Immunology Immunocard STAT!®MONO TEST [Immunology Manual]		Page **1** of **4**
Doc#: IMM 201	**Section:** IMMUNOLOGY	**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 (not used here).

REAGENTS/SUPPLIES:

Provided: 25 test sticks
25 test tubes
25 transfer pipets
27 capillary pipets
1 diluent (contains buffer with 0.2% sodium azide)
1 Mono positive control (contains rabbit anti-beef stroma in tris buffer with 0.2% sodium azide and 0.05% gentamycin sulfate preservatives)
1 Mono negative control (contains goat albumin in tris buffer with 0.2% sodium azide)
1 work station
1 Directional insert

Store test sticks and reagents tightly capped at 15-30 degrees C. Do not use after expiration date.

Not provided:
Timer

HAZARDS/PRECAUTIONS:

- All reagents are for in vitro diagnostic use only.
- Follow lab safety guidelines in the collection, handling, storage and disposal of patient specimens
- The diluent and controls contain sodium azide which may react with copper or lead plumbing. Use copious amounts of water if discarding down sink.
- Do not interchange or mix components from different kit lots.

SPECIMEN:

Serum from separator tube or red-top tube
Plasma from EDTA or heparin tube
• 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 POLICY:

External QC is with run each shipment or lot and every 30 days thereafter using controls supplied with the kit.
Mono Positive Control
Mono Negative Control
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.

Each stick contains internal QC presenting as a Red line indicating an acceptable test result**.** Patient results are not reported unless the line is present. Internal QC results are documented on the worksheet for the test.

PROCEDURE:

1	Using transfer pipette provided, add one drop of serum or plasma to tube provided.
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; positive result for the detection of infectious mononucleosis heterophile antibody.
2	**Negative:** A Red Control Line and no blue test line; 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, repeat test using new Test stick. If it happens repeatedly, call Meridian Bioscience Technical Services at 1-800-343-3858.

Immunocard Mono
Revised 7/10/2019

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

Date of Origination and Document Control Number	8/10/2015	Michelle Baker
Revision History/ Biennial Review:	8/10/2017	Michelle Baker
Revision History/ Biennial Review:	7/10/2019	Michelle Baker

Immunocard Mono
Revised 7/10/2019

Immunology Immunocard STAT!®MONO TEST [Immunology Manual]		Page **4** of **4**
Doc#: IMM 201	**Section:** IMMUNOLOGY	**Date:** July 10, 2019

Revision History/ Biennial Review:	6/14/2021	Michelle Baker
Revision History/ Biennial Review:	6/13/2023	Kimberly Breighner
Revision History/ Biennial Review:		

Document Information

Document Title

Mono Test, ImmunoCard STAT

Document Description

N/A

Approval Information

Approved On: 09/22/2023

Approved By: Sherilyn Solanick POCC

Approval Expires: 06/19/2025

Approval Type: Manual Entry

Document Location: / Laboratory - Hanover / Hanover - Immunology

Keywords: Mono, serum,plasma

Printed By: Sherilyn Solanick

Standard References: N/A

Note: This copy will expire in 24 hours