IMM.KIT.2.0 INFECTIOUS MONONUCLEOSIS – SURE-VUE MONO RAPID LATEX AGGLUTINATION TEST

PRINCIPLE

The Sure-Vue® Mono reagent is a suspension of polystyrene latex particles of uniform size coated with highly purified Paul-Bunnell antigen from bovine red cell membranes. The degree of purity of the antigen is such that Sure-Vue® Mono only reacts with infectious mononucleosis heterophile antibodies. For this reason, "differential" absorptions are not necessary. Latex particles allow visual observation of the antigen-antibody reaction. If infectious mononucleosis heterophile antibodies are present in serum, the latex suspension changes its uniform appearance and a clear agglutination becomes evident.

OWNERS

Manager, Regional Hematology
Technical Quality Team

RELATED DOCUMENTS

SPECIMEN

A. Specimen type:
   1. Serum from red top or SST tube.
   2. EDTA plasma from lavender top

B. Preparation of sample/stability:
   1. For serum, permit blood to clot for at least 30 minutes.
   2. For non SST tube, separate serum/plasma from the cells.
   3. For SST or aliquoted samples - Samples are stable at room temperature for 24 hours, refrigerated (2-8°C) for 7 days, or frozen for 30 days.
   4. For serum/plasma samples that have not been separated from the cells – Samples should be tested within 24 hours.

C. Reject sample if gross hemolysis, lipemia, turbidity or contamination.

REAGENTS

A. Latex reagent:
   1. Suspension of polystyrene latex particles coated with Paul-Bunnell antigen in a buffer.
   2. Store at 2-8°C. Do not freeze.
   3. Unopened and opened latex reagent is stable through the expiration date on the label.
   4. Reagent dropper dispenses drops of 28 µL ± 10%.

EQUIPMENT

A. Disposable slides with 6 sections each are supplied in kit
B. Disposable stirrers
C. Timer

D. Optional rotator set at 80-100 rpm
E. Calibrated 50 µL pipette

CALIBRATION
N/A

QUALITY CONTROL
A. Positive control:
   1. Supplied in kit.
   2. Rabbit IgG anti-Paul-Bunnell antigen diluted in a buffer.
   3. Store at 2-8°C.
   4. Unopened and opened vial is stable through the expiration date on the label.

B. Negative control:
   1. Supplied in kit.
   2. Non reactive diluted human serum.
   3. Store at 2-8°C.
   4. Unopened and opened vial is stable through the expiration date on the label.

C. Both controls should be tested with each specimen or batch.

D. Do not use kit if QC is not reacting properly.

E. QC results should be documented by either recording onto the logsheet and/or entered into Sunquest computer system:
   C-MONON for negative. Enter "0".
   C-MONOP for positive. Enter "1".

F. Parallel QC and Patient Testing:
   1. A new lot/shipment must have parallel QC testing performed on it before it is put into use. To accomplish this, test positive and negative controls from the current and new kit with the latex reagent of the new kit.
   2. Test a patient from the current kit using reagent of the new kit to make a parallel comparison of kits.
   3. Record parallel QC and patient testing on worksheet and store in red mono screen parallel testing binder. The testing is performed at the regional laboratory.

PROCEDURE
A. Allow reagents, QC, and samples to reach room temperature (20-30°C).

B. Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.

C. Place 50 µL of the sample onto one section of the disposable slide.

D. Place one drop of reagent next to the drop of sample.

E. Mix both drops with a stirrer covering the whole surface of the slide section.

F. Gently rotate the slide for 3 minutes manually or on a rotary shaker set at 80-100 rpm.

G. Look for the presence or absence of agglutination after the aforementioned period of time.

REPORTING RESULTS

A. Interpretation of results

The presence of agglutination indicates a clinically significant concentration of infectious mononucleosis heterophile antibodies in the sample.

1. Positive reactions:
   a. Large clumping with clear background.
   b. Moderate clumping with fluid slightly opaque in background.
   c. Small clumping with opaque fluid in background
2. Negative Reactions:
   a. No visible clumping, uniform suspension.

B. Result entry

Computer Entry	**Sunquest**	**Toplab**
Function	MEM	3,3,1
Worksheet	Site specific	Site specific
Test	MONSC or MONOR	654 or 8013
Method	Site specific	Site specific

Result	**Sunquest**	**Toplab**
Positive	POS	P
Negative	NEG	N

C. Normal result: Negative

D. Critical result: N/A

LIMITATIONS

A. As with all diagnostic assays, the results of the Sure-Vue® Mono assay should be interpreted in light of the clinical symptoms shown by the patient.

B. Occasionally, detectable levels of heterophile antibodies are late in developing in patients symptomatic for infectious mononucleosis. If symptoms persist, it is recommended to repeat the assay in several days.

REFERENCES

Sure-Vue® Mono product insert. BioKit, Barcelona, Spain 05/09.

WRITTEN BY (Pre-SharePoint): Shannon Davila, MT(ASCP)
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MONO Log Sheet

Manufacturer:_____ Date Opened:_____
Kit Lot #:_____ Exp Date:_____

Date	Patient Name or satellite computer label	ACCN #	POS CTRL (Pos)	NEG CTRL (Neg)	Patient Results (Pos/Neg)	Checked & Entered	Tech ID

Reviewed by:_____ Date:_____