic IM occurs during late adolescence (15-24 years of age). Infectious mononucleosis is caused by the Epstein-Barr Virus (EBV). The laboratory diagnosis of IM is based on the detection of IM heterophile antibodies. These heterophile antibodies are directed against antigens found in bovine, sheep and horse erythrocytes. The Sure-Vue Signature Mono Test utilizes an extract of bovine erythrocytes to give the required sensitivity and specificity.

IV. PRINCIPLES OF TEST

The Sure-Vue *Signature* Mono Test uses color immunochromatographic dipstick technology with bovine erythrocyte extract coated on the membrane. In the test procedure, serum plasma or whole blood is mixed with the Diluent. Then the Test Stick is placed in the mixture and the mixture migrates along the membrane. If the specific IM heterophile antibody is present in the sample, it will form a complex with the bovine erythrocyte extract immobilized on the membrane and a visible blue Test Line will appear to indicate a positive result.

V. KIT CONTENTS AND STORAGE

- 25 Test Sticks in a container
- 25 Test Tubes
- 25 Transfer pipettes
- 25 Capillary Tubes with 1 Capillary Bulb
- 1 Diluent (contains buffer with 0.2% sodium azide)
- 1 Mono Positive Control (contains rabbit anti-beef stroma in tris buffer with 0.2% sodium azide and 0.05% gentamycin sulfate preservatives)
- 1 Mono Negative Control (contains goat albumin in tris buffer with 0.2% sodium azide)
- 1 Work Station
- 1 Directional insert

NOTE: Extra components (tubes, pipettes, capillary tubes) have been provided for your convenience.

Store the Test Sticks and reagents tightly capped at 15° - 30° C (59° - 86° F).

Do not use the Test Sticks or reagents after their expiration dates.

At this facility, kits are stores: Room Temp 15° -30° C.

VI. MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection containers

Timer

VII. PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.
- The Diluent and Controls contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded Diluent or Controls down a sink
- The capillary bulb contains dry natural rubber.
- **WARNING:** Capillary bulb contains natural rubber latex which may cause allergic reactions. A small percentage of the population may have a heightened sensitivity to natural rubber latex, and prolonged use may cause allergic reactions in such persons. In the event you have or suspect you may have, such hypersensitivity, you are advised to seek non-latex alternatives. If during use, rashes or other signs of discomfort occur, discontinue use immediately and consult your physician. Safe use of this product by or on latex-sensitized individuals has not been established. Please consult your institution's policies regarding use of this product.
- Do not interchange or mix components from different kit lots.

VIII. PATIENT PREPARATION & SPECIMEN COLLECTION

Highlands Regional Medical Center's procedure for patient preparation is: Whole Blood

Highlands Regional Medical Center procedure for sample labeling is: 2 patient identifiers, date, time & initials of collector.

Specimen Collection and Handling:

Whole Blood Sample

Obtain specimens by acceptable medical technique. Collect whole blood samples using a tube containing EDTA. Test whole blood specimens within 24 hours. Specimens must be at room temperature (15° - 30° C; 59° - 86° F) when tested.

Highlands Regional Medical Center's procedure for transporting specimens is: immediately to laboratory at room temperature.

Highlands Regional Medical Center's procedures for rejected specimens are: Clotted, stability out of range and improper tube collected.

IX: QUALITY CONTROL & ASSURANCE

External Quality Control

For external QC testing, use the controls provided in the kit. Add one free falling drop of control to the Test Tube and then proceed in the same manner as with a patient sample. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, it is recommended that positive and negative external controls be run with each new lot and with each new untrained operator. Some commercial controls may contain interfering additives. The use of these controls is not recommended.

Internal Quality Control

The Sure-View *Signature* Mono Test provides two levels of internal procedural controls with each test procedure.

- The red control line is an internal positive control. The Test Stick must absorb the proper amount of sample and be working properly for the red Control Line to appear.
- A clear background is an internal negative control. If the test has been performed correctly and the Test Stick is working properly, the background will clear to give a discernible result.

If the red Control Line does not appear, the test is invalid. If the background does not clear and interferes with the test result, the test may be invalid. Call Technical Services if you experience either of these problems.

QC Testing Frequency and Documentation

Highlands Regional Medical Center's, external QC is run: When new box is opened

Results of External QC and actions(s) taken when control results are unacceptable are documented: and no patient performed prior to QC in range.

X. TEST PROCEDURE

STEP 1

Addition of Specimen:

Use the Transfer Pipette provided and add one drop to the Test Tube.

STEP 2

Slowly add 1 drop of Diluent to the bottom of the Test Tube.

Mix

STEP 3

Remove the Test Stick(s) from the container. Re-cap the container immediately.

Place the Absorbent End of the Test Stick into the treated sample. Leave the Test Stick in the Test Tube.

STEP 4

Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears.

Discard used test tubes and Test Sticks in the suitable biohazardous waste container.

For this facility, sample swabs, used test tubes and Test Sticks are disposed: in red biohazard bags.

XI. INTERPRETATION OF RESULTS

Notes

A blue or red line, which appears uneven in color density, is considered a valid result.

Positive

A blue Test Line and a red Control Line is a positive result for the detection of infectious mononucleosis heterophile antibody. Note that the blue line can be any shade of blue.

Negative

A red Control Line but no blue Test Line is a negative result. No infectious mononucleosis heterophile antibody has been detected.

Invalid

If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. IF this occurs, repeat the test on a new Test Stick or call Technical Service.

In the event this test becomes inoperable, Highlands Regional Medical Center's course of action for the patient sample is: to send sample to Reference Laboratory.

XII. RESULT REPORTING

Highlands Regional Medical Center's procedure for patient result reporting is: Negative or Positive result in Laboratory Information System (LIS).

XIII. LIMITATIONS

- As with all diagnostic assays, the results obtained by this test yield data that must be used as an adjunct to other information available to the physician.
- The Sure-View *Signature* Mono Test is a qualitative test for the detection of IM heterophile antibody.
- A negative result may be obtained from patients at the onset of the disease due to heterophile antibody levels below the sensitivity of this test kit. IF symptoms persist or intensify, the test should be repeated.
- Some segments of the population with acute IM are heterophile antibody negative.

XV. PERFORMANCE CHARACTERISTICS & POL STUDIES

Refer to Directional Insert

XVI. REFERENCES

Refer to Directional Insert

XVII. ASSISTANCE

For technical assistance, call Technical Service at 800-332-1042.