Rapid Response®

Measles Test Cassette
(Whole Blood/Serum/Plasma)

REF MEA-13C
MEA-13C25
MEA-13C40

Product Insert

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 laboratory *in vitro* diagnostic use only.

Intended Use

The Rapid Response® Measles Test Cassette 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]

Principle

The Rapid Response® Measles Test Cassette 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 coloured 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 coloured line appears in IgM test line region as a result. Therefore, if the specimen contains measles IgG antibodies, a coloured line will appear in IgG test line region. If the specimen contains measles IgM antibodies, a coloured line will appear in IgM test line region. If the specimen does not contain measles antibodies, no coloured line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Reagents

The test contains anti-human IgM and anti-human IgG as the capture reagent, measles antigen as the detection reagent. A goat anti-rabbit IgG is employed in the control line system.

Precautions

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

Materials

Materials provided

- Test cassettes
- Droppers
- Buffer
- Product insert

Materials required but not provided

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

Storage and Stability

Store as packaged in the sealed pouch either at room temperature or refrigerated 35.6-86°F (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 Rapid Response® Measles Test Cassette 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 pad. 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.

Test Procedure

Allow the test, specimen, buffer and/or controls to equilibrate to room temperature (59-86°F; 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:

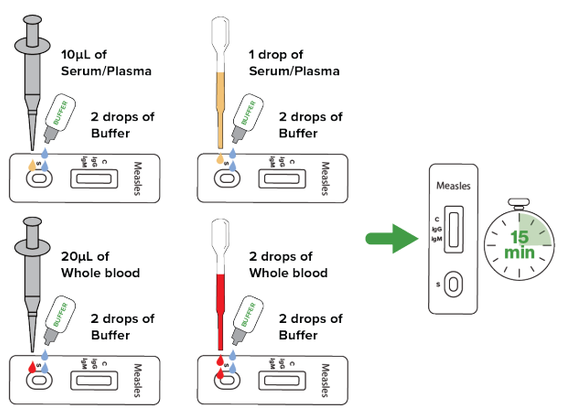
- Use a dropper: Hold the dropper vertically and **transfer 1 full drop of serum or plasma** (approximately **10µL**) to the specimen well(S), then **add 2 drops of buffer** (approximately **80µL**) and start the timer.
- Use a pipette: To **transfer 10µL of serum or plasma** to the specimen well(S),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

For Whole Blood (Venipuncture/Fingerstick):

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

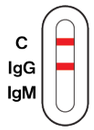
3. Wait for the coloured line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.

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

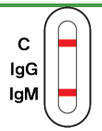


Results Interpretation

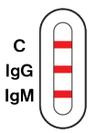
Positive



IgG POSITIVE:* Two coloured lines appear. One coloured line should always appear in the control line region (C) and another line should be in the IgG line region.



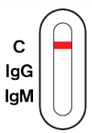
IgM POSITIVE:* Two coloured lines appear. One coloured line should always appear in the control line region (C) and another line should be in the IgM line region.



IgG and IgM POSITIVE:* Three coloured lines appear. One coloured 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.

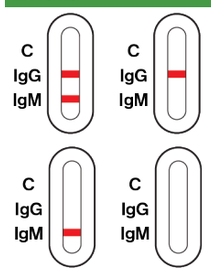
***NOTE:** The intensity of the colour in the test line regions may vary depending on the concentration of measles antibodies present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.

Negative



One coloured 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 coloured 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 TEST PROCEDURE 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 Rapid Response® Measles Test Cassette 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 Rapid Response® Measles Test Cassette 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 Rapid Response® Measles Test Cassette was compared with a leading commercial ELISA; the results were tabulated as below.

IgG Results

Item		ELISA		Total Result
Rapid Response® Measles Test Cassette	Result	Positive	Negative	
	Positive	46	1	47
	Negative	1	22	23
Total Result		47	23	70

Relative sensitivity: 97.9% (95%CI*: 88.7%~100%)
Relative specificity: 95.7% (95%CI*: 78.1%~99.9%)
Accuracy: 97.1% (95%CI*: 90.1%~99.7%)
*Confidence Intervals

IgM Results

Item		ELISA		Total Result
Rapid Response® Measles Test Cassette	Result	Positive	Negative	
	Positive	18	3	21
	Negative	1	48	49
Total Result		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

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of 5 specimens: 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 a IgM strong positive. Three different lots of the Rapid Response® Measles Test Cassette 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 Rapid Response® Measles Test Cassette 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 Rapid Response® Measles Test Cassette 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.

Glossary of Symbols

Consult instructions for use
Test per Kit
Do Not Reuse
Store between 35.6°F to 86°F
Use by
REF Catalogue #
LOT Lot Number
IVD For *in vitro* diagnostic use only

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