

# ImmunoCard STAT<sup>®</sup> Mono Test

**CLIA Complexity:**  
Whole Blood – Waived  
Serum or Plasma – Non-Waived

**REF** Catalog No. 755725

**IVD** *In vitro* Diagnostic Medical Device

## FOR LABORATORY AND PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

### INTENDED USE

The ImmunoCard STAT<sup>®</sup> 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.

### SUMMARY AND EXPLANATION OF TEST

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)<sup>(1,2)</sup>. 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 ImmunoCard STAT<sup>®</sup> Mono Test utilizes an extract of bovine erythrocytes to give the required sensitivity and specificity.

### PRINCIPLES OF TEST

The ImmunoCard STAT<sup>®</sup> 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.

### KIT CONTENTS AND STORAGE

- 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)
- 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

**Note:** Extra components (tubes, pipettes, capillary tubes) have been provided for your convenience.

Store the Test Sticks and reagents tightly capped at 15-30C.  
Do not use the Test Sticks or reagents after their expiration dates.

### MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers.
- A timer or watch.

## PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.
- The Diluent and Controls 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 a sink.
- The Capillary Bulb contains dry natural rubber.
- Do not interchange or mix components from different kit lots.

## RISK AND SAFETY PHRASES

**Positive Control, Negative Control, Diluent  
Harmful - Sodium Azide**

### RISK PHRASES:

- R22 Harmful if swallowed  
R32 Contact with acids liberates very toxic gas

### SAFETY PHRASES:

- S35 This material and its container must be disposed of in a safe way.

## SPECIMEN COLLECTION AND PREPARATION

### *Serum, Plasma, or Whole Blood Sample*

Obtain specimens by acceptable medical technique. Collect whole blood samples using a tube containing EDTA or heparin as an anticoagulant. Other anticoagulants have not been tested. Serum and plasma specimens may be refrigerated (2-8C) and tested within 48 hours; serum and plasma specimens held for longer times should be frozen (below -10C) and tested within 3 months. Test whole blood specimens within 24 hours. Specimens must be at room temperature (15-30C) when tested.

### *Fingertip Whole Blood*

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. Place your fingertip over the opening in the bulb. Squeeze the bulb to dispense the whole blood sample into the test tube.

## QUALITY CONTROL

### *External Quality Control*

For external QC testing, use the controls provided in the kit. Add one free falling drop of control to the Test Tube and then proceed in the same manner as with a patient sample. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, Meridian Bioscience recommends that positive and negative external controls be run with each new lot and with each new untrained operator. Some commercial controls may contain interfering additives. The use of these controls is not recommended.

### *Internal Quality Controls*

The ImmunoCard STAT! Mono Test provides two levels of internal procedural controls 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 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 Meridian Bioscience Technical Services if you experience either of these problems.

## 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 ImmunoCard 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<sup>(1)</sup>.

## EXPECTED VALUES

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 four years of age <sup>(1)</sup>. While the incidence of IM reflects wide seasonal, ethnic and geographical variation, a large epidemiological study noted that the highest incidence of symptomatic IM occurred during late adolescence (15-24 years of age) <sup>(2)</sup>.

## PERFORMANCE CHARACTERISTICS

A total of 439 specimens (183 serum, 176 plasma and 80 whole blood) were evaluated by two clinical labs in a clinical study. Test results of the ImmunoCard STAT! Mono Test were compared to results obtained with a commercially available latex particle agglutination test for the qualitative determination of infectious mononucleosis heterophile antibodies. Discrepancies between the results given by the ImmunoCard STAT! Mono Test and the latex particle agglutination test were resolved by Epstein-Barr Virus (EBV) specific serological assays. In these assays, the specific antibodies to the EBV capsid antigen (IgM) and EBV nuclear antigen-1 (IgM and IgG) were determined.

### Serum Specimens:

		Comparative Test	
		+	-
ImmunoCard STAT! Mono Test	+	74	8*
	-	0	101

\*6 out of 8 tested positive by EBV testing

### Plasma Specimens:

		Comparative Test	
		+	-
ImmunoCard STAT! Mono Test	+	67	15*
	-	0	94

\*8 out of 15 tested positive by EBV testing

### Whole Blood Specimens:

		Comparative Test	
		+	-
ImmunoCard STAT! Mono Test	+	30	3*
	-	0	47

\*1 out of 3 tested positive by EBV testing

### All Specimens:

		Comparative Test	
		+	-
ImmunoCard STAT! Mono Test	+	171	26*
	-	0	242

\*15 out of 26 tested positive by EBV testing

When compared to a commercially available latex particle agglutination test for infectious mononucleosis heterophile antibodies, the ImmunoCard STAT! Mono Test showed a sensitivity of 100% and a specificity of 90.3%. The overall agreement was 94.1%.

Fifteen of the twenty-six discrepant samples were determined to be recent or acute EBV infections by EBV serological testing, in which case the sample was considered positive. Including the samples confirmed positive by EBV serological testing, the overall clinical study specificity of the ImmunoCard STAT! Mono Test is 95.9% and the overall sensitivity is 100%.

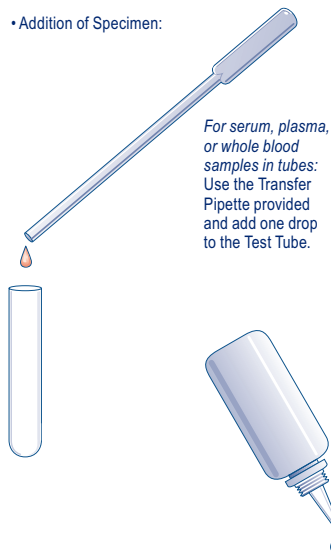
### POL Studies

An evaluation of the ImmunoCard STAT! Mono Test was conducted at three physicians' offices or clinical laboratories where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of negative (5), low positive (3) and moderate positive (4) specimens for three days. The results obtained had 99.1% agreement (107/108) with the expected results.

## TEST PROCEDURE



- Addition of Specimen:



*For serum, plasma,  
or whole blood  
samples in tubes:  
Use the Transfer  
Pipette provided  
and add one drop  
to the Test Tube.*



*For fingertip blood:  
After filling a capillary  
tube end to end,  
dispense all of  
the blood into the  
Test Tube.*

- Slowly add 1 drop of Diluent to the bottom of the Test Tube.



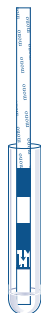
- Mix.

- 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.

- Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears.

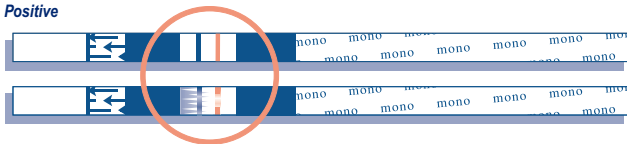


## INTERPRETATION OF TEST RESULTS

### Notes

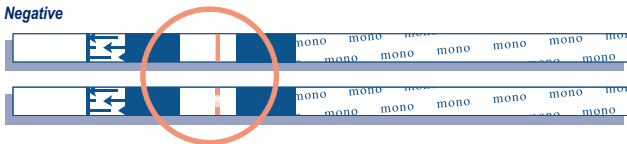
A blue or red line which appears uneven in color density is considered a valid result.

### Positive



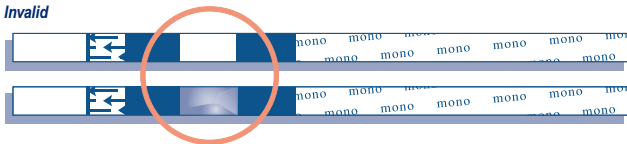
A blue Test Line and a red Control Line is a positive result for the detection of infectious mononucleosis heterophile antibody. Note that the blue line can be any shade of color and can be lighter or darker than the line in the picture.

### Negative



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

### Invalid



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 Meridian Bioscience Technical Services.

## REFERENCES

1. Lennette, E.T., Epstein-Barr Virus, in Manual of Clinical Microbiology. Balows, A., Hausler, W.J. Jr., Herrmann, K.L., Isenberg, H.D., Shadomy, H.J., Editors, 5th Edition, American Society for Microbiology, Washington D.C., pp847-852, 1991.
2. Heath, C.W. Jr., Brodsky, A.L., Potolsky, A.I., Infectious Mononucleosis in a General Population. Am. J. Epidemiol., 95:46, 1972.

## ASSISTANCE

For technical assistance, call Meridian Bioscience Technical Services at 800-343-3858.

## RE-ORDER

No.755725 (25 Tests)

## MANUFACTURED FOR:

Meridian Bioscience  
3471 River Hills Drive  
Cincinnati, OH 45244 USA

ImmunoCard STAT! is a registered trademark of Meridian Bioscience, Inc.

Licensed under U.S. Patent Nos. 5,714,389; 5,989,921 and 6,485,982 and related non-U.S. patents and patent applications.

 Genzyme Diagnostics, Cambridge, MA 02139 USA



**Meridian**  
**Bioscience, Inc.**  
Inspired Science. Trusted Solutions.™

Cincinnati, OH 45244  
Tel: 800-343-3858  
513-271-3700  
Fax: 513-272-5432

[www.meridianbioscience.com](http://www.meridianbioscience.com)

## KEY TO COMPONENT LABELING



Use by YYYY-MM



Batch code



Catalog number



Contents sufficient for <n> tests



*In vitro* diagnostic medical device



Temperature limitation



Manufacturer



Consult instructions for use



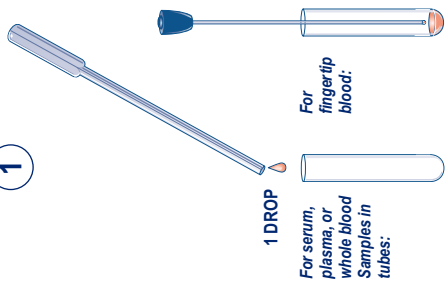
Authorized representative  
in the European Community



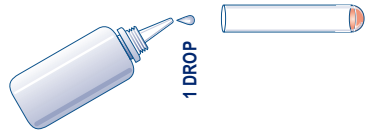
Caution, consult  
accompanying documents

# ImmunoCard<sup>®</sup> STAT<sup>®</sup> Mono Test

1



2



3



4

