TRAINING UPDATE

Lab Location:	All Sites	**Date Distributed:**	2/16/22
Department:	Core Lab	**Due Date:**	3/4/22

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Sure Vue Color Mono Test (AHC.IM01)

Description of change(s):

The current Mono test method is discontinued. The "Sure Vue Color Mono Test" is the new method. Read the attached SOP and note the changes highlighted in yellow. The most notable changes are as follows:

- Results will be reported as REAC (reactive) or NR (non-reactive).
- After mixing sample and reagent and spreading over the entire circle, gently **rotate the card for 2 minutes**. Observe for agglutination under high intensity light.

This revised SOP will be implemented on February 17, 2022

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Sure Vue Color Mono Test**	
Prepared by	Ashkan Chini	Date:
Owner	Robert SanLuis	Date:

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Monotest (Qualitative)	Agglutination	MONO

Synonyms/Abbreviations
Monospot

Department
Core Laboratory

2. ANALYTICAL PRINCIPLE

The Sure Vue Color Mono Test is based on the reaction between infectious mononucleosis (IM) antibodies in the sample to be tested and dyed, color-enhanced horse erythrocytes. A visible agglutination takes place with horse erythrocytes when IM heterophil antibodies are present. Lack of agglutination indicates the absence of IM heterophil antibody in the test sample.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Serum None
Collection Container	Serum: plain red-top evacuated blood collection tubes or serum separator tubes (SST)
Volume - Optimum **- Minimum**	1 ml 0.05 mL (approx. one drop)

Criteria		
Transport Container and Temperature	Collection tube at room temperature	
Stability & Storage Requirements	Room Temperature:	Fresh samples should be used
	Refrigerated:	(2-8°C) 72 hours
	Frozen:	(-20°C or colder) If testing cannot be performed within 72 hours
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Contaminated, lipemic, or grossly hemolyzed sera should not be used because of the possibility of nonspecific results.	
Other Considerations	None	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

Note: Do not interchange components of one kit with those of another kit.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Sure Vue Color Mono Test Kit	Fisher HealthCare, 23-038101

Note: Do **not** exchange components of different kits

4.2 Reagent Preparation and Storage

Reagent	**Dyed Colored Enhanced Horse Erythrocyte**
Storage	Store at 2-8°C in an upright position
Stability	Remains stable until the expiration date printed on the vial
Preparation	Reagent is ready to use. Gently shake to ensure homogeneity.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Included with kit, refer to section 4.1 for details.

6.2 Control Preparation and Storage

Control	Reactive and Nonreactive Control
Preparation	Controls are ready to use. Gently mix to ensure homogeneity. **Note:** Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
Storage/Stability	Remains stable until the expiration date printed on the vial

6.3 Frequency

Both controls are to be tested with each patient testing. Controls need to be tested on each new lot number or new shipment of the same lot of reagent.

6.4 Tolerance Limits and Criteria for Acceptable QC

Reactive Control result: Any degree of agglutination or rimming within the test area as compared to the nonreactive control.

Nonreactive Control result: Smooth or finely granular suspension with no visible agglutination.

IF	THEN
Control results are not as expected	1. Make sure the reagent kit is at room temperature, mix the reagent and controls to ensure homogeneity and repeat the test. 2. If step 1 does not resolve the problem, repeat the test using a new test kit or a different lot of test kit. 3. If step 2 does not resolve the problem, suspend patient testing and notify the tech in charge or supervisor.

6.5 Documentation

Record Quality Control results on Mono Quality Control Log.

6.6 Quality Assurance Program

- Each new lot number or new shipment of the same lot of reagent must be tested with external control materials. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test.
- The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Not applicable

7.2 Equipment

Not applicable

7.3 Supplies

Timer
Stirrers

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Test Preparation and Run
1.	Allow all reagents and samples to warm to room temperature (20-30° C) before use. Remove reagents from foam holders. Do not heat reagents in a water bath.
2.	Deliver one free-falling drop of each sample and controls onto a separate circle on the test card. Note the location of each sample by using the numbers located below and to the left of each circle.
3.	Shake the vial of Dyed, Color-Enhanced Horse Erythrocytes gently to uniformly mix the suspension. Add one free-falling drop of reagent to each control and sample.
4.	Using the flat end of the stirrer pipets, mix each sample and reagent and spread over the entire circle.
5.	Gently rotate the card for 2 minutes. Observe for agglutination under high intensity light. All test results should be compared to both Reactive and Nonreactive controls.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

REACTIVE (Result as REAC): Any degree of agglutination or rimming within the test area.
NONREACTIVE (Result as NR): Smooth or finely granular suspension with no visible agglutination.

Use LIS function MEM to enter results.

Enter Shift: (1, 2, or 3)
Worksheet: Use WUR3 for WAH, SUR3 for SGMC, GUR3 for GEC, FMAN for FWMC.
Test: <Enter>
Enter "A" (Accept)
Enter Accession number
Press <Enter> until Result screen is displayed

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions, such as an unusually high percentage of abnormal results.

10.6 Repeat Criteria and Resulting

N/A

11. EXPECTED VALUES

11.1 Reference Ranges

Nonreactive (NR)

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Infectious mononucleosis involves the reticuloendothelial tissue and is believed to be caused by the Epstein-Barr virus. It is generally limited to and affects children and young adults. Infectious mononucleosis may be confused on a symptomatic basis with other diseases. Detectable levels of unique heterophil antibodies are produced in patients with infectious mononucleosis.

13. PROCEDURE NOTES

- **FDA Status**: Approved / Cleared
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

- Reaction times longer than specified might cause false positive results due to a drying effect.
- Due to possible prozone effects, the strength of agglutination in the screening test is not indicative of the IM heterophil antibody titer.
- False negative results have been reported. Some of these may represent cases of IM which persistently remain sero-negative for the IM heterophil antibody. However, some false negative results have been shown to be due to a delayed IM heterophil antibody response.
- Bacterial contamination of reagents or specimens may cause false positive results.

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

N/A

14.4 Clinical Sensitivity/Specificity/Predictive Values

- IM heterophil antibody titers have been shown to persist in some cases for months and years after clinical symptoms have subsided. Conversely, IM heterophil antibodies have been detected prior to the onset of clinical symptoms. Thus, caution should be exercised in the interpretation of test results.
- Patients with exceptionally high levels of the serum sickness heterophil antibody may test falsely positive for the IM heterophil.
- The IM heterophil has been associated with several diseases such as leukemia, Burkitt's lymphoma, pancreatic carcinoma, viral hepatitis, cytomegalovirus infections and others. In these cases, it is difficult to disprove the possibility of concurrent disease states.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

The controls contain human serum or plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the controls should be considered potentially infectious and universal precautions should be used.

The reagent and controls contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide buildup.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Current package insert for Sure Vue Color Mono Test
4. Mono Quality Control log (AG.F41)

17. REFERENCES

Sure Vue Color Mono Test package insert, Fisher Healthcare, Revised 10/2021.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP I012.002		
000	11/28/11	Page 1	Update owner	L Barrett	C Reidenauer
000	11/28/11	3.2	Update stability to match pkg insert Added reject criteria for lipemia and contaminated sera	C Reidenauer	C Reidenauer
000	11/28/11	6.4	Add corrective action for QC failure	L Barrett	C Reidenauer
000	11/28/11	6.7	Delete testing with samples	L Barrett	C Reidenauer
000	11/28/11	7.3	Remove rotator	A Chini	C Reidenauer
000	11/28/11	8.2	Remove “rotary shaker”	A Chini	C Reidenauer
000	11/28/11	11.2	Update title to local terminology	L Barrett	C Reidenauer
000	11/28/11	15	Update to standard content	L Barrett	C Reidenauer
000	11/28/11	16	Add current package insert & BPT SOP	C Reidenauer	C Reidenauer
000	11/28/11	19	Remove package insert	L Barrett	C Reidenauer
001	1/23/18	Header	Add other sites	L Barrett	R SanLuis
001	1/23/18	Page 1	Update owner	L Barrett	R SanLuis
001	1/23/18	4,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
001	1/23/18	6.3	Add with new lot or shipment	L Barrett	R SanLuis
001	1/23/18	10.1.5	Add resulting via MEM	L Barrett	R SanLuis
001	1/23/18	10.5	Review data moved from section 6	L Barrett	R SanLuis
001	1/23/18	15	Update to new standard wording	L Barrett	R SanLuis
001	1/23/18	16	Move log from section 19	L Barrett	R SanLuis
001	1/23/18	17	Update package insert date	L Barrett	R SanLuis
001	1/23/18	Footer	Version # leading zero’s dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
2	6/12/18	3.2	Remove plasma sample type	L Barrett	R SanLuis
3	2/9/22	Header	Updated Title, Changed site to All Labs	D Collier	R SanLuis
3	2/9/22	Page 1	Updated Title and Preparer	A Chini	R SanLuis
3	2/9/22	2.0	Updated analytical principle to match package insert.	A Chini	R SanLuis
3	2/7/22	3.2	Updated wording format, removed “Timing Considerations”	A Chini	R SanLuis
3	2/9/22	4.1	Updated kit name and Catalog #	A Chini	R SanLuis
3	2/9/22	4.2	Updated Reagent prep and storage, moved control info to 6.2	A Chini	R SanLuis
3	2/9/22	6.2	Control prep and storage moved from 4.2 to 6.2	A Chini	R SanLuis

3	2/9/22	6.3, 6.4	Update to new standard wording and format	A Chini	R SanLuis
3	2/9/22	8.0	Updated procedure to match new method package insert.	A Chini	R SanLuis
3	2/9/22	10.1	Removed 10.1.1 to 10.1.6 Changed to match package insert. Removed grading, Added FWMC, and changed pos/neg to REAC (reactive) NR (non-reactive)	D Collier	R SanLuis
3	2/9/22	11.0	Changed from negative to non-reactive	A Chini	R SanLuis
3	2/9/22	12.0	Updated clinical significance	A Chini	R SanLuis
3	2/9/22	14.0. 14.4	Updated limitations of Method	A Chini	R SanLuis
3	2/9/22	15.0	Added additional Safety information	A Chini	R SanLuis
3	2/9/22	16.0	Removed BPT SOP	D Collier	R SanLuis
3	2/9/22	17.0	Updated package insert	A Chini	R SanLuis
3	2/9/22	footer	Changed SOP prefix to AHC	D Collier	R SanLuis

19. ADDENDA

None