

OnSite Chlamydia Rapid Test			
Latex rapid test	Positive	Negative	Total
Positive	32	2	34
Negative	2	74	76
<b>Total</b>	<b>34</b>	<b>77</b>	<b>110</b>

Relative Sensitivity: 94.1%, Relative Specificity: 97.4%, Overall Agreement: 96.4%

**Cross-Reactivity**

To confirm the specificity of *OnSite* Chlamydia Rapid Test, 15 serotypes were tested and demonstrated to yield Chlamydia-positive results. In addition *C. Pneumonia* and *C. psittaci* were tested with the *OnSite* Chlamydia Rapid Test and gave positive results.

Cross-reactivity with other organisms has been studied using suspensions of 10<sup>7</sup> CFU/ml (CFU — colony forming unit) and demonstrated to yield Chlamydia-negative results. *Staphylococcus aureus* was tested at 1x10<sup>7</sup> cells/test and also yielded negative results. The organisms tested are listed below:

<i>Candida albicans</i>	<i>Neisseria lactamica</i>	<i>Saccharomyces cerevisiae</i>
<i>Escherichia coli</i>	<i>Neisseria meningitides</i>	<i>Streptococcus faecalis</i>
<i>Gardnerella vaginalis</i>	<i>Neissera meningitidi</i>	<i>Streptococcus Group B</i>
<i>Klebsiella pneumoniae</i>	<i>Proteus vulgaris</i>	<i>Streptococcus pneumoniae</i>
<i>Neisseria gonorrhoeae</i>	<i>Pseudomonas aeruginosa</i>	

- 3.4 Set up timer.
- 3.5 Read the result within 15 minutes. Depending on the number of the *C. trachomatis* organisms on the swab, some positive results may be visible as soon as 1 minute. However, to confirm negative results the complete reaction time of 15 minutes is required.

**Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.**

**QUALITY CONTROL**

Using individual *OnSite* Chlamydia Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C -30°C.
5. The temperature of the test area falls outside of 15°C -30°C.

Expected results are as follows:

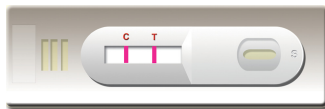
**Negative Control**

Only the C band shows color development. The T band shows no color development.



**Positive Control**

Both C and T bands show color development.



The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.

**INTERPRETATION OF ASSAY RESULT**

1. **NEGATIVE RESULT:** If only the C band is developed, the test indicates that no detectable *C. trachomatis* is present in the specimen. The result is negative.



2. **POSITIVE RESULT:** If both C and T bands are developed, the test indicates for the presence of *C. trachomatis* in the specimen. The result is positive.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.



**PERFORMANCE CHARACTERISTICS**

**Clinical Performance**

A total of 110 samples from susceptible subjects were tested by the *OnSite* Chlamydia Rapid Test and by a commercial latex rapid test. Comparisons for all subjects are shown in the following table:

**LIMITATIONS OF TEST**

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of *C. trachomatis* antigen in the swab specimen from individual subjects. **For optimal test performance, proper sample collection and storage procedures are critical.** Failure to follow the procedure may give inaccurate results.
2. The *OnSite* Chlamydia Rapid Test is limited to the qualitative detection of *C. trachomatis* antigen in human endocervical or encourethral swab specimens. The intensity of the test band does not correlate with antigen titer of the specimen.
3. The *OnSite* Chlamydia Rapid Test does not specifically differentiate between *C. trachomatis*, *C. Pneumonia* or *C. Psittaci*. Detection of *Chlamydia* is dependent on the number of organisms 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. The minimum detection level of this test may vary according to serovar.
4. A negative result for an individual subject indicates absence of detectable *C. trachomatis* antigen. However, a negative test result does not preclude the possibility of exposure to *C. trachomatis*.
5. A negative result can occur if the quantity of the *C. trachomatis* antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present in the swab specimen sampled.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

**REFERENCES**

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4. Chernesky, M.A. et al. "Detection of Chlamydia Trachomatis Antigens by Enzyme Immunoassay and Immunofluorescence in Genital Specimens from Symptomatic and Asymptomatic Men and Women," *J. Infect. Dis.*, Vol. 154 (1986): 141-148.
5. Hipp, S.S., Y. Haun and D. Murphy. "Assessment of Enzyme Immunoassay and Immunofluorescence Tests for Detection of Chlamydia Trachomatis," *J. Clin. Microbiol.*, Vol. 25 (1987): 1938-1943.
6. Schachter J. NAATs to diagnose *Chlamydia trachomatis* genital infection: A promise still unfulfilled. *Exp. Rev. Mol. Diag* 2001; 1:137-144

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**Index of Symbol**

	Attention, see instructions for use
	For <i>in vitro</i> diagnostic use only
	Catalog #
	Lot Number
	Use by
	Tests per kit
	Store between 2-30°C
	Do not reuse
	Manufacturer
	Date of manufacture