

Instructions for Use

Version: 1.0.1

Revision date: 13-Feb-25

Human Chlamydia Rapid Test Kit

Catalog No: abx472013

Size: 50 tests

Storage: Store all reagents at 2 —30°C. Keep dry.

Application: For qualitative detection of Chlamydia in female cervical swab, male urethral swab, and male urine specimens.

Introduction and assay principle

Abbexa's Chlamydia Rapid Test Kit detects Chlamydia through visual interpretation of color development on the internal strip. *Chlamydia trachomatis* antigen-specific antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-*Chlamydia trachomatis* antibodies which are conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient *Chlamydia trachomatis* antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that sufficient volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

Kit Components

- Test cassettes: 50
- Extraction Buffer A
- Extraction Buffer B
- Extraction tubes
- Polyester swabs

Material Required But Not Provided

- Timer
- Distilled water
- Urine sample cup
- Male urethral swabs
- Centrifuge

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A. Sample preparation

It is recommended that specimens be tested immediately after collection. If this is not possible, place swab specimens in a dry transport tube for storage or transport. The swabs may be stored for 4-6 hours at room temperature (15-30°C) or up to 3 days at 4°C. Urine samples may be stored for up to 24 hours at room temperature. Do not freeze. Equilibrate specimens to room temperature before testing. **Do not use normal saline (0.9% NaCl) to treat swabs before collecting samples.**

- **Female cervical swab specimens:** Use the swab provided in the kit. Alternatively, plastic-shaft polyester swabs may be used. Remove excess mucus from the endocervical area with a cotton ball and discard. Insert the swab into the endocervical canal, until most of the tip is no longer visible. The aim is to collect the columnar or cuboidal epithelial cells located past the squamocolumnar junction. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise), then stand for 15 seconds. Withdraw the swab carefully, avoiding contamination from exocervical or vaginal cells.
- **Male urethral swab specimens:** Collect specimens with standard plastic or wire-shaft sterile polyester swabs. Patients should avoid urination for at least one hour prior to sample collection. Insert the swab about 2-4 cm into the urethra. Rotate the swab 360° in one direction (clockwise or counterclockwise), then stand for 10 seconds. Withdraw the swab.
- **Male urine specimens:** Collect sample from the first urine passed in the morning. Collect 15 – 30 ml into a sterile urine cup. Invert the container to mix the sample and take 10 ml into a centrifuge tube. Add 10 ml of distilled water and centrifuge at 3000 rpm for 15 minutes. Discard all supernatant carefully, and dry any remnants on the tube rim.

B. Assay procedure

1. Female cervical swab or Male urethral swab specimens:

1. Hold Extraction Buffer A vertically and add 5 drops (approximately 250 µl) to a clean extraction tube.
2. Immediately insert the swab, compress the bottom of the tube and rotate the swab 15 times. Let stand for 2 minutes.
3. Add 6 drops (approximately 300 µl) of Extraction Buffer B to the extraction tube. The solution will turn turbid. Compress the bottom of the tube and rotate the swab 15 times until the solution turns clear with a slight green or blue tint. If there is blood on the swab, the color will turn yellow or brown. Let stand for 1 minute.
4. Press the swab against the side of the tube and withdraw the swab whilst squeezing the tube. Fasten the dropper tip on top of the extraction tube.
5. Take a test cassette and lay it flat on a clean table. Holding the extraction tube vertically, slowly add 3 drops (approximately 100 µl) of extracted sample to the sample well on the test cassette. *Avoid trapping air bubbles in the sample well. Do not add solution to the result window.*
6. Leave at room temperature for 10 minutes, then analyze the result. Results should not be interpreted after 20 minutes.

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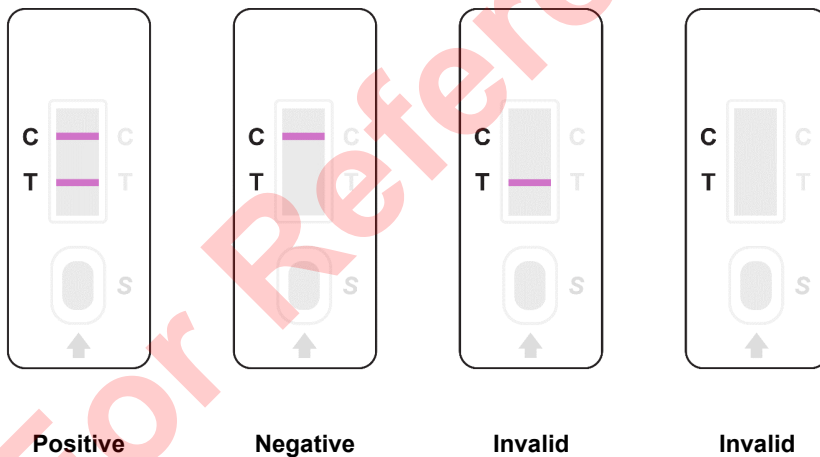
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2. Male Urine Specimens:

1. Add 6 drops (approximately 300 µl) of Extraction Buffer B to the urine pellet in the centrifuge tube. Mix thoroughly by pipetting up and down until the suspension is homogenous.
2. Transfer the solution to a clean extraction tube and let stand for 1 minute.
3. Hold Extraction Buffer A vertically and add 5 drops (approximately 250 µl) to the extraction tube. Vortex or tap the bottom of the tube to mix. Let stand for 2 minutes.
4. Fasten the dropper tip on top of the extraction tube.
5. Take a test cassette and lay it flat on a clean table. Holding the extraction tube vertically, slowly add 3 drops (approximately 100 µl) of extracted sample to the sample well on the test cassette. *Avoid trapping air bubbles in the sample well. Do not add solution to the result window.*
6. Leave at room temperature for 10 minutes, then analyze the result. Results should not be interpreted after 20 minutes.

Results analysis

- **Positive result:** A colored line is observed in both the control (C) section and the test (T) section.
- **Negative result:** A colored line is observed in the control (C) section but not the test (T) section.
- **Invalid result:** No colored line is observed in the control (C) section.



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Notes:

1. Read the entire procedure carefully prior to testing.
2. The test cassettes should be brought to room temperature before use.
3. After opening the aluminium foil, use the test cassette as soon as possible.
4. Samples should be clear with no visible particles, turbidity, or bacterial pollution.
5. Do not mix or re-use the disposable pipettes to avoid cross-contamination.
6. Avoid touching the cassette membrane through the sample well or test result window.
7. Do not use 0.9% sodium chloride to treat swabs before collecting samples.
8. Excessive blood (>20 µl in case of female swabs and >10 µl in case of male swabs) may cause false positive results.
9. Endocervical samples from female patients should not be collected during the menstrual period.
10. This kit is for the qualitative detection of *Chlamydia trachomatis* in female cervical swab, male urethral swab, and male urine specimens. For other sample types, a preliminary experiment is recommended to determine the compatibility with this kit. Positive samples can be tested with another method (e.g. HPLC, LC/MS) for quantitative results.
11. This kit is for research use only and the results are for reference only. It is recommended to use this kit in conjunction with another detection method.
12. All waste should be disposed of appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.
13. In case of urinary tract infection, the possibility of false positive should be considered.
14. No meaning should be inferred from the color intensity or width of any apparent bands.
15. Do not eat, drink or smoke in any area where specimens and kits are handled.
16. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
17. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
18. 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 cassette. If the problem persists, discontinue using the test kit immediately.
19. Humidity and temperature can adversely affect results.

Technical Support

For troubleshooting and technical assistance, please contact us at support@abbexa.com.