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. The Test Strip 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-bovine stroma in tris buffer with 0.2% sodium azide and 0.05% gentamicin 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. 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.
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). 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 erythrocytes 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-bovine 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
• 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.
• Dilution of specimen should be carried out before testing to avoid the breakdown of blood clots or red blood cells. 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. 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 an 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) for 48 hours, but not frozen. Whole blood specimens should not be refrigerated (2° – 8°C; 36° – 46°F) but are stable at room temperature (15° – 30°C; 59° – 86°F) when tested.

FOR LABORATORY AND PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

KEY TO COMPONENT LABELING
Use by YYYY-MM-DD
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.

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 with the black bulb onto the capillary tube. Place your finger over the opening in the bulb. Squeeze the bulb to displace 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 quality 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 clearly 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 latex agglutination 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. If symptoms persist or intensify, the test should be repeated.
- Some segments of the population with acute IM are heterogeneous antibody negative.

**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.

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).

**PERFORMANCE CHARACTERISTICS**

A total of 439 specimens (185 serum, 15 plasma and 80 whole blood) were evaluated by two clinical lots in a comparative 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 (IgG and IgM) were determined.

### Serum Specimens:

<table>
<thead>
<tr>
<th>Comparative Test</th>
<th>Whole Blood Specimens:</th>
<th>Comparative Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sure-Vue® Signature Mono Test</td>
<td></td>
<td>86% 9% 5%</td>
</tr>
<tr>
<td>Sure-Vue® Signature Mono Test</td>
<td>30% 3% 47%</td>
<td></td>
</tr>
<tr>
<td>*1 out of 3 tested positive by EBV testing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Plasma Specimens:

<table>
<thead>
<tr>
<th>Comparative Test</th>
<th>All Specimens:</th>
<th>Comparative Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sure-Vue® Signature Mono Test</td>
<td></td>
<td>57% 15% 28%</td>
</tr>
<tr>
<td>Sure-Vue® Signature Mono Test</td>
<td>51% 20% 29%</td>
<td></td>
</tr>
<tr>
<td>*8 out of 15 tested positive by EBV testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*15 out of 26 tested positive by EBV testing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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%.

Fifteen of the twenty-six discrepant patients were determined to be recent or acute EBV infections by EBV serological assays. The lesions considered positive, including the samples confirmed positive by EBV serological testing, the overall clinical sensitivity of the Sure-Vue® Signature Mono Test is 95.9% and the overall specificity is 100%.

### POL Studies

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 met 95.1% agreement (107/108) with the expected results.

### REFERENCES


### RE-ORDER

No. 23-200-275 (25 Tests)

Sure-Vue® is a registered trademark of Fisher Scientific Company, LLC.

Manufactured for:

Fisher HealthCare

9999 Veteran’s Memorial Drive
Houston, TX 77090

800-640-0640 Fax: 800-290-0290

www.fisherhealthcare.com

**TEST PROCEDURE**

**Absorbent End**

**Result Window**

**Handle End**

**STEP 1**

**Addition of Specimen**

For serum, plasma, or whole blood specimens in tube:

Use the Transfer Pipette provided and add one drop to the Test Tube.

For finger tip 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.**

**Rinse** the container immediately.

**Place the Absorbent End of the Test Stick into the treated sample.**

**Leave the Test Stick in the Test Tube.**

**STEP 4**

**Read results at 5 minutes.**

Positive results may be read as soon as the red Control Line appears.

**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 Diagnostic Technical Service.

  **Notes**

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

**ASSISTANCE**

For technical assistance, call Technical Service at (800) 352-1042.
Having tested the randomly coded panel consisting of negative (5), low positive (3) and moderate positive (4) laboratories where testing was performed by personnel with diverse educational backgrounds. Each site POL Studies

by EBV serological testing, in which case the sample was considered positive. Including the samples Fifteen of the twenty-six discrepant samples were determined to be recent or acute EBV infections 90.3%. The overall agreement was 94.1%.

heterophile antibodies, the Sure-Vue Plasma Specimens:

Mono Test is 95.9% and the overall sensitivity is 100%.

Internal Quality Controls

Sure-Vue 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 specific test for the detection of EBV heterophile antibodies. • A negative result may be obtained from patients of the onset of the disease due to heterophile antibody levels below the sensitivity of this test if symptoms persist or intensify, the test should be repeated. • Some segments of the population with acute EBV are heterogeneous antibody positive.**

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.** 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).

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 (IgG and IgM) were determined.

Serum Specimens: Comparative Test Whole Blood Specimens: Comparative Test

Sure-Vue Signature Mono Test + 96 96 Sure-Vue Signature Mono Test - 0 0

*1 out of 3 tested positive by EBV testing

Plasma Specimens: Comparative Test All Specimens: Comparative Test

Sure-Vue Signature Mono Test + 67 67 Sure-Vue Signature Mono Test - 0 0

*1 out of 15 tested positive by EBV testing

Fifteen of the twenty-six discrepant samples were determined to be recent or acute EBV infections by EBV serological testing. The test result considered positive, including the samples confirmed positive by EBV serological testing, the overall clinical specificity of the Sure-Vue Signature Mono Test is 95.9% and the overall sensitivity is 100%.

PQI Studies

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 were 99.1% agreement (197/200) with the expected results.


RE-ORDER No. 23-200-275 (25 Tests)

Sure-Vue® is a registered trademark of Fisher Scientific Company LLC. Licensed under U.S. Patent Nos. 5,714,389; 5,989,921 and 6,485,962 and related non-U.S. patent applications.

MANUFACTURED FOR:

Fisher Scientific Company

38100-2.indd 4-6
4/20/2009 11:30:08 AM
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 finger 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 untrimmed 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 clearly give a clean red Control Line.

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 antibodies.

• 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. 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
Heterophile antibody reactivity is observed in approximately 50–90% of adults and children with EBV-caused IM. This percentage drops to approximately 50% for children under four years of age. 3

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). 4

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 (IgG and IgM) were determined.

Serum Specimens: Comparative Test

<table>
<thead>
<tr>
<th>Sure-Vue Signature Mono Test</th>
<th>-</th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood Specimens:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sure-Vue Signature Mono Test</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Plasma Specimens:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sure-Vue Signature Mono Test</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

*Out of 3 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 99.3%. The overall agreement was 94.1%. 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. If symptoms persist or intensify, the test should be repeated.

**Internal Quality Controls**

1. 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.

2. For serum, plasma, or whole blood specimens in tubes:

For each specimen:

Addition of Specimen

STEP 1
Add one free falling drop of specimen to 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. Tie-crimp the container immediately.

STEP 4
Expected results after 5 minutes. Positive results may be read as soon as the red Control Line appears.

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 Diagnostic Technical Service.

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

RE-ORDER
No. 23-200-275 (25 Tests)
Sure-Vue® is a registered trademark of Fisher Scientific Company L.L.C.
Fisher Healthcare
9999 Veteran’s Memorial Drive
Houston, TX 77090
800-640-0640
Fax: 800-290-0290
www.fisherhealthcare.com

REFERENCES

POC Studies
Fifteen of the twenty-six discrepant samples were determined to be recent or acute EBV infections by EBV serological testing which was considered positive, including the samples confirmed positive by EBV serological testing, the overall clinical specificity of the Sure-Vue Signature Mono Test is 95.9% and the overall sensitivity is 100%.

P.O. box 1234
9999 Veteran’s Memorial Drive
Houston, TX 77090
800-640-0640
Fax: 800-290-0290
www.fisherhealthcare.com
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). 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% gentamicin 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 an 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) for up to 48 hours. Serum or plasma specimens may be frozen (below -10°C; 14°F) and tested within 3 months. Whole blood specimens should be tested within 24 hours. Specimens must be at room temperature (15° – 30°C; 59° – 86°F) when tested.