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SUBJECT: Immunocard STAT MONO, Meridian BRAND RAPID TEST

1. PRINCIPLE:

The Meridian Immunocard STAT Mono Test is a rapid test for the detection of heterophile antibodies specific to infectious mononucleosis (IM) in human blood. The test is a chromatographic immunoassay for the determination of IM heterophile antibodies in human serum, plasma, or whole blood. In the procedure, serum, plasma, or whole blood is mixed with diluent. Then the test stick is placed in the mixture and the mixture migrates up the stick by capillary action.
If the specific Infectious Mononucleosis heterophile antibody is present in the sample, it will form a complex with the bovine erythrocyte extract conjugated color particles. The complex will then be bound by bovine erythrocyte extract immobilized on the membrane and a visible blue test line will appear to indicate a positive result. A pink control line will always appear if the test system is valid and the mixture migrates successfully up the test stick.

2. CLINICAL SIGNIFICANCE:

Infectious Mononucleosis is an acute, self-limiting disease caused by the Epstein-Barr virus. Infection with EBV in early life usually is asymptomatic, however up to 50% of infection occurring in young adulthood and adolescence will develop clinical manifestations associated with IM.

3. SPECIMEN:

A. COLLECTION AND PROCESSING:

EDTA or Heparinized whole blood, serum, or plasma may be used. Other anticoagulants have not been tested and should, therefore, be avoided.
Serum or plasma may be stored refrigerated at 2-8 C for up to 48 hours prior to testing.
Whole blood samples are acceptable for 24 hours stored at room temperature.
All samples should be tested at room temperature.

B. REJECTION:

No significant interference from hemolyzed, lipemic, or icteric samples. If the control line is visible you may report the result.

4. REAGENTS, STANDARDS, AND CONTROLS:

25 Test sticks, 25 test tubes, 25 transfer pipettes, 25 capillary tubes with 1 capillary bulb, 1 diluent (contains buffer with 0.2% sodium azide.
Negative Control (1.0 ml): Goat albumin in tris buffer with 0.2% sodium azide.
Positive Control (1.0 ml): IM with rabbit anti-beef stroma in tris buffer with 0.2% sodium azide and 0.005% gentamycin sulfate preservatives.
All included in test kit along with extra tubes, pipettes, capillary tubes, and capillary bulb.

B. CONTROL PROCEDURE:

Internal quality control: The Meridian Mono test has a built-in procedural control included in the test. The appearance of a pink to red line in the control region assures that the correct test procedure was

followed, indicating sufficient volume of fluid was used and that capillary flow occurred. At the end of 5 minutes, formation of the control line verifies that the sample has flowed through the test region and that the test is complete. The test should be considered invalid if the control line does not appear.
A clear background in the result window is considered and internal negative control. However when whole blood samples are tested, the background may be slightly reddish due to the low level hemolysis of some RBCs. This is acceptable as long as it does not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the reading of the result.

External quality control: Positive and negative controls are supplied with the kit. The external controls must be performed when a new box is opened, recorded on the Kit test log and entered in the LIS.

5. PROCEDURE:

A. PERFORMANCE:

EDTA or Heparinized WHOLE BLOOD, Serum, or Plasma:

1. Mix specimen well.
2. Draw sample into the provided transfer pipette.
3. Hold in a vertical position and dispense one drop into a test tube supplied with the kit.
4. Immediately add 1 drop of diluent to the test tube and mix together.
5. Place a test stick into the test tube with the absorbent end down and arrows pointing down.
6. Set a timer for 5 minutes.
7. Read results at 5 minutes.

B. CALCULATIONS:

n/a

C. INTERPRETATION OF RESULTS:

Positive: Two colored lines appear. A pink line in the control region and a blue line in the test region. A positive result indicates that there are IM heterophile antibodies in the patient sample. It is not recommended to compare the color intensity of the lines.
Negative: Only a pink line appears in the control region. No apparent faint colored line on the test line region. A negative result indicates that there are no IM heterophile antibodies in the patient sample or that the concentration is below the detection level.
Invalid: Absence of a pink line in the control region. The test should be repeated as an improper test procedure may have been performed or deterioration of reagents may have occurred. Repeat the test with a new test device. If the problem persists, call POCT office or Technical service at 800-343-3858.

6. QC PERFORMANCE POLICY:

External controls are performed when a new box is opened. Internal controls are checked with each sample tested. In the absence of a positive internal control line the test is invalid. Control results are recorded on the Kit test log sheet and in the LIS. The lid of the box is marked with initials of person performing QC testing with date indicating acceptable to use.

A. CALIBRATION AND CALIBRATION VERIFICATION

n/a

B. FAILURE/REMEDIAL ACTION:

If controls do not perform as expected, do NOT report results of patient testing. Call Tech Supervisor or POCT staff. The test may be sent to NVML at SRMC. Or ask core lab to send a kit with a different lot number.

7. EXPEXCTED RESULTS:

A. REPORTABLE RANGE:

n/a

B. REFERENCE RANGE:

Negative

C. CRITICALVALUES:

n/a

8. LIMITATIONS AND INTERFERRING SUBSTANCES:

A negative result does not rule out the possibility of IM because the antibodies to heterophile antigen may be absent or may not be present in sufficient quantity to be detected.
During the acute phase of IM, heterophile antibodies are detectable in 80 – 85% of patients. Heterophile antibodies are detectable during the first month of illness and decrease rapidly after week four.

9. METHOD VALIDATION:

November-December 2012

10. REFERENCES:

Meridian Bioscience Immunocard STAT Mono Test package insert; 3854-3, Oct. 2009 , Cincinnati, OH 45244.

Policy Approval:

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