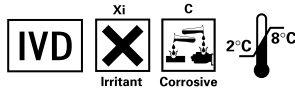


**NOTE : This Package Insert is intended for
Informational Use Only.**

Do not use for performing assay. Please refer to the most current package insert accompanying your test kit.

An Enhanced Optical ImmunoAssay for the Rapid Detection of Chlamydia Antigen from Endocervical Swabs



Intended Use

The BioStar® OIA® CHLAMYDIA assay is an Optical ImmunoAssay (OIA) for rapid qualitative detection of chlamydia antigen directly from endocervical swab specimens. This test is intended for in vitro diagnostic use to aid in the diagnosis of female *C. trachomatis* infections.

Summary and Explanation

Organisms of the genus *Chlamydia* are obligate intracellular parasites causing a variety of diseases in human and animal species. *C. pneumoniae* is now recognized as a cause of community acquired pneumonia and *C. psittaci* is known to cause disease in both humans and animals. *C. trachomatis*, characterized by its 15 distinct serovars, is responsible for a variety of diseases in humans. As obligate intracellular parasites, chlamydia require cell culture for their isolation. These methods may require up to 72 hours to obtain a result. Timely diagnosis and treatment of chlamydial infection may be facilitated by more rapid methods.

Chlamydia trachomatis is now recognized as the most prevalent cause of sexually transmitted disease in the United States with approximately four million cases being diagnosed annually.¹ Chronic infection with this organism in the female reproductive tract may lead to pelvic inflammatory disease, salpingitis, ectopic pregnancy and infertility. Infants acquiring Chlamydia at birth are at significant risk of developing conjunctivitis and pneumonia.² It has been estimated that the annualized health care costs of Chlamydia infection and its sequelae are in excess of two billion dollars per year.¹ The clinical diagnosis of Chlamydia infections in females is not precise and may be confused with other etiologies. Misdiagnosis and improper treatment may lead to chronic infection and serious sequelae. The BioStar OIA CHLAMYDIA test detects extracted genus specific chlamydia lipopolysaccharide (LPS) from cervical swabs, thus providing a significant aid in the diagnosis of Chlamydia infection.

Viable organisms are not required for the detection of chlamydia antigen with this test.

Principle of the Test

The BioStar OIA CHLAMYDIA test involves the extraction of a lipopolysaccharide antigen unique to Chlamydia species from the cervical swab specimen and the subsequent use of Optical ImmunoAssay technology for the qualitative detection of this specific antigen. The Optical ImmunoAssay technology allows for the direct visual detection of the physical change in optical thickness of molecular thin films resulting from the binding reactions. The signal is generated by the change in the reflection of light through the molecular thin films formed on an optical substrate.

White light reflected through the molecular thin film results in a predominant visual background gold color. This color will not change unless the thickness of the optical molecular thin film is changed (Figure 1). When a liquid sample containing antigen from Chlamydia species is placed on the test surface, binding occurs between the antigen and wafer surface, causing an increased thickness in the molecular thin film. An antibody-enzyme and conjugate are then added to further increase the film thickness. Once these reactions take place, the optical path through the film is changed, causing a corresponding change in the gold color to purple/blue, thereby indicating a positive result. The change in optical thickness is due to the binding of specific antigen. If the antigen is not present in the sample, no binding takes place. The original molecular thickness remains unchanged and the test surface retains its original gold color, indicating a negative result. The clear endpoint and unequivocal results observed with the optical detection system lead to a very sensitive, easily interpreted assay system.

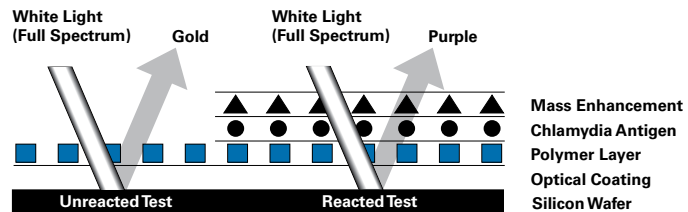


Figure 1.

Illustrative side view of the test surface showing the change in optical path due to the immunological reaction of a positive specimen.

Reagents and Materials Provided

Reagent 1A - 3.8 mL

Extraction Reagent: pH 6.0 buffer solution containing dithioerythritol and a broad spectrum protease. **Caution: Irritant.** Refrigerate at 2° to 8°C.

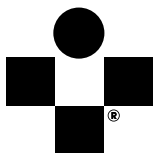
Reagent 1B - 8.0 mL

Extraction Reagent: pH 13.0 buffer solution containing chenodeoxycholic acid.

Caution: Corrosive, Irritant. Refrigerate at 2° to 8°C.

Reagent 2 - 8.0 mL

Neutralizer: pH 7.0 buffer solution containing guanidine - HCl preserved with 0.5% ProClin® 300 Preservative. **Caution: Irritant.** Refrigerate at 2° to 8°C.



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Reagent 3 - 1.0 mL

Conjugate: pH 8.0 buffered protein solution containing anti (*C. trachomatis*) antibody (murine) conjugated to Horseradish Peroxidase (HRP) and preserved with 0.5% ProClin[®] 300 solution. Refrigerate at 2° to 8°C.

Reagent 4 - 125 mL

Wash Solution: pH 7.8 saline buffer preserved with 0.1% ProClin[®] 300 preservative. Refrigerate or store at room temperature (2° to 30°C).

Substrate - 2.0 mL

pH 5.5 aqueous solution of tetramethylbenzidine (TMB) and hydrogen peroxide. Refrigerate at 2° to 8°C.

Positive Control - 1.2 mL

pH 7.0 protein solution containing inactivated *C. trachomatis* and preserved with 0.5% ProClin[®] 300 preservative. Refrigerate at 2° to 8°C.

Test Devices - 30 ea

Protein coated surface spotted with goat anti-mouse IgG as a procedural control. Refrigerate or store at room temperature (2° to 30°C).

Extraction Tubes - 30 ea

Refrigerate or store at room temperature (2° to 30°C).

Transfer Pipettes - 30 ea

Refrigerate or store at room temperature (2° to 30°C).

Swabs - 30 pkgs

Two sterile polyester swabs per package.

Refrigerate or store at room temperature (2° to 30°C).

Materials Required but not Provided

Stopwatch or timer for controlling the incubation times.

Storage and Stability

Upon receipt, the BioStar OIA CHLAMYDIA reagents should be tightly capped and stored refrigerated at 2°-8°C, or as indicated above. For user convenience, the Reagent tray may be stored at room temperature (15°-30°C) for up to 12 hours, and then returned to refrigeration (2°-8°C) after use. As indicated above, the Extraction Tubes, Wash Solution, and Test Devices may be stored at room temperature for convenience. If the materials and reagents are stored and handled properly, they are stable until the expiration date printed on the kit. Reagents should not be used beyond the expiration date printed on the label.

Precautions

The BioStar OIA CHLAMYDIA test is intended for in vitro diagnostic use only.

This test is for use with endocervical swab specimens only.

- Reagents contain up to 0.5% ProClin 300 as a preservative.
 - Reagents 1A, 1B and 2 contain materials that may cause irritation. Refer to the product MSDS for further information.
 - Reagent 1B contains corrosive 0.2N Sodium Hydroxide, pH 12.8. Refer to product MSDS for further information.
 - Do not interchange caps among reagents. Contamination may occur and compromise test results.
- A new disposable transfer pipette should be used for each specimen and test.
- Care should be taken not to touch the test surface or subject it to abrasion. This may cause scratches and potential damage to the test surface, resulting in altered test interpretation.
- All patient swabs should be handled as though they are capable of transmitting disease using universal precautions specified in the OSHA Bloodborne Pathogen Rule, Dec. 1991. Observe established precautions against microbiological hazard throughout all procedures and dispose of swabs and reagent tubes in biohazard containers in accordance with federal, state, and local regulations. Use of protective gloves is recommended. Washing hands thoroughly after performing the test is recommended.
- Do not interchange reagents from different kit lots. Do not use reagents beyond kit expiration date.

Specimen Collection, Preparation, and Storage

Proper sample collection for the detection of chlamydia antigen depends upon adherence to proper technique. Chlamydia organisms are intracellular parasites of squamocolumnar epithelial cells lining the transitional zone of the endocervix. It is necessary to collect these cells for the detection of chlamydia antigen.

Two polyester swabs in a collection tube are provided with BioStar OIA CHLAMYDIA kit for sample collection and are the only swabs validated for use with this test. To insure proper specimen collection, use the two swabs in the following manner:

- Using one swab, remove excess mucous and pus from the cervical os. Discard swab.
- Using the second swab, insert the swab into the endocervical canal and firmly rotate for approximately 10 to 20 seconds to ensure adequate sampling.

- Upon removal of swab, avoid touching the vaginal wall. Place the swab back into the collection device tube and use for transport to the lab or for storage of the specimen. Specimens may be stored dry at room temperature (15°-30°C) for up to 24 hours. If longer storage is required, specimens may be stored dry for up to 5 days at 2°-8°C. Do not freeze the swabs after sample collection.

Test Procedure

Remove refrigerated components from refrigerated storage and allow to warm at room temperature (15°-30°C) for approximately 30 minutes. Reagent 4 (Wash) will take up to 2 hours to warm to room temperature if kept refrigerated. Store Reagent 4 at room temperature (15°-30°C) after opening the kit. See Storage and Stability. Remove an Extraction Tube from the kit for each sample to be tested and place it upright in a rack or holder. Label Extraction Tubes and Test Devices with appropriate patient information. Place Test Devices on a level surface while the assay is being performed.

- Add 2 free-falling drops of Reagent 1A (Extraction Solution - **warning: irritant**) into the Extraction Tube.
- Add patient swab to the Extraction Tube and thoroughly mix the solution with the swab so that the liquid migrates into the fiber tip. Wait for a minimum of 2 minutes but not more than 3 minutes. The solution should be yellow.
Note: Blood on swabs may interfere with color changes.
Note: Thorough mixing is essential to ensure proper extraction of specimen.
- Hold the swab shaft to the side and add 6 free-falling drops of Reagent 1B (Extraction Solution) directly into the Extraction Tube. **Warning: Irritant, Corrosive.** Avoid contact with eyes and/or mucous membranes. Thoroughly mix the solution with the swab by rubbing swab on the side of the tube. The solution will change to a purple/blue color. Allow the swab to stand in the Extraction Tube for a minimum of 2 minutes but not more than 3 minutes.
Note: Blood on swabs may interfere with color changes.
- Holding the swab shaft to the side, add 6 free-falling drops of Reagent 2 (Neutralizer - **warning: irritant**) directly into the Extraction Tube. Rub swab vigorously on side of tube while mixing contents. Remove swab while squeezing tube to express all liquid from swab. The solution will change to a red/orange color. **After neutralization, the samples may be stored for a maximum of 2 hours at room temperature.**
Note: Blood on swabs may interfere with color changes.
- Use a clean Transfer Pipette to mix extracted sample thoroughly then place 1 drop of the extracted sample directly onto the center of the gold, reflective surface of the corresponding Test Device. Wait for a minimum of 5 minutes but not more than 6 minutes.
- Add one drop of Reagent 3 (Conjugate) directly to sample drop, taking care not to touch the sample drop and contaminate the dropper tip. Wait for 5 minutes, but not more than 6 minutes.
- Wash the test surface vigorously with a steady stream of Reagent 4 (Wash Solution), taking care not to exceed the capacity of the absorbent material surrounding the test surface.
Note: Vigorous washing will aid in obtaining a clean test surface.
- Confirm that the blotter in the Test Device lid is in position I. Close the Test Device at the corners. Leave Test Device closed for at least 10 seconds to remove residual moisture from the surface.
Note: Blot with a clean surface each time blotting is necessary. If in position II for first blot, move to position I for the second blot. Repeated blotting in the same position or applying pressure in the center when closing test device may compromise test results.
- Open the lid and apply 1 drop of Substrate directly onto the center of the test surface of the Test Device and let stand for at least 5 minutes but not more than 6 minutes.
Note: Do not cover entire surface of the Test Device with Substrate. The gold, unreacted area surrounding the reaction circle serves as a negative Internal Control and as a reference for comparing signal intensity.
- Repeat Step No. 7, washing the test surface vigorously with Reagent 4 (Wash Solution). See Procedure Note in Step No. 7.
- Move the blotter in the lid of the Test Device to position II. Close the test device at the corners. Leave closed for at least 10 seconds. See Procedure note in Step No. 8. Open the lid and examine the test surface for a color change. (See **Interpretation of Test Results.**)

Interpretation of Test Results

Upon completion of each test, the test surface should be examined under a bright light source. The light must be reflected off the test surface to observe the test results.

A positive Internal Control dot is present on each test surface. It appears as a small blue/purple dot in the center of the test surface upon completion of each test. A negative test result will show only the positive Internal Control dot. A positive test result will show the positive Internal Control dot within the reaction circle. With very strong positive results, the positive Internal Control dot may be less apparent within the reaction circle.

A positive result should be reported as positive for the presence of chlamydia antigen. A negative result should be reported as a presumptive negative for chlamydia antigen. Examine under bright light source to observe results.

Positive or Weak Positive Result

Filled-in blue/purple colored reaction circle of any intensity appears in the center of the Test Device surface. Blue/purple positive Internal Control dot may not be apparent with strongly positive results.



Negative Result:

No filled-in blue/purple colored reaction circle of any intensity appears on the test surface. The blue/purple positive Internal Control dot is in the center of the Test Device.



Invalid Result:

No blue/purple positive Internal Control dot or a solid blue/purple color over entire test surface.



If an invalid result occurs, repeat the procedure following the instructions carefully. If an invalid result is obtained again, a test result can not be reported.

- BioStar Technical Services at (303) 530-3888 or (800) 637-3717.

The reacted test surface and the color change associated with a positive reaction will not deteriorate over time; therefore, the Test Device may be considered a permanent record. If a Test Device is to be saved for reference, the blotting material in the lid should be removed and disposed of in a biohazard container. The device should be closed for storage.

Quality Control

Quality control procedures are designed to monitor reagent performance and ensure the accuracy of reported test results. Each laboratory should refer to the quality assurance plan established for their laboratory. Quality control procedures should be performed in accordance with the requirements of each laboratory's accrediting organization.

Built-in Control features include:

Reagent controls: The color change from yellow to purple/blue during the extraction process indicates that the proper reagents have been added and mixed. The internal extraction reagent control serves as an indicator that proper pH conditions have been established and reagents are functioning properly. Following extraction, addition of the neutralizer (Reagent 2) will change the color of the extracted sample from purple/blue to red/orange indicating proper conditions for assay function.

Internal Controls: Each BioStar OIA CHLAMYDIA Test Device has a built-in positive Internal Control dot which appears as a small blue/purple dot in the center of each test surface following the completion of the test. The appearance of the positive Internal Control dot ensures the integrity of the detection reagent and that the test detection steps were performed properly. The gold unreacted test surface surrounding the positive Internal Control dot or positive patient sample is a negative Internal Control and acts as a background reference, and indicates there were no immunologically interfering substances in the specimens. Because the Internal Controls are performed with every patient sample, it is a - BioStar recommendation to document the results of these controls for each sample performed (Quality Control Log Sheets are available upon request from - BioStar).

Positive and Negative External Controls

To use the Positive Control provided in the BioStar OIA CHLAMYDIA kit, thoroughly mix the contents of the dropper bottle by inverting it 7-10 times. Place one drop of the Positive Control into an Extraction Tube after Reagent 1A has been added. Proceed with the extraction protocol in the same manner as with a patient specimen according to the Test Procedure, excluding the swabs. The Positive Control should yield a positive test result with the BioStar OIA CHLAMYDIA test. If a positive test result is not obtained, repeat the test by preparing another positive control and carefully following the procedure. Good laboratory practices suggest that External Controls, when performed, should be tested in the same manner as patient samples. A positive control swab may be prepared by adding 2 drops of Positive Control to a clean swab. A negative control swab may be prepared by absorbing 2 drops of a cell suspension of a non-Chlamydia organism, such as Group B streptococcus, ATCC strain 12386, or BioStar OIA CHLAMYDIA wash solution onto a clean swab. Both control swabs should be processed in the same manner as patient samples, following the test procedure instructions. The Negative Control should produce a negative result.

Remedial Actions

When External Controls fail to perform as expected, test results from patient specimens should be considered invalid and not reported. Controls may be repeated and if results are still invalid, contact Technical Services at the phone number listed below. When Internal Controls fail to meet the requirements for a valid test (see Interpretation of Test Results), the patient result should

be considered invalid, and results should not be reported. Each laboratory should evaluate and perform remedial actions according to their established quality assurance program prior to reporting patient results. The test may be repeated within two hours, using the same patient test solution. Repeat the assay procedure, beginning with Step No. 5 through Step No. 11 in **Test Procedure**, using a new Test Device. If invalid results are obtained a second time, contact - BioStar Technical Services at (303) 530-3888 or (800) 637-3717.

Limitations

As with other diagnostic procedures, the results obtained with this kit should be used as an adjunct to clinical observations and information available to the physician. The BioStar OIA CHLAMYDIA test is a qualitative method intended for use in determining the presence of chlamydia antigen in cervical swab specimens only.

- The BioStar OIA CHLAMYDIA test is intended for use only with endocervical specimens collected with - BioStar swabs. Performance of the BioStar OIA CHLAMYDIA test with other clinical samples has not been determined.
- **Negative results may occur due to inadequate sample collection**, or the use of swab collection systems other than those provided with the BioStar OIA CHLAMYDIA kit. Negative results may also occur if the specimen contains sufficiently low numbers of microorganisms to fall below the level of sensitivity of the test. If a negative test result is obtained and clinical symptoms persist, the initial result should be confirmed by repeating the test with another specimen.
- The BioStar OIA CHLAMYDIA test results are presumptive for all negative results and for positive results in cases where the diagnosis could lead to adverse psychosocial impact.
- Reliable results are dependent on adequate specimen collection. Specimen adequacy can only be assessed by microscopic visualization of columnar epithelial cells in genital tract specimens.
- As with other non-culture methods, the BioStar OIA CHLAMYDIA test should not be used in the investigation of suspected sexual abuse or other medical-legal indications.
- The predictive value of a positive test decreases when prevalence decreases. Interpretation of positive results in a low risk patient population should be made with caution.
- The BioStar OIA CHLAMYDIA test should not be used to determine therapeutic success or failure as residual antigen may be present after therapy.
- Betadine® medicated douche and JOHNSON & JOHNSON K-Y JELLY® lubricant were tested and shown not to interfere with the performance of this product. Gynol II® contraceptive jelly was found to interfere with positive assay signal if in a concentration of >1.0% of the total specimen volume. The above mentioned products do not cause false positive reactions with this assay. Grossly bloody specimens may interfere with a positive test result. It is unknown what effects other products may have on the BioStar OIA CHLAMYDIA test performance.
- The BioStar OIA CHLAMYDIA test will not specifically differentiate *C. trachomatis*, *C. pneumoniae*, or *C. psittaci*.
- Detection of chlamydia is dependent on the number of organisms (elementary and/or reticulate bodies) present in specimens. This may be affected by specimen collection methods and patient factors such as age, history of STD, and presence of symptoms.

Expected Results

The overall incidence of chlamydia disease in women has been reported to be minimally 5%.⁴ Risk factors such as age less than 25 years and multiple sex partners are indicators of possible chlamydia infections.⁵ A significant number of women may be asymptomatic and may be at risk for chronic ascending infection.⁶ In the case of pregnant women, there is a potential risk of passage of chlamydia to the newborn. A positive BioStar OIA CHLAMYDIA test indicates the presence of chlamydia antigen. In conjunction with clinical observations, a positive test may indicate the use of appropriate antimicrobial therapy.

Performance Characteristics

The BioStar OIA CHLAMYDIA test performance was compared to standard primary McCoy cell culture isolation techniques for *C. trachomatis*. A two center study was performed in which endocervical swabs from women with and without symptoms were taken and processed for cell culture, BioStar OIA CHLAMYDIA test and direct fluorescent antibody (DFA - Syva MicroTrak®) (306 samples, Site 1 only). In all cases, cell culture monolayers were stained at 48 to 72 hours with Chlamydia specific fluorescent monoclonal antibody for the detection of inclusion bodies. Specimens for cell culture were transported to the site's laboratory where they were placed in cell culture within 24 hours of sampling. BioStar OIA CHLAMYDIA swabs were stored at 2°C-8°C and tested within 5 days of receipt of the specimen.

Of 606 samples tested, 49 were culture positive. Of these, 40 were BioStar OIA CHLAMYDIA positive. There were an additional 6 samples that were culture negative, BioStar OIA CHLAMYDIA positive. All 6 of these samples were confirmed to be true positives by DFA analysis of culture transport media or directly from the patient specimen taken for DFA. Of the 551

BioStar® OIA® CHLAMYDIA

samples negative by BioStar OIA CHLAMYDIA assay and culture, three were positive by DFA. Considering all culture positive samples or DFA confirmed BioStar OIA CHLAMYDIA positive samples as true positives the resulting overall sensitivity and specificity of BioStar OIA CHLAMYDIA test are 83.6% and 100%.

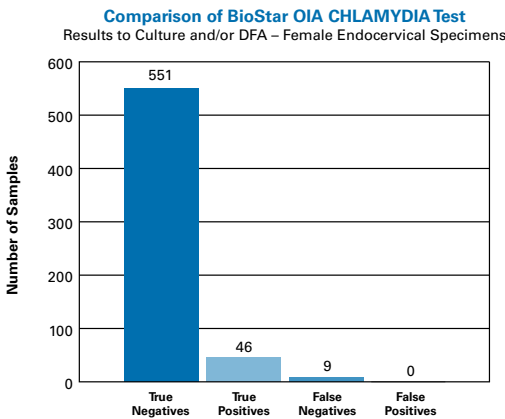
Performance Summary

Performance Summaries Female Endocervical Specimen					
Culture	Positive	Negative	Negative	Positive	Negative
OIA CHLAMYDIA	Positive	Positive	Positive	Negative	Negative
DFA ¹	Not Done	Positive	Negative	Not Done	Not Done
Interpretation ²	(TP)	(TP)	(FP)	(FN)	(TN)
Site 1	26	5	0	6	269
Site 2	14	1	0	3	282
Total	40	6	0	9	551

1. DFA performed on specimen or culture transport medium.
2. Interpretation of results as compared to culture/DFA: TP = True Positive, FP = False Positive, FN = False Negative, TN = True Negative.

Performance by Site Female Endocervical Specimen					
Site	Prevalence	Sensitivity (95% C.I.)	Specificity (95% C.I.)	PPV ³	NPV ⁴
1	12.1%	83.8% (71.9-95.7)	100% (98.6-100)	100.0%	97.8%
2	6.0%	83.3% (58.6-96.4)	100% (98.7-100)	100.0%	98.9%
Total	9.1%	83.6% (73.9-93.4)	100% (99.3-100)	100.0%	98.3%

3. Positive Predictive Value calculated using Baye's theorem.
4. Negative Predictive Value calculated using Baye's theorem.



Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of the BioStar OIA CHLAMYDIA test, the following organisms were grown in culture and tested at a concentration of at least 10⁷ organisms/test. Cell density was confirmed by plating an aliquot of the suspension, growing the organism and counting the number of colonies formed. None of the organisms listed below gave a positive result in the BioStar OIA CHLAMYDIA test.

Staphylococcus aureus
(Protein A producer)
Staphylococcus aureus
Enterococcus faecalis
Klebsiella pneumoniae
Pseudomonas aeruginosa
Escherichia coli
Lactobacillus fermentum
Proteus mirabilis
Salmonella choleraesuis
subspecies *choleraesuis*
serotype: *Minnesota*
Salmonella choleraesuis
subspecies *choleraesuis*
serotype: *Minnesota (R595)*
Salmonella choleraesuis
subspecies *choleraesuis*
serotype: *typhimurium*

Gardnerella vaginalis
Streptococcus Group A
Streptococcus Group B
Streptococcus Group F
Streptococcus Group G
Haemophilus influenzae
Acinetobacter calcoaceticus
Candida glabrata
Candida albicans
Neisseria gonorrhoeae
Moraxella lacunata
Peptostreptococcus productus
Ureaplasma urealyticum
Mycoplasma hominis

In addition, these organisms were cultured and tested and found to not interfere with the test:
HSV-1, HSV-2 and *Trichomonas vaginalis*

The fifteen serovars of *C. trachomatis* as well as representative strains of *C. psittaci* and *C. pneumoniae* have been tested on the BioStar OIA CHLAMYDIA test and have been shown to be reactive; the limits of detection ranged from 23 to 1245 EB's per test.

Reproducibility

Clinical Sites

The two clinical sites performed reproducibility studies on four coded antigen (inactivated EB's in stabilizing buffer) samples representing four levels of reactivity in the BioStar OIA CHLAMYDIA test. Each site performed testing on each sample six times over the course of the clinical study. There was 100% agreement at both sites between test results and expected results.

Physician's Office Testing

To assess the ability of personnel in a physician's office setting to perform the BioStar OIA CHLAMYDIA test, 20 coded swabs spiked with varying levels of inactivated EB's as well as swabs with buffer control were run in a blind fashion. These samples included samples that gave borderline reactivity in the BioStar OIA CHLAMYDIA test. The office personnel were trained on BioStar OIA CHLAMYDIA technique - BioStar staff. Overall, the agreement between test results and expected results was 92%.

Key to Component labeling

LOT	lot number	store between x°C and y°C
manufactured by		consult Package Insert
2004-01	kit or component expires January 31, 2004	
corrosive	harmful	irritant
REF	catalog number	IVD for <i>in vitro</i> diagnostic use
sufficient for [n] tests	do not reuse	
CONTROL +	CONTROL -	Positive and Negative Controls
STERILE EO	sterilized using ethylene oxide	
EC REP	authorized representative in the European community	

References

- Washington, Eugene A., et al. "Chlamydia trachomatis Infections in the United States. What are they Costing Us?" *JAMA*, 257:2070, 1987.
- Schachter, J., et al. "Prospective Study of Chlamydial Infection in Neonates." *Lancet*, August 25, 1979, Vol. 2.
- Pfaff, J.A. "Chlamydial Antigen Testing on Female Patients Presenting to Emergency Department." *Military Medicine*. Vol. 156, July 1991.
- "Recommendations for the Prevention and Management of Chlamydia trachomatis Infections, 1993." *Morbidity and Mortality Weekly Report*. Vol 42, Aug. 6, 1993.
- "Chlamydia Prevalence and Screening Practices - San Diego County, California, 1993." *Morbidity and Mortality Weekly Report*. Vol. 43, May 27, 1994.
- Cates WW, Wasserheit, J.N. "Genital Chlamydial Infections: epidemiology and reproductive sequelae." *Am. J. Obstet. Gynecol.* 164:1771, 1987.
- Colton, T. "Statistics in Medicine." Little Brown and Company. 1974.

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Betadine® is a registered trademark of Purdue Products, L.P.
Syva MicroTrak® is a registered trademark of Syva Company.

Patents Issued: U.S. Patents 4,558,012; 5,468,606; 5,482,830; 5,418,136; 5,541,057; 5,550,063; 5,629,214; 5,639,671; 5,955,377 and additional patents pending. Corresponding rights granted or pending elsewhere.

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