



A rapid test for the qualitative detection of Infectious Mononucleosis (IM) heterophile antibodies in whole blood. For professional *in vitro* diagnostic use only. Rx Only.

CLIA Category: Waived

INTENDED USE

The Clearview® MONO test (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood to aid in the diagnosis of infectious Mononucleosis.

SUMMARY

Infectious Mononucleosis is caused by the Epstein-Barr virus, which is a member of the herpesvirus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur. Diagnosis of IM is made based on the presence of heterophile antibodies. Infectious mononucleosis heterophile antibodies belong to the IgM class. They are present in 80-90% of acute IM cases and can be detected in 60-70% of patients during the first week of clinical illness.¹⁻⁴

The Clearview MONO test (Whole Blood) is a simple test that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect IM heterophile antibodies in whole blood in just minutes.

PRINCIPLE

The Clearview MONO test (Whole Blood) is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood. In this test procedure, bovine erythrocyte extracted antigen is coated on the test line region of the cassette. The sample reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the coated bovine erythrocyte extracted antigen. If the sample contains IM antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain IM heterophile antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains bovine erythrocyte extracted antigen-coated particles and bovine erythrocyte extracted antigen coated membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimen samples and kits are handled.
- The negative control contains human plasma. Handle controls and all specimen samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimen samples.
- The positive and negative controls contain sodium azide as a preservative, which may form potentially explosive metal azide if it reacts with lead or copper plumbing. Large quantities of water should be used to flush discarded controls down a sink.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen samples are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION

The Clearview MONO test (Whole Blood) can be performed using whole blood from venipuncture or fingerstick.

To collect Venipuncture Whole Blood samples:

Collect anti-coagulated blood sample (sodium or potassium heparin, sodium or potassium EDTA, sodium or potassium citrate and sodium oxalate) following standard laboratory procedures.

To collect Fingerstick Whole Blood samples:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Holding the capillary tube horizontally, touch the end of the tube to the blood until filled to the line; avoid air bubbles.
- Place the bulb onto the top end of the capillary tube.
- Squeeze the bulb to dispense the whole blood.

Testing should ideally be performed immediately after the samples have been collected. Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood samples.

If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

MATERIALS PROVIDED

- 30 Test cassettes
- 30 Disposable pipettes
- 40 Disposable heparinized capillary tubes and 2 dispensing bulbs
- 1 Positive control (1 mL; Goat anti-mono antibody, 0.09% sodium azide)
- 1 Negative control (1 mL; Diluted human plasma, 0.09% sodium azide, infection risk)
- 1 Sample buffer (5 mL; Disodium hydrogen phosphate, sodium chloride and casein, 0.09% sodium azide)
- 1 Directional insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Timer

DIRECTIONS FOR USE

(Please refer to the illustration)

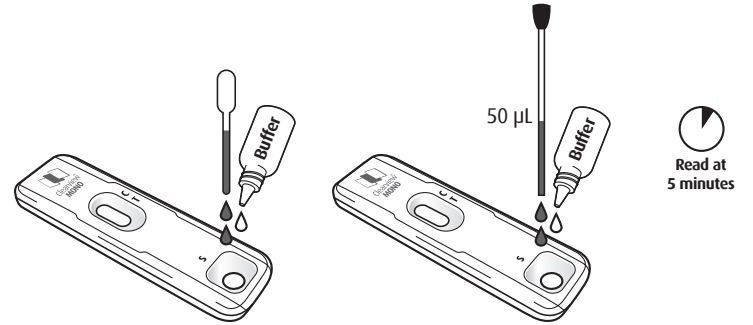
Allow the test cassette, sample, buffer and controls to reach to room temperature (15-30°C) before testing.

- Remove the test cassette from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
- Place the test cassette on a clean and level surface.

For **Whole Blood (Venipuncture)** samples: Hold the pipette upright and add **2 drops of whole blood** (about 50 µL) to the sample well (S) of the test cassette. Then add **1 drop of Sample Buffer** to the sample well (S). Start the timer.

For **Whole Blood (Fingerstick)** samples: Add **one capillary tube of blood** (about 50 µL) to the sample well (S) of the test cassette. Then add **1 drop of Sample Buffer** to the sample well (S). Start the timer.

- Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read. Do not read the result after 10 minutes.



2 drops of **Venipuncture** whole blood + 1 drop of Buffer **OR** 50 µL **Fingerstick** whole blood + 1 drop of Buffer

INTERPRETATION OF RESULT



POSITIVE³: Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). A positive result means that IM heterophile antibodies were detected in the sample.

³NOTE: The shade of the red color in the test line region (T) will vary based on the amount of IM heterophile antibodies in the sample. Any shade of red in the test line region (T) should be considered positive.

NEGATIVE: One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test cassette. If the result is still invalid, stop using the test kit and contact Alere Technical Support at (866) 216-0094.

QUALITY CONTROL

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

EXTERNAL QUALITY CONTROL

Quality control requirements must be performed in accordance with local, state, and federal regulations or accreditation requirements. Optimally, Alere recommends that positive and negative external controls be run with each new lot and with each new untrained operator. External positive and negative controls are supplied in the kit. Other commercial controls are not recommended if they have not been validated with this product.

PROCEDURE FOR EXTERNAL QUALITY CONTROL TESTING

Using the positive or negative external controls in place of a patient sample, add 1 drop of positive or negative control solution to the sample well (S) of a new test cassette, then add 1 drop of Sample Buffer. Start the timer. Continue with Step 3 in the Directions For Use section.

If unexpected results are seen when running the controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another cassette. If the problem persists, discontinue use of the test kit immediately and contact Alere Technical Support at (866) 216-0094.

LIMITATIONS

- The Clearview MONO test (Whole Blood) is for *in vitro* diagnostic use only. The test should be used for the detection of IM heterophile antibodies in whole blood samples only. Neither the quantitative value nor the rate of increase in Mononucleosis antibody concentration can be determined by this qualitative test.
- The Clearview MONO test (Whole Blood) will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of Mononucleosis infection.
- Grossly hemolysed samples will yield invalid results. Strictly follow the Directional Insert instructions to obtain accurate results.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- This assay has not been established for patients under 18 years of age. A heterophile antibody response is observed in approximately 80-90% of adults and children with EBV-caused IM.⁶

EXPECTED VALUES

Epstein-Barr virus infection during adolescence or young adulthood causes infectious mononucleosis 35% to 50% of the time.^{1,5}

The incidence of EBV-associated infectious mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults- about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

PERFORMANCE CHARACTERISTICS

A total of 611 clinical samples were tested by three independent sites in a clinical study. Slide agglutination served as the reference method for the study. Serum, plasma and whole blood were also collected for the detection of IM heterophile antibodies by the Clearview MONO test.

Of the 611 clinical samples collected, 185 were considered positive and 426 clinical specimens were considered negative by slide agglutination method. The results for each sample matrix are summarized below.

SERUM	Slide agglutination	
	+ -	
Clearview MONO	+ 72 0	Positive Agreement = 72/72 > 99% (95%-100%)** Negative Agreement = 168/168 > 99% (98%-100%)**
	- 0 168	
PLASMA	Slide agglutination	
	+ -	
Clearview MONO	+ 58 1	Positive Agreement = 58/58 > 99% (94%-100%)** Negative Agreement = 181/182 > 99% (97%-99%)*
	- 0 181	
WHOLE BLOOD	Slide agglutination	
	+ -	
Clearview MONO	+ 50 0	Positive Agreement = 50/55 = 91% (80%-97%)* Negative Agreement = 76/76 > 99% (95%-100%)**
	- 5 76	
ALL SPECIMENS	Slide agglutination	
	+ -	
Clearview MONO	+ 180 1	Positive Agreement = 180/185 = 97% (94%-99%)* Negative Agreement = 425/426 > 99% (99%-99.99%)* *Denotes 95% Confidence Interval **Denotes 97.5% Confidence Interval
	- 5 425	

In addition, the clinical samples were tested with a commercially available rapid diagnostic test kit. 611 serum, plasma and whole blood specimens were used to compare the Clearview MONO test to a comparator test. The results showed a >99% agreement between the two test kits. The results for each sample matrix are summarized below.

SERUM	Comparator test	
	+ -	
Clearview MONO	+ 72 0	Positive Agreement= 72/73 = 99% (93%-99%)* Negative Agreement= 167/167 > 99% (98%-100%)**
	- 1 167	
PLASMA	Comparator test	San Diego
	+ -	
Clearview MONO	+ 59 0	Positive Agreement= 59/60 = 98% (91%-99%)* Negative Agreement= 180/180 > 99% (98%-100%)**
	- 1 180	
WHOLE BLOOD	Comparator test	
	+ -	
Clearview MONO	+ 50 0	Positive Agreement= 50/51 = 98% (90%-99%)* Negative Agreement= 80/80 > 99% (96%-100%)**
	- 1 80	
ALL SPECIMENS	Comparator test	
	+ -	
Clearview MONO	+ 181 0	Positive Agreement = 181/184 = 98% (95%-99%)* Negative Agreement = 427/427 > 99% (99%-100%)** *Denotes 95% Confidence Interval **Denotes 97.5% Confidence Interval
	- 3 427	

INTERFERENCE STUDIES

No interference with the Clearview MONO test results was observed in samples containing high levels of hemoglobin (up to 10 mg/mL), bilirubin (up to 1,000 mg/dL) and human serum albumin (up to 100 mg/mL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 60% and when icteric and lipemic samples were tested.

POL STUDIES

Three physicians' offices were used to conduct an evaluation of the Clearview MONO test. Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (15), low positive (15), moderate positive (15) and invalid (15) for three days. The results obtained had a >99% correlation with the expected results.

NON-LABORATORY USER STUDY

A total of 77 untrained, inexperienced, non-laboratory participants were enrolled at three separate locations to demonstrate that they could follow the product instructions and perform the Clearview MONO test (Whole Blood) and obtain results similar to those obtained by trained laboratory technicians. Each participant received four blinded spiked whole blood samples: one negative, one invalid, one low positive and one medium positive.

Study participants were instructed to follow the Directional Insert and Procedure instructions to test the provided samples and record their test results. No other instruction or training was given. Upon completion of the test, participants filled out a brief questionnaire regarding the test procedure and ease of use of the labeling. The following results were obtained:

Site	Low Positive	Medium Positive	Negative	Invalid	Total Correct
A	23/27=85% (66-96%)*	25/27=93% (76-99%)*	27/27>99% (87-100%)*	27/27>99% (87-100%)*	102/108=94% (88-98%)*
B	25/27=93% (76-99%)*	25/27=93% (76-99%)*	27/27>99% (87-100%)*	27/27>99% (87-100%)*	104/108=96% (91-99%)*
C	23/23>99% (85-100%)*	23/23>99% (85-100%)*	23/23>99% (85-100%)*	23/23>99% (85-100%)*	92/ 92>99% (96-100%)*

*Denotes 95% Confidence Interval

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- Omori, M. 2002 Mononucleosis. <http://www.emedicine.com/EMERG/topic319.htm>
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Product No. 92401

Clearview® MONO whole Blood, Serum, Plasma

A rapid test for the qualitative detection of Infectious Mononucleosis (IM) heterophile antibodies in whole blood, serum and plasma. For professional *in vitro* diagnostic use only. Rx Only.

	Whole blood	Serum, Plasma
CLIA Category:	Waived	Non-waived (moderate)

INTENDED USE

The Clearview® MONO test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma to aid in the diagnosis of infectious Mononucleosis.

SUMMARY

Infectious Mononucleosis is caused by the Epstein-Barr virus, which is a member of the herpesvirus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur. Diagnosis of IM is made based on the presence of heterophile antibodies. Infectious mononucleosis heterophile antibodies belong to the IgM class. They are present in 80-90% of acute IM cases and can be detected in 60-70% of patients during the first week of clinical illness.¹⁻⁴

The Clearview MONO test is a simple test that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect IM heterophile antibodies in whole blood, serum or plasma in just minutes.

PRINCIPLE

The Clearview MONO test is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma. In this test procedure, bovine erythrocyte extracted antigen is coated on the test line region of the cassette. The sample reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the coated bovine erythrocyte extracted antigen. If the sample contains IM antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain IM heterophile antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains bovine erythrocyte extracted antigen-coated particles and bovine erythrocyte extracted antigen coated membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimen samples and kits are handled.
- The negative control contains human plasma. Handle controls and all specimen samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimen samples.
- The positive and negative controls contain sodium azide as a preservative, which may form potentially explosive metal azide if it reacts with lead or copper plumbing. Large quantities of water should be used to flush discarded controls down a sink.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen samples are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION

The Clearview MONO test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

To collect Venipuncture Whole Blood samples:

Collect anti-coagulated blood sample (sodium or potassium heparin, sodium or potassium EDTA, sodium or potassium citrate and sodium oxalate) following standard laboratory procedures.

To collect Fingerstick Whole Blood samples:

- Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Holding the capillary tube horizontally, touch the end of the tube to the blood until filled to the line; avoid air bubbles.
- Place the bulb onto the top end of the capillary tube.
- Squeeze the bulb to dispense the whole blood.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.

Testing should ideally be performed immediately after the samples have been collected. Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood samples. Serum or plasma samples may be stored at 2-8°C for up to 3 days. For long term storage, samples should be kept below -20°C.

Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

MATERIALS PROVIDED

- 30 Test cassettes
- 30 Disposable pipettes
- 40 Disposable heparinized capillary tubes and 2 dispensing bulbs
- 1 Positive control (1 mL; Goat anti-mono antibody, 0.09% sodium azide)
- 1 Negative control (1 mL; Diluted human plasma, 0.09% sodium azide, infection risk)
- 1 Sample buffer (5 mL; Disodium hydrogen phosphate, sodium chloride and casein, 0.09% sodium azide)
- 1 Directional insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Centrifuge (for serum or plasma only)
- Timer

DIRECTIONS FOR USE

(Please refer to the illustration)

Allow the test cassette, sample, buffer and controls to reach to room temperature (15-30°C) before testing.

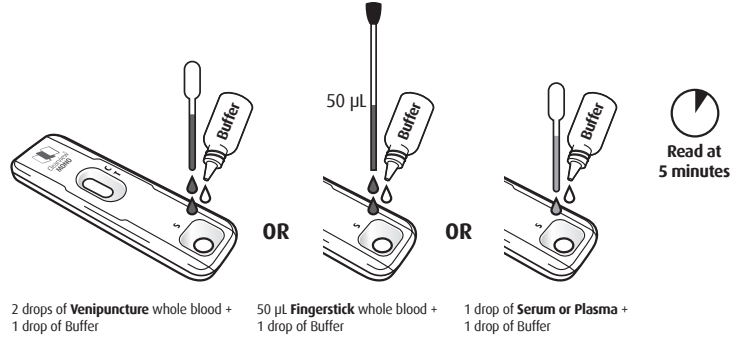
- Remove the test cassette from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
- Place the test cassette on a clean and level surface.

For **Whole Blood (Venipuncture)** samples: Hold the pipette upright and add **2 drops of whole blood** (about 50 µL) to the sample well (S) of the test cassette. Then add **1 drop of Sample Buffer** to the sample well (S). Start the timer.

For **Whole Blood (Fingerstick)** samples: Add **one capillary tube of blood** (about 50 µL) to the sample well (S) of the test cassette. Then add **1 drop of Sample Buffer** to the sample well (S). Start the timer.

For **Serum or Plasma** samples: Hold the pipette upright and add **1 drop of serum or plasma** (about 25 µL) to the sample well (S) of the test cassette. Then add **1 drop of Sample Buffer** to the sample well (S). Start the timer. Avoid trapping air bubbles in the sample well (S). See the illustration above.

- Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read. Do not read the result after 10 minutes.



INTERPRETATION OF RESULT



POSITIVE®: Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). A positive result means that IM heterophile antibodies were detected in the sample.

*NOTE: The shade of the red color in the test line region (T) will vary based on the amount of IM heterophile antibodies in the sample. Any shade of red in the test line region (T) should be considered positive.

NEGATIVE: One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test cassette. If the result is still invalid, stop using the test kit and contact Alere Technical Support at (866) 216-0094.

QUALITY CONTROL

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

EXTERNAL QUALITY CONTROL

Quality control requirements must be performed in accordance with local, state, and federal regulations or accreditation requirements. Optimally, Alere recommends that positive and negative external controls be run with each new lot and with each new untrained operator. External positive and negative controls are supplied in the kit. Other commercial controls are not recommended if they have not been validated with this product.

PROCEDURE FOR EXTERNAL QUALITY CONTROL TESTING

Using the positive or negative external controls in place of a patient sample, add 1 drop of positive or negative control solution to the sample well (S) of a new test cassette, then add 1 drop of Sample Buffer. Start the timer. Continue with Step 3 in the Directions For Use section.

If unexpected results are seen when running the controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another cassette. If the problem persists, discontinue use of the test kit immediately and contact Alere Technical Support at (866) 216-0094.

LIMITATIONS

- The Clearview MONO test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of IM heterophile antibodies in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of increase in Mononucleosis antibody concentration can be determined by this qualitative test.
- The Clearview MONO test will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of Mononucleosis infection.
- Grossly hemolysed samples will yield invalid results. Strictly follow the Directional Insert instructions to obtain accurate results.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- This assay has not been established for patients under 18 years of age. A heterophile antibody response is observed in approximately 80-90% of adults and children with EBV-caused IM.⁶

EXPECTED VALUES

Epstein-Barr virus infection during adolescence or young adulthood causes infectious mononucleosis 35% to 50% of the time.^{1,5}

The incidence of EBV-associated infectious mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults- about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

PERFORMANCE CHARACTERISTICS

A total of 611 clinical samples were tested by three independent sites in a clinical study. Slide agglutination served as the reference method for the study. Serum, plasma and whole blood were also collected for the detection of IM heterophile antibodies by the Clearview MONO test.

Of the 611 clinical samples collected, 185 were considered positive and 426 clinical specimens were considered negative by slide agglutination method. The results for each sample matrix are summarized below.

SERUM	Slide agglutination		Positive Agreement = 72/72 > 99% (95%-100%)** Negative Agreement = 168/168 > 99% (98%-100%)**
	+	-	
Clearview MONO	72	0	
	0	168	
PLASMA	Slide agglutination		Positive Agreement = 58/58 > 99% (94%-100%)** Negative Agreement = 181/182 > 99% (97%-99%)*
	+	-	
Clearview MONO	58	1	
	0	181	
WHOLE BLOOD	Slide agglutination		Positive Agreement = 50/55 = 91% (80%-97%)* Negative Agreement = 76/76 > 99% (95%-100%)**
	+	-	
Clearview MONO	50	0	
	5	76	
ALL SPECIMENS	Slide agglutination		Positive Agreement = 180/185 = 97% (94%-99%)* Negative Agreement = 425/426 > 99% (99%-99.99%)* *Denotes 95% Confidence Interval **Denotes 97.5% Confidence Interval
	+	-	
Clearview MONO	180	1	
	5	425	

In addition, the clinical samples were tested with a commercially available rapid diagnostic test kit. 611 serum, plasma and whole blood specimens were used to compare the Clearview MONO test to a comparator test. The results showed a >99% agreement between the two test kits. The results for each sample matrix are summarized below.

SERUM	Comparator test		Positive Agreement= 72/73 = 99% (93%-99%)* Negative Agreement= 167/167 > 99% (98%-100%)**
	+	-	
Clearview MONO	72	0	
	1	167	
PLASMA	Comparator test		Positive Agreement= 59/60 = 98% (91%-99%)* Negative Agreement= 180/180 > 99% (98%-100%)**
	+	-	
Clearview MONO	59	0	
	1	180	
WHOLE BLOOD	Comparator test		Positive Agreement= 50/51 = 98% (90%-99%)* Negative Agreement= 80/80 > 99% (96%-100%)**
	+	-	
Clearview MONO	50	0	
	1	80	
ALL SPECIMENS	Comparator test		Positive Agreement = 181/184 = 98% (95%-99%)* Negative Agreement = 427/427 > 99% (99%-100%)** *Denotes 95% Confidence Interval **Denotes 97.5% Confidence Interval
	+	-	
Clearview MONO	181	0	
	3	427	

INTERFERENCE STUDIES

No interference with the Clearview MONO test results was observed in samples containing high levels of hemoglobin (up to 10 mg/mL), bilirubin (up to 1,000 mg/dL) and human serum albumin (up to 100 mg/mL).The test results were also unaffected when the hematocrit was altered ranging from 20% to 60% and when icteric and lipemic samples were tested.

POL STUDIES

Three physicians’ offices were used to conduct an evaluation of the Clearview MONO test. Personnel with various educational backgrounds performed the testing. Each physician’s office tested a randomly coded panel of samples consisting of negative (15), low positive (15), moderate positive (15) and invalid (15) for three days. The results obtained had a >99% correlation with the expected results.

NON-LABORATORY USER STUDY

A total of 77 untrained, inexperienced, non-laboratory participants were enrolled at three separate locations to demonstrate that they could follow the product instructions and perform the Clearview MONO test and obtain results similar to those obtained by trained laboratory technicians. Each participant received four blinded spiked whole blood samples: one negative, one invalid, one low positive and one medium positive.

Study participants were instructed to follow the Directional Insert and Procedure instructions to test the provided samples and record their test results. No other instruction or training was given. Upon completion of the test, participants filled out a brief questionnaire regarding the test procedure and ease of use of the labeling. The following results were obtained:

Site	Low Positive	Medium Positive	Negative	Invalid	Total Correct
A	23/27=85% (66-96%)*	25/27=93% (76-99%)*	27/27>99% (87-100%)*	27/27>99% (87-100%)*	102/108=94% (88-98%)*
B	25/27=93% (76-99%)*	25/27=93% (76-99%)*	27/27>99% (87-100%)*	27/27>99% (87-100%)*	104/108=96% (91-99%)*
C	23/23>99% (85-100%)*	23/23>99% (85-100%)*	23/23>99% (85-100%)*	23/23>99% (85-100%)*	92/ 92>99% (96-100%)*

*Denotes 95% Confidence Interval

REFERENCES

- Pediatr Clin North Am* 1997 Dec;44(6):1541-56
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