Chlamydia Rapid Test Device
(Swab/Urine)

INTENDED USE

The Chlamydia Rapid Test Device (Swab/Urine) is a rapid chromatographic immunoassay, that utilizes antibodies specific for Chlamydia, to qualitatively detect *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 inclusions 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 mother to neonate can result in inclusion conjunctivitis pneumonia. In men, complications of Chlamydia infection include 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 (48-72 hours) and not routinely available in most institutions.

PRINCIPLE

Antibodies specific to the Chlamydia antigen are 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 up to react with the antibody to Chlamydia on the membrane and generate a colored line in the test line 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.

PROCEDURE

1. Extract the Chlamydia antigen according to the specimen type.

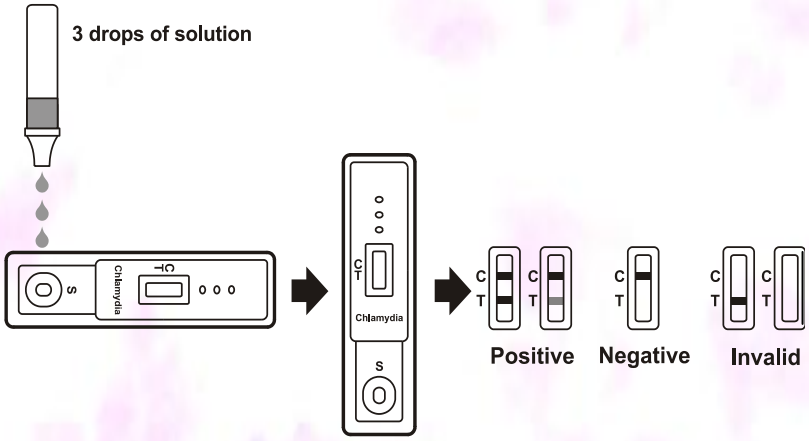
For Female Cervical or Male Urethral Swab Specimens:

- Hold the Reagent A bottle vertically and **add 5 full drops of Reagent A** to the extraction tube. Insert the swab, compress the bottom of the tube and rotate the swab 15 times. Let stand for 2 minutes.
- Fill the pipette for Reagent B up to the marked line, then **add the Reagent B**. Compress the bottom of tube and **rotate the swab 15 times.** Let stand for 1 minute.
- Press the swab against the side of the tube and withdraw the swab while squeezing the tube. Fit the dropper tip on top of the extraction tube.

For Male Urine Specimens:

- Fill the pipette for **Reagent B** to the marked line, then **add the Reagent B** to the urine pellet in the centrifuge tube, 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 1 minute**. Hold the **Reagent A** bottle upright and **add 5 full drops of Reagent A,** add 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.

2. **Read results at 10 minutes**. Do not read results after 20 minutes.



PERFORMANCE

For **Female Cervical Swab Specimens**:

Method		PCR		Total Results
Chlamydia Rapid Test Device	Results	Positive	Negative	
	Positive	46	3	49
	Negative	6	87	93
Total Results		52	90	142

Relative Sensitivity: 88.5% (76.6%-95.6%)* Relative Specificity: 96.7% (90.6%-99.3%)*
Relative Accuracy: 93.7% (88.3%-97.1%)* * 95% Confidence Interval

For **Male Urethral Swab Specimens**:

Method		PCR		Total Results
Chlamydia Rapid Test Device	Results	Positive	Negative	
	Positive	40	8	48
	Negative	11	104	115
Total Results		51	112	163

Relative Sensitivity: 78.4% (64.7%-88.7%)* Relative Specificity: 92.9% (86.4%-96.9%)*
Relative Accuracy: 88.3% (82.4%-92.8%)* * 95% Confidence Interval

For **Male Urine Specimens**:

Method		PCR		Total Results
Chlamydia Rapid Test Device	Results	Positive	Negative	
	Positive	20	0	20
	Negative	2	35	37
Total Results		22	35	57

Relative Sensitivity: 90.9% (70.8%-98.9%)* Relative Specificity: >99.0% (90.0%-100.0%)*
Relative Accuracy: 96.5% (87.9%-99.6%)* * 95% Confidence Interval

REFERENCE CODE	*DESCRIPTION*	*TESTS PER KIT*
8537306	Chlamydia Screen	20

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