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NADAL. Chlamydia Test (Ref. 212001) Puritan Medical Products Company LLC

1.Intended Use

The NADAL• Chlamydia Test (swab/urine) is a rapid visual immunoassay for the qualitative presumptive detection of *Chlamydia trachamatis* in female cervical swab, male urethral swab and male urine specimens. This test is intended for use as an aid in the diagnosis of Chlamydia infection. The NADAL Chlamydia Test is designed for professional use only.

2. Introduction and Clinical Significance

The genera *Chlamydia* and *Chlamydaphifa* include, among others, three species: *Chlamydia trachamatis* (*C. trachamatis*), the recently reclassified *Chlamydophifa pneumonioe* (*C. pneumoniae*), primarily associated with humans, as well as *Chlamydia psittaci* (*C. psittaci*), primarily associated with animals.

C. trachomatis comprises 15 known serovars and is associated with trachoma and genitourinary infections. 3 out of 15 serovars are associated with lymphogranuloma venereum (LGV). *C. trachomatis* infections are the most common sexually transmitted bacterial diseases. *C. trachamatis* infection is characterised by 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 diseases (PIO) and increased incidence of ectopic pregnancies and infertility. Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis and pneumonia. In men, at least 40% of cases of nongonococcal urethritis are associated with *Chlamydia* infection and epididymitis. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are symptomatic.

C. psittad infection is associated with respiratory diseases in individuals exposed to infected birds and is not transmitted from human to human.

C. pneumoniae, first isolated in 1983, is associated with respiratory infections and pneumonia.

Earlier Chlamydia infection has been diagnosed by the detection of Chlamydia inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labour-intensive, expensive, lengthy (2-3 days) and not routinely available In most institutions. Direct tests such as immunofluorescence assays (IFA) require specialised equipment and a skilled operator to read the result. Today Chlamydia are frequently detected by PCR.

3. Test Principle

The NADAL & Chlamydia Test (swab/urine) detects Chlamydia trachomatis through visual interpretation of colour development on the internal test strip. Antigen-specific lipopolysaccharide (LPS) monoclonal antibody is immobilised in the test line region of the membrane. During testing, the specimen reacts with other monoclonal anti-Chlomydio-LPS antibodies conjugated to coloured particles and precoated onto the conjugate pad of the test. The mixture then migrates along the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient Chlamydia antigens in the specimen, a coloured line will appear in the test line region of the membrane. The presence of this coloured line indicates a positive result, while its absence indicates a negative result.

The appearance of a coloured line in the control line region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Reagents and Materials Supplied

Each test consists of a reagent strip mounted in a plastic housing. The amount of C. trachamatis antibody precoated in the test line region is less than 0.001 mg, the amount of streptavidin precoated in the control line region is about 0.0003 mg. The conjugate pad contains 0.002 mg C. trachomatis antibody coupled onto red latex particles.

Provided additional material according to 93/42/EEC:

- 1 NADAL• Chlamydia test cassettes
- 1 sterile female cervical swabs CE 0086
- 1 extraction tubes with dropper-tips
- 1 extraction buffer A (3ml) containing 0.2M NaOH
- 1 extraction buffer B (93ml) containing 0.2M HCl
- 1 package insert

5.Additional Materials Required

- For male urine samples: specimen collection containers, disposable pipettes, centrifuge
- For male urethral samples: special swabs
- For female cervical swabs: additional swab or cotton ball to remove excessive mucus
- Timer

6.Storage & Stability

The test kit should be stored at 2-30°C and used until the expiry date printed on the packaging. The test cassette should remain in the sealed foil pouch until use. Do not freeze the test kit. Care should be taken to protect components of the test kit from contamination. Do not use the test if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

7. Warnings and Precautions

H319 Causes serious eye irritation
H315 Causes skin irritation

- For professional in-vitro diagnostic use only.
- Carefully read through the test procedure prior to testing.
- Do not use the test beyond the expiration date indicated on the package.
- Do not use tests or swabs if the foil pouches are damaged.
- To avoid cross-contamination of specimens, do not reuse tests or extraction tubes.
- Do not add samples to the reaction area (result area).
- In order to avoid contamination, do not touch the reaction area (result area).
- Do not substitute or mix components from different test kits, e.g. dropper-tips or caps from different extraction buffer bottles.
- Do not eat, drink or smoke In the area where specimens and test kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.
- Handle all specimens as If they contain Infectious agents. Observe established precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
- The test kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially Infectious, and handled In accordance with usual safety precautions (e.g. do not ingest or Inhale).
- Extraction buffer A and extraction buffer B are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- Humidity and extreme temperature can adversely affect test results.
- When the test procedure is completed, dispose of swabs carefully after autoclaving them at 121°C (or at least 20 minutes. Alternatively, swabs can be treated with 0.5% sodium hypochlorite (I.e., household bleach) for one hour before disposal.
- Used testing materials should be discarded according to local regulations.
- Do not use cytology brushes with pregnant patients.

8. Specimen Collection and Preparation

- The quality of specimens obtained is of extreme Importance. Detection of Chlamydia requires a vigorous and thorough collection technique which provides cellular material rather than Just body fluids. Do not use 0.9% sodium chloride to treat swabs before collecting specimens.

To collect female cervical swab specimens:

- Use the swab provided with the test kit.
- Before specimen collection, remove excess mucus from the endocervlcal area with a separate swab or a cotton ball and discard It.
- The swab should be Inserted Into the endocervlcal canal, past the squamocolumnar Junction, until most of the tip Is no longer visible. This will, permit the aquisition of columnar or cuboidal epithelial cells, which are the main reservoir of Chlamydia bacteria.
- Firmly rotate the swab for 15-20 seconds and then withdraw It. Avoid contamination with exocervlcal or vaginal cells.
- If the swab Is to be tested Immediately, insert It Into the extraction tube.

To collect male urethral swab specimens:

- Standard wire-shaft, fiber-tipped swabs or cytology brushes (not provided) should be used for urethral specimen collection. Instruct patients not to urinate for at least one hour prior to specimen collection.
- Insert the swab Into the urethra about 2-4 cm, rotate It for 3-5 seconds and then withdraw It.
- If the swab is to be tested Immediately, Insert It Into the extraction tube.

To collect male urine specimens:

- Collect 15-30 ml of clean, first morning urine in a sterile urine specimen container. First morning urine specimens are preferable in order to obtain the highest concentrations of Chlamydia antigens.
- Mix the urine specimen by Inverting the container. Transfer 10 ml of the urine specimen Into a centrifuge tube, add 10 ml plstllled water and centrifuge the suspension at 3,000 rpm for 15 minutes. Keeping the tube Inverted, carefully discard the supernatant. Remove any supernatant from the rim of the tube by dabbing It with absorbent paper.
- If the test Is to be conducted Immediately, treat the urine pellet according to section 9 "Test Procedure".

For cervical or urethral swab specimens:

- Holding the bottle with the extraction buffer A upright, add 8 drops to_ the extraction tube.
- Insert the patient swab Into the extraction tube and wait for 2 minutes. In the meantime, rotate the swab using a circular motion, and press It against the sides of the extraction tube so that the liquid is expressed from the swab and can reabsorb. Repeat this process 15x.
- Holding the bottle with the extraction buffer B upright, add 8 drops. Mix the liquids with the swab Squeeze the swab firmly against the sides of the extraction tube for 1 minute to expel as much liquid as possible from the swab. Discard the swab following the guide-lines for handling infectious agents. Attach the dropper tip to the extraction tube.
- The extracted specimen can be kept at room temperature for 60 minutes without affecting the test result.
- Add 3 drops (approximately 100 µL) of the extracted specimen from the extraction tube to the specimen well of the test cassette. Start the timer. Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the reaction area (result area).
- As the test begins to work, the colour will migrate along the membrane. The result should be read after 10 minutes. Do not interpret the result after more than 20 minutes.

For male urine specimens:

- Holding the bottle with the extraction buffer A upright, add 8 drops to the urine pellet in the centrifuge tube. Then draw the liquid up and down with a pipette to vigorously mix it until the suspension is homogeneous.
- Transfer the whole solution from the centrifuge tube into an extraction tube. Let it stand for 2 minutes.
- Holding the bottle with the extraction buffer B upright, add 8 drops to the extraction tube. Vortex It or tap the bottom of the 1 tube to mix the solution. Let it stand for 1 minute.
- Attach the dropper tip to the extraction tube. Add 3 drops (approximately 100 µL) of the extracted specimen from the extraction tube to the specimen well (S) of the test cassette. Start the timer. Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the reaction area (result area). As the test begins to work, the colour will migrate along the membrane.
- Wait for the coloured line(s) toappear. The result should be read after 10 minutes. Do not interpret the result after more than 20 minutes.

10. Result Interpretation

Positive:
Two coloured lines appear on the membrane. One line appears in the control line region (C) and the other line appears in the test line region (T).

Negative:
Only one coloured line appears in the control line region (C). No coloured line appears in the test line region (T).

nvalid:
The control line fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

• Note: The colour intensity In the test line region (T) may vary depending on the concentration of the analyte present in the specimen. Therefore, any shade of colour in the test line region should be considered positive. Note that this is a qualitative test only
• and cannot determine the concentration of the ana1yte in the specimen.
• Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for the control line failure.

11. Quality Control

• An internal procedural control is included in the test cassette:
• 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.
• Good laboratory practice (GLP) recommends the use of control materials to ensure proper test kit performance.

12. Limitations

• • The NADAL• Chlamydia Test (swab/urine) is for professional in-vitro diagnostic use only and should only be used for the qualitative detection of C. trachomatis. No meaning should be inferred from the colour intensity or width of any apparent lines.
• The test does not differentiate between C. trachomatis, C. pneumoniae or C. pslttaci. However it should not be used for the detection of other Chlamydia than C. trachomatis, as only the described sample material has been tested with patient material. Of the three Chlamydia species, usually only C. trachomatis is present in the urogenital tract. For this reason, if the intended sample material is used, cross-reactivity with other Chlamydia spec. that could influence the detection of C. trachomatis is not to be expected. A positive result most likely indicates an infection with C. trachoma tis.
• Detection of *Chlamydia* depends on the number of bacteria present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of STD, presence of symptoms, etc. Especially in chronic infections without clear symptoms the number of pathogens may be low. The minimum detection level of this test may vary according to the serovar. If bacterial burden Is very low in the sample, false negative results cannot be excluded.
• Samples containing high amounts of mucus or blood may cause false positive results.
• As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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