

Rapid Immunoassay

Cassette Test Device

For the detection of

Chlamydia Antigen



See external label



2°C-30°C

 $\Sigma = 20, 40, 100$ tests

Product Code: 85226400030

FOR IN VITRO USE ONLY

Warning: A positive result is not useful for establishing a diagnosis of Chlamydia. In most situations, such a result may reflect a prior treated infection; a negative result can exclude a diagnosis of Chlamydia except for incubating or early primary disease.

INTENDED USE

InSTIcheck™ Chlamydia rapid test is a rapid chromatographic immunoassay for the qualitative detection of *Chlamydia trachomatis* directly from endocervical swab or 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 or 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. This Chlamydia Rapid Test Device (Swab/Urine) is a rapid test to qualitatively detect the Chlamydia antigen from a cervical swab, and urine specimens, providing results in 5-15 minutes. The test utilizes antibodies specific for Chlamydia to selectively detect Chlamydia antigen from cervical swabs, and urine specimens.

PRINCIPLE

The InSTIcheck™ Chlamydia Rapid Test Device (Swab/Urine) is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from cervical swabs and urine specimens. In this 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 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.

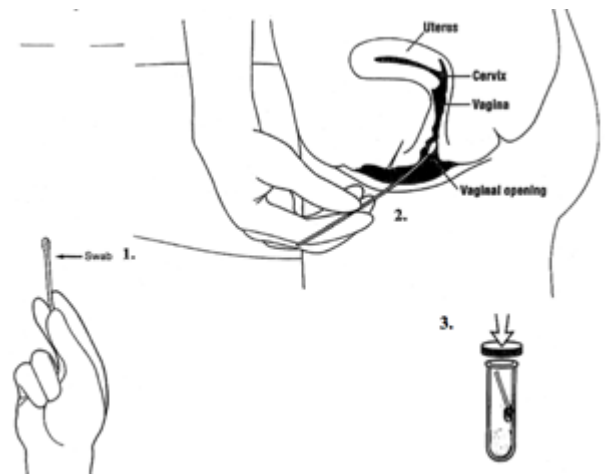
PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.

- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Use separate, clean transfer pipettes for different specimens.
- The InSTIcheck™ Chlamydia device should remain in its original sealed pouch until ready for use.
- Store as packaged at room temperature or refrigerated in the sealed pouch at 4-30 °C.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

1. **Female Patient:** Remove any excess mucus from the potentially infected site with the first swab, and then discard it.
2. Rub the second swab vigorously over the infected end urethral lining and end cervical cells in the canal wall.
3. As Chlamydia is intracellular organisms, firm contact must be made with the canal wall for proper specimen collection. The rubbing action dislodges the endothelial cells and allows the swab to absorb the bacteria. Improper collection will result in poor visual readings and may cause invalid results.



1. **Male Patient:** Insert the swab into the urethra of the penis. Gently rotate with sufficient pressure to dislodge the epithelial cells. Allow the swab to remain inserted for a few seconds after rotation.
2. Carefully remove the swab avoiding contact with any external surfaces.

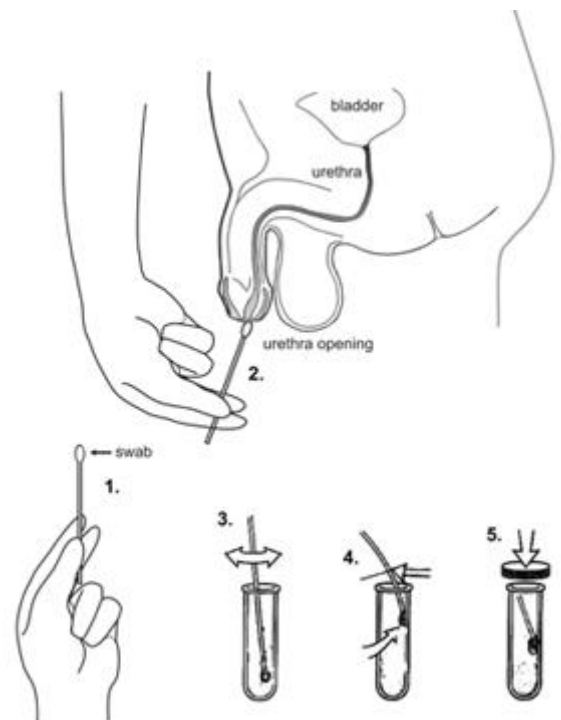
Urine specimen: Female patients should not cleanse the labial area prior to providing the specimen. First-void urine (patient should not have urinated for 1 hour prior to specimen collection) or endocervical/urethral swab specimen. Collect 15ml urine specimen; centrifuge the urine specimen at high speed (1,500-3,000 rpms) for 15 minutes. Discard the supernate. Use the precipitate for detection. Treat the urine sediment according to **Direction for Use**, if the test is to be conducted immediately.

Materials Provided

- Individually Pouched Test Devices & Pipettes
- 1 Buffer A/1 Bottle
- 1 Buffer B/2 Bottle
- Urethral Swabs (sterile)
- Positive control
- Negative control
- 1 Package insert

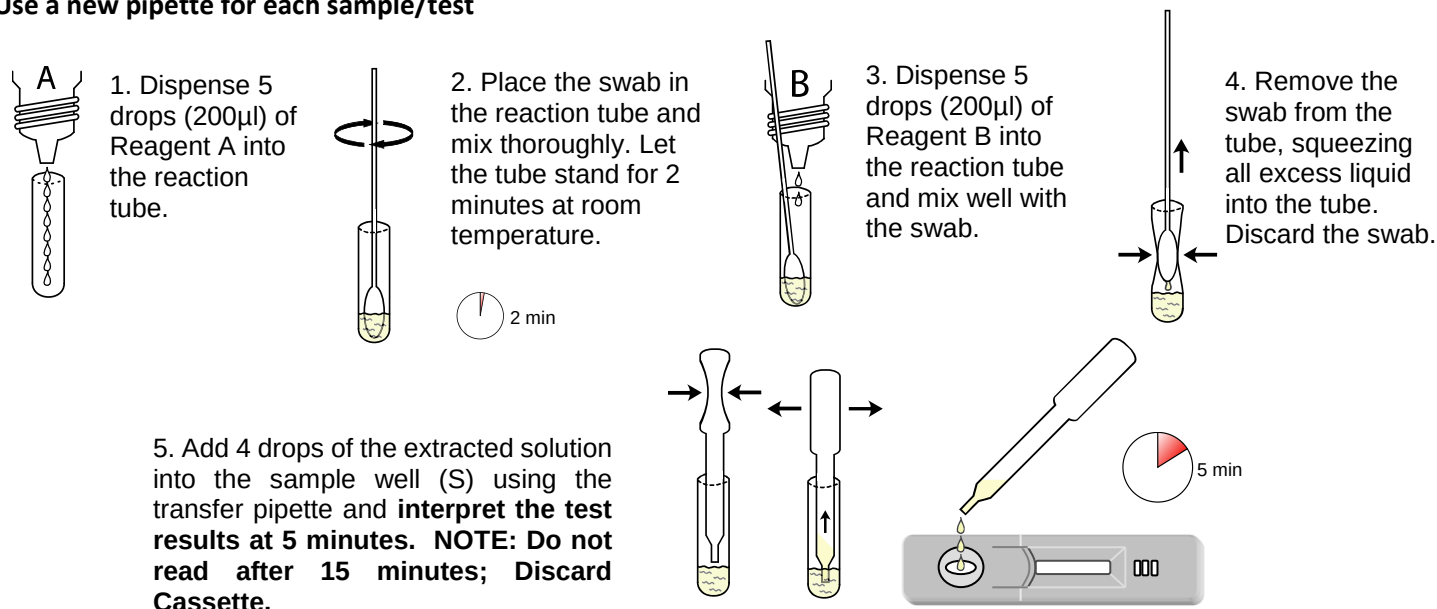
Materials May Be Required But Not Provided

- Centrifuge tube (for urine specimens only)

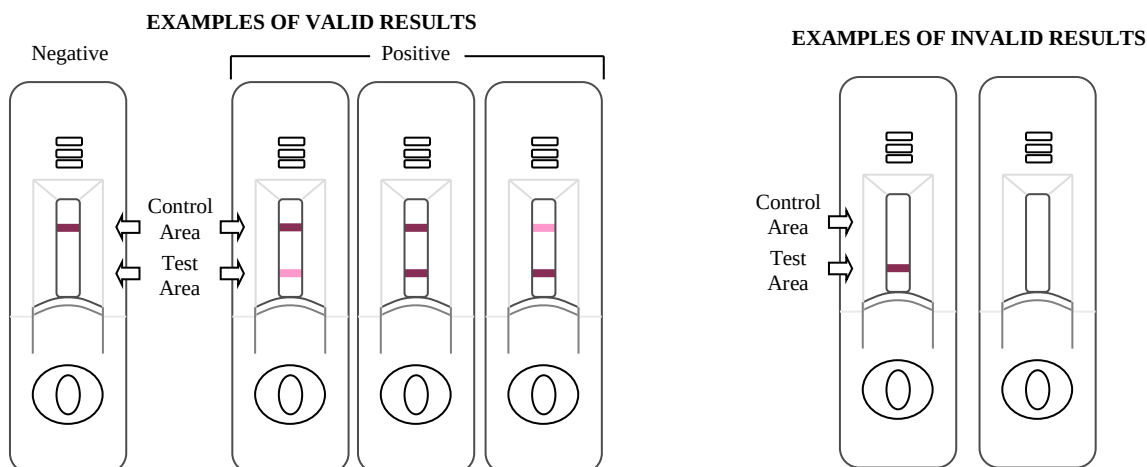


DIRECTIONS FOR USE

Allow test device, assay buffers, specimen, and/or controls to equilibrate to room temperature (18-30°C) prior to testing. Use a new pipette for each sample/test



INTERPRETATION OF RESULTS



POSITIVE: **RED bands** will appear in the control and test areas, which indicate a positive result for Chlamydia antigen.

NOTE: Low titers of Chlamydia antigens might result in a faint line appearing in the test region. Therefore, any shade of RED (not grey) in the test region (T) should be considered positive.

NEGATIVE: One colored “RED” band will appear in the control area only, with no distinct colored line in the test window. This indicates a negative result.

INVALID: A distinct colored line in the Control area should always appear. The test is invalid if no line forms in the control window. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

NOTE: The test result can be read as soon as a distinct red color line appears in the test window. The test line will appear before the control line in most of the strong positive cases. The test line may appear after the control line in weak positive cases, and the control line may be darker than the test line.

QUALITY CONTROL

Built-in Control Features The InSTIcheck™ Chlamydia test contains built-in control features. A solid red line appearing in the Control Area of the Result Window indicates that several of the built-in control features for the test are working. Because the method of processing the built-in control and detecting features are identical, the appearance of a line in the Control Area ensures that the device's functionality is preserved. In addition, the Control Area line is a sign that the seal on the foil storage pouch has not been breached and that the device has been protected from outside contaminants. Because capillary flow cannot be accomplished without a properly assembled device and the correct volume of fluid, the appearance of a line in the Control Area also means that the device's components are accurately positioned and linked correctly and that the assay has been performed properly. Finally, if the Control Area line does not develop within 15 minutes, the test result should be considered invalid.

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

As with other diagnostic procedures, the results obtained with this kit should be used as an adjunct to clinical observations and information available to the physician. The InSTIcheck™ Chlamydia test is a qualitative method intended for use in determining the presence of Chlamydia antigen in cervical swab specimens or urine only.

- A proper endocervical specimen must be obtained using the swab provided, for best results. Though a patient may be at the onset of the disease, negative results may also occur if the specimen contains sufficiently low numbers of microorganisms to fall below the level of sensitivity of the test.
- If a negative test result is obtained and clinical symptoms persist, the initial result should be confirmed by repeating the test with another specimen.
- The InSTIcheck™ Chlamydia test will not specifically differentiate *C. trachomatis*, *C. pneumoniae*, or *C. psittaci*.
- Detection of Chlamydia is dependent on the number of organisms (elementary and/or reticulate bodies) present in specimens. This may be affected by specimen collection methods and patient factors such as age, history of STD, and presence of symptoms.
- Test results should be interpreted in conjunction with other laboratory and clinical data available to the physician. Standard chlamydial cell culture methods should be used in the evaluation of suspected sexual abuse and for other medicolegal cases where diagnosis could lead to adverse psychosocial impact.
- Spermicides, gynecological lubricants and talcum powder were evaluated in the test and did not affect the expected results at concentrations up to 4.5 mg/test. The presence of mucus and whole blood in cervical specimens does not have an inhibitory effect on the test. However, grossly bloody specimens (approximately 100µL whole blood/test) may interfere with your ability to read the test result and therefore invalidate the result.
- Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.

PERFORMANCE CHARACTERISTICS

The performance of the InSTIcheck™ Chlamydia was compared to that of conventional culture assay techniques. Two endocervical specimens were collected from patients. One swab was used for the conventional culture method and the other was used for the InSTIcheck™ Chlamydia test. The results are summarized below:

Swab Method:

Method		EIA		Total
InSTIcheck™	Results	Positive	Negative	Results
Chlamydia	Positive	42	5	47
Cassette	Negative	3	135	138
Total Results		45	140	185

Relative Sensitivity: >94.4%;

Relative Specificity: 99.3%;

Accuracy: 97.6%;

95% Confidence Interval

Urine Method:

Method		EIA		Total
InSTIcheck™	Results	Positive	Negative	Results
Chlamydia	Positive	80	0	80
Cassette	Negative	8	140	148
Total Results		88	140	228

Relative Sensitivity: >90.9%; Relative Specificity: 99.0%; Accuracy: 96.5%; 95% Confidence Interval

Cross-Reactivity

The antibody used in the InSTIcheck™ Chlamydia has been shown to detect all known Chlamydia serovars. Chlamydia psittaci and Chlamydia pneumoniae strains have not yet been tested with the InSTIcheck™ Chlamydia test. Cross reactivity with other organisms has been studied using suspensions of 10⁹ Colony Forming Units (CFU)/mL. The following organisms were found negative when tested with the InSTIcheck™ Chlamydia test:

<i>Acinetobacter calcoaceticus</i>	<i>Neisseria lactamica</i>
<i>Citrobacter freundii</i>	<i>Neisseria meningitidis</i>
<i>Candida albicans</i>	<i>Proteus vulgaris</i>
<i>Corynebacterium glutamicum</i>	<i>Pseudomonas aeruginosa</i>
<i>Enterobacter aerogenes</i>	<i>Salmonella typhi</i>
<i>Escherichia coli</i>	<i>Staphylococcus epidermis</i>
<i>Gardnerella vaginalis</i>	<i>Streptococcus faecalis</i>
<i>Klebsiella pneumoniae</i>	<i>Streptococcus pyogenes</i>
<i>Neisseria gonorrhoeae</i>	<i>Candida albicans</i>

REFERENCES

1. Washington, Eugene A., et al. "Chlamydia trachomatis Infections in the United States. What are they Costing Us?" JAMA, 257:2070, 1987.
2. Schachter, J., et al. "Prospective Study of Chlamydial Infection in Neonates." Lancet, August 25, 1979, Vol. 2.
3. Pfaff, J.A. "Chlamydial Antigen Testing on Female Patients Presenting to Emergency Department." Military Medicine. Vol. 156, July 1991.
4. "Recommendations for the Prevention and Management of Chlamydia trachomatis Infections, 1993." Morbidity and Mortality Weekly Report. Vol 42, Aug. 6, 1993.
5. "Chlamydia Prevalence and Screening Practices - San Diego County, California, 1993." Morbidity and Mortality Weekly Report. Vol. 43, May 27, 1994.
6. Cates W., Wasserheit, J.N. "Genital Chlamydial Infections: epidemiology and reproductive sequelae." Am. J. Obstet. Gynecol. 164:1771, 1987.
7. Colton, T. "Statistics in Medicine". Little Brown and Company. 1974.

ASSISTANCE

If you have any questions regarding the use of this product, contact your local distributor or First Diagnostic™ Corporation at sales@firstdiagnostic.com.

Lab Name:

Procedure #:

Procedure:

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

First Diagnostic provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

Lab Name:

LOG SHEET

Record Built-in Procedural Controls on the first patient tested each day.

	Date	Patient Name	Negative Procedural Control (Clear Bkgd)	Positive Procedural Control (Red Line)	Test Results At 10 minutes	Lot Number/Exp. Date	Technician
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

REF

85226400030 - InSTIcheck™ Chlamydia Test Kit – 07/01/20012

IVD



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First Diagnostic™

Corporation

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EC REP

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