TruQuick™ Mycoplasma Pne. Ag 20T

A rapid test for the qualitative detection of *Mycoplasma pneumoniae* antigen in throat swabs.

REF **TQ5520** IVD **Rx Only**

INTENDED USE
TruQuick Mycoplasma Pne. Ag is a rapid immunoassay for the qualitative detection of *Mycoplasma pneumoniae* (*M. pneumoniae*) antigens in throat swabs. It is intended to aid in the rapid differential diagnosis of *M. pneumoniae* infections.

SUMMARY AND EXPLANATION OF THE TEST
M. pneumoniae is one of three species of Mycoplasma that frequently cause infection in humans.[1] *M. pneumoniae* most commonly causes upper respiratory tract infections, but can also cause pneumonia. The identification of the *M. pneumoniae* will help the management of the disease with appropriate antibiotic treatment. This *M. pneumoniae* immunoassay is intended to detect *M. pneumoniae* antigen qualitatively. Because this one-step *M. pneumoniae* rapid test is easy to carry out, it is widely used as a screening test device and as an aid in the diagnostics of *M. pneumoniae* disease.

BIOLOGICAL PRINCIPLES
In this test, antibody specific to *M. pneumoniae* antigen is coated on the test line region of the Test Cassette. During testing, the extracted throat swab specimen reacts with an antibody to *M. pneumoniae* that is coated onto particles. The mixture migrates up the membrane to react with the antibody to *M. pneumoniae* on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates 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 Cassette contains *Mycoplasma pneumoniae* particles coated on the membrane. Each cassette is packaged in a foil pouch.
- Sample Extraction Buffer: A buffered extraction solution containing Proclin 300 as a preservative. The Extraction Buffer is supplied ready for use.
- Extraction Tube Tips
- Extraction Tubes
- Sterilized Swabs:
- Workstation
- Package Insert

MATERIALS NOT PROVIDED
- Timer

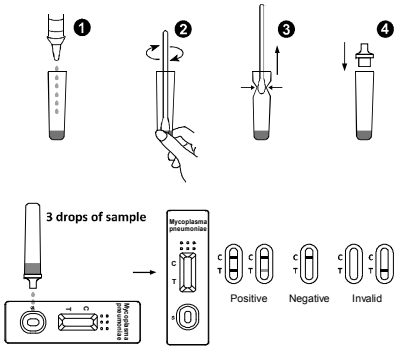
PRECAUTIONS
Please read all the information in this package insert before performing the test.
1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. If the *M. pneumoniae* antigen rapid test was kept refrigerated, let all the reagents warm up to room temperature (15-30 C) before proceeding with the test.
4. Wear gloves when handling the samples, avoid touching the reagent membrane with your fingers.
5. Discard gloves, swabs, test tubes, and test devices in accordance with the local regulation.
6. Visibly Bloody samples should not be used for the testing.

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

SHELF LIFE AND STORAGE
Store the test kit at room temperature or refrigerated (2-30 C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging.

SPECIMEN COLLECTION AND PREPARATION
Use freshly collected throat swab samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.
- **Throat Swabbing**
  Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the membrane. Avoid contaminating the swab with saliva.

TEST PROCEDURE
Allow the test device, test sample and buffer to equilibrate to room temperature (15-30 C) prior to testing.
1. Remove the Test Cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the Extraction Reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the Extraction Tube freely without touching the edge of the tube. Add 10 drops of solution (Approx. 500 µL) to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube to expel as much liquid as possible from the swab and remove it from the tube. Discard the swab in accordance with local biohazard waste disposal protocols. See illustration 3.
5. Fit the dropper tip on top of the Extraction Tube. Place the Test Cassette on a clean and level surface. See illustration 4.
6. Add three drops of the solution (approx.120 µL) to the sample well and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
POSITIVE: Two colored lines appear. One colored line appears in the control region (C), and one colored line in the test region (T). The shade of color may vary but it should be considered positive whenever there is even a faint line.
NEGATIVE: Only one colored line appears in the control region (C), and no line in the test region (T). The negative result indicates that there is no *M. pneumoniae* in the sample or the concentration of *M. pneumoniae* is below the detectable range.
INVALID: No line appears in the control region (C). The test is invalid even if there is a line in the test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. 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.
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive 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 Mycoplasma Pne. Ag has been compared with a leading commercial PCR test. The correlation between these two systems is over 98%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Mycoplasma Pne. Ag is an acute-phase screening test for qualitative detection. Sample collected may contain antigen levels below the reagent's sensitivity threshold, so a negative test result does not exclude infection with *M. pneumoniae*.
2. TruQuick Mycoplasma Pne. Ag detects both viable and nonviable *M. pneumoniae* antigen. Test performance depends on antigen load in the sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. Performance of the test has not been established for monitoring treatment of *M. pneumoniae*.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick Mycoplasma Pne. Ag was evaluated with specimens obtained from 271 patients. PCR was used as the reference method. Specimens were considered positive if PCR indicated a positive result. Specimens were considered negative if PCR indicated a negative result.

Method		PCR		Total
	Results	Positive	Negative	Result
TruQuick Mycoplasma Pne. Ag	Positive	33	3	36
	Negative	2	233	235
Total Result		35	236	271

Sensitivity: 94.3% (95% CI*: 80.8%~99.3%);
Specificity: 98.7% (95% CI*: 99.6%~100.0%);
Correlation: 98.2% (95% CI*: 95.7%~99.4%). *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 15 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. The specimens were correctly identified > 99% of the time.

Inter-Assay Precision
Between-run precision was determined by 15 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three different lots of TruQuick Mycoplasma Pne. Ag were tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
No crossreactivity was observed with samples containing the following microorganisms:
1. **Virus**
   Influenza virus A(H1N1,H3N2), Influenza virus B; Adenovirus Type 1~8,11,19,37, Coxsackie virus Type A16,B1~5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus, Parainfluenza virus Type 1~3, Poliovirus Type 1~3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14.
2. **Chlamydiae**
   Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis
3. **Bacteria**
   Acinetobacter baumannii, Bacteroides fragilis, Bordetella pertussis, Candida albicans, Candida glabrata, Cardiobacterium hominis, EikeneUa corrodens, Enterococcus gallinarum. Escherichia coil, Haemophilus phrophlus, Haemophilus infiuenzae, Haemophilus parainfluenzae, Haemophilus paraphrophilus, Kingella kingae, Klebsiella pneumoniae, Listeria monocytogenes, Moraxella catarrhalis, Neisseria gonorrhoeae, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus sp. group C, G, F, *Streptococcus mutans.*

ANALYTICAL SENSITIVITY
Titration studies performed with *Mycoplasma pneumoniae* antigen diluted in PBS have shown the limit of detection to be 8 x 10^3 CFU/mL.

TESTS FOR INTERFERING SUBSTANCES
Swabs were spiked with 100 µL of the following potentially interfering substances at the starting concentration of 1% and then spiked with organisms to represent low, middle and high *M. pneumoniae* samples. None of the substances interfered in the assay.

Cherry Halls® cough drops	Vicks® Chloroseptic spray
Menthol Halls® cough drops	Cepacol® Chloroseptic spray
Robitussin® cough syrup	Listerine® mouthwash
Dimetapp® cough syrup	Scope® mouthwash

REFERENCES

1. Al-Moyed KA, Al-Shamahy HA. *Mycoplasma pneumoniae* infection in Yemen: incidence, presentation and antibiotic susceptibility. East Mediterr Health J. 2003 May;9(3):279-90.

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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	Rx 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.