TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/5/2018
Department:	Core Lab	**Due Date:**	7/31/2018
		Implementation:	**7/9/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Monotest (Qualitative) SGAH.IM01 v3

Description of change(s):

Change to make SOP match practice

Section	Reason
3.2	Remove plasma sample type

This revised SOP will be implemented on July 9, 2018

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

Technical SOP

Title	**Monotest (Qualitative)**	
Prepared by	Hannah Tran	Date: 10/5/2009
Owner	Robert SanLuis	Date: 1/23/2018

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

Review		
Print Name	**Signature**	**Date**

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1. TEST INFORMATION

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

Synonyms/Abbreviations
Monospot

Department
Core Laboratory

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2. ANALYTICAL PRINCIPLE

The Sure-Vue™ Color Mono reagent is a suspension of specially treated horse red blood cells. Added coloration of the suspension facilitates the recognition of positive and negative reactions.
The serum or plasma being tested is mixed on a test slide with the reagent. The appearance of dark agglutinates against a blue-green background is indicative of heterophile antibody. If no heterophile antibodies are present, the horse cells remain unagglutinated against a green-brown background.

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 ~~or Plasma~~ None	
Collection Container	Serum: plain red-top evacuated blood collection tubes or serum separator tubes (SST) ~~Plasma: EDTA tube~~	
Volume **- Optimum** **- Minimum**	1 ml 0.05 mL (approx. one drop)	
Transport Container and Temperature	Collection tube at room temperature	
Stability & Storage Requirements	Room Temperature:	Fresh samples should be used, see Timing Considerations below
	Refrigerated:	(2-8°C) 72 hours
	Frozen:	(-20°C or colder) see Timing Considerations below
Timing Considerations	If testing cannot be performed immediately, separate serum~~/plasma~~ and store at 2-8°C for up to 72 hours. For longer periods, sample should be stored frozen (-20°C)	

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Criteria	
Unacceptable Specimens & Actions to Take	Reject highly lipemic, or contaminated sera. 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	Gross lipemia or microbial contamination should be rejected (see above).
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

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Sure-Vue Color Mono	Fisher HealthCare, 23-038016

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

4.2 Reagent Preparation and Storage

Assay Kit	
Reagent a	Positive control
Container	1 mL bottle
Reagent b	Negative control
Container	1 mL bottle
Reagent c	Red cells reagent
Container	0.7 mL bottle
Storage	2 - 8°C. Do Not Freeze
Stability	Stable through expiration date shown on label
Preparation	Ready as supplied. When stored, red cells show a complete sedimentation, once shaken a uniform suspension should be obtained.

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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

Refer to section 4.2 for details.

6.3 Frequency

One kit positive and one kit negative control are to be tested with each patient run, and with each new kit lot number or new shipment.

6.4 Tolerance Limits and Criteria for Acceptable QC

Test controls as in procedure for patients. The expected qualitative results should be obtained:

Shift	QC Material	Positive	Negative
ALL (Perform with each test)	Positive I.M. Serum Control (Human)	Agglutination	
	Negative I.M. Serum Control (Human)		No Agglutination

If control results are not as expected:

1. Repeat QC if result exceeds acceptable limits.
2. If repeat testing does not produce acceptable QC, discard kit and repeat QC with a new kit.
3. If testing still does not produce acceptable QC, then notify supervisor immediately. Do not report patient results until acceptable QC results are obtained. Refer to Laboratory Quality Control Program.

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.

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- 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

Automatic pipettes
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	Specimen / Reagent Preparation
1.	Allow the reagents and sample to reach room temperature (20 - 30°C).

8.2	Test Run
1.	Place 50µL of the sample (or a drop of control) onto one circle of the slide.
2.	Shake the reagent vial and add 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.
3.	Mix all drops with separate stirrers covering the whole surface of each circle.
4.	Rotate the slide manually, rocking the slide slowly and gently for ONE MINUTE. Then allow it to remain UNDISTURBED on a flat surface for an additional one (1) minute.
5.	In a well-lit area, WITHOUT DISTURBING THE SLIDE, examine immediately for agglutination and record the results.
6.	After recording results, discard used test slides into biohazardous waste container.

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8.3	Special Handling
1.	The time limits prescribed in the procedure must be strictly observed.
2.	Disturbing the slide when interpreting the results may cause agglutination to be dispersed.

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

10.1.1 Dark agglutination against a blue-green background constitutes a positive result and indicates the presence of IM heterophile antibodies.

10.1.2 Positive Reaction:

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

10.1.3 Roughness or no visible clumping of the cells against a green-brown background is a negative result.

10.1.4 Both controls must give the expected results for patient testing to be valid.

10.1.5 Use LIS function MEM to enter results.

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

10.1.6 Record the control results on the Mono Quality Control log.

10.2 Rounding

N/A

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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

Negative

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Used in the diagnosis of infectious mononucleosis

13. PROCEDURE NOTES

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

14. LIMITATIONS OF METHOD

- 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 asymptomatic for IM. If symptoms persist it is recommended to repeat the assay in several days. Some patients may remain persistently negative, especially children and

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adolescent. It has been reported that only 80 to 90% of adults and less than 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.
- Assay performance characteristics have not been established for matrices other than serum or EDTA plasma.

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

- Differerent studies of the presence of IM heterophile antibodies in blood donors show that the incidence of the disease ranges from 0.9 to 1.7%. As presence of IM heterophile antibodies indicates a relatively recent infection, these results suggest that the true incident of the disease is higher than the number of diagnosed cases. In a study performed using 99 blood bank sera from the Center of Barcelona, the incidence of positive results was 3%.
- The sensitivity of Sure-Vue Color Mono was qualitatively tested using 48 samples presumptively positive for IM heterophile antibodies and compared to a commercially available horse red cell slide test. The sensitivity of the Sure – Vue Color Mono relative to the red cell slide test was 97.9%.
- The Specificity of Sure-Vue Color Mono was qualitatively tested using 200 randomly selected serum patient samples presumptively negative for IM heterophile antibodies. The specificity of Sure-Vue Color Mono relative to the horse red cell slide test was 95.8%.

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.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Current package insert for Sure-Vue™ Color Mono
4. QDSE825v 1.0 BPT Procedure, Nov 7 2011
5. Mono Quality Control log (AG.F41)

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17. REFERENCES

Sure-Vue™ Color Mono package insert, BIOKIT, S.A. Barcelona, Spain, 12/2015.

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

19. ADDENDA

None

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