INTENDED USE
The Sure-Vue Signature Mono Test is intended for the qualitative detection of infectious mononucleosis (IM) 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 Pipettes
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 pipettes) 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.

WARNINGS AND PRECAUTIONS
For hazards and precautions, refer to the safety data sheet.

• For in-vitro diagnostic use only.
• Federal law restricts this device to sale by or on the order of a licensed practitioner.
• 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. For sites permitted to dispose of material down a sink: large quantities of water must be used to flush discarded control and diluent material down a sink.
• Do not interchange or mix components from different kit lots.

Recycled Content: Packaging, kit box and instructions for use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program.
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 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 by 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 (2) and moderate positive (3) specimens for three days. The results obtained had 94.1% agreement (50/53) with the expected results.

**TEST PROCEDURE**

**STEP 1**

Addition of Specimen

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

Use the Transfer Pipette provided and add one drop 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. Cover 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.

**HANDLE END**