Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) For professional use

ELISURE

IVD REF SIC-RDT-MSL-202058

A rapid chromatographic immunoassay intended for the qualitative detection of IgG/IgM antibodies to measles antigen in human whole blood, serum or plasma specimen.
For professional in vitro diagnostic use only.

INTENDED USE

The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG/IgM antibodies to measles in human whole blood, serum or plasma specimen.

SUMMARY

Measles is a highly contagious viral disease characterized by a clinically distinct prodrome of fever, coryza, conjunctivitis, cough and a pathognomic exanthem (Koplik's spots). The rash of Measles appears after a 3- to 5-days prodrome, some 14 days after exposure and may be associated with edema of the skin. The disease is the result of infection with the Measles Virus, genus Morbillivirus of the family Paramyxoviridae. Complications are: otitis media, pneumonia and encephalitis.
The virus infects the respiratory tract, and then spreads throughout the body. Measles is a human disease and is not known to occur in animals.
Before the introduction of measles vaccine in 1963 and widespread vaccination, major epidemics occurred approximately every 2-3 years and measles caused an estimated 2.6 million deaths each year.
The disease remains one of the leading causes of death among young children globally, despite the availability of a safe and effective vaccine.[1]

PRINCIPLES

The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to measles in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with measles antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to measles. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to measles, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result. Therefore, if the specimen contains measles IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains measles IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain measles antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided

• Test Cassette • Package insert • Droppers • Buffer

Materials required but not provided

• Centrifuge • Timer • Pipette • Lancets
• Specimen collection containers • Alcohol pad

WARNINGS AND PRECAUTIONS

1. For *in vitro diagnostic* use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.

1. To Collect **Fingerstick Whole Blood**:
   - 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.
2. To Collect **Venipuncture Whole Blood**:
   Collect venipuncture whole blood specimen into a collection tube containing EDTA-K2, sodium citrate, heparin sodium and potassium oxalate. Do not use hemolyzed blood for testing. Mix whole blood by inversion and use in the test as outlined in the Test Procedure.
3. To collect **Plasma/Serum**:
   Step 1:
   Collect venipuncture blood specimen into collection tube containing EDTA-K2, sodium citrate, heparin sodium and potassium oxalate for plasma or collection tube without anticoagulants for serum.
   Step 2:
   To prepare plasma specimen, centrifuge collected specimens and carefully transfer the plasma into a new pre-labeled tube.
   To prepare serum specimen, allow blood to clot, centrifuge collected specimens and carefully transfer the serum into a new pre-labeled tube.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens can be stored at 2-8°C for up to 3 days and -20°C for 12 months. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. It is recommended not to freeze and thaw more than 3 times in both serum and plasma specimens.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

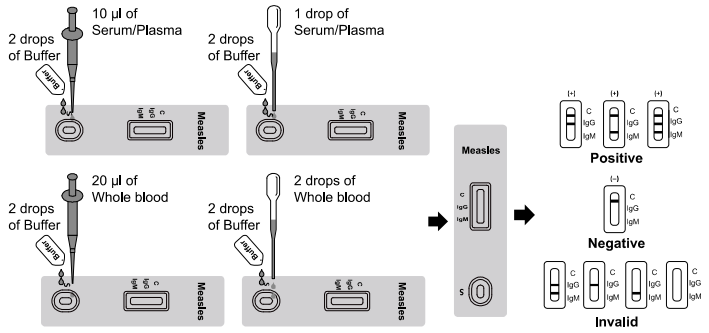
- To use a dropper: Hold the dropper vertically and **transfer 1 full drop of serum or plasma** (approximately 10 µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a pipette: To **transfer 10 µL of serum or plasma** to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL)and start the timer.

For Whole Blood (Venipuncture/Fingerstick):

- To use a dropper: Hold the dropper vertically, **transfer 2 full drops of whole blood** (approximately 20 µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a pipette: To **transfer 20 µL of whole blood** to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL) and start the timer.

3. Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.

Note: Once the buffer vial is opened, please make sure the kit to be used up within 6 months.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.
IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.
IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.
***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of measles antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM region.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The DIRECTIONS FOR USE and the INTERPRETATION OF RESULTS must be followed closely when testing for the presence of measles virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to measles virus in whole blood, serum or plasma specimens as an aid in the diagnosis of patients with suspected measles virus infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to measles can be determined by this qualitative test.
3. The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to measles in the specimen and should not be used as the sole criteria for the diagnosis of measles infections.
4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive and clinical symptoms persist, It is recommended to re-sample the patient a few days later or test with a molecular diagnostic device to rule out infection in these individuals.
6. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) was compared with a leading commercial ELISA; the results were tabulated as below.

Performance of IgG Specimen

Method		ELISA		Total Results
Measles IgG/IgM Rapid Test	Results	Positive	Negative	
	Positive	46	1	47
	Negative	1	22	23
Total Results		47	23	70

Relative sensitivity: 97.9% (95%CI*: 88.7%~100.0%)
Relative specificity: 95.7% (95%CI*: 78.1%~99.9%)
Accuracy: 97.1% (95%CI*: 90.1%~99.7%) *Confidence Intervals

Performance of IgM Specimen

Method		ELISA		Total Results
Measles IgG/IgM Rapid Test	Results	Positive	Negative	
	Positive	18	3	21
	Negative	1	48	49
Total Results		19	51	70

Relative sensitivity: 94.7% (95%CI*: 74.0%~99.9%)
Relative specificity: 94.1% (95%CI*: 83.8%~98.8%)
Accuracy: 94.3% (95%CI*: 86.0%~98.4%) *Confidence Intervals

Limitation of Detection

The minimum detection level is 1:32 for measles IgM positive specimen and 1:280 for measles IgG positive specimen.

Precision

Intra-Assay

Within-run precision has been determined by using negative, IgG weak positive, IgG Strong positive, IgM weak positive and IgM strong positive. The negative, IgG weak positive, IgG strong positive, IgM weak positive and IgM strong positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same 5 specimens: negative, IgG weak positive, IgG strong positive, IgM weak positive and IgM strong positive. Three different lots of the Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, IgG weak positive, IgG strong positive, IgM weak positive and IgM strong positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has been tested for anti-RSV, anti-Adenovirus, HAMA, anti-HAV IgG, anti-HBV IgG, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-CMV IgG, TOXO IgG, Rubella IgG, anti-HSV 1 IgG and anti-HSV 2 IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using The Measles IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

Ascorbic Acid: 2 g/dL	Hemoglobin: 1100 mg/dL
Gentisic Acid: 20 mg/dL	Oxalic Acid: 600 mg/dL
Bilirubin: 1000 mg/dL	Salicylic Acid: 20 mg/dL
Acetaminophen: 20 mg/dL	Creatin: 200 mg/dL
Albumin: 2000 mg/dL	EDTA: 20 mg/dL

BIBLIOGRAPHY

1. van den Ent MMVX, Brown DW, Hoekstra EJ, Christie A, Cochi SL. Measles mortality reduction contributes substantially to reduction of all-cause mortality among children less than five years of age, 1990–2008. J Infect Dis. 2011; 204: S18–23.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use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Number: M150573302B
Revision date: 2026-07-20