PreventID® **Chlamydia**

Manual (FOR PROFESSIONAL USE)

REF KSTICH502GP

Intended Use

The **PreventID® Chlamydia** is a rapid chromatographic immunoassay for the qualitative detection of *Chlamydia trachomatis* in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection.

Introduction

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 inclusion 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 [1]. Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis or pneumonia. In men, complication of Chlamydia includes urethritis and epididymitis. At least 40% of the non-gonococcal 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 (18–72 hours) and not routinely available in most situations.

The **PreventID® Chlamydia** is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens and delivers the result in 10 minutes.

Test Principle

The **PreventID® Chlamydia** is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical, male urethral and 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 colour line in the test region. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents

The test contains Chlamydia antibody coated particles and and Chlamydia antibodies coated on the membrane.

Materials

Materials Provided

- Test devices, individually packed TEST
- Extraction tubes
- Tube rack
- Sterile female cervical swab (individually packed with orange cap)
- Bottle with extraction reagent 1 (0.2 M NaOH)
- Bottle with extraction reagent 2 (0.2 M HCl)
- Dropper tips
- Manual

Materials Required but not Provided: Timer or stop watch, urine cup (for male urine specimens only), centrifuge tube (for male urine specimens only), Positive control, Negative control, sterile male urethral swab

Storage and Stability

Store as packaged in the sealed pouch at room temperature or refrigerated (2–30°C). The test is stable through the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. **Do not freeze.** Do not use beyond the expiry date.

Precautions

1. For professional *in vitro* diagnostic use only. Do not use after the expiry date.
2. Do not use if pouch is damaged. Open the pouch only when using the test.
3. Do not eat, drink or smoke in the area where the specimens and kits are handled.
4. Do not use the test device if the pouch is damaged.
5. 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.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. The used test should be discarded according to local regulations.
8. Humidity and temperature can adversely affect results.
9. Use sterile swabs to get the endocervical samples.
10. Read the instruction carefully before performing the test.
11. Do not mix reagents from different lots.
12. If you have any questions please contact Preventis GmbH.

Sample Collection and Sample Preparation

The **PreventID® Chlamydia** can be performed using female cervical swab, male urethral swab and 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.

Female Cervical Swab Specimens:

- Use the swab provided in the kit. Alternatively, any sterile 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 collection specimens.
- If the test is to be conducted immediately, put the swab into the extraction tube.

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

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 Directions for Use.

It is recommended that specimens be processed as soon as possible after collection. If immediate 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 allowed to reach the room temperature (15–30 °C) before testing.

Test Procedure

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

1. Remove the test device 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.
2. Extract the Chlamydia antigen according to the specimen type.

   Female Cervical or Male Urethral Swab Specimens:

   - Hold the bottle with extraction reagent 1 vertically and add **5 drops of extraction reagent 1 (approx. 300 µL)** to the extraction tube. Extraction reagent 1 is colourless. Immediately insert the swab, compress the bottom of extraction tube and rotate swab 15 times. **Let stand for 2 minutes.**
   - Hold the bottle with extraction reagent 2 vertically add **6 drops of extraction reagent 2 (approx. 250 µL)** to the extraction tube. The solution would turn turbid. Compress the bottom of extraction 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 colour will turn yellow or brown. **Let stand 1 minute.**
   - Press the swab against the side of extracton tube and withdraw the swab while squeezing the extraction tube. Keep as much liquid in the extraction tube as possible. Fit the dropper tip on top of extraction tube.

   Male Urine Specimens:

   - Hold the bottle with extraction reagent 2 vertically and add **6 drops of extraction reagent 2 (approx. 250 µL)** to the urine pellet in the centrifuge tube, then shake the centrifuge tube vigorously until the suspension is homogeneous.
   - Transfer all the solution from the centrifuge tube to an extraction tube. **Let stand for 1 minute.** Hold the bottle with extraction reagent 1 upright and add **5 drops of extraction reagent 1 (approx. 300 µL)** 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.

3. Place the test device on a clean and level surface *(Fig. 1)*. Add **3 full drops of the extracted solution (approx. 100µl)** to the sample application window (S) of the test device, then start the timer. Avoid trapping air bubbles in the sample application window.
4. Wait for the colour to appear. **Read the result at 10 minutes**, do not interpret the result after 20 minutes.

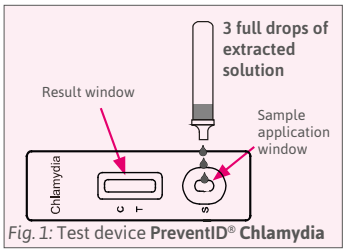

Fig. 1: Test device **PreventID® Chlamydia**

Note: It is suggested not to use the extraction reagent, beyond 6 months after opening the vial.

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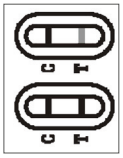
Test Interpretation



Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T). A positive result indicates that Chlamydia was detected in the specimen.

Note: The intensity of the colour in the test line region (T) will vary depending on the concentration of Chlamydia present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

Negative: One coloured line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Chlamydia antigen is not present in the specimen, or is present below the detectable level of the test.

Invalid: Control line fails to appear. 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.

If the problem persists, discontinue using the test kit immediately and contact Preventis.

Test Characteristics

Expected values

For women attending STD clinics and other high-risk populations, the prevalence of Chlamydia infection has been reported to between 20% and 30%. In a low-risk population such as those patients attending obstetrics and gynecology clinics, the prevalence is approximately 5% or less.
Reports show that for men attending STD clinics, the prevalence of Chlamydia infection is approximately 8% in asymptomatic men and 11% in symptomatic men [1, 2]. Normal carriage rates of Chlamydia in asymptomatic men are less than 5% [3].

Sensitivity

The **PreventID® Chlamydia** has been evaluated with specimens obtained from patients of STD clinics. PCR is used as the reference method for the **PreventID® Chlamydia**. Specimens were considered positive if PCR indicated a positive result. Specimens were considered negative if PCR indicated a negative result. The results show that **PreventID® Chlamydia** has a high sensitivity relative to PCR.

Specifity

The **PreventID® Chlamydia** uses an antibody that is highly specific for Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens. The results show that the **PreventID® Chlamydia** has a high specificity relative to PCR.

		Female Cervical Swab Specimens		
Method		**PCR**		**Total Results**
PreventID® Chlamydia	Results	Postive	Negative	
	Positive	42	4	46
	Negative	3	156	159
Total Results		45	160	205

Relative Sensitivity: 93.3% (81.7%–98.6%)*
Relative Specifity: 97.5% (93.7%–99.3%)*
Overall Accuracy: 96.6% (93.1%–98.6%)* *95% Confidence Intervals

		Male Urethral Swab Specimens		
Method		**PCR**		**Total Results**
PreventID® Chlamydia	Results	Postive	Negative	
	Positive	50	5	55
	Negative	8	115	123
Total Results		58	120	178

Relative Sensitivity: 86.2% (74.6%–93.9%)*
Relative Specifity: 95.8% (90.5%–98.6%)*
Overall Accuracy: 92.7% (87.8%–96.1%)* *95% Confidence Intervals

		Male Urine Specimens		
Method		**PCR**		**Total Results**
PreventID® Chlamydia	Results	Postive	Negative	
	Positive	35	0	35
	Negative	2	60	62
Total Results		37	60	97

Relative Sensitivity: 94.6% (81.8%–99.3%)*
Relative Specifity: >99.9% (95.1%–100%)*
Overall Accuracy: 97.9% (92.7%–99.7%)* *95% Confidence Intervals

Cross Reactivity

The antibody used in the **PreventID® Chlamydia** has been shown to detect all known Chlamydia serovars. Chlamydia psittasi and Chlamydia pneumoniae strains have been tested with the **PreventID® Chlamydia**, and were shown to cross react when tested in suspensions of 10^9 Colony Forming Units (CFU)/ml. Cross reactivity with other organisms has been studied using suspensions of 10^9 CFU/ml. The following organisms were found negative when tested with the **PreventID® Chlamydia**:

Acinetobacter calcoaceticus
Acinetobacter spp
Enterococcus faecalis
Enterococcus faecium
Staphylococcus aureus
Klebsiella pneumoniae
Pseudomonas aeruginosa
Neisseria meningitides
Salmonella choleraesius
Candida albicans
Proteus vulgaris
Gardnerella vaginalis
Proteus mirabilis
Neisseria gonnorhea
Group B/C Streptococcus
Haemophilus influenzae
Branhamella catarrhalis

Quality Control

An internal procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
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.

Test Limatations

1. The **PreventID® Chlamydia** 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.
2. 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.
3. 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.
4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
5. Excessive blood on the swab may cause false positive results.

References:
1. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachmatis in Urine of Asymptomatic Men. J.Clinical Microbiology, (1994), 32,24-27.
2. Jaschek,G. et al Direct Detection of Chlamydia trachomatis in Urine Specimens from Symptomatic and Asymptomatic Men by Using a Rapid Polymerase Chain Reaction Assay. J. Clinical Microbiology, (1993), 31,1209-1212.
3. Schachter, J Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine, (1982), 72, 60-69.

Temperature limitation	Manufacturer
IVD *In vitro* diagnostic device	LOT Lot number
REF Catalogue number	Expiry date
Keep away from sunlight	Do not reuse
Read user instructions	Σ n Contains sufficient for <n> tests
EC REP Authorized Representative	

CE 0123 Stand: 2020-04-07

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