Chlamydia Antigen (CHL)

CE 0123

Product-#: D-CHL-S23-002

Rapid test for the qualitative detection of Chlamydiae

INTENDED USE

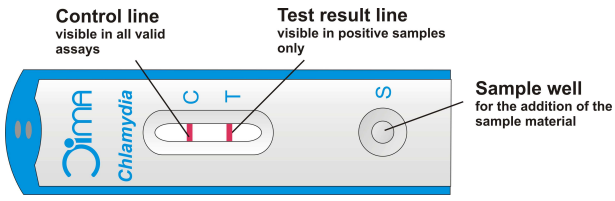
The DIMA® Chlamydia rapid antigen test is an in-vitro diagnostic membrane immunoassay intended for the rapid, qualitative detection of chlamydia antigen from female endocervical swabs and male urethral swabs or urine samples, and supports the diagnosis of chlamydia infection.

SUMMARY

The genus Chlamydia is made up of three species: Chlamydia trachomatis, Chlamydia pneumoniae (1), a primarily human pathogen, and Chlamydia psittaci, a primarily animal pathogen. Chlamydia trachomatis consists of 15 known serovars. These are associated with urogenital infections and lymphogranuloma venereum (LGV). Chlamydia trachomatis infections are the most common bacterial sexually transmitted diseases. In the USA there are about 4 million new cases every year, mainly cervicitis and non-gonococcal urethritis (8). This organism also causes conjunctivitis and pneumonia in children (2, 4–7). Chlamydia trachomatis infections have both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of chlamydia infections in women include cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility. Vertical transmission of the disease from the mother to the neonate during parturition can result in inclusion conjunctivitis and pneumonia (8). In men at least 40% of all cases of non-gonococcal urethritis are associated with Chlamydia infections and epididymitis (6). Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are symptomatic (8). Chlamydia psittaci infections are associated with respiratory diseases in individuals exposed to infected birds and are not transmitted from human to human. Chlamydia pneumoniae, which was first isolated in 1983, is associated with respiratory infections and pneumonia (2). Traditionally chlamydia infections have been diagnosed by the detection of chlamydiae in tissue culture cells or polymerase chain reaction (PCR). Together with PCR, the culture method is the most sensitive and specific laboratory method, but it is labour-intensive and expensive, it takes a long time (2–3 days) and is not routinely available in most institutions (2, 3, 7). Direct tests such as immunofluorescence assay (IFA) require special equipment and a skilled operator to read the results.

PRINCIPLE

The chlamydia antigen test is a rapid immunochromatographic test. In the test procedure a clinical specimen is obtained and placed in an extraction tube with extraction solution A. After 2 minutes extraction solution B is added to the tube. After extraction 3 drops (approximately 120 µl) of the extracted sample are added to the test cassette sample well. In the test the membrane was coated with antigen-specific monoclonal antibodies on the test line and with a goat anti-rabbit antibody on the control line. During testing any antigens present react with the gold-marked monoclonal antibody and then move laterally on the membrane by capillary action. If the sample contains chlamydia antigens, a coloured line with a specific antibody-chlamydia-antibody gold particle complex will form on the membrane in the test band region. If no chlamydia antigen is present, only a pink line appears in the control band region. For control purposes, a coloured line always appears in the control zone, whether chlamydia is present or not.



STORAGE AND STABILITY

The test kit should be stored at room temperature or refrigerated (+2°C to +30°C) until the expiration date. Do not freeze. The test cassette should be stored in the sealed protective packaging and used immediately upon opening.

PRECAUTIONS

- For in vitro use only
- Do not use kit components after their expiry date. Do not mix kit components from different lots. Do not confuse solution bottle caps.
- Do not use test cassettes or swabs with damaged packaging.
- Do not dismantle test cassette.
- Use test cassette only once.
- The materials used in the test cassette (for example antibodies) are potentially infectious. With appropriate application however they pose no danger.
- Use appropriate precautions in the collection, handling, storage and disposal of the specimens and used kit contents. All specimens, reagents and controls should be treated as potentially infectious components. When the test procedure is complete, the swabs must be disposed of in accordance with the guidelines relating to contact with potentially infectious materials.
- Extraction solution A contains sodium hydroxide (an alkaline solution); extraction solution B contains hydrochloric acid (an acid solution). If either of the solutions comes into contact with the skin or eyes, rinse with plenty of water.
- Use only sterile Dacron swabs or cytology brushes for taking endocervical samples
- Do not use cytology brushes with pregnant patients.
- Avoid cross-contaminations of the samples by using separate swabs and extractiontubes for each sample.
- Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Wear protective clothing such as laboratory coats and disposable gloves for collection and testing of specimens.
- As with all diagnostic tests, the definitive clinical diagnosis should not be based on a single test, but should only be made by a doctor after all the clinical and laboratory results have been examined.

REAGENTS AND MATERIALS

- 20 test cassettes per test kit
- Extraction solution A: in a plastic dropper bottle; contains 0.2 M sodium hydroxide (7 ml).
  Xi: irritant; R 36/38 irritates eyes and skin
- Extraction solution B: in a plastic dropper bottle; contains 0.2 M hydrochloric acid (7 ml).
- Extraction tube and dropper cap: 20 per kit
- Plastic holder
- Package insert: 1 per kit

Additional material attached in accordance with 93/42/EEC:

- Sterilized swabs with Dacron tips (CE0482) : 20 per kit

Heinz Herenz Medizinalbedarf GmbH, Rudorffweg 10,21031 Hamburg, Germany

Available on request:

- Cytology brushes for the optimum taking of samples from cervical swabs
- Special swabs for taking samples from the urethra

Additionally required Utensils:

- Stopwatch
- For urine samples: Urine-storage vessel, one-way pipette and centrifuge
- For taking samples from the urethra: Special swabs

SPECIMEN COLLECTION AND STORAGE

The quality of specimen obtained is of the greatest importance (8). Detection of chlamydia requires a vigorous and thorough collection technique which provides cellular material rather than just body fluids.

For cervical specimens:

- Use the swab provided with the test kit.
- Before specimen collection, remove excess mucus from the endocervical area with a separate swab or cotton ball and discard. The swab should be inserted into the cervical 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 organisms. Firmly rotate the swab for 15 to 20 seconds without contaminating it with exocervical or vaginal cells.
- Alternatively, endocervical specimens can be collected with a cytology brush (caution: do not use cytology brushes with pregnant patients). After cleaning the exocervix with a Dacron swab, insert the cytology brush into the cervical canal, past the squamocolumnar junction. Leave in place for two to three seconds, rotate the cytology brush two full turns and withdraw the brush without touching any vaginal surface.
- Put the swab/cytology brush into the extraction tube if the test is to be carried out immediately after the specimen is collected.

For urethral specimens:

- Standard wire-shaft fibre-tipped swabs, or other special devices for collecting specimens (not provided) should be used for urethral specimen collection. Instruct the patients not to urinate for at least one hour prior to specimen collection.
- Insert the swab approximately 2 to 4 cm into the urethra, rotate for 3 to 5 seconds and remove. Place the swab in the extraction tube, if the test is to be performed immediately after the sample has been taken.

Storage of cervical and urethral samples:

- Do not place the swab in the transport container with medium, because the transport medium impedes the test; in addition, the ability of the organisms to survive is not necessary for the test. If the test cannot be performed immediately after the sample is taken, the patient samples should be placed in a dry transport tube for storage or transport.
- The swabs can be stored for 4 hours at room temperature (15 to 30°C) or 24 hours chilled (2 to 8°C). Do not freeze. All samples should be at room temperature (15-30°C) before the test is performed.

For male urine specimens:

- Instruct the patient to collect at least 20–40 ml of fresh urine in sterile container (not provided with the kit) without any preservative. First morning urine specimens contain the highest concentration of chlamydiae and are therefore preferred as specimen material.
- If the urine specimens are not to be tested immediately, they can be stored refrigerated (2–8°C) for 24 hours.

BIOSYNEX Deutschland GmbH
Robert-Bosch-Breite 23 • 37079 Göttingen
Deutschland

Phone: +49 (0)551 - 504 11 -0
Fax: +49 (0)551 - 504 11 -29
eMail: info@biosynex.de

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TEST PROCEDURE

I. Specimens extraction:

1. Prepare endocervical or urethral specimens:

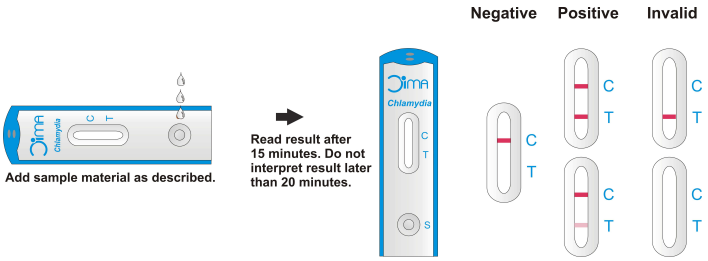
- Place a clean, identified extraction tube into the plastic holder. Add 5 drops of extraction solution A to the extraction tube.
- Immerse the patient's swab or the brush in the extraction tube and extract for 2 minutes at room temperature. During extraction, use a circular motion to roll the swab/brush against the side of the extraction tube so that the liquid is expressed from the swab/brush and can be reabsorbed. PLEASE NOTE: Blood must be thoroughly denatured with solution A, in particular when swab material contains blood. Non-denatured blood remaining in the dropper or on the side of the tube may produce false positive results.
- At the end of the extraction time, add 5 drops of the extraction solution B and mix the solution with the swab or brush. Then press the swab or brush firmly against the tube in order to squeeze as much liquid as possible out of the swab or brush. Discard the swab/brush in accordance with guidelines for handling infectious materials.
- The specimens extracted can be kept at room temperature for 60 minutes without affecting the results of the chlamydia test.

2. Prepare male urine:

- The urine specimens should be centrifuged in order to collect all the particles which may contain chlamydia cells. Centrifuge the urine (at least 15 ml) at 10,000 rpm for 10 minutes.
- Carefully drain the excess and add 5 drops of extraction solution A to the tube, re-suspend the pellet with a disposable pipette and incubate at room temperature for 2 minutes.
- Transfer the suspension into the extraction tube with a disposable pipette, add 5 drops of extraction solution B and mix (e.g. by means of bringing the solution up into a pipette repeatedly). The sample can now be placed in the test cassette without additional incubation time.

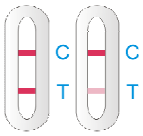
II. Test procedure

- Keep to the package insert instructions.
- Before opening the protective bag bring the test cassette to room-temperature.
- Remove the chlamydia antigen test from the protective pouch and place it on a clean, dry and level surface. Label the test cassette with patient or control identifications.
- Put the dropper cap on the extraction tube.
- Add 3 drops (approx. 120µl) of the extracted sample from the extraction tube into the round test cassette sample well marked with an S.
- Wait until pink lines appear. The test result should be read off within 15 minutes after adding the extracted suspension to the sample. Depending on the concentration of chlamydiae on the swab, some results may be visible after just 1 minute. However, to confirm negative results, the full reaction time of 15 minutes is required. After 20 minutes no further results should be interpreted.

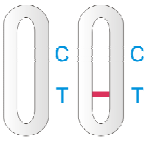


INTERPRETATION OF RESULTS

Negative:
A coloured line appears only in the control band region. No red band is visible in the test line region. This indicates that the sample does not contain any chlamydia antigen. This indicates that the sample does not contain any chlamydia antigen or that the quantity of chlamydia antigen was below the detection limit.



Positive:
In addition to the control line, a red line also appears in the test region. This indicates that the specimen contains chlamydia antigen.



Invalid:
If the control line does not appear, the test is invalid. This indicates a possible error in performing the test. The test should be repeated with a new test cassette. Either a fresh specimen may be collected or remaining extraction mixture can be used for this purpose.

LIMITATIONS OF THE PROCEDURE

The chlamydia antigen test does not specifically differentiate between C. trachomatis, C. pneumonia or C. psittaci. Detection of chlamydia is dependent on the concentration of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, previous history of STDs, presence of symptoms, etc.
As with all diagnostic tests, a definitive clinical diagnosis should not be made based on one single test, but only by a doctor following thorough review of all clinical and laboratory data. A negative result does not exclude chlamydia infection when the number of infectious agents is below the detection limit.

QUALITY CONTROL

- The chlamydia antigen test includes a procedural control. A pink coloured line in the control region of the membrane indicates proper performance of the test and reactive reagents.
- Good laboratory practice includes the use of external controls to ensure proper kit performance. Two commercial controls should be carried out on each lot. The two controls should consist of a negative control and a positive control with low levels of chlamydiae. The use of the weakly positive control will ensure that the test has not been adversely affected and that chlamydiae are detected at the stated sensitivity of the test system. For this purpose we recommend using positive and negative controls, which are to use and to handle according to the information of the manufacturer.

SENSITIVITY

To determine the sensitivity of the chlamydia antigen test, samples with various types of chlamydia were examined. The detection level of the chlamydia antigen test was set at 1.0 x 10^5 organisms per test based on spiked samples.

SPECIFICITY

The antibody mix used in the antigen test for Chlamydia is targeted at a genus-specific epitope, which is present in all 15 Chlamydia serovars. In addition, Chlamydia psittaci and Chlamydia pneumoniae strains have been tested with the chlamydia antigen test and gave positive results. Cross reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml specimen material. The following organisms were not detected using the chlamydia antigen test:

Acinetobacter calcoaceticus	Neisseria meningitidis
Proteus vulgaris	Neisseria lactamica
Salmonella typhi	Escherichia coli
Acinetobacter spp.	Gardnerella vaginalis
Staphylococcus aureus	Streptococcus faecalis
Candida albicans	Streptococcus faecium
Neisseria catarrhalis	Pseudomonas aeruginosa
Neisseria gonorrhoea	Trichomonas vaginalis

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The test results corresponded with those obtained from patient samples that were tested with a different CE-marked rapid chlamydia test (relative diagnostic sensitivity or specificity > 99.0%). The diagnostic sensitivity is lower compared to more sensitive test methods (e.g., PCR).

BIBLIOGRAPHY

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SYMBOLS USED

IVD	For in vitro diagnostic use only		For single use only
Σ	Content		Expiry date
LOT	Lot number		Storage temperature
	Manufacturer		

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BIOSYNEX Deutschland GmbH
Robert-Bosch-Breite 23 • 37079 Göttingen
Deutschland

Phone: +49 (0)551 - 504 11 -0
Fax: +49 (0)551 - 504 11 -29
eMail: info@biosynex.de