Chlamydia
Rapid Test Device (Swab/Urine)

REF	A40110120

For professional in vitro diagnostic use only.

INTENDED USE

The Chlamydia Rapid Test Device is a rapid immunochromatographic assay for the qualitative, presumptive detection of Chlamydia trachomatis in human female cervical swab, male urethral swab and male urine specimens.
The Chlamydia Rapid Test Device is an in-vitro diagnostic device intended for use as an aid in the diagnosis of chlamydia infection in symptomatic or asymptomatic individuals. This test is used for laboratory professional use only. It is not intended for near-patient or self-testing. The test procedure is not automated.
Test results should not be used as a sole basis for diagnosis but recommended to interpreted by a physician in the clinical context.

INTRODUCTION

The genus Chlamydia includes three species: *chlamydia trachomatis* (*C. trachomatis*), the recently described *chlamydia pneumoniae* (*C. pneumoniae*), primarily associated with humans, and *chlamydia psittasi* (*C. psittasi*), primarily associated with animals. *Chlamydia trachomatis* comprises 15 known serovars, is associated with trachomatis and gentourinary infection, and three serovars are associated with lymphogranuloma venereum (LGV). *Chlamydia trachomatis* infections are the most common bacterial sexually transmitted diseases. Approximately 4 million new cases occur each year in the United States, primarily cervicitis and nongonococcal urethritis. In 2020, an estimated 128.5 million new infections with *Chlamydia trachomatis* occurred worldwide among adults aged 15 to 49 years. The global prevalence among people aged 15-49 years was estimated to be 4.0% for women and 2.5% for men. This organism also causes conjunctivitis and infant pneumonia. *Chlamydia trachomatis* infection 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 cervictis, urethritis, endometritis, pelvic inflammatory diseases (PID) and increased incidence of ectopic pregnancy and infertility. Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis and pneumonia. In men, at least 40% of cases of nongonococcal urethritis are associated with chlamydia infection and epididymitis. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are symptomatic.
Chlamydia psittasi infection is associated with respiratory disease in individuals exposed to infected birds and is not transmitted from human to human. *Chlamydia pneumonia*, first isolated in 1983, is associated with respiratory infections and pneumonia. Traditionally, chlamydia infection has been diagnosed by the detection of chlamydia inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labour intensive, expensive, lengthy (2-3 days) and not routinely available in most institutions. Direct tests such as immunofluorescence assay (IFA) require specialized equipment and a skilled operator to read the result.

PRINCIPLE

The Chlamydia Rapid Test Device (Swab/Urine) detects *chlamydia trachomatis* through visual interpretation of color development on the internal strip. Antigen-specific lipopolysaccharide (LPS) monoclonal antibodies are immobilized on the test region of the membrane. Anti-Chlamydia antibodies conjugated to colored particles are immobilized on the conjugated pad. A sample is added to the buffer which is optimized to release the antigens from specimen.
During testing, the extracted antigens of *chlamydia trachomatis* of binds to anti-Chlamydia antibodies conjugated to colored particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the antigen-specific lipopolysaccharide (LPS) monoclonal antibodies at the test region. Excess colored particles will be captured at the internal control zone.
The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices — Each test contains colored conjugates and reactive reagents precoated at the corresponding regions.
- Reagent A — 0.2M NaOH
  Warning
  H315: Skin Irrit
  H319: Eye Irrit
- Reagent B — 0.2M HCl
  Warning
  H315: Skin Irrit
  H319: Eye Irrit
- Extraction tubes & tips — For specimen processing
- Tube stand — Workstation
- Sterilized swabs — For specimen collection
- Package insert — For operating instructions

Materials Required but Not provided

- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
- It's a single use test. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Use only dacron or rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- Reagents A & B are only suitable for extracting *Chlamydia trachomatis* in female cervical swab, male urethral swab and male urine specimens.
- Reagents A & B are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.
- Do not use cytology brushes with pregnant patients.

INCIDENT REPORTING

If using this product directly or indirectly led, might have led or might lead to any of the followings that may occur serious incident:

- the death of a patient, user or other person;
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health;
- a serious public health threat

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

The quality of specimen obtained is of extreme importance. Detection of chlamydia requires a vigorous and thorough collection technique which provides cellular material rather than just body fluids. **Do not use 0.9% sodium chloride to treat swabs before collecting specimens.**

For female cervical specimens:

- Use the swab provided with the kit.
- Before specimen collection, remove excess mucus from the endocervical area with a separate swab or 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 chlamydia organisms. Firmly rotate the swab for 15 - 20 seconds without contamination with exocervical or vaginal cells.
- If the swab may be tested immediately, replace the swab into the extraction tube.

For male urethral specimens:

- Standard wire-shafted fiber-tipped swabs or cytology brushes (not provided) should be used for urethral specimen collection. Instruct the patients not to urinate at least one hour prior to specimen collection.
- Insert the swab 2-4 cm into the urea, rotate for 3-5 seconds and withdraw it. If the swab may be tested immediately, replace the swab into the extraction tube.

For 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 the 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 supernatant, keep the tube inverted and remove any supernatant from the rim of tube by blotting onto absorbent paper.
- If the test is to be conducted immediately, treat the urine pellet according to the Directions for Use.

Do not place the swab in any transport device containing medium. Transport medium interferes with the assay, and viability of organisms is not required for the assay. If immediate testing is not possible, patient samples should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4 hours at room temperature (15-30°C) or 24 hours refrigerated (2-8°C). The urine specimens can be stored refrigerated (2-8°C) for 24 hours. Do not freeze. All specimens should be allowed to reach a room temperature of 15-30°C before testing.

PROCEDURE

Allow the test, specimen, reagents, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil 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 Endocervical or urethral swab specimens:

- Place a clean extraction tube in the workstation. **Add 8 drops of reagent A** to the extraction tube.
- Immerse the patient swab into the extraction tube and wait 2 minutes. While waiting, use a circular motion to roll the swab against the side of the extraction tube so that the liquid is expressed from the swab and can reabsorb.
- **Add 8 drops of reagent B**. Squeeze the swab firmly against the tube to expel as much liquid as possible from the swab for 1 minute. Discard the swab following guidelines for handling infectious agents. Fit the dropper tip on top of the extraction tube.
- The extracted specimen can remain at room temperature for 60 minutes without affecting the test result.

For Male Urine Specimens:

- **Add 8 drops of reagent A** to the urine pellet in the centrifuge tube, then draw the liquid up and down with a pipette to vigorously mix until the suspension is homogeneous.
- Transfer all the solution in the centrifuge tube to an extraction tube. Let stand for 2 minute. Hold the Reagent B bottle upright and **add 8 drops of Reagent B** to the extraction tube. Vortex or tap the bottom of the tube to mix the solution. Let stand for 1 minutes.
- Fit the dropper tip on top of the extraction tube.

3. **Add 3 drops (approximately 100 µL)** of extracted specimen from the extraction tube to the specimen well (S) of the test cassette.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result window.
   As the test begins to work, color will migrate across the membrane.

4. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Discard the swab, extraction tube, nozzle and test device following guidelines for handling infectious agents.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

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.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test, and cannot determine the concentrations of analytes in specimens.
2. Insufficient specimen volume, incorrect operation procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen 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 Chlamydia Rapid Test Device (Swab/Urine) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of *Chlamydia trachomatis*. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The test does not differentiate between *C. trachomatis*, *C. pneumonia* or *C. psittaci*.
3. Detection of chlamydia is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of sexually transmitted diseases, presence of symptoms, etc. The minimum detection level of this test may vary according to serovar.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Table: Ecotest® Chlamydia Rapid Test Device vs. Commercial PCR Chlamydia Test Device

Female Cervical Specimens:

Relative Sensitivity: 97.0% (93.7%-98.6%)*
Relative Specificity: 98.3% (96.3%-99.2%)*
Overall Agreement: 97.8% (96.2%-98.7%)*
***95%Confidence Interval**

		PCR Comparison kit		
		+	-	**Total**
Ecotest Chlamydia	+	197	6	203
	-	6	342	348
Total		203	348	551

Male Urethral Specimens

Relative Sensitivity: 97.7% (94.3%-99.1%)*
Relative Specificity: 96.7% (93.4%-98.4%)*
Overall Agreement: 97.2% (95.0%-98.4%)*
***95% Confidence Interval**

		PCR Comparison kit		
		+	-	**Total**
Ecotest Chlamydia	+	172	7	179
	-	4	207	211
Total		176	214	390

Male Urine Specimens

Relative Sensitivity: 98.5% (92.1%-99.7%)*
Relative Specificity: 94.3% (86.2%-97.8%)*
Overall Agreement: 96.4% (91.8%-98.4%)*
***95% Confidence Interval**

		PCR Comparison kit		
		+	-	**Total**
Ecotest Chlamydia	+	67	4	71
	-	1	66	67
Total		68	70	138

Analytical Performance Characteristic

The limit of detection (LOD) of Chlamydia Rapid Test Device is 1.0×10^7 org/mL for *Chlamydia trachomatis* culture.

Cross-Reactivity

Negative samples and low reactive samples spiked with each potentially cross-reacting microorganisms were tested, and the device presented no cross-reactivity or microbial interference with these microorganisms.

Acinetobacter calcoaceticus	*Gardnerella vaginalis*	*Neisseria meningitides*
Acinetobacter spp	Group B *Streptococcus*	*Proteus mirabilis*
Branhamella catarrhalis	Group C *Streptococcus*	*Proteus vulagris*
Candida albicans	*Hemophilus influenzae*	*Pseudomonas aeruginosa*
Enterococcus faecalis	*Klebsiella pneumoniae*	*Salmonella choleraesius*
Enterococcus faecium	*Neisseria gonorrhea*	*Staphylococcus aureus*
Staphylococcus epidermidis	*Escherichia coli*	Adenovirus
Lactobacillus casei		

Interfering Substances

The assay performance of Chlamydia Rapid Test Device (Swab/Urine) is not affected by substances at concentrations listed below.

Interfering substances	**Concentration of analyate**
Cimetidine	79.2μmol/L
Hemoglobin	2g/L
Bilirubin	342μmol/L
Triglyceride	37mmol/L
Ethanol	86.8mg/dL
Omeprazole	17.4 μmol/L
Mucin	1%
Human serum albumin	60g/L

Precision

Reproducibility

Reproducibility has been determined by using the precision panel containing negative, low positive, medium positive and high positive. Three different lots have been tested using these specimens by 3 operators over 5 days. The results are consistent between the different lots, sites and operators.

Repeatability

Repeatability has been determined by using the precision panel containing negative, low positive, medium positive and high positive. One kit lot has been tested using these specimens 2 runs per day by 1 operator over 20 days. The results are consistent for one lot products.

LITERATURE REFERENCES

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4. Schachter J. Chlamydial infections. N Engl J Med. 1978 Feb 23; 298(8): 428-35.
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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Importer	UDI	Unique device identifier
	Do not use if package is damaged and consult instructions for use		Do not reuse
	Not for self-testing		Not for near patient testing
EC REP	Authorized representative in the European Community		
CE	CE marking		

Assure Tech. (Hangzhou) Co., Ltd.
2nd-5th Floor, Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, China
contact@diareagent.com

CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain

Note: A summary of safety and performance for a class C product should be draw up and put into EUDAMED according to IVDR, for this product's, please see the website: (https://ec.europa.eu/tools/eudamed/#/screen/home)

Sterilized Swabs

Puritan Medical Products Co LLC
31 School Street, Guilford, Maine 04443-0149,United States

Emergo Europe
Westervoortsedijk 60 Arnhem 6827 AT, Netherlands

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangliang District, Yangzhou 225109 Jiangsu P.R. China

Llins Service & Consulting GmbH
Heinigstrasse 26, 67059 Ludwigshafen, Germany