UPMC | HANOVER

Department of Pathology/Laboratory *Policy/Procedure*

Immunology Immunocard STAT!®MONO TEST [Immunology Manual]		Page **1** of **3**
Doc#: IMM 201	**Section:** IMMUNOLOGY	**Effective Date:** July 10, 2019

SCOPE: This policy applies to UPMC Hanover.

KEYWORDS: MONO, Monostat,

PURPOSE:
The Immuno*Card* STAT! Mono Test uses color immunochromatographic dipstick technology with bovine erythrocyte extract coated on the membrane. In the test procedure, serum, plasma or 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.

POLICY:
The Immuno*Card* STAT! Mono Test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in the diagnosis of infectious mononucleosis. CLIA Complexity: Non-Waived for Serum or Plasma; Waived for Whole Blood

SPECIMEN:

Serum from separator tube or red-top tube
• Whole blood using EDTA or heparin
• Whole blood must be used within 24 hours. Plasma and serum may be refrigerated at 2°C-8°C and tested with 48 hours; or held frozen below -10°C for up to 3 months.
• All specimens must be at room temperature (15°C to 30°C) when tested.

QUALITY CONTROL: External QC to be run each shipment or lot and every 30 days thereafter.
• Mono Positive Control (contains rabbit anti-beef stroma in tris buffer with 0.2% sodium azide and 0.05% gentamycin sulfate preservatives)
• Mono Negative Control (contains goat albumin in tris buffer with 0.2% sodium azide)
• Run Positive and Negative controls as patients with one drop appropriate QC and one drop of diluent, mix and add test strip, incubating for 5 minutes.

PROCEDURE:

1	Using transfer pipette provided, add one drop of serum or plasma, or whole

	blood to tube provided. (Fingertip would add one capillary-filled tube of blood to tube.)
2	Slowly add 1 drop of Diluent to the bottom of the test tube. Mix.
3	Remove appropriate number of test sticks from container. Re-cap container immediately.
4	Place the Absorbent End of the Test stick into the treated sample. Leave Test stick in test tube.
5	Read results in 5 minutes. (Positive results may be read as soon as the red control line appears.)

RESULT INTERPRETATION:

1	**Positive:** A Blue Test line and a Red Control line is the positive result for the detection of infectious mononucleosis heterophile antibody.
2	**Negative:** A Red Control Line and no blue test line is a negative result. No infectious mononucleosis heterophile antibody has been detected.
3	**Invalid:** If after 5 minutes, no red Control Line appears or the background color makes reading the red control line impossible, the result is invalid. If this occurs, re peat test using new Test stick. If it happens repeatedly, call Meridian Bioscience Technical Services at 1-800-343-3858.

METHOD LIMITATIONS:

• 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.
• The Immuno*Card* STAT! Mono Test is a qualitative test for the detection of IM heterophile antibody.
• A negative result may be obtained from patients at the onset of the disease due to heterophile antibody levels below the sensitivity of this test kit. If symptoms persist or intensify, the test should be repeated.
• Some segments of the population with acute IM are heterophile antibody negative

PROCEDURE NOTES:
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) (1, 2). 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 Immuno*Card* STAT! Mono Test utilizes an extract of bovine erythrocytes to give the required sensitivity and specificity.
A blue or red line, which appears uneven in color density, is considered a valid result.

REFERENCES:

Meridian Immunocard STAT! package insert, Rev.3854-5, 10/15.Meridian Bioscience, Inc., 2471 River Hills Drive, Cincinnati, Ohio 45244, USA.

Document History

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