

JAN 27 2005

2.0 SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K043072.

GEN-PROBE® APTIMA® Assay for *Chlamydia trachomatis*

General Information

Submitted By: Gen-Probe Incorporated 10210 Genetic Center Drive San Diego, California 92121 phone: (858) 410-8000 fax: (858) 410-8622	Company Contact: Alan Maderazo, Ph.D., RAC Regulatory Affairs Specialist phone: (858) 410-8332 fax: (858) 410-8622 e-mail: alanma@gen-probe.com
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Trade Name: GEN-PROBE® APTIMA® Assay for *Chlamydia trachomatis*

Common or Usual Name: rRNA target-amplified nucleic acid probe test for the *in vitro* diagnostic detection of *Chlamydia trachomatis*

Classification Name: DNA Probe, Nucleic Acid Amplification, Chlamydia

Classification Code: Class 1

Medical Specialty: Microbiology

Product Code: MKZ

Registration Number: CFR 866.3120

Device Class: 1

Description: Reagents used to identify chlamydia directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on these diseases. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

Substantially Equivalent Devices:

GEN-PROBE® APTIMA® Combo 2 Assay

Becton Dickenson ProbeTec™ ET System CT and CT/GC Assays

Device Description

The APTIMA Assay for *Chlamydia trachomatis* is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection of rRNA from *Chlamydia trachomatis* in clinician-collected endocervical, vaginal and male urethral swab specimens, patient-collected vaginal swab specimens, and female and male urine specimens. The APTIMA Assay for *Chlamydia trachomatis* (APTIMA CT Assay) may be used to test specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.

Background on the Disease and Principle of the Test

The Disease

Chlamydia trachomatis (CT) infections are one of the most common sexually transmitted infections worldwide. In the United States alone, an estimated 783,242 new cases of *C. trachomatis* infections were reported in 2001 (CDC, 2003).

Chlamydiae are nonmotile, gram-negative, obligate intracellular bacteria. The *C. trachomatis* species is comprised of fifteen serovars that can cause disease in humans. The serovars D through K are the major cause of genital chlamydial infections in men and women (Schachter, 1985). Children born to infected mothers are at significantly higher risk for inclusion conjunctivitis and chlamydial pneumonia (Beem and Saxon, 1977; Frommell et al., 1979; Schachter and Grossman, 1981).

Screening for the presence of these diseases is the cornerstone for prevention strategies. A large number of these cases may be asymptomatic or have symptoms that are not specific; this makes reduction of the prevalence of chlamydial and gonococcal infections difficult. An accurate and prompt diagnosis of these infections is important to ensure appropriate patient

management, to prevent disease complications and their associated medical costs, and to control transmission to uninfected partners.

Historical and Conventional Methods

Historically, several methods for *C. trachomatis* detection have been utilized in the clinical laboratory, including cell culture, direct fluorescent antibody testing, and enzyme immunoassay. More recent methodologies for *C. trachomatis* detection include direct DNA probe assays and nucleic acid amplification tests (NAATs). Cell culture was once considered to be the “gold standard” for detection of *C. trachomatis*. Culture is quite specific, but recent publications have demonstrated that NAATs have a higher clinical sensitivity than culture (Buimer et al., 1996; Crothfelt et al., 1998; Jaschek et al., 1993; Stary et al., 1998). Due to its lower clinical sensitivity and variable performance between laboratories, culture has been replaced in many laboratories by direct DNA probe and NAATs.

First generation NAATs for *C. trachomatis* have technological issues that have limited their performance. These issues include cumbersome specimen processing and specimen inhibition that can yield false negative results (Chernesky et al., 1996; Goessens et al, 1997; Mahony et al., 1998; Peterson et al., 1997; Toye et al, 1998; Vincelette et al., 1999). The GEN-PROBE APTIMA Assay for *Chlamydia trachomatis* (APTIMA CT Assay) is a second generation NAAT that utilizes target capture, Transcription-Mediated Amplification (TMA), and Hybridization Protection Assay (HPA) technologies to streamline specimen processing, amplify target rRNA, and detect amplicon, respectively. Recent studies comparing performance and specimen inhibition of various amplification systems have demonstrated the benefits of target capture, TMA, and HPA (Chong et al., 2003; Gaydos et al, 2003).

Patient Care and Public Health Implications

C. trachomatis infections are one of the most common sexually transmitted infections worldwide with an estimated 783,242 new cases of *C. trachomatis* infections were reported in

2001 in the United States alone, (CDC, 2003). The *C. trachomatis* species is comprised of fifteen serovars that can cause disease in humans. The serovars D through K are the major cause of genital chlamydial infections in men and women (Schachter, 1985). *C. trachomatis* can cause nongonococcal urethritis, epididymitis, proctitis, cervicitis, acute salpingitis, and Pelvic Inflammatory Disease (PID) (Cates and Wasserheit, 1991; Holmes et al., 1975; Schachter 1978; Schachter et al., 1975). *C. trachomatis* infections are often asymptomatic in both males and females. Children born to infected mothers are at significantly higher risk for inclusion conjunctivitis and chlamydial pneumonia (Beem and Saxon, 1977; Frommell et al., 1979; Schachter and Grossman, 1981).

Treatment of symptomatic patients is only partially effective because of the large percentage of asymptomatic patients.

Intended Use

The APTIMA Assay for *Chlamydia trachomatis* is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) in clinician-collected endocervical, vaginal and male urethral swab specimens, patient-collected vaginal swab specimens*, and female and male urine specimens. The assay may be used to test specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.

*Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal swab specimen collection kit is not for home use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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JAN 27 2005

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Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121-4362

Re: k043072
Trade/Device Name: GEN-PROBE® APTIMA® Assay for *Chlamydia trachomatis*
Regulation Number: 21 CFR 866.3120
Regulation Name: Chlamydia serological reagents
Regulatory Class: Class I
Product Code: MKZ
Dated: November 5, 2004
Received: November 8, 2004

Dear Dr. Maderazo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

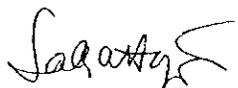
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043072

Device Name: GEN-PROBE® APTIMA® Assay for *Chlamydia trachomatis*

Indications For Use:

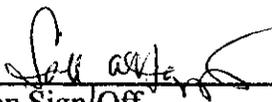
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Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign/Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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