



### OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab)

**REF** 176523F

**PIC** ID176523FVV86

**IVD** See External Label 20 Tests

Chlamydia (Female) RapiCard™	
Principle	Chromatographic Immunoassay
Detection	Qualitative
Specimen	Cervical Swab
Sensitivity (Swab)	93.3%
Specificity (Swab)	97.5%

#### PRODUCT FEATURES

- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

A rapid test for the qualitative detection of Chlamydia antigen in female cervical swab specimens. For professional in vitro diagnostic use only.

#### INTENDED USE

The Cortez Diagnostics, Inc. OneStep Chlamydia (Female) RapiCard™ InstaTest is a rapid chromatographic immunoassay for direct qualitative detection of Chlamydia trachomatis in female cervical swab specimens, to aid in the diagnosis of Chlamydia infection.

#### SIGNIFICANCE AND SUMMARY

Chlamydia trachomatis is one of the most common causes 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.<sup>1</sup> Vertical transmission of the disease during parturition from to neonate can result in inclusion conjunctivitis or pneumonia. Approximately 70% of women with endocervical 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.

The OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab specimens.

#### ASSAY PRINCIPLE

The OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical swab specimens. 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 up 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

The test contains Chlamydia antibody coated particles and Chlamydia antibodies coated on the membrane.

#### PRECAUTIONS

1. For professional *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 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.

#### STORAGE AND STABILITY

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

- The OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) can be performed using female cervical swab specimens.
- 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.

**To collect Female Cervical Swab Specimens:**

- Use the swab provided in the kit. Alternatively, any plastic-shaft swab may be use.
- 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.

**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 4-6 hours at room temperature (15-30°C) or refrigerated (2-8°C) for 24 hours. Do not freeze. All specimens should be allowed to reach the room temperature (15-30°C) before testing.**

### MATERIALS AND COMPONENTS

**Materials provided with the test kit**

- Test Cassettes
- Extraction Reagent 1 (0.2M NaOH)
- Extraction Reagent 2 (0.2M HCl)
- Package Insert
- Extraction Tubes
- Sterile Female Cervical Swabs
- Workstation
- Dropper Tips

**Materials required but not provided**

- Positive control
- Negative control
- Timer

### ASSAY PROCEDURE

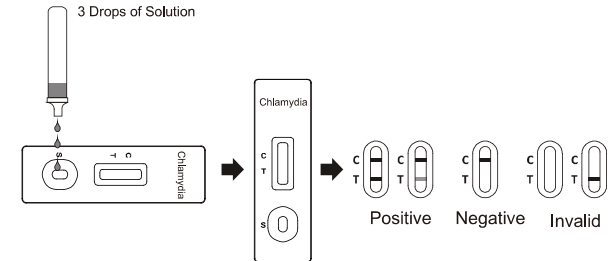
**Allow the test, reagents, swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Remove the test card from the seal pouch and use it as soon as possible. Best result 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 Swab Specimen:**

- Hold the **reagent 1** bottle vertically and add **5 drops of reagent 1 (approx. 300 µl)** to the extraction tube. 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 **reagent 2** bottle vertically add **6 drops of reagent 2 (approx. 250 µl)** to the extraction tube. The solution would turn turbid. Compress the bottle of tube and rotate the swab 15 times until the solution turn 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.
3. Place the test card on a clean and level surface. Add **3 full drops of the extracted solution (approx. 100 µl)** to the specimen well of the test card (S), 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.

**Note: It is suggested not to use the extraction reagent, beyond 6 months after opening the vial.**



### RESULTS

(Please refer to the illustration above)

**POSITIVE:** \* **Two colored lines appear. One colored line should be in the control line region (C) and another apparent 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 your local distributor.

### QUALITY CONTROL

An internal 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.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good



laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS OF THE PROCEDURE

- The OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) kit is for *in vitro* diagnostic use only. This test should be used for the detection of Chlamydia antigen from female cervical swab specimens. Neither the quantitative value nor the rate of increase in Chlamydia antigen concentration can be determined by this qualitative test.
- This test will only indicate the presence of Chlamydia antigen in specimens from both viable and non - viable Chlamydia. Performance with specimens other than female cervical swabs has not been assessed.
- 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.
- Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
- Excessive blood on the swab may cause false positive results.

### PERFORMANCE CHARACTERISTICS

#### Sensitivity

An evaluation of the OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) kit with specimens obtained from patients of STD clinics. PCR is used as the reference method for the Chlamydia (Female) RapiCard™ (Swab). Specimens were considered positive if PCR indicated a positive result. Specimens were considered negative if PCR indicated a negative result. The results show that OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) kit has a high sensitivity relative to PCR.

#### Specificity

The OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) uses an

antibody that is highly specific for Chlamydia antigen in female cervical swab. The results show that the OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) kit has a high specificity relative to PCR.

#### For Female Cervical Swab Specimens

Method	PCR			Total Result
	Results	Positive	Negative	
Chlamydia (Female) RapiCard™ (Swab)	Positive	42	4	46
	Negative	3	156	159
Total Results		45	160	205

Relative Sensitivity: 93.3% (81.7%-98.6%)\*

Relative Specificity: 97.5% (93.7%-99.3%)\*

Overall accuracy: 96.6% (93.1%-98.6%)\*

\*95% Confidence Intervals

#### Cross Reactivity

The antibody used in the OneStep Chlamydia (Female) RapiCard™ InstaTest (Swab) kit has been shown to detect all known Chlamydia serovars. *Chlamydia psittaci* and *Chlamydia pneumoniae* strains have been tested with the Chlamydia (Female) RapiCard™ (Swab) and were shown to cross react when tested in suspensions of 10<sup>9</sup> Colony Forming Unites (CFU)/ml. Cross reactivity with other organisms has been studied using suspensions of 10<sup>9</sup> CFU/ml. The following organisms were found negative when tested with the Chlamydia (Female) RapiCard™ InstaTest (Swab):

*Acinetobacter calcoaceticus*

*Acinetobacter spp*

*Enterococcus faecalis*

*Enterococcus faecium*

*Staphylococcus aureus*

*Klebsiella pneumoniae*

*Pseudomona aeruginosa*

*Neisseria meningitides*

*Salmonella choleraesuis*

*Candida albicans*

*Proteus vulgaris*

*Gardereella vaginalis*

*Proteus mirabilis*

*Neisseria gonorrhoea*

Group B/C *Streptococcus*

*Hemophilus influenza*

*Branhamella catarrhalis*

### REFERENCES

- Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachomatis in Urine of Asymptomatic Men. *J.Clinical Microbiology*, 32, 24-27, (1994).
- 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. Clinical Microbiology*, 209-1212, (1993).

- Schachter, J Sexually transmitted Chlamydia trachomatis infection. *Postgraduate Medicine*, 72, 60 -69, (198)

### MANUFACTURER AND BRAND DETAILS

ISO 13485:2016



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<b>Date Adopted</b>	2024-10
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