TruQuick™ Chlamydia 20T

A rapid test for the qualitative detection of Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens.

REF **TQ1020** IVD **Rx Only**

INTENDED USE
TruQuick Chlamydia is a rapid immunoassay for the qualitative detection of *Chlamydia trachomatis* in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection. Positive results should be used in conjunction with other test results and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. It is composed of elementary bodies (the infectious form) and reticulate or inclusion bodies (the replicating form). *C. trachomatis* has both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of Chlamydia infection in women include cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility.[1] Vertical transmission of the disease during parturition from to neonate can result in inclusion conjunctivitis or pneumonia. In men, complication of Chlamydia includes urethritis and epididymitis. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia infection. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic. Traditionally, Chlamydia infection has been diagnosed by detection of Chlamydia inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labor intensive, expensive, long (18-72 hours) and not routinely available in most situations.

TruQuick Chlamydia is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens.

BIOLOGICAL PRINCIPLES
In the test, antibody specific to the Chlamydia antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Chlamydia that is coated onto particles. The mixture migrates along the device to react with the antibody to Chlamydia on the membrane and generates a color line in the test region. The presence of this colored 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 Cassette: The Test Cassette contains Chlamydia antibody-coated particles and Chlamydia antibodies coated on the membrane. Each cassette is packaged in a foil pouch.
- Extraction Reagent 1 (0.2 M NaOH)
- Extraction Reagent 2 (0.2 M HCl)
- Extraction Tubes
- Sterile female cervical swabs
- Workstation
- Dropper tips
- Package insert

MATERIALS NOT PROVIDED
- Urine cup (For male urine specimens only)
- Centrifuge tube (For male urine specimens only)
- Sterile male urethral swabs
- Positive control
- Negative control
- Timer

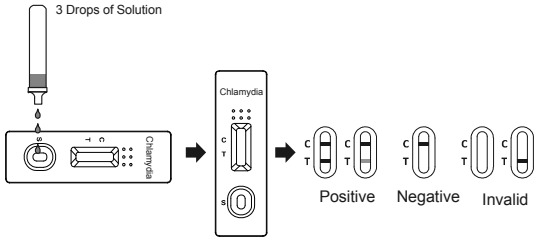
PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout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

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 Chlamydia can be performed using female cervical swab, male urethral swab and male urine specimens.
2. The quality of specimens obtained is of extreme importance. Detection of Chlamydia requires a vigorous and thorough collection technique that provides cellular material rather than just body fluids.
3. To collect **Female Cervical Swab Specimen**:
   - Use the swab provided in the kit. Alternatively, any plastic-shaft swab may be used.
   - Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the Chlamydia organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens.
   - If the test is to be conducted immediately, put the swab into the extraction tube.
4. To collect **Male Urethral Swab Specimens**:
   - Standard plastic-or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least one hour prior to specimen collection.
   - Insert the swab into the urethra about 2-4 cm, rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before collection swab.
   - If the test is to be conducted immediately, put the swab into the extraction tube.
5. To collect **Male Urine Specimens**:
   - Collect 15-30 mL of clean first morning urine in a sterile urine cup. First morning urine specimens are preferred to achieve the highest concentrations of Chlamydia antigen.
   - Mix the urine specimen by inverting container. Transfer 10 mL of the urine specimen into a centrifuge tube, add 10 mL distilled water and centrifuge at 3,000 rpm for 15 minutes.
   - Carefully discard the supernate, keep the tube inverted and remove any supernate from the rim of the tube by blotting onto absorbent pad.
   - If the test is to be conducted immediately, treat the urine pellet according to the **TEST PROCEDURE**.
6. It is recommended that specimens be processed as soon as possible after collection. If immediately testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swab may be stored for four to six hours at room temperature (15-30 C) or refrigerated (2-8 C) for 24 hours. Do not freeze. All specimens should be allow to reach the room temperature (15-30 C) before testing.

TEST PROCEDURE
Allow the test, reagents, specimens, and/or controls to reach room temperature (15-30 C) prior to testing.
1. Remove the Test Cassette from the pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Chlamydia antigen according to the specimen type.
   - **For Female Cervical or Male Urethral Swab Specimen:**
     - Hold the Extraction Reagent 1 bottle vertically and add **5 drops of Reagent 1** (approx. 300 µL) to the Extraction Tube. Extraction Reagent 1 is colorless. Immediately insert the swab, compress the bottom of tube and rotate swab 15 times. Let stand for 2 minutes.
     - Hold the Extraction Reagent 2 bottle vertically add **6 drops of Reagent 2** (approx. 250 µL) to the Extraction Tube. The solution should turn turbid. Compress the bottom of tube and rotate the swab 15 times until the solution turns clear with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand 1 minute.
     - Press the swab against the side of tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Fit the dropper tip on top of Extraction Tube.
   - **For Male Urine Specimens:**
     - Hold the Extraction Reagent 2 bottle vertically and add 6 drops of (approx. 250 µL) Reagent 2 to the urine pellet in the centrifuge tube, then shake the tube vigorously until the suspension is homogeneous.
     - Transfer all the solution in the centrifuge tube to an Extraction Tube. Let stand for 1 minute. Hold the Extraction Reagent 1 bottle upright and add 5 drops of (approx. 300 µL) Reagent 1 to the Extraction Tube. Vortex or tap the bottom of the tube to mix the solution. Let stand for 2 minutes.
     - Fit the dropper tip on top of the Extraction Tube.
3. Place the Test Cassette on a clean and level surface. Add 3 full drops of the extracted solution (approx. 100 µL) to the specimen well of the Test Cassette, then start the timer. Avoid trapping air bubbles in the specimen well.
4. Wait for the color to appear. Read the result at 10 minutes; do not interpret the result 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 Chlamydia was detected in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Chlamydia 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 Chlamydia 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.
A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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 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
For women attending STD clinics and other high-risk populations, the prevalence of Chlamydia infection has been reported to be between 20% and 30%. In a low-risk populations such as those patients attending obstetrics and gynecology clinics, the prevalence is approximately 5% or less.

Reports show that for men attending STD clinics, the prevalence of Chlamydia infection is approximately 8% in asymptomatic men and 11% in symptomatic men.[1, 2] Normal carriage rates of Chlamydia in asymptomatic men are less than 5%.[3]

LIMITATIONS OF THE PROCEDURE
1. TruQuick Chlamydia is for in vitro diagnostic use only. This test should be used for the detection of Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens. Neither the quantitative value nor the rate of increase in Chlamydia antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Chlamydia antigen in specimens from both viable and nonviable Chlamydia. Performance with specimens other than female cervical swabs, male urethral swabs and male urine has not been assessed.
3. Detection of Chlamydia is dependent on the number of organisms present in the specimen. This can be affected by specimen collection methods and patient factors such as age, history of Sexually Transmitted Diseases (STDs), presence of symptoms, etc. The minimum detection level of this test may vary according to serovar. Therefore, the test results should be interpreted in conjunction with other laboratory and clinical data available to the physician.
4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
5. Excessive blood on the swab may cause false-positive results.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity
TruQuick Chlamydia was evaluated with specimens obtained from patients of STD clinics. 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. The results show that TruQuick Chlamydia has a high sensitivity relative to PCR.

Specificity
TruQuick Chlamydia uses an antibody that is highly specific for Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens. The results show that TruQuick Chlamydia has a high specificity relative to PCR.

For **Female Cervical Swab Specimens**

Method		PCR		Total Results
TruQuick Chlamydia	Results	Positive	Negative	
	Positive	42	4	46
	Negative	3	156	159
Total Results		45	160	205

Sensitivity: 93.3% (95% CI: 81.7%-98.6%)*
Specificity: 97.5% (95% CI: 93.7%-99.3%)*
Correlation: 96.6% (95% CI: 93.1%-98.6%)*

*95% Confidence Intervals

For **Male Urethral Swab Specimens**

Method		PCR		Total Results
TruQuick Chlamydia	**Results**	Positive	Negative	
	Positive	50	5	55
	Negative	8	115	123
Total Results		58	120	178

Sensitivity: 86.2% (95% CI: 74.6%-93.9%)*
Specificity: 95.8% (95% CI: 90.5%-98.6%)*
Correlation: 92.7% (95% CI: 87.8%-96.1%)* *95% Confidence Intervals

For **Male Urine Specimens**

Method		PCR		Total Results
TruQuick Chlamydia	**Results**	Positive	Negative	
	Positive	35	0	35
	Negative	2	60	62
Total Results		37	60	97

Sensitivity: 94.6% (95% CI: 81.8%-99.3%)*
Specificity: >99.9% (95% CI: 95.1%-100%)*
Correlation: 97.9% (95% CI: 92.7%-99.7%)* *95% Confidence Intervals

REPRODUCIBILITY

Intra-assay Precision

Within run precision was determined using five replicates of swab specimens: 0.5% BSA-PBS, 1 x 10^7 org/mL, 2.5 x 10^7 org/mL. The specimens were correctly identified 100% of the time.

Inter-assay Precision

Between run precision was determined using the same specimens (0.5% BSA-PBS, 1 x 10^7 org/mL, 2.5 x 10^7 org/mL) and three lots of product. The 10 replicate specimens were correctly identified in all tests.

CROSSREACTIVITY

The antibody used in TruQuick Chlamydia has been shown to detect all known Chlamydia serovars. *Chlamydia psittasi* and *Chlamydia pneumoniae* strains have been tested with TruQuick Chlamydia, and were shown to crossreact when tested in suspensions of 109 CFU/mL. Crossreactivity with other organisms has been studied using suspensions of 109 CFU/mL. The following organisms were found negative when tested with TruQuick Chlamydia:

Acinetobacter calcoaceticus	*Pseudomona aeruginosa*	*Proteus mirabilis*
Acinetobacter spp	*Neisseria meningitides*	*Neisseria gonnorhea*
Enterococcus faecalis	*Salmonella choleraesius*	*Group B/C Streptococcus*
Enterococcus faecium	*Candida albicans*	*Hemophilus influenzae*
Staphylococcus aureus	*Proteus vulgaris*	*Branhamella catarrhalis*
Klebsiella pneumoniae	*Gardnerella vaginalis*	

ANALYTICAL SENSITIVITY

Genogroup 1 and 2 Chlamydia recombinant antigens diluted in a buffer were used to assess the assay limit of detection as shown below.

Antigen	LoD
Genogroup 1	5 x 10^6 org/mL
Genogroup 2	5 x 10^6 org/mL

REFERENCES

1. Sanders JW, et al. Evaluation of an enzyme immunoassay for detection of chlamydia trachmatis in urine of asymptomatic men. J Clin Microbiol 1994;32,24-27.
2. Jaschek G, et al. Direct detection of chlamydia trachomatis in urine specimens from symptomatic and asymptomatic men by using a rapid polymerase chain reaction assay. J Clin Microbiol 1993;31,1209-1212.
3. Schachter J. Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine, 1982;72, 60-69.

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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_x 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.