AG- CHLAMYDIA Ag RAPID TEST KIT

INTENDED USE

AstraGene's Chlamydia Ag Rapid Test Kit is a lateral flow immunochromatographic assay for the qualitative detection Chlamydia antigen in female cervical swab, male urethral swab or male urine specimens. The product can detect the Chlamydia serovars (D,E,F,H,I,K,G,J) and intended as a screening test and as an aid in the diagnosis of Chlamydia infection.

For professional in vitro diagnostic use only.

PRINCIPLE

AstraGene's Chlamydia Ag Rapid Test Kit is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical, male urethra or male urine. 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 colored 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.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassette with Desiccant	10 Cassette	1 Cassette
Extraction Reagent 1 (0.2M NaOH)	1 No's	1 No's
Extraction Reagent 2 (0.2M HCl)	1 No's	1 No's
Extraction tubes	10 No's	1 No's
Dropper tips	10 No's	1 No's
Sterile Female Cervical Swabs	10 No's	1 No's
Instruction for Use	1 No's	1 No's

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/CMDAg/24/01	AG/RTK/CMDAg/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Urine Cup (For Male Urine Specimens Only)
- Centrifuge Tube (For Male Urine Specimens Only)
- Sterile Male Urethral Swab
- Personal protective equipment in accordance with local recommendations (i.e. lab coat, face mask, face shield/goggles and gloves)
- Biohazard waste bin
- Pipette
- Clock or timer.

STORAGE &STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

SAMPLE COLLECTION & PREPARATION

Allow The Chlamydia Rapid Test (Swab/Urine) can be performed using female cervical swab, male urethral swab or male urine 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 used.

 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 specimen collection.

 If the test is to be conducted immediately, put the swab into the extraction tube.

To collect Male Urethral Swab Specimens:

 Standard plastic or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least 1 hour period to specimen collection.

 Insert the swab into the urethral about 2-4 cm, rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before specimen collection.

 If the test is to be conducted immediately, put the swab into the extraction tube.

To collect Male Urine Specimens:

 Collect 15-30 mL of clean first morning urine in a sterile urine cup. First morning urine specimens are preferred to achieve the highest concentrations of Chlamydia antigen.

 Mix the urine specimen by inverting container. Transfer 10 mL of the urine specimen into a centrifuge tube, add 10 mL distilled water and centrifuge at 3,000 rpm for 15 minutes.

 Carefully discard the supernatant, keep the tube inverted and remove any supernatant from the rim of the tube by blotting onto absorbent pad.

 If the test is to be conducted immediately, treat the urine pellet according to the **Procedure.**

 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 allow to reach the room temperature (15-30°C) before testing.

PROCEDURE

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

- Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Extract the Chlamydia antigen according to the specimen type.

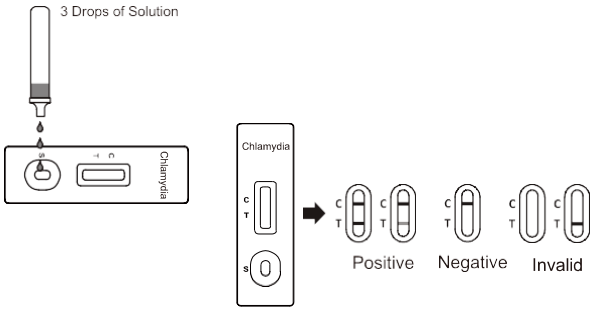
For Female Cervical or Male Urethral Swab Specimens:

- 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.

For Male Urine Specimens:

- Hold the reagent 2 bottle vertically and add 6 drops of (approx. 250 µL) reagent 2 to the urine pellet in the centrifuge tube, then shake the tube vigorously until the suspension is homogeneous.
- Transfer all the solution in the centrifuge tube to an extraction tube. Let stand for 1 minute. Hold the reagent 1 bottle upright and add 5 drops of (approx. 300 µL) reagent 1 to the extraction tube. Vertex or tap the bottom of the tube to mix the solution. Let stand for 2 minutes.
- Fit the dropper tip on top of the extraction tube.
- Place the test cassette on a clean and level surface. Add 3 full drops of the extracted solution (approx. 100 µL) to the specimen well of the test cassette (S), then start the timer. Avoid trapping air bubbles in the specimen well.
- 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.



RESULT INTERPRETATIONS

Positive

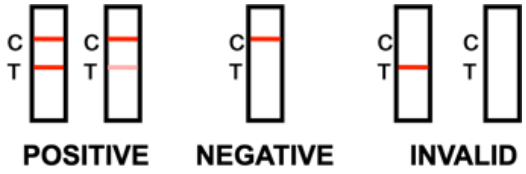
A clear colored control band (C) and a detectable test band (T) appear, indicating a positive result.
Band T: Positive for Chlamydia antigen

Negative:

A single-colored band appears only at the control region (C), indicating a negative result

Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.



SENSITIVITY & SPECIFICITY:

AstraGene's Chlamydia Ag Rapid Test Kit is Vs. Other commercial Rapid Test: Relative Sensitivity : 84.8% (77.28%-90.58%)* Relative Specificity : 95.4% (91.86%-97.66%)*

Accuracy : 91.7% (88.36%-94.35%)* *95% Confidence interval.

AstraGene's Chlamydia Ag Rapid Test Kit is Vs. PCR kit: Relative Sensitivity : 87.2 % (80.05%-92.50%)* Relative Specificity : 96.6%

(93.44%-98.53%)* Accuracy : 93.4 % (90.32%-95.70%)* *95% Confidence interval

LIMITATION OF THE PROCEDURE:

- AstraGene's Chlamydia Ag Rapid Test Kit is for in vitro diagnostic use only. This test should be used for the detection of Chlamydia antigen from female cervical swab, male urethral swab and male urine 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, male urethral swabs and male urine 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.

WARNING & PRECAUTIONS:

- For professional in vitro diagnostic 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 if 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 protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not test if the pouch is damaged.

SYMBOLS

Do not use if package is damaged

Batch Code

CE mark of Conformity

ISO

GMP

AstraGene FZ LLC, Office No. 208 – 209, Dubai Science Park Building, Dubai, United Arab Emirates
+971-4-8781222, contact@astragene.com