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Sure-Vue Mono Test

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose and objective of this procedure outlines the principle of the Sure-Vue™ Mono Test by Fisher Health Care and steps to perform this test. This document applies to all hospitals and laboratory testing sites.

II. SUMMARY:

A. Infectious mononucleosis is an acute infectious disease of viral etiology and it involves the reticuloendothelial tissue It is believed to be caused by the Epstein- Barr virus. The most frequent symptoms are fever, sore throat, swollen lymph glands in the neck, armpits, and groin, extreme fatigue, sore throat, head and body aches. Splenomegaly occurs in most patients. Mild liver damage that can cause temporary jaundice may occur.

B. The complications of infectious mononucleosis may include:

1. Ruptured spleen.
2. Kidney inflammation.
3. Hemolytic anemia.
4. Nervous system problems such as encephalitis or meningitis.
5. Inflammation of the heart muscle.
6. Heart rhythm problems.
7. Obstruction of the upper airways.

C. The Sure-Vue Mono Test, based on the Davidsohn test procedure, is accepted as the classic reference method in detecting infectious mononucleosis and may be used on patients less than 18 years of age.

D. Detectable levels of the Infectious Mononucleosis (IM) heterophil antibody can usually be expected to occur between the sixth and tenth day following the onset of symptoms.

III. PRINCIPLE:

The Sure-Vue™ Mono Test is based on the reaction between IM antibodies in the sample to be tested and

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.

IV. SPECIMEN COLLECTION AND HANDLING:

A. Serum:

   1. Use fresh serum collected by centrifuging clotted blood from a gold top (SST) tube. A Red top tube (no-additive) is an acceptable alternate specimen type.

B. If the test cannot be carried out on the same day, it may be stored between 2 and 8°C. If testing is not performed within 72 hours, serum samples must be frozen (-20°C).

C. Do not use hemolyzed, lipemic, or contaminated samples.

V. REAGENTS:

Materials from one kit must not be mixed with another kit. If one reagent is depleted, the remainder of the kit must be discarded. Quality Control (QC) material will be discarded after parallel testing is complete.

A. Reagents and Controls:

   1. Dyed, Color-Enhanced Horse Erythrocyte Reagent is a suspension of horse erythrocytes in buffer with 0.1% sodium azide as a preservative.
   2. Controls: (Postive and Negative) are human serum or defibrinated plasma (liquid) with 0.1% sodium azide as a preservative. All controls have been tested for HBsAg and for HIV-1, HIV-2 and HCV antibodies and have been found to be nonreactive, but they should considered potentially infectious and should be handle using standard precautions.
   3. For disposal of reagents and control materials, large quantities of water should be used to flush down the drain to prevent azide buildup in lead and copper plumbing during disposal. Dispose reagent and control bottles in Biohazard Waste.
   4. Do not use the erythrocyte reagent if it becomes contaminated.The erythrocyte reagent, once shaken, must be uniform without visible clumping. When stored a slight sedimentation may occur and should be considered normal.
   5. Do not use controls that appear turbid or have a visible precipitate.

VI. STORAGE:

A. The reagent and the controls will remain stable through the expiration date shown on the label if stored between 2 and 8 °C. Do not freeze. The reagents can be damaged by improper handling especially temperature extremes. Checking reagent with the positive and negative controls provided will permit detection of reagent deterioration.

B. The reagents should not be used after the expiration date shown on the label.

VII. SUPPLIES AND EQUIPMENT:

A. Sure-Vue™ Mono Kit

B. Positive and Negative Controls

C. Stirrer Pipette (included in kit)

D. Disposable Test Cards (included in kit)

E. Micropipette (optional)

F. Disposable stirrers or sticks (optional)

G. Rotator- if available

H. Timer

VIII. QUALITY CONTROL (QC):

A. Negative and Positive controls are packaged with the Sure-Vue™ kit.

B. Sure-Vue™ Controls should be tested prior to testing patient specimens when:

1. A new operator is being trained to perform this test
2. A new test kit lot is received
3. A new shipment of test kits is received

C. Sure-Vue™ Controls should be tested each time patient testing is performed

D. Controls should be tested in the same manner as serum samples following the Test Procedure.

E. Record QC results for each run on the Sure-Vue™ Mono Results Log.

F. For each new lot or shipment of kit received, perform QC testing in parallel with the old lot or shipment.

1. For Trenton, Taylor, Wayne: Record QC results for each kit opened on the Parallel Testing Worksheet.

IX. TEST PROCEDURE:

A. Allow the reagent and controls to reach room temperature (20 - 30°C).

1. Add one free-falling drop of the positive and negative controls from the dropper vials supplied to separate test circles on the disposable test card.
2. Place 50 µl of the sample on one test circle of the disposable test card. Technologist may use the stirrer pipette included in the kit or a micropipette. The stirrer pipette should be in a vertical position for accurate delivery of the sample.
3. Gently shake the Erythrocyte Reagent vial for homogeneity. Vigorous shaking should be avoided.
4. Add one free falling drop of Erythrocyte Reagent to the test sample and QC material.
5. Mix both drops together with a disposable stick or the flat end of the stirrer pipette included in the kit, making sure to cover the entire circle on the test card.
6. Gently rotate the slide for 2 minutes manually or on a rotary shaker set at 80-100 rotations per minute (rpm).
7. Look for the presence or absence of agglutination as compared to the positive and negative controls.

X. INTERPRETATION OF THE RESULTS:

A. Results are reported as either “Positive” or “Negative.”

B. POSITIVE REACTIONS:

1. Any degree of agglutination or rimming within the test area as compared to the negative control.

C. NEGATIVE REACTIONS:

1. Smooth or finely granular suspension with no visible agglutination.

D. The following comments are automatically added to the results for patients <5 and <10 years of age.

E. Only 30% of children under the age of 5 produce heterophile antibody. Suggest EBV panel.

F. Only 60% of children under the age of 10 produce heterophile antibody. Suggest EBV panel.

XI. MAINTENANCE (GROSSE POINTE ONLY):

A. DAILY: Measure the speed of the Rotator: Must be 100 rpms

1. Log on Daily worksheet

B. Introduction

1. The mixing of specimens is an operation in the laboratory setting that helps promote the combination of antigen and antibody. Proper mixing helps maintain the suspension of reagents that would otherwise separate. Inadequate mixing will result in invalid results or incorrect interpretation. Excessive mixing can cause denaturation of protein, hemolysis of red blood cells or foaming.

C. Principle

1. The rotator is an oscillating platform designed for a variety of reactions requiring smooth and consistent agitation. The speed of the moving platform is adjustable on most models.

D. Purpose

1. The instrument has routine maintenance performed. This record is retained for the life of the instrument.

E. Equipment

1. Hybritech Incorporation-Orbital Shaker

F. Materials

1. Timer
2. Pen
3. Gauze

G. Special Safety Precautions

1. Never place hands on or around platform while mixer is in operation.

H. Procedure

1. Check the power supply cord and plug daily. Discontinue use of instrument if broken or frayed. Notify Facilities and fill out orange work order tag or go online to fill out work order form.
2. The speed is estimated by counting the number of rotations made per minute.
   Use a timer and pen.
3. Hold the pen stationary and close to the rotating platform.
4. Allow the rotator to strike the pen.
5. Count the number of taps per minute (or count rotations in 15 seconds and multiply by 4).
6. The recommended speed of rotation is 100 revolutions per minute (rpm). If the speed is less that 95

or greater than 105 rpm then the speed must be adjusted.

7. The knob on the front of the machine can be adjusted by turning in either direction.
8. Record the rpm result on the Daily Maintenance Log.

XII. RESULT ENTRY:

A. Results of both patient and quality control must be written on the Sure-Vue Mono Results log.

B. Manually enter the patient results into the LIS.

XIII. REFERENCES:

1. Auwaerter, PG. Patient Education. Infectious mononucleosis (mono) in adults and adolescents (Beyond the Basics). In: UpToDate, Post TW (Ed.), UpToDate, Waltham, MA. Accessed on May 20, 2022. https://www.uptodate.com/contents/infectious-mononucleosis-mono-in-adults-and-adolescents-beyond-the-basics?search=patient-information-infectious-mononucleosis-mono-in-adults-and-adolescents&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
2. Sure-Vue Mono Test package insert, 6004-400SV Rev 12_2021 Fisher Healthcare Pittsburgh PA 15275

Attachments

Mono Patient/QC Log
Parallel Testing Worksheet.pdf

Approval Signatures

Step Description	Approver	Date
Medical Directors	Muhammad Arshad: Chief, Pathology	9/27/2024
Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	9/26/2024
Medical Directors	Jeremy Powers: Chief, Pathology	9/12/2024
Medical Directors	Ryan Johnson: OUWB Clinical Faculty	9/11/2024
Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	9/10/2024
Medical Directors	Masood Siddiqui: Staff Pathologist	9/9/2024
Medical Directors	John Pui: Chief, Pathology	9/9/2024
Policy and Forms Steering Committee Approval (if needed)	Leah Korodan: Mgr, Division Laboratory	9/9/2024
	Caitlin Schein: Staff Physician	9/5/2024
	Qian Sun: Tech Dir, Clin Chemistry, Path	8/14/2024
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	8/13/2024
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	Ashley Beesley: Mgr, Laboratory	7/8/2024
	Jennifer Yaker: Mgr, Laboratory	7/5/2024
	Leah Korodan: Mgr, Division Laboratory	7/3/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne