Performing Sure-Vue® Color Mono Assay

Principle

The **Sure-Vue® Color Mono** is a simple color enhanced slide test for the detection of infectious mononucleosis. The serum or plasma being tested is mixed on a test slide with a specially treated suspension of stabilized horse red blood cells. Added coloration of the horse cell suspension facilitates the recognition of positive and negative reactions. The appearance of dark agglutinates against a blue-green background (color change) indicates the presence of infectious mononucleosis heterophile antibodies. Small amounts of agglutination against a green-brown background (no color change) indicate very low levels of heterophile antibodies. If no heterophile antibodies are present, the horse red blood cells remain un-agglutinated against a green-brown background.

Materials and Reagents

The following reagents/materials are needed to perform the assay.

Reagent-color enhanced stabilized horse red blood cells
Positive control-serum containing heterophile antibodies of infectious mononucleosis
Negative control-serum containing no heterophile antibodies
Disposable cards/slides
Pipet and tips
Wood applicators or stirrers
Timer

Note: Reagents and controls should be stored at 2-8° C. **Do Not Freeze**. The reagents should not be used after the expiration date shown on the label.

Specimen

The sample required:

- Use fresh serum or EDTA plasma collected by centrifuging clotted blood.
- Store at 2-8°C for no longer than 72 hours after collection.
- For longer periods the samples must be frozen (-20°C).

Reject samples that are:

- Hemolytic or contaminated serum/plasma must not be used.
  Note: Discuss with lead or supervisor before rejecting a specimen

Quality Control

Prior to each set of determinations, the reagents should be tested using the positive and negative controls provided in the kit.

The reaction between the positive control and the reagent should show a clear agglutination, different from the uniform appearance of the negative control.
Refer to section - **Results Interpretation** on page 3.

Quality Control, continued

Document control results on the **QC section** of the patient log – ***Attachment A.***

If…	Then…
All controls are acceptable	Proceed with analyzing patient samples.
Any controls are unacceptable	• Evaluate and repeat controls • Consult with lead or supervisor as needed. • Document any action taken on the log

Parallel Testing:

New shipments and new lots of reagent are parallel tested according to the ***Quality Control Procedure*** –

- Document on the **Sure-Vue® Color Mono** parallel testing form – ***Attachment B*** and submit to a supervisor for approval before the product is put into use.
- After acceptance, the 'READY TO USE' stickers will be applied to the reagent kits.

Procedure

Follow the steps below to perform the Sure-Vue® Color Mono assay:

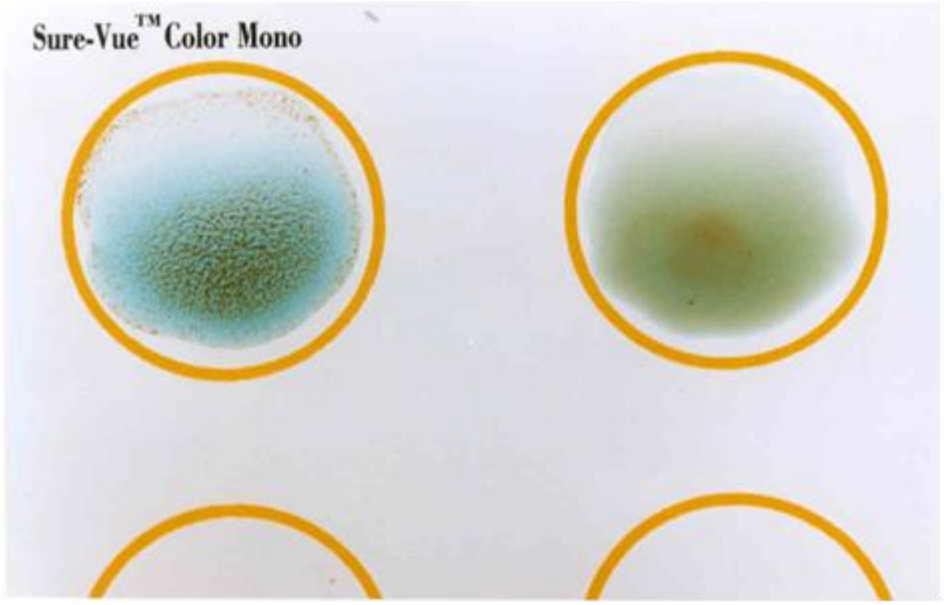
Step	Action
1	Allow reagents, controls and specimens to reach room temperature (20-30°C).
2	Gently shake the reagent vial to obtain a uniform suspension.
3	Label one well for each control and specimen.
4	Pipette 50 µL of serum or plasma onto the center of one of the circles on the slide.
5	Place one drop of reagent next to the drop of sample. **Note:** To assure proper delivery the reagent dropper must be held vertically and a single drop allowed to fall.
6	Using a stirrer mix and spread both drops over the whole circle.
7	Rock the slide slowly and gently for no longer than sixty seconds, then allow it to remain undisturbed on a flat surface for an additional sixty seconds allowing agglutination to fully develop.
8	Without disturbing the slide, examine immediately for agglutination and record the results on the worksheet. ***Caution:*** **Disturbing the slide when interpreting the results may cause agglutination to be dispersed.**

Result Interpretation

This section describes how to interpret assay results.

- A positive result appears as dark agglutination against a blue-green background.
- Small amounts of agglutination against a green-brown background indicate a weak positive infection.
- No agglutination against a green-brown background indicates a negative result.

NOTE: The following pictures illustrate positive and negative results.



3+ Large clumping with blue-green background
2+ Moderate clumping with blue-green background
1+ Small clumping with a green-brown background

Expected Values

A negative result is expected in normal individuals.

Reporting Results

Follow the steps below to enter and release results in CERNER:

Step	Action
1	Click on **ARE** (Accession Result Entry).
2	Scan the patient's barcode and click **RETRIEVE**.
3	Go to the result section.
4	The first result to enter is **Inf Mono**. Click the drop down arrow and choose the correct response, i.e. **NEGATIVE OR POSITIVE.**

Reporting Results, continued

Step	Action
5	Then enter the **QC** results also as **POSITIVE** and **NEGATIVE**.
6	Once all the results are entered, click **PERFORM.**
7	Then go back to the **ACCESSION** box, scan the barcode and click **RETRIEVE** again.
8	Verify that all the results were entered correctly. If yes, then click **VERIFY.**

Limitations

- The results of the Sure-Vue Color Mono assay should be interpreted in light of the clinical hematological and serological information of the patient.
- Occasionally detectable levels of heterophile antibodies are late in developing in patients symptomatic for IM. If symptoms persist, it is recommended to repeat the assay in several days. Some patients may remain persistently negative, especially children and adolescents. It has been reported that only 80 to 90% of adults and less that 50% of young children develop IM heterophile antibodies.
- Detectable levels of heterophile antibodies may persist for months, and more rarely for years, in some individuals.
- The time limits prescribed in the procedure must be strictly observed.
- Assay performance characteristics have not been established for matrices other than serum and EDTA plasma.

Attachements

- Mono Test Log – Attachment A
- Sure-Vue® Color Mono Parallel Testing form – Attachment B

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
Minor	1) Updated the process of reporting results to reflect changes on LIS. 2) Removed any reference to LMS.	Julius Salomon, 6/10/14			
Minor	Updated format and revised index number.	Julius Salomon, 7/1/17			