CHLAMY- CHECK- 1

Immunocromatographic Rapid Test for
Chlamydia Trachomatis

CE 0483

20 tests **REF 4009**

PRINCIPLE

a) Summary

Chlamydiae are obligate intracellular gram-negative bacteria belonging to three different species, i.e. *C.trachomatis*, *C.pneumoniae* and *C.psittaci* (1). These pathogens are known to be the cause of trachoma, which afflicts hundred millions people in the third world and have been belatedly recognized as the major etiologic agents of a variety of sexually transmitted urogenital tract infections in industrialized countries (2).

Human chlamydial infections include trachoma-inclusion conjunctivitis (TRIC), lymphogranuloma venereum (LGV) and an ever increasing number of sexually transmitted infections (at least 25 clinical syndromes) which were previously thought to be due to other agents or of unknown etiology (proctitis, cervicitis, infertility, Reiter's syndrome, epididymitis, pelvic inflammatory disease and ectopic pregnancy) (3,4).

Since chlamydial infections respond well to antibiotics treatment and are dramatically increasing in incidence, their accurate diagnosis in clinical laboratories is essential for successful therapy (5).

Various methods are available for the diagnosis of chlamydiae infections including cell culture, immunofluorescence, EIA or PCR (6,7).

b) Principle

CHLAMY CHECK-1 is a sensitive, specific and rapid test for the direct Chlamydiae detection which is suitable for the physician use or for running large series in the laboratory.

CHLAMY CHECK-1 test detects the chlamydia genus specific lipopolysaccharide (LPS) antigen. The method employs an unique combination of monoclonal-dye conjugate and solid phase antibodies to identify the LPS antigen in the swab samples with a high specificity and sensitivity.In this test the specimen (endocervical and urethral swab) is first treated with an extraction buffer to isolate *Chlamydia* LPS antigen when present and the extracted sample is then added in the device sample well.

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As the extract flows through the absorbent device, the labelled antibody-dye conjugate binds to the LPS antigen forming an antibody antigen complex. This complex binds to the antibody in the positive reaction zone and produces a pink-rose colour band when the LPS antigen concentration is present in the sample. In the absence of LPS antigen, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive reaction zone and control zone. Unbound conjugate binds to the reagents in the control zone producing a pink-rose colour band, demonstrating that the reagents are functioning correctly.

CHLAMY CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 20 tests.

Kit composition:	REF 4009
CHLAMY CHECK-1 Card	**20**
Sterile swabs	**20**
Extraction tube with filter caps	**20**
Extraction solution in plastic dropper bottles containing buffer, detergent and sodium azide (NaN_3 < 0.1%)	**2x10 ml**
Instruction leaflet	**1**

MATERIAL NOT PROVIDED IN THE KIT:

- Sterile urethral swabs
- Stop watch

STORAGE AND STABILITY

1. All CHLAMY CHECK-1 kit components should be stored at room temperature (4-30°C). ***Do not freeze the test kit.***
2. CHLAMY-CHECK-1 is stable until the expiry date stated on the package label.

PRECAUTIONS

1. For "IN VITRO" diagnostic use and professional use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of swabs carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5 to 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing such as laboratory coats and disposable gloves while assaying samples. Avoid any contact between hands and eyes or nose during specimens collection and testing.
4. Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
5. Read carefully the instruction notice before using this test.
6. Do not use beyond the expiration date which appears on the package label.
7. Do not use a test from a damaged protective wrapper.

SPECIMEN COLLECTION AND PREPARATION

For the best performance of any *Chlamydia trachomatis* test, an accurate sample collection technique is extremely important.

A) Endocervical specimens

1. Use the swab provided with the kit. Alternatively any shafted swabs with rayon or dacron tips may be used. Do not use swabs with cotton or calcium alginate tips, with wooden shafts, or impregnated with charcoal or transport media containing agar or gelatin.
2. Remove excess mucus from the endocervical area with a separate swab or cotton ball and discard.
   Note: failure to remove mucus may result in false-positive results.
3. Insert swab into the endocervical canal until most of the tip is no longer visible. Rotate the swab for 15-30 seconds, withdraw it without touching any vaginal surface. The swab can be transported and stored in dry format, in a plastic tube.
4. Testing should preferably be conducted immediately after specimen collection. If it is not possible, the specimen should be placed in a dry plastic tube and stored refrigerated (2-8°C) for a maximum of 72 hours. Do not freeze.

B) Urethral specimens

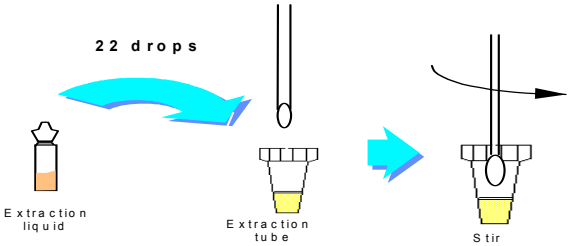
1. Standard wire-shafted fibre-tipped swabs or cytology brushes (not provided) should be used for urethral specimen collection. Instruct the patient not to urinate within 1 hour prior to the specimen collection
2. Insert the swab into the urethra about 2-4 cm, rotate for 3-5 seconds and withdraw it.
   For stability and transportation, see above in endocervical specimens.

ASSAY PROCEDURE

Bring all reagents, test units and swabs, at room temp. before use.

A) SAMPLE EXTRACTION

1. Fill the extraction tube with 22 drops (0.9ml) of extraction solution.
2. Immerse the swab in the extraction tube and swirl the swab vigorously for 10 seconds to ensure adequate mixing of swab specimen with the extraction solution.

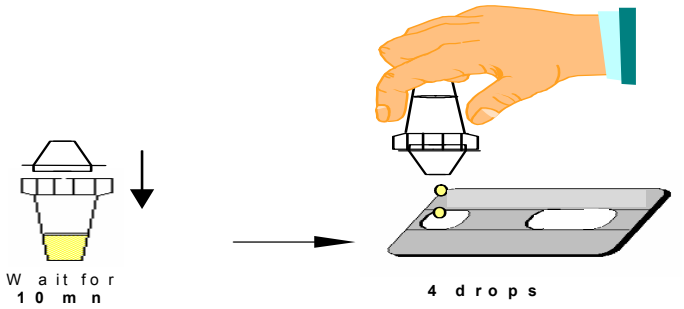


3. Place the extraction tube, containing the swab, into a test tube rack and leave for 10-15 minutes at room temp. (extraction).
4. Swirl the swab for a few seconds 2-3 times during the extraction time while pressing it against the tube wall.
5. At the end of the extraction time (10-15 minutes), thoroughly remove liquid from the swab by twisting it against tube wall while removing the swab from the tube.
6. Discard the swab as per the guidelines for handing infectious agents (see section precautions).

The swab extract can remain at room temperature for up to 30 minutes without affecting the result of the CHLAMY-CHECK -1.

B) TEST PROCEDURE

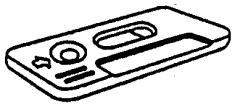
1. Remove CHLAMY CHECK-1 Test Unit from its protective wrapper and place on a level surface.
2. Label device with patient's name or control number.
3. Cap the extraction tube with the filter dropper (provided) and apply **six (4) drops (150 µl) of extract to the sample window (▷)**of the device.



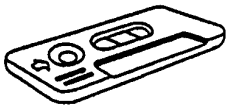
4. Allow each drop to absorb before adding the next one and avoid bubbles in the sample window when adding liquids.
5. Let the reaction proceed and read the result at 20 minutes after addition of the extract into the sample window **(▷)**.

READING TEST RESULTS

Negative :
Only one pink coloured line appears in the control window showing that the test has been carried out correctly. No line in the test window. The test is negative for chlamydial antigen.



Positive :
In addition to the coloured line in control window, a clearly-distinguishable pink coloured line also appears in the test window indicating a positive result for chlamydia antigen in the sample. Even a weak line in the test window should be interpreted as a positive result. Different intensities between test and control may occur but does not affect the interpretation of the results.



Inconclusive :
If no line appears in the control window, the test must be repeated with another test unit.
Either a fresh specimen may be collected or the remaining extraction mixture can be used for this purpose.

PERFORMANCES CHARACTERISTICS

A) ACCURACY

A study was performed on 425 endocervical specimen assayed using CHLAMY-CHECK-1 and cellular culture method. In case of discrepant results between the two methods, the specimen has been assayed using a PCR method (Amplicor-Roche).
The results of CHLAMY-CHECK-1 versus cellular culture are summarized in table 1.

		culture		Total
		+	-	
CHLAMY CHECK-1	+	67	1	68
	-	5	352	357
Total		72	353	425

Table 1: comparison of CHLAMY-CHECK-1 versus cellular culture.
From these results, the sensitivity of CHLAMY-CHECK-1 was 93% (67/72) and the specificity 99.7% (352/353).
Another study was performed using the *Chlamydia trachomatis* strain ref. ATCC VR 902 (L2 serotype) in order to evaluate the "absolute" sensitivity of CHLAMY-CHECK-1.
The detection threshold of CHLAMY-CHECK-1 lies between 57 and 570 elementary bodies per test.

B) CROSS REACTIONS

CHLAMY-CHECK-1 is detecting the LPS antigen which is common to various chlamydia species. Therefore *Chlamydia pneumoniae* and *Chlamydia psittaci* are cross-reacting.
On the other hand, no cross reaction was observed with most of micro-organisms that could be found in genital specimen.
The following list of micro-organisms didn't react with CHLAMY-CHECK-1.

Acholeplasma
Acinetobacter spp
Aeromonas spp
Bacteroides spp
Campylobacter spp
Candida spp
Citrobacter spp
Clostridium spp
Corynebacterium xerosis
Cytomegalovirus
Enterobacter spp
Escherichia coli
Fusobacterium
Gardnerella spp
Haemophilus influenzae
Herpes simplex virus
Klebsiella pneumoniae
Klebsiella spp
Lactobacillus spp
Listeria spp
Mycobacterium smegmatis
Mycoplasma spp
Neiseria gonorrhoeae
Peptococcus spp
Peptostreptococcus spp
Propionebacterium
Proteus spp
Pseudomonas spp
Salmonella spp
Saccharomyces cerevisiae
Serratia spp
Shigella spp
Staphylococcus spp (coag. Neg.)
Staphylococcus spp (coag. Pos.)
Streptococcus spp
Torulopsis globrata
Trichomonas spp
Ureaplasma urealyticum
Veinonella spp

C) PRECISION

1- Intra-assay
Within run precision was determined by using 5 replicates of chlamydia controls either negative and positive. The negative and positive values were correctly identified 100% of time.

2- Inter-assay
Between run precision was determined by using the same chlamydia controls with five different lots of reaction devices. Again, the negative and positive values were correctly identified 100% of time.

LIMITATIONS

1. (*) Dangerous reagents are marked by an asterisk. Refer to MSDS.
2. The CHLAMY CHECK-1 test is for in vitro diagnostic use only. The test should be used for the detection of *Chlamydia trachomatis* antigen only and for specimens collected from the endocervical or urethral regions.
3. Specimen with an excessive amount of mucus or blood may give false positive results.
4. Like all immunological tests for *Chlamydia trachomatis*, this test cannot distinguish between biologically active and inactive organisms.
5. This test will only indicate the presence or absence of *Chlamydia trachomatis* antigen in the specimens and should not be used as the only basis for the diagnosis of chlamydial infection.
6. If clinical symptoms persist and the test result is negative, additional follow-up testing with e.g. cell culture method is required.
7. As with all diagnostic procedures, a diagnosis should not be based on a single test result but on a synopsis of laboratory results, clinical investigations and patient's history.

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Temperature limitation


Consult operating instructions


Do not re-use

IVD
In vitro diagnostic use

Manufactured by VEDALAB – Rue de l'Expansion – ZAT du Londeau
CERISE – B.P. 181 – 61006 ALENÇON Cedex - FRANCE

Swabs: STERILE EO CE 0120

IVD CE 0483

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