TruQuick™ Legionella 10T

A rapid test for the qualitative detection of *Legionella pneumophila* antigen in urine specimen.

REF **TQ4310** IVD **Rx Only**

INTENDED USE
TruQuick Legionella is an in vitro diagnostic test based on immunochromatographic assay. It is designed for detection of soluble antigen from *Legionella pneumophila* serogroup 1 in human urine specimen.

SUMMARY AND EXPLANATION OF THE TEST
Legionellosis is a serious pneumonia caused by bacteria of the genus Legionella assigned to the family Legionellaceae. This family now includes 48 species and over 60 serogroups. Approximately 20 species are implicated in human disease. The overwhelming majority of *Legionella* infections are caused by *Legionella pneumophila*. Legionnaires' disease is the major clinical manifestation of *Legionella* infection although extra-pulmonary infection and non-pneumonic disease like Pontiac fever occur. The name Legionella pneumophila was derived from the dramatic outbreak at the 1976 American Legion Convention in Philadelphia.[1]

Legionella pneumophila is responsible for approximately 90% of infections, and of these, over 80% are due to a single serogroup, serogroup 1.[2] *Legionella* bacteria are small faintly staining Gram-negative rods with polar flagella. *Legionella* bacteria have a widespread distribution in both natural and manmade aquatic habitats. They are readily found in fresh water, cooling towers and potable water systems. The organisms can survive in a wide range of conditions, and temperature is a critical determinant for *Legionella* proliferation. Nosocomial infection is particularly associated with colonization of hospital hot water system by Legionella.

The incubation period of Legionnaires' disease after being exposed to the bacteria is from two to ten days. Most patients who are admitted to the hospital develop high fever often higher than 39.5 C (103 F). Cough can be the first sign of a lung infection. Other common symptoms include headaches, muscle aches, chest pain, and shortness of breath. Gastrointestinal symptoms are common.

Legionnaires' disease (LD) is not contagious. The disease is transmitted by aerosol, and there is no evidence for direct person-to-person transmission. Person at risk are those whose immune system is compromised, including transplant recipients, the elderly, cigarette smokers, or those showing chronic obstructive pulmonary disease or chronic renal disease.[3]

Diagnosis of legionellosis can be difficult because signs and symptoms are nonspecific and do not distinguish *L. pneumophila* infections from other common causes of pneumonia. *L. pneumophila* infections are considered to be fairly common but they are probably underdiagnosed and under-reported. The underdiagnosis of legionellosis can in part be attributed to the need for rapid, specific and sensitive diagnostic testing methods.

TruQuick Legionella detects soluble antigen from *L .pneumophila* serogroup 1 in urine.[2]

BIOLOGICAL PRINCIPLES
This is a ready-to-use membrane test based on colloidal gold particles. This test allows detection of *Legionella pneumophila* LPS in urine samples. The test sensitivity and specificity come from monoclonal and polyclonal anti-Legionella antibodies. Mouse anti-*Legionella* antibodies are conjugated to colloidal gold particles and dried on a conjugate absorbent pad. Each strip is sensitized with goat anti-*Legionella* antibodies at the T-line region and with a control antibody at the C-line region when the urine sample migrates, conjugate is rehydrated and migrates along with the sample. If *L. pneumophila* urinary antigens are present in the sample, a complex between the anti-*L. pneumophila* conjugates and the *L. pneumophila* antigens is formed that will be caught by the specific anti-*L. pneumophila* reagent coated on the stick. Results appear in 15 minutes in the form of a red line that develops on the strip.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassette: The Test Cassette contains mouse anti-*Legionell*a particles and goat anti-*Legionella* coated on the membrane.
- Droppers
- Package Insert

MATERIALS NOT PROVIDED
- Specimen Collection Container
- Timer

PRECAUTIONS
1. All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
2. All reagents are for in vitro diagnostic use only.
3. Pouch must be opened with care
4. Avoid touching nitrocellulose with your fingers.
5. Wear gloves when handling samples.
6. Never use reagents from another kit.
7. Green lines indicate immunoreagents adsorption sites. Green color disappears during the test.
8. Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.
9. Dispose of gloves, test tubes and used devices in accordance with GLP.
10. Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

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

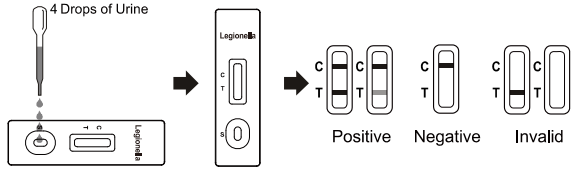
SHELF LIFE AND STORAGE
An unopened pouch may be kept at between 2-30 C and used until the shelf life date indicated on the packaging. Once the pouch is opened, run the test immediately. **DO NOT FREEZE.**

SPECIMEN COLLECTION AND PREPARATION
Specimens to be tested should be obtained and handled by standard methods for the collection of urine sample. Urine specimens should be collected in standard containers. The use of Proclin 300 as preservative has been validated on TruQuick Legionella.

Urine sample specimens must be tested as soon as possible after they are collected. If necessary, they can be stored at 2-8 C for up to 1 week or at -10 C to -20 C for longer periods of time.

Although it requires added processing time, the antigens present in the urine can be concentrated with a disposable concentrator or a centrifugation system.

TEST PROCEDURE
Allow the test, specimen, and/or controls to reach room temperature (15-30 C) prior to testing.
1. Open the pouch and remove the device. Once opened, run the test immediately.
2. Swirl urine gently to mix before testing.
3. Add 4 drops of swirled urine sample (approx. 100 µL) to the sample well.
4. Wait for the colored line to appear. Read the results at **15** minutes, do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A positive result indicates that *L. pneumophila* was detected in the specimen.
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *L. pneumophila* present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that *L. pneumophila* antigen is not present in the specimen, or is present below the detectable level of the test.
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 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 line region (C) is an internal valid 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 Legionella has been compared with a leading commercial EIA test, demonstrating an overall correlation of 99.1%.

LIMITATIONS OF THE PROCEDURE
The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
A positive test does not rule out the possibility that other pathogens may be present. Kit test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the reagent's sensitivity threshold. If a sample is given a negative result despite the observed symptoms, a culture should be started to check the sample.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick Legionella was evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. EIA was used as laboratory evidence.

Method		EIA		Total Results
	Result	Positive	Negative	
TruQuick Legionella	Positive	40	0	40
	Negative	1	68	69
Total Results		41	68	109

Sensitivity: 97.6% (95% CI*: 87.1%~99.9%);
Specificity: > 99.9% (95% CI*: 95.7%~100%);
Correlation: 99.1% (95% CI*: 95.0%~99.9%). *Confidence Intervals

REPRODUCIBILITY
To check intra-batch accuracy (repeatability), negative, low positive, middle positive and high positive urine samples were processed 15 times on kits of the same production batch in the same experimental conditions. The samples produced the expected results in 100% of cases.

To check inter-batch accuracy (reproducibility), the same 15 samples (low, middle, and high positive and negative) were processed on kits from three different production batches. The samples produced the expected results in 100% of cases

CROSSREACTIVITY
Crossreactivity with the following organisms has been studied at 1 x 10^9 org/mL. There was no crossreactivity with the organisms at 1 x 10^9 org/mL to be tested with TruQuick Legionella.

Adenovirus	*Aspergillus niger*	*Campylobacter jejuni*
Campylobacter coli	*Clostridium difficile*	*Candida albicans*
E. coli (different strains)	*Enterobacter cloacae*	*Enterococcus faecalis*
Escherichia hermanni	*Haemophilus influenzae*	*Helicobacter pylori*
HMPV	*Influenza A/B*	*Klebsiella pneumoniae*
Legionella longbeachae	*Legionella bozemanii* (sg1)	*Moraxella catarrhalis*
Mycobacterium avium	*Mycoplasma hominis*	*Mycobacterium intracellulare*
Mycoplamsa pneumonia	*Mycobacterium tuberculosis*	*Neisseria meningitidis*
Neisseria meningitidis (sg C)	*Nocardia asteroides*	*Parainfluenzae*
Proteus mirabilis	*Pseudomonas aeruginosa*	*Rhinovirus* RSV
S. typhimurium	*Salmonella enteritidis*	*Shigella sonnei*
Streptococcus Group B, C, F, G	*Streptococcus pyogenes*	*Streptococcus mutans*
Serratia marcescens	*Staphylococcus aureus*	*Streptococcus pneumonia*
Shigella flexneri	*Staphylococcus epidermidis*	*Ureaplasma urealyticum*
Vibrio parahemolyticus	*Yersinia enterocolitica* (types 3,9)	

REFERENCES

1. Diederen BMW. Legionella spp. and Legionnaires' disease. J Inf. 2008;56:1-12.
2. Helbig JH, et al. Pan-European study on culture-proven Legionnaires' disease. Eur J Clin Microbiol Infect Dis. 2002;21:710-716.
3. Fields BS, et al. Legionella and Legionnaires' disease: 25 years of investigation. Clin Microbiol Rev. 2002;15:506-526.

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SNTQ4310 **REV. 06/17**

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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.