

InSTIcheck™ Chlamydia

Rapid Immunoassay

Cassette Test Device

For the detection of
Chlamydia Antigen



Product Code: ATF-128

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 qualitatively detects *Chlamydia trachomatis* antigen directly from endocervical swab or urine specimens. The test is intended for use in the rapid diagnosis of Chlamydial infection.



SUMMARY

Chlamydia trachomatis is now recognized as the most prevalent cause of sexually transmitted disease in the United States with approximately four million cases being diagnosed annually. 1 Chronic infection with this organism in the female reproductive tract may lead to pelvic inflammatory disease, salpingitis, ectopic pregnancy and infertility. Infants acquiring Chlamydia at birth are at significant risk of developing conjunctivitis and pneumonia. 2 It has been estimated that the annualized health care costs of Chlamydia infection and its sequelae are in excess of two billion dollars per year. 1 The clinical diagnosis of Chlamydia infections in females is not precise and may be confused with other etiologies. Misdiagnosis and improper treatment may lead to chronic infection and serious sequelae. The InSTIcheck™ Chlamydia test detects extracted genus specific chlamydia lipopolysaccharide (LPS) from cervical swabs, thus providing a significant aid in the diagnosis of Chlamydia infection.

Chlamydia trachomatis is one of the most significant sexually transmitted human pathogens causing non-gonococcal urethritis, post-gonococcal urethritis, proctitis, cervicitis, infertility and endometritis. If early diagnosis and treatment fail, these infections can result in acute epididymitis in the male, or pelvic inflammatory disease and ectopic pregnancy in the female. Unlike classical culture methods for identification which require 48-72 hours to produce results, the InSTIcheck™ Chlamydia test requires only 10 minutes.

PRINCIPLE

The InSTIcheck™ Chlamydia test involves the chemical extraction of the Chlamydia antigen (lipopolysaccharide, LPS) followed by solid-phase immunometric assay technology for the qualitative detection of extracted LPS. In the test procedure, an endocervical specimen is collected with a swab and Chlamydia antigens are extracted from the

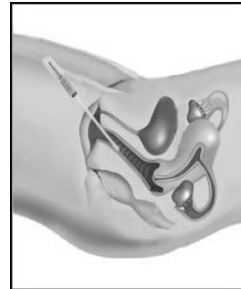
specimen with extraction reagents. The extract is added to the sample well with the aid of a transfer pipette and allowed to soak in. If Chlamydia antigen is present in the specimen, it will react with the conjugate dye, which binds to the antibody on the membrane to generate a colored line in the test window. The presence of two colored lines, one in the test window and the other in the control window, indicates a positive result, while the absence of a line in the test window indicates a negative result.

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. 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.
3. **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

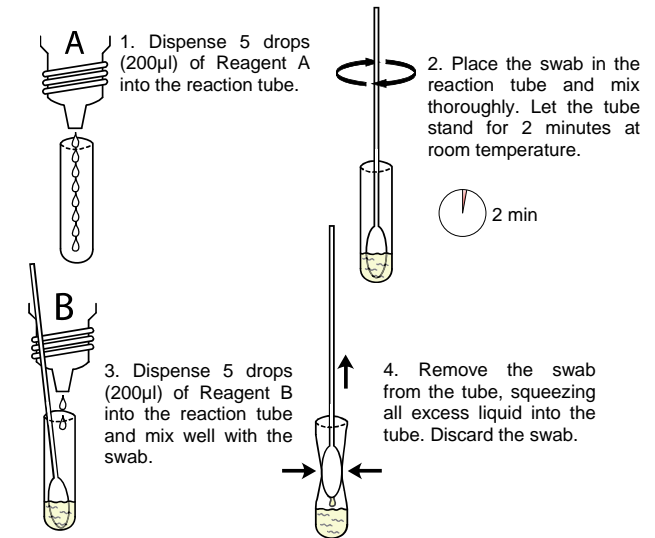
- 25 Individually Pouched Test Devices & Pipettes
- 1 Reagent A Bottle
- 1 Reagent B Bottle
- 1 Package insert

Materials Required But Not Provided

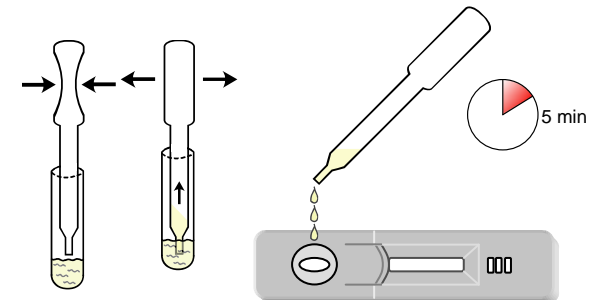
- Test Tubes
- Swabs

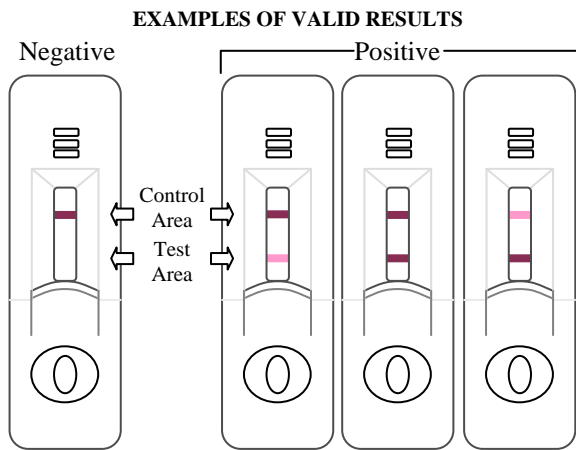
DIRECTIONS FOR USE

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

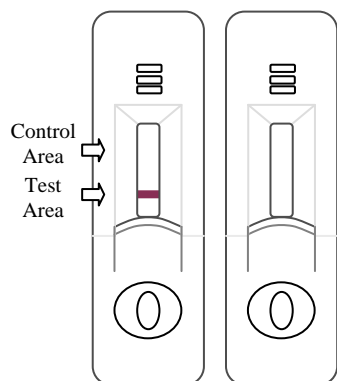


5. Add 4 drops of the extracted solution into the sample well (S) using the transfer pipette and interpret the test results at 5 minutes. **NOTE: Do not read after 15 minutes; Discard Cassette.**





EXAMPLES OF INVALID RESULTS



POSITIVE: Two 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 in the test region (T) should be considered positive.

NEGATIVE: One color 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 pink-purple 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 Quality Control A solid line appearing in the Control Area of the Result Window indicates that several of the built-in control features for the InSTIcheck™ Chlamydia 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 can not 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 10 minutes, the test result should be considered invalid.

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.
- 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 STD, presence of symptoms, etc.
- 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.

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:

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

Relative Sensitivity: >94.4%

Relative Specificity: 97.8%

Accuracy: 96.7%

To confirm the specificity of InSTIcheck™ Chlamydia, the following organisms were tested at 1×10^7 cells/mL, yielding negative results:

<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 epidermidis</i>
<i>Gardnerella vaginalis</i>	<i>Streptococcus faecalis</i>
<i>Klebsiella pneumoniae</i>	<i>Streptococcus pyogenes</i>
<i>Neisseria gonorrhoeae</i>	

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