Mycoplasma IgM Device

(2–30°C) (Rapid Test Device)

CATALOGUE NUMBER	KIT SIZE
RADMPN1	20 Tests

Intended Use:
The Mycoplasma IgM Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative detection of IgM antibody against *Mycoplasma pneumoniae* in human whole blood, serum and plasma samples. This kit is intended for use as an aid in the diagnosis of chest infections. For *in vitro* diagnostic use by trained personnel only.

Summary:
Mycoplasma pneumoniae is a bacterium which causes a range of chest infections including tracheobronchitis (chest cold) and pneumonia by damaging the lining of the respiratory system. Symptoms include sore throat, fatigue, fever, pain when breathing and a dry cough. Often the pneumonia caused by this bacterium is less severe than that caused by other infectious agents. However, individuals with a compromised immune system and those recovering from respiratory illness are at increased risk of suffering more serious pneumonia. The disease is spread via inhalation of aerosolised droplets containing the bacteria which are dispersed by coughing and sneezing and lack of hand washing hygiene.

Test Principle:
The Mycoplasma IgM Device (Whole Blood/Serum/Plasma) detects IgM antibody to *Mycoplasma pneumoniae* by immunochromatography resulting in development of coloured bands. Anti-human IgM is coated at the test line region of the device. During testing, the sample reacts with *M. pneumoniae* antigen conjugated to coloured particles and precoated near the sample well of the test. The mixture migrates up the membrane by capillary action and interacts with the antibody at the test line. If *Mycoplasma pneumoniae* IgM is present in the sample, a coloured band will form at the test line region of the device. The presence of this coloured band indicates a positive result, while absence of test line band indicates a negative result. The appearance of a coloured band at the control region serves as a procedural control, indicating that the proper volume of sample has been added and correct membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Buffer
Disposable pipettes
Instructions For Use sheet

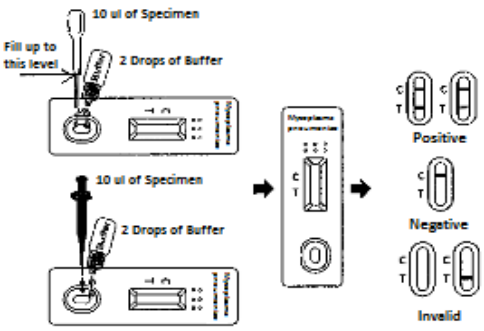
Materials not provided: Timer, specimen collection container, centrifuge, lancets, Heparinized capillary tubes and dispensing bulb

Precautions:
- Do not use after expiry date.
- Do not eat, drink or smoke in the area where the samples or kits are handled.
- Do not use test if pouch is damaged.
- Handle all 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 samples.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

Reagent Preparation and Stability:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

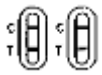
Sample Collection and Storage:
The Mycoplasma Device is intended for use with human whole blood (collected via venepuncture or fingerstick), serum, or plasma samples only.
To collect Fingerstick Whole Blood samples, wash the target finger then massage it to encourage blood flow to the fingertip. Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Squeeze the finger to extract a drop of blood. Use the pipette to draw up the whole blood to the level indicated.
Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed samples.
Testing must be performed immediately for samples collected by the fingerstick method. For venepuncture, serum and plasma do not leave the samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2 - 8ºC for up to 3 days. For long term storage, samples should be kept below -20ºC. Whole blood collected by venepuncture may be stored at 2 - 8ºC for up to 24 hours. Do not freeze whole blood samples.
Samples must be brought up to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

Assay Procedure:



Bring tests, samples, buffer, and/or controls to room temperature (15-30°C) before use.
Remove the test device from its sealed pouch, place it on a clean, level surface and use it straight away. Use the pipette to draw up the sample (whole blood, serum or plasma) to the level indicated (approximately 10 µL) and transfer it to the sample well. See illustration. Add 2 drops of Buffer to the sample well (approximately 80 µL) and start a timer.
Wait for coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Results Interpretation:



POSITIVE: Two coloured bands appear. One band appears at the control line (C) and another band appears at the test line (T).
Note: The intensity of colour of the test band will vary according to the concentration of anti-Mycoplasma pneumonia IgM in the sample. Therefore, any detectable band should be considered as a positive result.

NEGATIVE: Only one coloured band appears, in the control region. There is no colour development at the test line.

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Quality Controls:
Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient sample volume and correct procedural technique.
External controls are not supplied with this kit. 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 of the Test:
1. The Mycoplasma IgM Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use and should only be used for the qualitative detection of anti-*Mycoplasma pneumoniae* IgM. Neither the quantitative value nor the rate of increase in antibody can be determined by this test.
2. The Mycoplasma IgM Device (Whole Blood/Serum/Plasma) will only indicate the presence of anti-*Mycoplasma pneumoniae* IgM in the sample and should not be used as the sole criteria for the diagnosis of infection. A confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. The test result may be recorded as negative shortly after infection or at certain timeframes during infection when the antibody may be present at concentrations below the sensitivity level of the test. If clinical symptoms persist, additional testing using other clinical methods is recommended.

Performance Characteristics:
Sensitivity, Specificity and Accuracy
The Mycoplasma IgM Device (Whole Blood/Serum/Plasma) has been evaluated against a predicate *Mycoplasma pneumoniae* rapid test using clinical samples. The results show a high sensitivity and specificity for the Mycoplasma IgM Device with an overall accuracy of 98.9%.

Method		Predicate rapid test		Total Result
Mycoplasma IgM Device	Results	Positive	Negative	
	Positive	111	3	114
	Negative	2	355	357
Total Result		113	358	471

Relative sensitivity: 98.2% (95%CI*: 93.8% - 99.8%);
Relative specificity: 99.2% (95%CI*: 97.6% - 99.8%);
Accuracy: 98.9% (95%CI*: 97.5% - 99.7%). *Confidence Interval

Precision
Intra-Assay precision was determined using 10 replicates of 4 samples: a negative sample , a low positive, a medium positive and a high positive. The four samples were correctly identified >99% of the time.

Inter-Assay precision was determined by 10 separate assays using the same four samples as above. Three different lots of Mycoplasma IgM Device were tested over a 10-day period. The four samples were correctly identified >99% of the time.

Cross-Reactivity
The Mycoplasma IgM Device (Whole Blood/Serum/Plasma) has been tested using, HBsAg, HBsAb, HBeAg, HBcAb, syphilis and anti-HIV positive samples. The results showed no cross-reactivity.

Interfering Substances
The Mycoplasma IgM Device has been tested to check for potential interference by highly haemolysed, lipaemic or icteric samples. No interference was detected by samples containing up to 1000 mg/dl haemoglobin, up to1000 mg/dl bilirubin and up to 2000 mg/dl human serum albumin.

References

1. Clyde WA. Clinical overview of typical *Mycoplasma pneumoniae* infections. Clin Infect. Dis 17: S32-S37; 1993.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by date
	Manufacturer		

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