



A rapid, direct binding test for visual detection of *Chlamydia trachomatis* antigen.

*For professional in vitro diagnostic use only.*

### INTENDED USE

The ABI Chlamydia One-Step Test (Device or Cassette) is a rapid and sensitive direct binding test for visual detection of *Chlamydia trachomatis* antigen in endocervical or endourethral swab specimens.

### SUMMARY AND EXPLANATION

*Chlamydia trachomatis* is one of the most common sexually transmitted pathogens. It is a major cause of cervicitis, urethritis, endometritis and pelvic inflammatory disease in women. Serious complications can result in salpingitis, infertility and ectopic pregnancy. If transmitted to infants during birth, Chlamydia can cause conjunctivitis and pneumonia. 50 to 70 percent of infected women are asymptomatic, which makes diagnosis extremely important.

*Chlamydiae* are related to gram-negative bacteria. They are intracellular in nature and are unable to synthesize adenosine triphosphate (ATP). The extracellular elementary body form is infectious while the intracellular reticulate form is metabolically active.

Epidemiological patterns indicate infections of *Chlamydia trachomatis* parallel or exceed those of *Neisseria gonorrhoea* and the two often occur together. The primary method for detection of Chlamydia is growth of the organism in cell culture. Other methods include direct fluorescence assays (DFA), Enzyme Immunoassays (EIA) and nucleic acid probing.

### PRINCIPLE OF THE PROCEDURE

The ABI One-Step Chlamydia Test utilizes the chemical extraction of a carbohydrate antigen from chlamydia followed by a double sandwich immunoassay for the qualitative detection of *Chlamydia trachomatis*. The assay is conducted by adding pre-treated specimen to the sample well of the cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored dried conjugate of colloidal gold-mono-clonal antibody. The sample reconstitutes the dried conjugate. If *Chlamydia trachomatis* antigen is present in the sample, it will react with the monoclonal antibody to form a complex of colloidal gold-mono-clonal antibody-Chlamydia. This complex migrates up the membrane strip and through the band of immobilized antibody. Because the immobilized antibody is able to bind to the *Chlamydia trachomatis* antigen molecule of the migrating complex, a visible reddish band is formed along the exact location of the immobilized antibody. If there is no *Chlamydia trachomatis* antigen present in the treated sample, the colloidal gold-mono-clonal antibody conjugate will pass through the immobilized antibody band and no colored line will form – a negative test result.

Further up the membrane is a control region. The reagents in this band will bind only conjugate and form a colored line, regardless of whether *Chlamydia trachomatis* antigen is present in the sample or not. Appearance of the control line assures reagent integrity as well as correct testing procedure.

### REAGENTS

The test contains monoclonal (murine) anti-Chlamydia coated particles and monoclonal anti-Chlamydia coated on the membrane.

### PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as infectious agents. Wear disposable gloves throughout specimen collection and assay procedure.
- The test should be discarded in a proper biohazard container after testing.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4 - 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

**Note: Use only the samples swabs provided with the kit.**

Use specimen swabs to collect specimens using the following procedures:

#### Female Patients

Two sterile Dacron™ swabs with plastic shafts are required in the female collection procedure. One swab is used to prepare the sample site; the other is used for sample collection.

- a) Remove any excess mucus from potentially infected site with the first swab, and then discard the swab.
- b) Rub the second swab vigorously over the infected endourethral lining and cervical cells in the canal wall. As Chlamydia are 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. Vaginal specimens are not useful.

#### Male Patients

One metal-shafted sterile Dacron™ swab is needed for male penile sample collection. Do not use a plastic-shafted swab in this procedure:

- a) 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.
- b) Carefully remove the swab avoiding contact with any external surfaces
- c) Place the swab into the extraction tube and add 6 drops (300µL) of Extraction Buffer A on the swab and rotate swab gently. Incubate at room temperature (15 to 30°C) for 5 minutes. Then add 12 drops (600µL) of Extraction Buffer B into the tube. Twirl the swab vigorously for 10 seconds, and then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab into an appropriate biohazard disposal container. Cap the tube and mix contents by

gentle swirling. The swab extract must be tested immediately.

### Specimen Storage

Specimen swabs not extracted immediately can be stored at 2 - 8°C and tested within 24 hrs.

### PROCEDURE

#### Materials Provided

- Test devices
- Extraction Buffer A
- Extraction Buffer B
- Extraction Tube

#### Female Testing Kit Only

- Female Swab, 50 pcs/25 tests: Plastic-shafted sterile Dacron™ swab for testing female patients.

#### Male Testing Kit Only

- Male Swab, 25 pcs/25 tests: Metal-shafted sterile Dacron™ swab for testing male patients.
- Package Insert

#### Materials Required But Not Provided

- Timer
- External Controls
- Test tube rack
- Pipette

### DIRECTIONS FOR USE

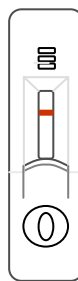
Allow the test device, samples and/or controls to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 4 full drops of sample (approx. 200µL) into the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. It is important that the background is clear before the result is read.  
Note: Do not interpret the result after 15 minutes.

### INTERPRETATION OF RESULTS



1. Positive Result  
Two colored lines appear in the results window, one in the control area and one in the test area. This indicates the presence of antibodies to HCV. The test result can be read as soon as a distinctive pink-purple line appears in the test area. In most strong positive cases, the test line will appear before the control line. When the level of antibodies to HCV is very low, the Test line may be very light purple.



2. Negative Result  
Only one colored line in the results window, in the control area, with no distinctive colored line in the test area. This indicates that no antibody to HCV was detected.



3. Invalid Result  
A distinct colored line should always appear in the control area. The test is invalid if no line forms in the control area.

**NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of Chlamydia antigen present in the specimen. However, the quantitative value cannot be determined by this qualitative test.

### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

It is recommended that a positive Chlamydia control and a negative Chlamydia control be evaluated to verify proper test performance when a new shipment of test devices is received.

Users should follow their federal, state or local and laboratory guidelines concerning frequency for running external controls.

### LIMITATIONS

1. This test provides a presumptive diagnosis for Chlamydia. A confirmed, infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
2. A specimen swab that contains too much blood may cause weak false positive results. Therefore, bloody swabs should be avoided.

### EXPECTED VALUES

Negative results are expected in healthy non-infected women and men.