CHLAMYDIA DEVICE (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCLM1	20 Tests

Intended Use:

The Chlamydia Rapid Test Device (Swab/Urine) is a rapid chromatographic 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.

Summary:

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). Chlamydia 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. 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 labour intensive, expensive, long (18-72 hours) and not routinely available in most situations.

The Chlamydia Rapid Test Device (Swab/Urine) is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens.

Test Principle:

The Chlamydia Rapid Test Device (Swab/Urine) is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical, male urethral and male urine. Anti-Chlamydia antibody is coated at the test line region of the device. During testing, extracted sample reacts with anti-Chlamydia antibody conjugated to particles that is coated in the sample well. The mixture migrates up and interacts with the antibody at the test region. Development of a coloured line in the test line region indicates a positive result, while no line appearing indicates a negative result. To serve as a procedural control, a coloured line should always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagent

The test contains Chlamydia antibody coated particles and Chlamydia antibody coated on the device.

Materials Provided

Individually pouched test devices
Extraction reagent 1
Extraction reagent 2
Extraction tube
Sterile female cervical swabs
Dropper tip
Instructions for Use sheet

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 professional in vitro diagnostic use only. Do not use after the expiry 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.

Reagent Storage and Stability:

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiry date.

Specimen Collection and Preparation:

- The Chlamydia Rapid Test Device (Urine/Swab) can be performed using female cervical swab, male urethral swab and male urine specimens.
- The quality of specimen obtained is of extreme importance. Detection of chlamydia requires a vigorous and thorough collection technique which provides cellular material as well as body fluid.
- **For female cervical specimens:**
  - Use the swab provided in 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 allows acquisition of columnar or cuboidal epithelial cells, a significant location of chlamydia bacteria. Firmly rotate the swab for 15 seconds without contamination with exocervical or vaginal cells. Do not use normal saline on the swabs before collection.
  - If the swab is to be tested immediately, place the swab into the extraction tube.
- **For male urethral specimens:**
  - Standard wire-shafted, fibre-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 the swab 360° in one direction, let stand for 10 seconds, then withdraw. Do not use normal saline on the swabs before collection.
  - If the swab is to be tested immediately, place 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 as described below.
- 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 4-6 hours at room temperature (15-30°C) or refrigerated for 24 hours (2-8°C). Do not freeze. All specimens should be allowed to reach a room temperature of 15-30°C before testing.

Assay Procedure:

Allow the test, specimen, reagents, and 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 Chlamydia antigen according to the specimen type.

For Endocervical or urethral swab specimens:

- Place a clean extraction tube on a flat clean surface. Add 5 drops of Reagent 1 (approximately 300 µl) to the extraction tube. Reagent 1 is colourless. Immediately insert the swab, squeeze the bottom of tube and rotate swab 15 times. Let stand for 2 minutes.
- Invert Reagent 2 bottle and add 6 drops (approximately 250 µl) to the extraction tube. The solution goes turbid. Squeeze the bottom of tube and rotate the swab 15 times until the solution turn clear with a slight blue-green tint. If the swab is bloody, the colour will turn yellow or brown. Let stand for 1 minute.
- Press the swab against the side of tube and withdraw the swab while squeezing the tube. Retain as much liquid in the tube as possible. Fit the dropper tip on top of extraction tube.

For Male Urine Specimens:

- Invert Reagent 2 bottle and add 6 drops of (approximately 250 µl) to the urine pellet in the centrifuge tube, then vortex the tube thoroughly until the suspension is homogeneous.
- Transfer all the solution in the centrifuge tube to an extraction tube. Let stand for 1 minute. Invert Reagent 1 bottle and add 5 drops of (approximately 300 µl) to the extraction tube. Vortex 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 device on a clean and level surface. Add 3 full drops of the extracted solution (approximately 100 µl) to the specimen well of the test device, then start the timer. Avoid trapping air bubbles in the specimen well.
4. Wait for coloured line(s) to appear. Record results at 10 minutes. Do not interpret resultss after 20 minutes.

Interpretation of Results:

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T). This positive result indicates that Chlamydia was detected in the specimen.

NEGATIVE: Only one coloured band appears, in the control region (C). No band appears in the test region (T). A negative result indicates that Chlamydia antigen is not present in the specimen or is present below the cut-off level of the test.

INVALID: Control band 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 your local distributor.

Quality Controls:

- Internal procedural controls are included in the test. A coloured 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. 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 indicate the presence of Chlamydia antigen in specimens from both

viable and non-viable 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 bacteria 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 are to be interpreted in conjunction with other laboratory and clinical data available to the physician.
4. The outcome of therapeutic measures cannot be determined as antigen may persist following appropriate antimicrobial treatment.
5. Excessive blood on the swab may cause false positive results.

Expected Values:

For women attending STD clinics and other high-risk populations, the prevalence of Chlamydia infection has been repeated to between 20% and 30%. In a low-risk population such as those patients attending obstetrics and gynaecology 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. Normal carriage rates of Chlamydia in asymptomatic men are less than 5%.

Performance Characteristics:

Sensitivity:

The Chlamydia Rapid Test Device (Swab/Urine) has been evaluated with specimens obtained from patients of STD clinics. PCR was used as the reference method for the Chlamydia Rapid Test Device (Swab/Urine) and used as the confirmatory results. The results show that Chlamydia Rapid Test Device (Swab/Urine) has a high sensitivity relative to PCR.

Specificity:

The Chlamydia Rapid Test Device (Swab/Urine) 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 the Chlamydia Rapid Test Device (Swab/Urine) has a high specificity relative to PCR.

For **Female Cervical Swab Specimens:**

Method		PCR		Total
		Positive	Negative	
Chlamydia Rapid Test	Positive	42	4	56
	Negative	3	156	159
	Total	45	160	205

Relative Sensitivity: 93.3% (81.7%-98.6%)* Relative Specificity: 97.5% (93.7%-99.3%)*
Relative accuracy: 96.6% (93.1%-98.6%)* *95% Confidence Intervals

For **Male Urethral Swab Specimens:**

Method		PCR		Total
		Positive	Negative	
Chlamydia Rapid Test	Positive	50	5	55
	Negative	8	115	123
	Total	58	120	178

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

For **Male Urine Specimens:**

Method		PCR		Total
		Positive	Negative	
Chlamydia Rapid Test	Positive	35	0	35
	Negative	2	60	62
	Total	37	60	97

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

Cross-Reactivity

The antibody used in the Chlamydia Rapid Test Device (Swab/Urine) has been shown to detect all known Chlamydia serovars. Chlamydia *psittasi* and Chlamydia *pneumoniae* strains have been tested with the Chlamydia Rapid Test Device (Swab/Urine), and were shown to cross react when tested in suspensions of 109 Colony Forming Units (CFU)/ml. The following organisms were found negative when tested with the Chlamydia Rapid test Device (Swab/Urine):

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

References:

1. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachmatis in Urine of Asymptomatic Men. J. Clinical Microbiology, 32,24-27, (1994).
2. Jaschek. G. et al Direct Detection of Chlamydia trachomatis in Urine Specimens from Symnptomatic and Asymptomatic Men by Using a Rapid Polymerase Chain Reaction Assay. J. Clinical Microbiology, 31, 1209-1212, (1993).
3. Schachter, J Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine, 72, 60-69, (1982).

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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