INDICATION

For the rapid detection of Chlamydia Trachomatis antigens in swab specimens. **For *in vitro* diagnostic use only, except in the United States where it is intended for Research Use Only.**

SUMMARY

Chlamydia trachomatis is one of the most common sexually transmitted pathogens. It is a major cause of cervicitis, urethritis, endometritis, and pelvic inflammatory disease in women. Serious complications can result in salpingitis, infertility, and ectopic pregnancy. If transmitted to infants during birth, Chlamydia can cause conjunctivitis and pneumonia.
Chlamydia is related to gram-negative bacteria. The primary method for detection of chlamydia is growth of the organism in cell culture. Other methods include direct fluorescence assays (DFA), enzyme immunoassay (EIA), and nucleic acid probing. The Chlamydia Rapid Test is a simple and rapid test which can detect Chlamydia trachomatis antigen directly from swabs, allowing physicians to administer therapy immediately.

TEST PRINCIPLE

The RAP-2858 Chlamydia Rapid Test is a lateral flow, immunochromatographic assay which utilizes a unique combination of monoclonal antibodies to selectively identify Chlamydia trachomatis antigen in endocervical or endourethral swab specimens with a high degree of sensitivity. The antigens are extracted from the specimen with two reagents—one to lyse the cells and one to neutralize the solution. The extracted specimen is pipetted to the sample well (cassette) or sample pad (dipstick) to begin the assay. During the assay, the extract is first allowed to react with colloidal gold reagents which have been labeled with anti-Chlamydia antibody. The extract then moves to a membrane precoated with anti-Chlamydia antibody at the test region. If Chlamydia trachomatis antigens are present in the specimen, a pink-colored band will develop on the membrane in proportion to the amount of antigen present. Absence of this pink-colored band in the test region suggests a negative result. To serve as a procedural control, a pink-colored band in the control region will always appear regardless the presence of Chlamydia trachomatis antigens.

PACKAGE SIZE

270 mm per uncut sheet

REAGENTS PROVIDED

1. Test device packed in a protective, sealed foil pouch.
2. Test Extraction Buffer A (Reagent A), 0.2N sodium hydroxide, ready for use.
3. Test Neutralization Buffer B (Reagent B), 0.1N hydrochloric acid, ready for use.

ACTIVE INGREDIENTS:

Coated Antibodies:

Control region: Goat anti-mouse(Ig G) polyclonal antibody
Test region: Mouse monoclonal anti-Chlamydia antibody A

Labeled Antibodies:

Colloidal gold conjugate of monoclonal anti- Chlamydia antibody B

STORAGE AND STABILITY

The RAP-2858 Chlamydia Rapid Test, including both reagents can be stored at room temperature or refrigerated (2-25°C) out of direct sunlight until the expiration date printed on the outer box.
Do not freeze.

ASSAY PROCEDURE

Procedural Note:

1. Read the package insert carefully before starting the assay.
2. 2. If specimens or reagents have been stored in the refrigerator, allow all specimens and reagents to warm to room temperature (18-25°) before testing.
3. All drops must be free falling with the reagent bottles held vertically. In order to avoid contamination of reagents, do not allow the tips of the bottles to come in contact with the extraction cup or other surfaces.

Extraction:

1. Place the specimen swab into the extraction cup. Add 5 drops of Reagent A to extraction cup. Mix contents well with the swab and let stand for 2 minutes, but no longer than 10 minutes.
2. Add 5 drops of Reagent B to extraction cup. Mix contents well with the swab and let stand for 2 minutes (no longer than 10 minutes). Remove liquid from the swab by pinching the rim of the extraction cup between thumb and finger and gently remove the swab from the cup.
3. The extraction mixture can be tested immediately or at any time within the following 24 hours.

Assay:

1. Bring all reagents and specimens to room temperature. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test device from its foil pouch and use it as soon as possible.
2. Label the device with specimen identification.
3. *Dipstick:*
   Dip the device into the extract with the arrows pointing down for ten seconds. Do not dip past the line indicated by the arrows.
4. *Cassette:*
   Add 3 drops of specimens from the extraction cup to the sample well (S).
5. Read results in 10 minutes.

INTERPRETATION OF RESULTS

Positive (+): Presence of two pink-colored bands, one in the control region (C) and another in the thest region (T), indicates a positive result and that the sample contains Chlamydia trachomatis antigens.

Negative (-): Presence of one pink-colored band in the control region (C) only, indicates the result is negative for Chlamydia trachomatis antigens.

Invalid(x): If after 10 minutes no band is visible or if a pink-colored band appears in the test region (T) only, the test is invalid and should be repeated using a new test device.

Note:
Do not interpret results after 15 minutes !

PERFORMANCE CHARACTERISTICS

Sensitivity Study
The analytical sensitivity of the RAP-2858 Chlamydia Rapid Test was determined by testing serial dilutions of cultured specimens. The detection limit of the RAP-2858 Chlamydia Rapid Test was determined to be 5 X 106 CFU/ml.

Specificity Study
To determine the specificity of the RAP-2858 Chlamydia Rapid Test to C. trachomatis, 15 serovars were tested at different levels of organisms. Positive results obtained at the level of 5 X 106 CFU/ml for all C. trachomatis.

Cross Reactivity
Cross-reactivity studies with organisms likely to be found in the urogenital tract were also performed using the RAP-2858 Chlamydia Rapid Test. Organisms tested at 1 X 108 Orgs/ml produced negative results in RAP-2858 Chlamydia Rapid Screen Test.

Group B Streptococcus
Pseudomonas aeruginosa
Staphylococcus aureus
Proteus vulgaris
Streptococcus faecalis
Escherichia coli
Neisseria lactima
Neisseria gonorrhoeae
Streptococcus pneumoniae
Neisseria sicca
Neisseria meningitidis
Candida albicans
Neisseria subflava
Klebsella pneumoniae
Garonerella vaginalis
Saccharomyces cerevisiae
Neisseria lactamica

ASSAY COMPARISONS
Against QuickVue®, accuracy of RAP-2858 Chlamydia Rapid Test was tested against 103 individual clinical swab specimens. Results have been tabulated below:

		QuickVue®		
		+	-	Total
RAP-2858 Chlamydia	+	37	2	39
	-	3	61	64
	Total	40	63	103

Sensitivity: 93.0%
Specificity: 97.0%
Over all accuracy: 96.0%

QUALITY CONTROL

- **Appearance:** All material is visually inspected before their use in manufacture.
- **Specificity:** 10 test kits are randomly selected and tested with negative control panel. All test results must be negative.
- **Sensitivity:** 10 test kits are randomly selected and tested with positive control panel. All test results must be positive.
- **Internal Control:** A colored band must appear in the control region of the membrane with each tested kit, which indicating proper performance and reagent reactivity.
- **Reproducibility:** Randomly selected test kits from different lots must give the same results when assaying the same sample.

METHOD OF MANUFACTURE

Nitrocellulose Membrane Manufacture:

- The purified Anti-Chlamydia monoclonal antibody, diluted in phosphate buffer saline, is coated on the test region. Simultaneously, goat anti- mouse IgG polyclonal antibody, diluted in phosphate buffer saline, is coated on the control region.
- The coated membrane is dried for a minimum of 24 hours then sealed in an aluminum bag which contains silica gel desiccant.

Anti-Chlamydia colloidal gold conjugate pad manufacture:

- A buffer solution containing mouse Anti-Chlamydia monoclonal antibody/colloidal gold conjugate is coated onto non-woven cloth sheets.
- The gold conjugate pad is dried for minimum 24 hours then sealed in an aluminum bag which contains desiccant.

Test Device Assembly:

- The coated membrane, the conjugate pad, and an absorbent pad is applied to an adhesive-coated backing.
- Waterproof label is applied over the conjugate pad and the absorbent pad, the assembled sheet of material is cut into strips. The test strips are then vacuum-dried for a minimum of 4 hours.
- The assembled test strip is sealed in an aluminum pouch along with a desiccant packet.

PRECAUTION

- The test is for in vitro diagnostic use only, except in the United States where it is intended for Research Use Only.
- Do not use beyond the expiration date printed on the outside of the foil pouch.
- Do not remove the device from pouch until just prior to use.
- Do not mix reagents and bottle caps from different kits.
- Do not touch the swab tip at any time. Wash hands after performing the test.
- Use only the sterile swabs. Contaminated swabs may give faulty results.
- Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. Properly dispose of all contaminated waste such as swabs, test units and extract.
- Reagents A and B are slightly caustic. If these reagents contact the skin or eyes, flush with large volumes of water.

SPECIMEN COLLECTION AND STORAGE

A specimen should be collected by standard male or female specimen collection methods. Swabs should be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a sterile, dry, tightly capped cup or bottle. Specimens can be refrigerated (2-8°) for up to 5 days, preferably in a transportation cup. Do not freeze. Swab may be transported to the test site under ambient conditions. Transport media should not be used.

LIMITATIONS

- The test is limited to the detection of Chlamydia trachomatis in swab specimens.
- The test does not differentiate between carriers and infected individuals.
- Pharyngitis may be caused by organisms other than Chlamydia trachomatis.
- Negative results may be obtained when the amount of extracted antigen is below the sensitivity of the test. False negatives may result from improperly collected specimens. If negative or questionable results are obtained, the test should be repeated using a new swab specimen.
- The test only allows for the detection of Chlamydia as a presumptive indication of Chlamydia trachomatis infection. However cases in which patient swabs test negative while the patients' clinical symptoms are indicative of Chlamydia infection should be investigated further.
- A test result read after 15 minutes may not be consistent with the original reading obtained within the 10 minute test period.

REFERENCES

1. Chemesky, M.A. et al. "Detection of Chlamydia trachomatis Antigens by Enzyme Immunoassay and Immuno-fluorescence in Genital Specimens from Symptomatic and Asymotomatic Men and Women," J. Infect. Dis., Vol. 154 (1986): 141-148.
2. Schamter, J. "Breaking the chain of Chlamydial infection," Contemp. Obstet Gynecol., Vol. 30 (1987): 146-159

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