RightSign®

Chlamydia Rapid Test Cassette
Swabs/ Urine Samples
Package Insert

REF WCHL-C71	English

Rapid test for the qualitative detection of Chlamydia antigens in cervical swabs in women and urethral swabs and urine samples in men.
For professional in vitro diagnostic use only.

INTENDED USE

The Chlamydia rapid test cassette is a chromatographic, immunoassay-based test for the qualitative detection of Chlamydia trachomatis in cervical and urethral swabs as well as urine samples to support the diagnosis of Chlamydia infections.

SUMMARY

Chlamydia trachomatis is the most common cause of sexually transmitted veneral infections worldwide. Chlamydia trachomatis infections have a high prevalence and asymptomatic transmission rate and often result in serious complications for women and newborns. The complications for women include cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID), frequent ectopic pregnancies and infertility. Vertical transmission to the newborn during childbirth can lead to inclusion conjunctivitis and pneumonia. Complications of Chlamydia in men include epididymitis and urethritis. At least 40% of the non-gonorrheic urethritides are due to Chlamydia infection. Approx. 70% of endocervical infections in women and up to 50% of urethral infections in men are asymptomatic. In the past, Chlamydia infections were diagnosed by detecting chlamydial inclusion bodies in tissue culture cells. While the culture method is the most sensitive and specific detection method, it is also the labour-intensive, expensive and time-consuming method (18-72h) and is unavailable in many surgeries and situations.

PRINCIPLE

The Chlamydia rapid test cassette is a qualitative, immunoassay-based membrane test for the detection of Chlamydia antigens in cervical (women) and urethral (men) swabs and male urine samples. The test line region was coated with Chlamydia antigen-specific antibodies. During testing, the extracted antigen solution reacts with the Chlamydia antibodies in the test line region and creates a coloured line. A coloured test line indicates a positive result, while the absence of a test line indicates a negative result. A control line serves as an integrated procedural control and appears if sufficient sample material has been added and membrane wicking has occurred.

REAGENTS

This test contains Chlamydia antibody-coated particles and 0.02% NaN3 buffer solution.

PRECAUTIONS

1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for the proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when the specimens are assayed.
5. The used materials should be discarded according to local regulations regarding infectious agents.
6. Humidity and temperature can adversely affect the results.
7. Do not use the test if the foil pouch is damaged.

STORAGE AND STABILITY

The test in the sealed pouch can either be refrigerated or stored at room temperature (2-30°C). The test is stable through the expiration date printed on the sealed pouch and must remain in the sealed pouch until use. Do not use the test/ test materials after the expiration date and do not freeze them!

SPECIMEN COLLECTION AND PREPARATION

1. The Chlamydia rapid test can be performed with sample material from cervical swabs (women) and urethral swabs and urine samples (men).
2. The quality of the specimen is extremely important. The specimens must be collected extremely carefully, since the Chlamydia rapid test must be performed with a specimen containing more cell material than body fluids.

Specimen Collection in Women (Cervical Swab)

- Use the supplied swab or alternatively a swab with plastic handle.
- Remove excessive cervical mucous with a gauze swab and discard it before collecting the sample.
- Insert the swab into the endocervical canal until its head is barely visible. This allows the collection of epithelial cells, which contain the largest number of Chlamydia. Twist the swab 360° (clockwise or counterclockwise), wait 15 seconds and remove it. Avoid contamination of the specimen with vaginal or exocervical cells. The swab does not need to be moistened and should never be soaked with 0.9% NaCl solution.
- If you want to perform the test immediately, place the swab in the provided reaction tube.

Specimen Collection in Men (Urethral Swab)

- Use standard sterile swabs with plastic or wire handle (not included in delivery). Instruct the patient not to urinate at least 1 hour prior to specimen collection.
- Insert the swab approx. 2-4cm deep into the urethra and twist it 360°. Wait 10 seconds before removing the swab. The swab does not need to be moistened before use and should never be soaked with 0.9% NaCl solution.
- If you want to perform the test immediately, place the swab in the provided reaction tube.

Specimen Collection in Men (Urine Sample)

- The test requires 15-30ml morning urine in a sterile urine breaker, as the concentration is usually highest in morning urine.
- Shake the urine breaker to mix, then pour 10ml of the specimen into a centrifuge tube, add 10ml of distilled water and centrifuge the mixture at 3.000rpm for 15 minutes.
- Carefully remove the supernatant in the centrifuge tube and dab the rim with an absorbent paper towel.
- If you want to perform the test immediately, proceed as described in “performing the test”.
- It is recommended to perform the test immediately after specimen collection.
- If it is not possible to perform the test immediately, store the swab in a specimen tube with dry transport medium. The swab can be stored at room temperature for 4-6 hours or refrigerated (2-8°) for 24 hours.
- Specimens should not be frozen and must be brought to room temperature prior to testing.

TEST MATERIALS

Provided materials

- 25 test cassettes
- Extraction solution 1 (0.15M NaOH)
- Extraction solution 2 (0.2N HCl, 0.02% NaN3, 37mg/ml MOPSO sodium salt)
- 25 reaction tubes
- Cervix swabs, sterile
- Package insert
- Dropper caps

Materials required but not provided

- Urine breakers (for male urine samples)
- Centrifuge tubes (for urine samples)
- Sterile urethral swabs
- Positive control
- Negative control
- Timer

TEST PERFORMANCE

The test cassettes, reagents, specimens and control solutions must have reached room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and perform the test as soon as possible.
2. Extract the Chlamydia antigens according to the specimen used.

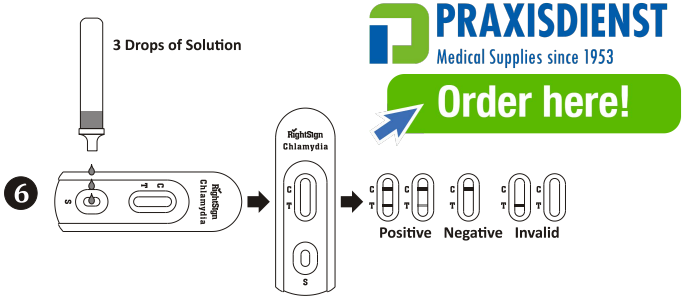
When using cervical or urethral swabs:

- Hold the bottle with the solution 1 vertically over a reaction tube and add 5 drops of the colourless reaction solution 1 (approx. 250µl). Dip the swab into the solution and press the squeeze the end of the reaction tube. Twist the swab approx. 15 times and leave the mixture alone for 2 minutes.
- Hold the bottle with the solution 2 vertically above the reaction tube and add 6 drops of the reaction solution 2 (approx. 300µl). A slight greenish or bluish coloration is normal. If the specimen contained blood, a yellow or brown colouration is normal too. Leave the mixture alone for 1 minute.
- Press the swab to the wall of the reaction tube before removing it completely. Ensure that as much solution as possible remains in the reaction tube. Screw the dropper cap on.

When using urine samples (only men):

- Hold the bottle vertically over the centrifuge tube and add 5 drops of reaction solution 2 (approx. 250µl). Shake the tube to obtain a homogenous solution.
- Add the solution from the centrifuge tube to a reaction tube and let it sit for a minute. Then add 5 drops (approx. 250µl) of the reaction solution 1. Tap the tube to mix the solution. After 2 more minutes, place a dropper cap onto the reaction tube.

- Place the test cassette on a flat and level surface. Add 3 drops of specimen solution (approx. 120µl) to the specimen well of the test cassette. Avoid the formation or inclusion of air bubbles. Start the timer.
- Read the test result after 10 minutes. During this time, at least the control line should have appeared. Results read after more than 20 minutes are generally no longer usable and thus invalid.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: 2 coloured lines appear. The 1st line appears in the control line region (C) and the second line appears in the test line region (T). A positive result means that Chlamydia has been detected in the specimen.

NOTE: Even though this is a qualitative test, the intensity of the test line may vary depending on the Chlamydia concentration. Therefore, any shade of colour in the test line region should be considered positive.

NEGATIVE: 1 coloured line appears. One line appears in the control line region (C) and no line appears in the test line region (T). A negative result means that the specimen contains no Chlamydia or that the concentration is below minimum detection levels.

INVALID: no control line appears. If no control line appears in the control line region (C), the test results are invalid. This is likely due to insufficient specimen application or incorrect procedural techniques. Review the procedure and repeat the test with a new cassette.

If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

This test is equipped with an integrated procedural control. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen application and adequate membrane wicking. Positive and negative control solutions are not supplied with this kit but their regular use is recommended.

LIMITATIONS

1. The Chlamydia rapid test is only intended for in vitro diagnostic use. It should only be used for the detection of Chlamydia antigens in cervical and urethral swabs and urine samples. It delivers no quantitative results and should not be used to estimate the increase or decrease of antigen concentrations.
2. This test detects the presence of viable and non-viable Chlamydia antigens in cervical and urethral swabs and urine samples (men). Test results with other sample material were not examined.
3. The detection of Chlamydia depends on the organism concentration in the sample. Other factors include the age, previous sexually transmitted diseases, the presence of symptoms, etc. The minimum detection levels depend on the serotype of the infective agent. Therefore, the results of rapid tests should always be interpreted with other laboratory results and clinical information.
4. Therapeuthic success or failure cannot be proven with this test, as antigens may still be detectable after successful therapy.
5. A high blood content in the specimen can lead to false positive results.

EXPECTED VALUES

For women who are already being treated for sexually transmitted diseases and for other high-risk groups, the calculated general risk of contracting Chlamydia is about 20-30%.

For women who do not belong to any risk group and come to gynaecological screening appointments or antenatal care, the calculated risk is about 5% or less.

The risk for men who are already being treated for sexually transmitted diseases is approx. 8% if the disease is asymptomatic and 11% if they are experiencing symptoms. For healthy men, the risk of Chlamydia is <5%.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

The Chlamydia rapid test has been tested with samples from STD treatment centres and PCR was chosen as a reference method. The samples were considered positive if the result of the PCR was positive and negative if the PCR was negative. The results show that the sensitivity of the Chlamydia rapid test is similar to that of the PCR.

SPECIFICITY

This Chlamydia rapid test uses antibodies that are highly specific to Chlamydia antigens in female cervical swabs, male urethral swabs and urine samples. The results show that the specificity of the Chlamydia rapid test is similar to that of the PCR.

Female cervical swabs

Method		PCR		Total
Chlamydia Rapid Test	Result	Positive	Negative	
	Positive	36	4	40
	Negative	4	110	114
Total		40	114	154

Relative sensitivity: 90% (76.3%-97.2%)*
Relative specificity: 96.5% (91.3%-99.0%)*
Relative accuracy: 94.8% (90.0%-97.8%)*

Male urethral swabs

Method		PCR		Total
Chlamydia Rapid Test	Result	Positive	Negative	
	Positive	38	6	44
	Negative	9	100	109
Total		47	106	153

Relative sensitivity: 80.9% (66.7%-90.9%)*
Relative specificity: 94.3% (88.1%-97.9%)*
Relative accuracy: 90.2% (84.3%-94.4%)*

Male urine samples

Method		PCR		Total
Chlamydia Rapid Test	Ergebnis	Positive	Negative	
	Positive	24	0	24
	Negative	2	45	47
Total		26	45	71

Relative sensitivity: 92.3% (74.9%-99.1%)*
Relative specificity: >99.9% (93.6%-100%)*
Relative accuracy: 97.2% (90.2%-99.7%)*

Cross-Reactivity

The antibodies used in this Chlamydia rapid test were able to detect all known Chlamydia serotypes. At concentrations of 10^9 colony-forming units, Chlamydia psittaci and Chlamydia pneumoniae strains showed cross-reactivity with this rapid test. The organisms below did not show any cross-reactivity at concentrations of 10^9 CFO/ml.

Acinetobacter calcoaceticus	Pseudomona aeruginosa	Proteus mirabilis
Acinetobacter spp	Neisseria meningitidis	Neisseria gononorrhea
Enterococcus faecalis	Salmonella choleraesuis	Group B/C Streptococcus
Enterococcus faecium	Candida albicans	Hemophilus influenzae
Staphylococcus aureus	Proteus vulgaris	Branhamella catarrhalis
Klebsiella pneumoniae	Gardnerella vaginalis	

BIBLIOGRAPHY

1. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachmatis in Urine of Asymptomatic Men. *J.Clinical Microbiology*, 32,24-27, (1994).
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*, 31,1209-1212, (1993).
3. Schachter, J Sexually transmitted Chlamydia trachomatis infection. *Postgraduate Medicine*, 72, 60-69, (1982).

Index of Symbols

	Consult Instructions for use		Tests per kit	EC REP	Authorised Representative
IVD	*For in vitro diagnostic use only*		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use it the package is damaged		corrosive		Acute toxicity
	Irritating				

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