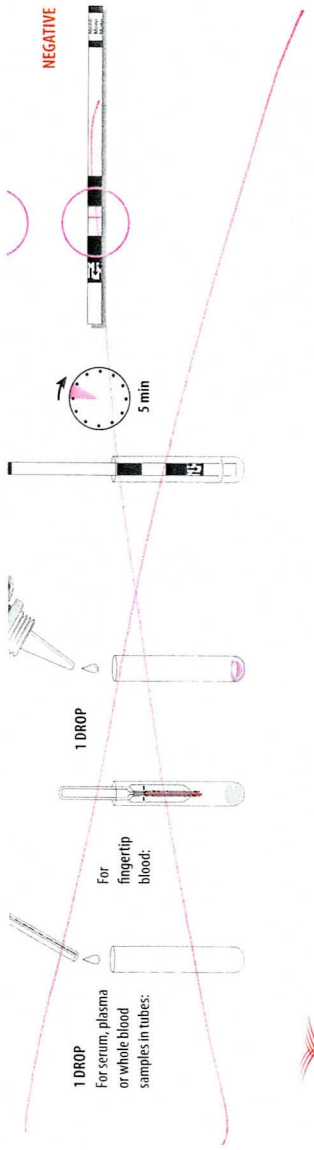

CardinalHealth™

KEY TO COMPONENT LABELING

CONTROL −	Negative Control
CONTROL +	Positive Control
DIL	Diluent
REF	Catalog Number
	Use By
LOT	Batch Code
	Temperature limitation
	Manufacturer
℞ Only	Federal Law restricts sale of this device to or on the order of a licensed practitioner.
	Do Not Reuse
Σ n	Contains sufficient for "n" tests
	Consult Instructions For Use
IVD	In Vitro Diagnostics
	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

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.

Distributed by:
Cardinal Health
3651 Birchwood Drive
Waukegan, IL 60085 USA Rev. B 03/19
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Manufactured by:
Corporate Headquarters
Sekisui Diagnostics, LLC
4 Hartwell Place, Lexington, MA 02421

CH1145(E)1 3181-3

CardinalHealth™

Cardinal Health™ Mono II Rapid Test

For Laboratory and Professional *In Vitro* Diagnostic Use Only • Test Stick for Single Use Only

REF CH1145
IVD
℞ Only

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

INTENDED USE

The Mono II Rapid 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 Mono II Rapid Test utilizes an extract of bovine erythrocytes to give the required sensitivity and specificity.

PRINCIPLES OF TEST

The Mono II Rapid 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 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.
- **Caution:** Federal Law restricts sale of this device to or on the order of a licensed practitioner.
- Do not interchange or mix components from different kit lots.

CardinalHealth™

Cardinal Health™ Mono II Rapid Test

CardinalHealth™

KEY TO COMPONENT LABELING

CONTROL –	Negative Control
CONTROL +	Positive Control
DIL	Diluent
REF	Catalog Number
	Use By
LOT	Batch Code
	Temperature limitation
	Manufacturer
Rx Only	Federal Law restricts sale of this device to or on the order of a licensed practitioner.
	Do Not Reuse
Σ n	Contains sufficient for "n" tests
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IVD	In Vitro Diagnostics
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CardinalHealth™

Cardinal Health™ I

For Laboratory and Professional *In Vitro* Diag

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1 Directional Insert

Note: Extra components (tubes, pipettes, capill have been provided for your convenience.

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 three 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 pipette horizontally, and touch the tip of the pipette to the drop of blood on the patient's finger until it fills completely to the line. **Note:** Filling is automatic; never squeeze the pipette bulb while collecting sample.

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, Cardinal Health 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 Mono II Rapid 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 is invalid. If the background does not clear and interferes with the test result, the test may be invalid. Call 800-332-1042 for Technical Assistance 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 Mono II Rapid 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 Mono II Rapid 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 Mono II Rapid 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	
		+	–
Mono II Rapid Test	+	74	8*
	–	0	101

*6 out of 8 tested postitive by EBV testing

Plasma Specimens		Comparative Test	
		+	–
Mono II Rapid Test	+	67	15*
	–	0	94

*8 out of 15 tested postitive by EBV testing

Whole Blood Specimens		Comparative Test	
		+	–
Mono II Rapid Test	+	30	3*
	–	0	47

*1 out of 3 tested postitive by EBV testing

All Specimens		Comparative Test	
		+	–
Mono II Rapid Test	+	171	26*
	–	0	242

*15 out of 26 tested postitive by EBV testing

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

Fifteen of the 26 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 Mono II Rapid Test is 95.9% and the overall sensitivity is 100%.

POL Studies

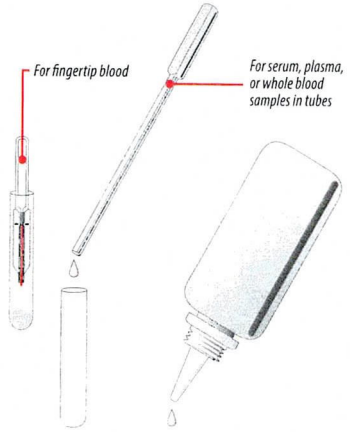
An evaluation of the Mono II Rapid Test was conducted at three physicians' offices or clinical laboratories where testing was performed by personnel with diverse educational backgrounds. Each site tested the randomly coded panel consisting of negative (5), low positive (3) and moderate positive (4) specimens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

TEST PROCEDURE

STEP 1

For fingertip blood: To dispense all the patient sample, place pipette into the test tube and squeeze the bulb. Remove pipette and discard in the appropriate biohazard container.
NOTE: If pipette does not fully dispense the patient's sample, recollect the sample using a new capillary pipette.

For serum, plasma, or whole blood samples in tubes: Add 1 drop



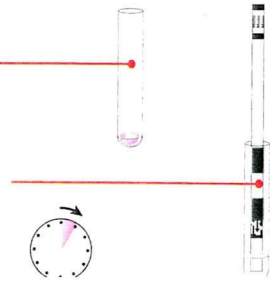
STEP 2

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

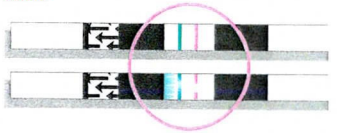


STEP 4

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

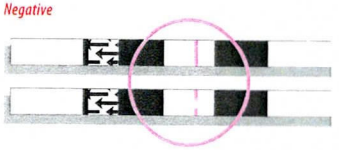
INTERPRETATION OF TEST RESULTS

Positive



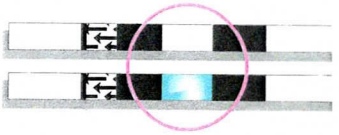
A blue Test Line and a red Control Line is a positive result for the infectious mononucleosis heterophile antibody. ***Note that the L any shade of blue and can be lighter or darker than the line in***

Negative



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

Invalid



If after 5 minutes, no red Control Line appears or background col the red Control Line impossible, the result is invalid. If this occur on a new Test Stick or call Technical Assistance at 800-332-1042.

NOTES

A blue or red line which appears uneven in color density is consic

The appearance of a dry white line located near the Test and/or C positions has been observed on some test sticks. When present i visible at the read time. This artifact is most often seen with plas specimens and has no impact on the performance of the assay.