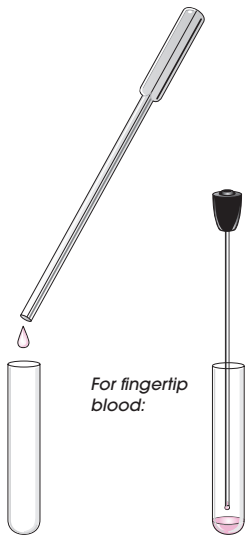


Sure-Vue[®] Signature Mono Test

①

1 DROP

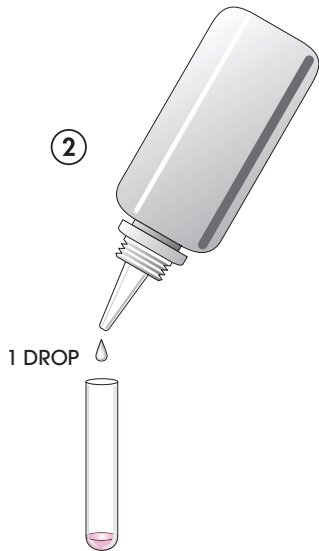
*For serum,
plasma or
whole blood
samples
in tubes:*



*For fingertip
blood:*

②

1 DROP

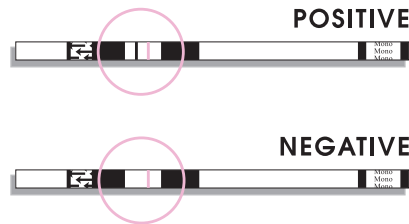


③



5 min.

④



F Fisher HealthCare

Rev. 3810-2, 05/09

Sure-Vue[®] *Signature*

Mono Test

CLIA Complexity: Waived for Whole Blood
Non-Waived for Serum or Plasma

FOR LABORATORY AND PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

INTENDED USE

The Sure-Vue[®] *Signature* 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).^(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 Sure-Vue *Signature* Mono Test utilizes an extract of bovine erythrocytes to give the required sensitivity and specificity.

PRINCIPLES OF TEST

The Sure-Vue *Signature* 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 in a container
- 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 and capillary bulb) have been provided for your convenience.

Store the Test Sticks and Reagents tightly capped at 15°–30°C (59°–86°F).

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.
- **WARNING:** Capillary bulb contains natural rubber latex which may cause allergic reactions. A small percentage of the population may have a heightened sensitivity to natural rubber latex, and prolonged use may cause allergic reactions in such persons. In the event you have, or suspect you may have, such hypersensitivity, you are advised to seek non-latex alternatives. If during use, rashes or other signs of discomfort occur, discontinue use immediately and consult your physician. Safe use of this product by or on latex-sensitized individuals has not been established. Please consult your institution's policies regarding use of this product.
- Do not interchange or mix components from different kit lots.

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°–8°C; 36°–46°F) and tested within 48 hours; serum and plasma specimens held for longer times should be frozen (below -10°C; 14°F) and tested within 3 months. Test whole blood specimens within 24 hours. Specimens must be at room temperature (15°–30°C; 59°–86°F) 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, we recommend 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 Sure-Vue Signature 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 Technical Service 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 Sure-Vue Signature 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.⁽¹⁾

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.⁽¹⁾

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).⁽²⁾

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 Sure-Vue Signature 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 Sure-Vue Signature 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

		Comparative Test	
		+	-
Sure-Vue Signature Mono Test	+	74	8*
	-	0	101

*6 out of 8 tested positive by EBV testing

Whole Blood Specimens:

Comparative Test

		Comparative Test	
		+	-
Sure-Vue Signature Mono Test	+	30	3*
	-	0	47

*1 out of 3 tested positive by EBV testing

Plasma Specimens:

Comparative Test

		Comparative Test	
		+	-
Sure-Vue Signature Mono Test	+	67	15*
	-	0	94

*8 out of 15 tested positive by EBV testing

All Specimens:

Comparative Test

		Comparative Test	
		+	-
Sure-Vue Signature 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 Sure-Vue Signature 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 Sure-Vue Signature Mono Test is 95.9% and the overall sensitivity is 100%.

POL Studies

An evaluation of the Sure-Vue Signature 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

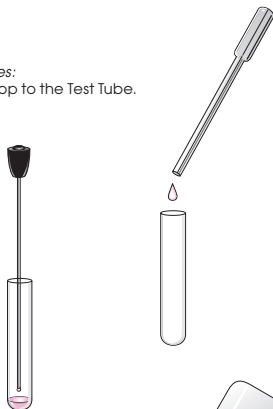


STEP 1

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.



STEP 2

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

Mix.



STEP 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.



5 min



STEP 4

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

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., pp 847-852, 1991.
2. Heath, C.W. Jr., Brodsky, A.L., Potolsky, A.I., Infectious Mononucleosis in a General Population. Am. J. Epidemiol., 95:46, 1972.

RE-ORDER

No. 23-200-275 (25 Tests)

Sure-Vue® is a registered trademark of Fisher Scientific Company L.L.C.

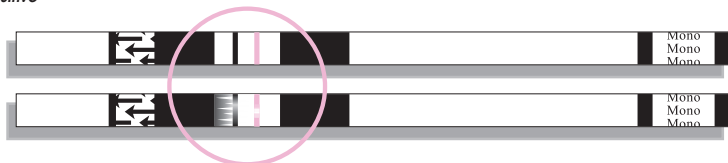
Licensed under U.S. Patent Nos. 5,714,389; 5,989,921 and 6,485,982 and related non-U.S. patents and patent applications.

ASSISTANCE

For technical assistance, call Technical Service at (800) 332-1042.

INTERPRETATION OF TEST RESULTS

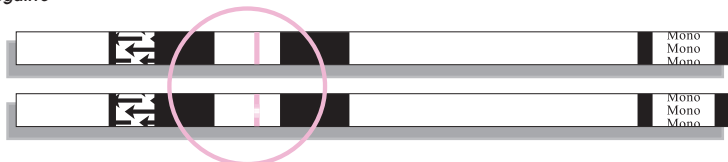
Positive



A blue Test Line and a red Control Line is a positive result for the detection of infectious mononucleosis heterophile antibody.

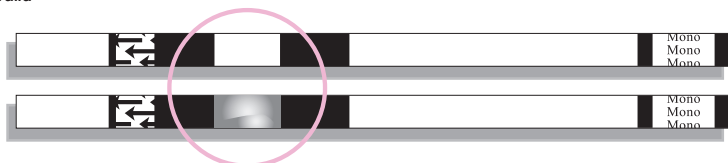
Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.

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 Genzyme Diagnostics Technical Service.

Notes

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

Manufactured for:



Fisher HealthCare

9999 Veteran's Memorial Drive
Houston, TX 77038
800-640-0640 Fax: 800-290-0290
www.fisherhealthcare.com

KEY TO COMPONENT LABELING



Use by YYYY-MM-DD



Batch code



Catalog number



Contents sufficient for $\langle n \rangle$ tests



In vitro diagnostic medical device



Temperature limitation



Manufacturer



Consult instructions for use



Authorized representative
in the European Community



Caution, consult accompanying
documents.