TruQuick™ Myco pne IgG/IgM 25T

A rapid test for the qualitative detection of IgG and IgM antibodies to *Mycoplasma pneumoniae* (*M. pneumoniae*) in whole blood, serum or plasma.

REF **TQ5925** IVD **Rx Only**

INTENDED USE
TruQuick Myco pne IgG/IgM is a rapid immunoassay for the qualitative detection of IgG and IgM antibodies to *Mycoplasma pneumoniae* in whole blood, serum, or plasma to aid in the diagnosis of *Mycoplasma pneumoniae* infection.

SUMMARY AND EXPLANATION OF THE TEST
Mycoplasma pneumoniae is the causative agent of respiratory tract infectious diseases and complication of other systems. There will be a symptom with headache, fever, dry cough, and muscle pain. People of all age groups can be infected while youth, middle-aged and children under 4 years old have a higher infection rate. 30% of the infected population may have a whole lung infection.

In normal infection, MP-IgG can be detected as early as one week after infected, continue to rise very rapidly, peaking in about 2-4 weeks, decreasing gradually in six weeks, disappear in 2-3 months. Detection of MP-IgM/IgG antibody can diagnose MP infection in early stage.

BIOLOGICAL PRINCIPLES
TruQuick Myco pne IgG/IgM is a qualitative membrane based immunoassay for the detection of *Mycoplasma pneumoniae* IgG and IgM antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG or IgM is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with *M. pneumoniae* antigen coated particles in the test. This mixture migrates along the length of the test and interacts with the immobilized anti-human IgG or IgM. If the specimen contains *M. pneumoniae* IgG and/or IgM antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain *M. pneumoniae* 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The test contains *M. pneumoniae* antigen-coated particles and anti-human IgG and IgM coated on the membrane. Each cassette is packaged in a foil pouch.
- Buffer: A buffered solution containing Proclin 300 as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge
- Timer

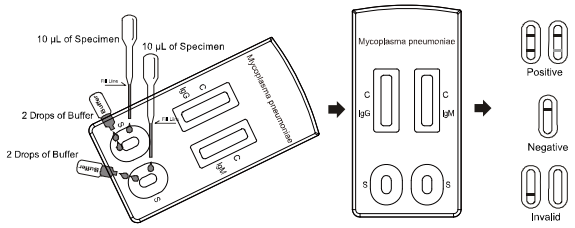
PRECAUTIONS
1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
Store as packaged in the sealed pouch 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 beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick Myco pne IgG/IgM can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.
2. Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
3. To collect Fingerstick Whole Blood specimens:
   - 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.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens 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 two days of collection. For long term storage, specimens should be kept below -20 C. 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. Specimens should not be frozen and thawed repeatedly for more than three times.
6. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically, draw the specimen (whole blood/serum/plasma) up to the Fill Line as shown in illustration below (approximately 10 µL). Transfer the specimen to the sample well (S) each, then hold the buffer bottle vertically and add 2 drops of Buffer (approximately 80 µL) to the sample well (S) each, and start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *M. Pneumonia* antibody present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).
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 Cassette. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick Myco pne IgG/IgM has been compared with other commercially *M. pneumoniae* rapid test, the overall accuracy could reach to 93.7%.

LIMITATIONS OF THE PROCEDURE
1. This reagent is designed for the qualitative screening test. Concentration of MP-IgG and/or MP-IgM cannot be determined by this qualitative test.
2. Negative result may occur when detecting short-term infected specimens or window period specimens, indicate that the specific antibodies of MP does not exist or the concentration is below detection limit.
3. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
5. Abnormal results may occur according to operator error or drug use. If AIDS is still suspected, a specimen should be collected later and tested again.

SPECIFIC PERFORMANCE CHARACTERISTICS
Clinical Sensitivity, Specificity and Accuracy
TruQuick Myco pne IgG/IgM was compared with commercial *M. pneumoniae* rapid Test Cassette; the results show that TruQuick Myco pne IgG/IgM has a high sensitivity and specificity.

For IgG

Method		Other Rapid Test		Total Results
TruQuick Myco pne IgG/IgM	Results	Positive	Negative	
	Positive	110	22	132
	Negative	9	351	360
Total Results		119	373	492

Sensitivity: 92.4% (95% CI*: 86.1%-96.5%)
Specificity: 94.1% (95% CI*: 91.2%-96.3%)
Correlation: 93.7% (95% CI*: 91.2%-95.7%) *Confidence Interval

For IgM

Method		Other Rapid Test		Total Results
TruQuick Myco pne IgG/IgM	Results	Positive	Negative	
	Positive	115	15	130
	Negative	6	359	365
Total Results		121	374	495

Sensitivity: 95.0% (95% CI*: 89.5%-98.2%)
Specificity: 96.0% (95% CI*: 93.5%-97.7%)
Correlation: 95.8% (95% CI*: 93.6%-97.4%) *Confidence Interval

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of five specimens: a negative, an IgG low positive, an IgM low positive, an IgG medium positive, an IgM medium positive. The negative, low positive and medium positive values were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays on the same five specimens. Three different lots of TruQuick Myco pne IgG/IgM were tested. The specimens were correctly identified > 99% of the time

CROSSREACTIVITY
Sera containing known amounts of antibodies to *M. pneumoniae* have been tested with sample from patients diagnosed with HAV, HBV, HCV, HEV, HIV and Syphilis. No crossreactivity was observed, indicating that TruQuick Myco pne IgG/IgM has a high degree of specificity for antibodies to *M. pneumoniae*.

TESTS FOR INTERFERING SUBSTANCES
The following substances showed no interference when tested with negative and IgG or IgM positive samples:

Ascorbic acid 2 g/dL	Acetaminophen 20 mg/dL
Gentisic acid 20 mg/dL	Albumin 2 g/dL
Oxalic acid 600 mg/dL	Caffeine 20 mg/dL
Bilirubin 1 g/dL	Acetylsalicylic acid 20 mg/dL
Hemoglobin 1 g/dL	

CE

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	R. Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.