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Subject **Mono Test Procedure**	**Attachments** ☐ Yes ☒ No
Key words – infectious mononucleosis, Epstein-Barr Virus (EBV), heterophile antibodies	**Number** **GHI-PC-Clinic Lab Procedures- Mono v. 07-2009**
Category Provision of Care	**Effective Date** **July 2009**
Manual Clinic Laboratory Procedure Manual Quick Clinic Laboratory Procedure Manual	**Last Review Date** **February 2015**
Issued By Clinic Laboratory Administration	**Next Review Date** **February 2016**
Applicable Clinic Laboratory staff	**Origination Date** **December 2008**
	Retired Date
Level of Complexity Non Waived	**Contact Laboratory Technical Consultants**
Review Responsibility Laboratory Technical Consultants	**Approved Date** **December 2008**
APPROVAL(S) Laboratory Medical Director	

Mono Test
Clinic Lab Procedure (Pages 1-6)
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PURPOSE/PRINCIPLE

This procedure provides instruction for performing the OSOM Mono Test. The OSOM Mono Test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in whole blood as an aid in the diagnosis of infectious mononucleosis. The OSOM Mono Test uses color immunochromatographic dipstick technology with bovine erythrocyte extract coated on the membrane. In the test procedure whole blood is mixed with the Diluent. Then the Test Stick is placed in the mixture and the mixture migrates along the membrane. If the specific IM 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.

The diagnosis of infectious mononucleosis (IM) is suggested on the basis of the clinical symptoms of fever, sore throat and swollen lymph glands. The highest incidence of symptomatic IM occurs during late adolescence (15-24 years of age). Infectious mononucleosis is caused by the Epstein-Barr Virus (EBV). The laboratory diagnosis of IM is based on the detection of IM heterophile antibodies. These heterophile antibodies are directed against antigens found in bovine, sheep and horse erythrocytes. The OSOM Mono Test utilizes an extract of bovine erythrocytes to give the required sensitivity and specificity. A heterophile

antibody response is observed in approximately 80 – 90% of adults and children with EBV-caused IM. This percentage drops to approximately 50% for children under the age of four years.

SPECIMEN INFORMATION

1. Whole blood collected in EDTA or heparin is stable for 24 hours.
2. Fingerstick whole bood – hold the capillary tube horizontally while collecting the sample. Touch the end of the capillary tube to the drop of blood on the patient's finger. Fill the capillary tube completely. Place the small end of the black bulb onto the capillary tube and place your fingertip over the opening of the bulb. Squeeze the bulb to dispense the whole blood sample into the test tube.
3. Specimens should be at room temperature (15-30°C) before testing.

REAGENT/EQUIPMENT/SUPPLIES

1. OSOM Mono Test kit, Genzyme Diagnostics. Each kit contains:
   a. 25 Test Sticks in a container
   b. 25 Test Tubes
   c. 25 Transfer Pipettes
   d. 25 Capillary Tubes with 1 Capillary Bulb
   e. 1 Diluent, contains buffer with 0.2% sodium azide
   f. 1 Mono Positive Control, contains rabbit anti-beef stroma in tris buffer with 0.2% sodium azide and 0.05% gentamycin sulfate preservatives.
   g. 1 Mono Negative Control, contains goat albumin in tris buffer with 0.2% sodium azide.

      NOTES:
      Store Test Sticks and reagents tightly capped at room temperature, 15-30°C.
      Do not use Test Sticks or reagents past their labeled expiration date.
      Do not interchange or mix components from different kit lots.
2. Timer

SPECIAL SAFETY PRECAUTIONS

1. The Diluent and Contols contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded Diluent or Controls down sink.

QUALITY CONTROL

1. External Quality Control
   a. Positive and Negative Controls provided in the OSOM Mono Test kit should be run with each box opened. Controls must perform as expected prior to reporting patient results.
   b. Add one free falling drop of control to the Test Tube and then proceed in same manner as with patient sample.
2. Internal Quality Control
   a. Two levels of internal procedural controls are performed with each test procedure.
      - The red Control Line is an internal positive procedural control. The Test Stick must absorb the proper amount of test material and be working properly for the red Control Line to appear.

- A clear background is an internal negative procedural control. If the test has been performed correctly and the Test Stick is working properly, the background will be clear to give a discernible result.

- If the red Control Line does not appear, the test may be invalid. If the background does not clear and interferes with the test result, the test may be invalid. Call Genzyme Diagnostics Technical Service at the number listed in the OSOM package insert if you experience either of these problems.

PROCEDURE

1. Use the transfer pipette provided to add one drop of whole blood to a Test Tube labeled with patient identification.

2. Slowly add 1 drop of Diluent to the bottom of the Test Tube and mix.

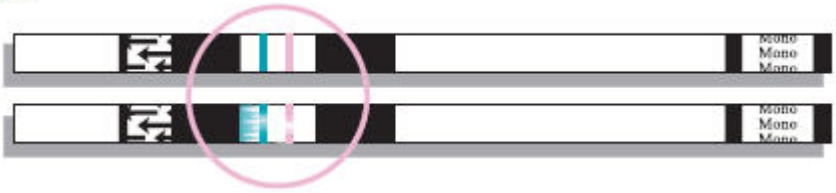
3. Remove the Test Stick(s) from the container. Re-cap the container immediately. Place the Absorbent End of the Test Stick into the treated sample. Leave the Test Stick in the Test Tube.

4. Set timer for 5 minutes. Read result at 5 minutes. Positive results may be read as soon as the red Control Line appears.

INTERPRETATIONS/RESULTS

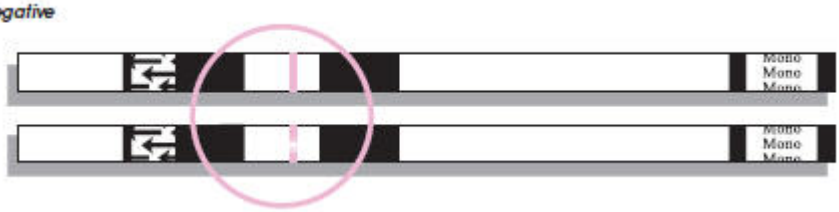
1. Positive Result: a blue Test Line and a red Control Line is a positive result for the detection of infectious mononucleosis heterophile antibody. The blue line can be any shade of blue.

Positive



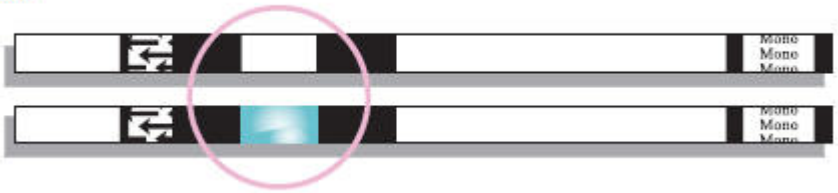
2. Negative Result: a red Control Line but no blue Test Line is a negative result. No infectious mononucleosis heterophile antibody has been detected.

Negative



3. Invalid Result: If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick or call Genzyme Diagnostics Technical Service at the number listed in the package insert.

Invalid



NOTE:
A blue or red line which appears uneven in color density is considered a valid result.

REFERENCE RANGES (EXPECTED RESULTS)
Negative

REPORTING RESULTS
Clinic Labs: see the Computer Entry section of this procedure

Quick Clinics:
1. enter results on test log sheet
2. send test log sheet to Clinic Lab for result entry into the Laboratory Computer System

LIMITATION OF PROCEDURE
1. A negative result may be obtained from patients at the onset of the disease due to heterophile antibody levels below the sensitivity level of this test kit. If symptoms persist or intensify, the test should be repeated.

2. Some segments of the population with acute IM are heterophile antibody negative.

3. The OSOM Mono Test is a QUALITATIVE test for the detection of IM heterophile antibody.

4. As with all diagnostic assays, the results obtained by this test yield data that must be used as an adjunct to other information available to the physician.

REFERENCES

1. OSOM Mono Test package insert, Genzyme Diagnostics, 9/07.
2. Blood Collection Procedure (Phlebotomy)

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Computer Order and Result Entry

MONO TEST
Order Codes: MONO-W, MONIF-W

RESULTING: MONS-W

WORKSHEET:

Function MEM Worksheet HM2_ _ (HEME MISC 2 __)

RESPONSE:

NOTE: If results are invalid (control line not visible), re-test per procedure instructions.

MONS	(A battery which includes the MONO test for the result and QA tests to document your kit quality tests.)	
Code	**Name**	**Response**
MOCON	MONO Serum Pos Con Bar	Y or N Y (= YES, the control bar is present) N (= NO, the control bar is NOT present)
MOBAC	MONO Neg Clear Background	Y or N Y (= YES, the background is clear) N (= NO, the background is NOT clear)
MOKIT	MONO Kit Lot Number	Enter the lot number (12345) from the kit box. If there is a letter in the kit lot number, put a **;** in front of the lot number (;A1234)
MONO	MONO Test	POS, NEG, INCN **If INCN (Inclusive), the ETC INMON (Inconclusive Mono tests may result from cross reactions or early Mono. If Mono is suspected, suggest repeating Mono test in one week.) will append to the result.

RESULTING: MONIF-W

WORKSHEET:

Function MEM Worksheet HM2_ _ (HEME MISC 2 __)

Order Codes: MONIF-W

ORDERING: If MONIF (Mono If) ordered→ HEDF (differential) must be ordered.

RESULTING:

WORKSHEET:

Function MEM Worksheet HM2_ _ (Heme Misc 2)

ADDITIONAL INFORMATION:

If a Mono "if" is ordered:

a. Accept the differential results in OEM.

b. Go into MEM, worksheet HM2_ _ to accept Mono If answer

Pos Example: Hemogram, diff, and MONIF ordered.

Resulted Diff = > 35% total lymphs.

a. MEM, Worksheet: HM2_ _, Test: MONIF

Computer will display:

MONIF: number of Lymphs-HIDE <<Do Not Report>>

ADD Test MONS-OBL (Mono test ordered by lab)

Request complete -- returning to manual result entry

Accept (A), Modify (M), or Reject (R)?

b. Accept. Mono test is automatically ordered. The Mono "If" test will be hidden.

Note: **If MONS-OBL needs to be ordered "waiting" so it can be resulted at the clinic:**

1. Go into Order Entry under the access number
2. MONS-OBL test will display
3. Retype mono order: MONS-**W**-OBL

The W must be the first priority code

4. Accept
5. See above to result the MONS.

Neg Example: Hemogram, diff, and MONIF ordered.

Resulted Diff = < 35% total Lymphs.

a. MEM, Worksheet: HM2_ _, Test MONIF.

Computer will display:

MONIF: MNI Mono test not indicated.

Accept (A), Modify (M), or Reject (R)?

b. Accept. This will result the Mono If with MNI (Mono Not Indicated).

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