K053446

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

JUL 2 6 2006

General Information

Submitted By:	Company Contact:
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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:

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 Device:

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

Device Description

Clearance of this premarket notification extends the clinical performance claims of the commercially available GEN-PROBE APTIMA Assay for *Chlamydia trachomatis* to include PreservCyt liquid Pap specimens (collected and processed by the Cytyc ThinPrep 2000 Processor) as acceptable testing specimens. The ancillary kit formulated for this specific application is the commercially available GEN-PROBE APTIMA Specimen Transfer Kit. The components of the APTIMA Specimen Transfer Kit include: (1) a transport tube containing transport media with a penetrable cap and (2) specific instructions for use regarding decontamination and specimen processing procedures. The APTIMA Specimen Transfer Kit may only be used in conjunction with GEN-PROBE APTIMA Assays for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae.*

Intended Use

APTIMA Assay for *Chlamydia trachomatis* package insert:

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,[1] and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens collected in the PreservCyt® Solution and processed with the Cytyc ThinPrep® 2000 System. The assay may be used to test specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.

[1] 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.

Ancillary Kit package insert:

The GEN-PROBE APTIMA Specimen Transfer Kit is only for use with GEN-PROBE APTIMA Assays for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*. The GEN-PROBE APTIMA Specimen Transfer Kit allows for APTIMA Assay testing of gynecological specimens collected and processed by the Cytyc ThinPrep 2000 Processor according to the instructions provided.

APTIMA Assay for *Chlamydia trachomatis*

A complete description of the APTIMA Assay for *Chlamydia trachomatis* is provided in the commercialized package insert.

Summary of Non-Clinical (Analytical Laboratory) Performance Data

Limit of Detection (Analytical Sensitivity)

C. trachomatis analytical sensitivity (limit of detection) was determined by directly comparing dilutions of CT organisms in cell culture and in the APTIMA CT assay. The analytical sensitivity claim for the assay is one Inclusion-Forming Unit (IFU) per assay (7.25 IFU/swab, 5 IFU/mL urine, and 9.75 IFU/mL PreservCyt Solution liquid Pap) for all 15 CT serovars. However, dilutions of less than one IFU/assay of all serovars tested positive.

Analytical Specificity

A total of 154 culture isolates were evaluated using the APTIMA CT Assay. These isolates included 86 organisms that may be isolated from the urogenital tract and 68 additional organisms that represent a phylogenetic cross-section of organisms. The tested organisms included bacteria, fungi, yeast, parasites and viruses. All organisms except *C. psittaci, C. pneumoniae, U. urealyticum* and the viruses were tested at $1.0x10^6$ cells/assay in Kova-trol/Urine Transport Media and 60 organisms were tested in Swab Transport Media. The Chlamydia and Neisseria organisms were tested in the PreservCyt Solution media. *C. psittaci* VR601 was tested at $8x10^4$ cells/assay and *C. psittaci* VR125 was tested at $1x10^5$ cells/assay. *C. pneumoniae*was tested at $4x10^3$ cells/assay and U. urealyticum was tested at $6.7x10^6$ cells/assay. The viruses were tested as follows: (a) herpes simplex virus I: $2.5x10^4$ $TCID_{50}$/assay, (b) herpes simplex virus II: 6.0x104 $TCID_{50}$/assay, (c) human papillomavirus 16: $2.9x10^6$ DNA copies/assay and (d) cytomegalovirus: $4.8x10^5$ cells/assay. The list of organisms tested is shown in Table 1.

Table 1 - APTIMA CT Assay Analytical Specificity

ORGANISM	ORGANISM	ORGANISM
Achromobacter xerosis	*Escherichia coli*	*Neisseria mucosa* (3)
Acinetobacter calcoaceticus	*Flavobacterium meningosepticum*	*Neisseria sicca* (3)
Acinetobacter Iwoffi	*Fusobacterium nucleatum*	*Neisseria subflava* (14)
Actinomyces israelii	*Gardnerella vaginalis*	*Neisseria perflava*
Actinomyces pyogenes	*Gemella haemolysans*	*Neisseria polysaccharea*
Aerococcus viridans	*Haemophilus ducreyi*	*Paracoccus denitrificans*
Aeromonas hydrophila	*Haemophilus influenzae*	*Peptostreptococcus anaerobius*
Agrobacterium radiobacter	Herpes simplex virus I	*Peptostreptococcus productus*
Alcaligenes faecalis	Herpes simplex virus II	*Plesiomonas shigelloides*
Bacillus subtilis	Human papilloma virus 16	*Propionibacterium acnes*
Bacteriodes fragilis	*Kingella dentrificans*	*Proteus mirabilis*
Bacteriodes ureolyticus	*Kingella kingae*	*Proteus vulgaris*
Bifidobacterium adolescentis	*Klebsiella oxytoca*	*Providencia stuartii*
Bifidobacterium brevi	*Klebsiella pneumoniae*	*Pseudomonas aeruginosa*
Branhamella catarrhalis	*Lactobacillus acidophilus*	*Pseudomonas fluorescens*
Brevibacterium linens	*Lactobacillus brevis*	*Pseudomonas putida*
Campylobacter jejuni	*Lactobacillus jensonii*	*Rahnella aquatilis*
Candida albicans	*Lactobacillus lactis*	*Rhodospirillum rubrum*
Candida glabrata	*Legionella pneumophila* (2)	*Saccharomyces cerevisiae*
Candida parapsilosis	*Leuconostoc paramensenteroides*	*Salmonella minnesota*
Candida tropicalis	*Listeria monocytogenes*	*Salmonella typhimurium*
Chlamydia pneumoniae	*Micrococcus luteus*	*Serratia marcescens*
Chlamydia psittaci (2)	*Moraxella lacunata*	*Staphylococcus saprophyticus*
Chromobacterium violaceum	*Moraxella osloensis*	*Staphylococcus aureus*
Citrobacter freundii	*Morganella morganii*	*Staphylococcus epidermidis*
Clostridium perfringens	*Mycobacterium smegmatis*	*Streptococcus agalactiae*
Corynebacterium genitalium	*Mycoplasma genitalium*	*Streptococcus bovis*
Corynebacterium xerosis	*Mycoplasma hominis*	*Streptococcus mitis*
Cryptococcus neoformans	*N. meningitidis* Serogroup A	*Streptococcus mutans*
Cytomegalovirus	*N. meningitidis* Serogroup B	*Streptococcus pneumoniae*
Deinococcus radiodurans	*N. meningitidis* Serogroup C (4)	*Streptococcus pyogenes*
Derxia gummosa	*N. meningitidis* Serogroup D	*Streptococcus salivarius*
Eikenella corrodens	*N. meningitidis* Serogroup Y	*Streptococcus sanguis*
Enterobacter aerogenes	*N. meningitidis* Serogroup W135	*Streptomyces griseinus*
Enterobacter cloacae	*Neisseria cinerea* (4)	*Trichomonas vaginalis*
Entercoccus avium	*Neisseria dentrificans*	*Ureaplasma urealyticum*
Entercoccus faecalis	*Neisseria elongata* (3)	*Vibrio parahaemolyticus*
Entercoccus faecium	*Neisseria flava*	*Yersinia enterocolitica*
Erwinia herbicola	*Neisseria flavescens* (2)	
Erysipelothrix rhusiopathiae	*Neisseria lactamica* (9)	

(n) = number of strains tested
All organisms tested produced a negative result in the APTIMA CT Assay.

Interference Studies

The following interfering substances were individually spiked into swab, PreservCyt liquid Pap and/or urine specimens: 10% blood, contraceptive jelly, spermicide, moisturizer, hemorrhoidal anesthetic, body oil, powder, anti-fungal cream, vaginal lubricants, feminine spray and leukocytes ($1x10^6$ cells/mL). The following interfering substances were individually spiked into urine specimens: 30% blood, urine analytes, protein, glucose, ketones, bilirubin, nitrate, urobilinogen, pH 4 (acidic), pH 9 (alkaline), leukocytes ($1x10^6$ cells/mL), cellular debris, vitamins, minerals, acetaminophen, aspirin and ibuprofen. All were tested for potential assay interference in the absence and presence of CT at the estimated rRNA equivalent of 1 cell/assay (5 fg/assay). The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism. No interference was observed with any of the tested substances. No inhibitors of amplification were observed in the APTIMA CT Assay.

Recovery

Escherichia coli, Gardnerella vaginalis, *Lactobacillus acidophilus*, *Bacteroides ureolyticus,* and *Staphylococcus epidermidis* (1×10^8 cells/assay) were added to samples containing the rRNA equivalent of approximately one CT IFU (5 fg). These additions did not interfere with the amplification and detection of CT rRNA using the APTIMA CT Assay.

Liquid Pap Specimen Stability Studies

Data to support the recommended shipping and storage conditions for PreservCyt Solution liquid Pap samples were generated with negative processed and unprocessed liquid Pap samples. For the unprocessed samples, four pools of PreservCyt Solution samples were tested after being stored in the Cytyc PreservCyt Solution vial. Each specimen pool was spiked with 1-10 IFU CT/assay, held at 2°C, 10°C, and 30°C, then tested at baseline and on days 5, 7, 8, 14, 18, 21, 25 and 36 depending on the storage

temperature. All of the spiked samples were positive for CT at all times and temperatures.

For the processed samples, four pools of PreservCyt Solution samples were used to determine processed specimen stability at 2°C to 30°C. Each negative sample pool was spiked with 1-10 IFU CT/assay, then tested at baseline. Prior to processing, the PreservCyt Solution samples were stored at 30°C for seven (7) days to simulate the time lapse between sample collection, Pap processing and shipment to a microbiology testing lab. After seven days at 30°C, 1 mL aliquots of each pool were transferred to an APTIMA Specimen Transfer Tube and tested at baseline before being placed at 2°C, 10°C, and 30°C. The processed samples were then tested for 17 days stored at 30°C and 36 days stored at 2°C to 10°C. All of the spiked samples were positive for CT at all times and temperatures.

Data to support longer storage conditions were generated from four pools of negative processed PreservCyt Solution samples tested at below freezing temperatures. Each pool was spiked with 1-10 IFU CT/assay, then tested at baseline. Each pool was first placed at 30°C for 14 days and then stored at -20°C or -70°C over the course of 106 days. All of the spiked samples were positive for CT at all times and temperatures.

Precision

PreservCyt specimen within-laboratory precision with the ACT Assay was determined by spiking PreservCyt vials with 20 CT IFU per vial (0.1 IFU per reaction) and 100 CT IFU per vial (0.5 IFU per reaction). Vials containing 1,000 CT IFU per vial (5 IFU per reaction) and unspiked PreservCyt vials were tested as positive and negative controls. Ten vials spiked at each IFU level and ten unspiked vials were divided between two operators. The operators vortexed the vials and then transferred 14 aliquots (1.0 mL each) per vial into 14 APTIMA Transfer Tubes as per the APTIMA Specimen Transfer Kit package insert. The operators were blinded to the samples' titers. Each of the resulting Pap-STM samples was tested once in the ACT Assay. A total of five runs were

performed over a five-day period for 140 results at each IFU level. The results are summarized in Table 2.

Table 2: APTIMA CT Assay Within-Laboratory Precision Data for PreservCyt Using a 4-Member Precision Panel Containing 0 to 1000 IFU/20 mL of CT Cells.

Panel Member	IFU/20mL PreservCyt	IFU/ rxn	n	Agreed	% Agrmt.	Mean RLU (x1000)	Within-Operator		Between-Day		Between-Operator		Total	
							SD (x1000)	CV (%)	SD (x1000)	CV (%)	SD (x1000)	CV (%)	SD (x1000)	CV (%)
A	20	0.1	140	140	100	6501.7	734.8	11.3	0	0.0	546.9	8.4	916	14.1
B	100	0.5	140	138*	98.6	6337.7	1054.7	16.6	0	0.0	947.2	14.9	1417.6	22.4
C	1000	5	140	140	100	6521.9	909	13.9	247.1	3.8	393.9	6	1021	15.7
D	0	0	140	140	100	1.2	0.8	N/A	0	N/A	0.4	N/A	0.9	N/A

* discordant results were one negative result and 1 equivocal result

Note: Variability from some factors may be numerically negative, which can occur if the variability due to those factors is very small. When this occurs, the variability as measured with SD and %CV is set to zero (16). N/A = not applicable for negative panel members. Operator = Run. Samples with discordant results were included in the signal variability analysis.

PreservCyt Liquid Pap Specimen Clinical Study Results

A prospective multi-center clinical study was conducted to evaluate the use of the PreservCyt Solution (a component of the ThinPrep 2000 System) as an alternative medium for gynecological specimens for the detection of CT by the APTIMA CT Assay. One thousand six hundred forty-seven (1,647) symptomatic and asymptomatic female subjects attending OB/GYN, family planning, public health, women's, and STD clinics were evaluated in the clinical study. Of the 1,647 evaluable subjects, 1,288 were asymptomatic subjects and 359 were symptomatic subjects. Subjects were enrolled from sites with CT prevalence that ranged from 2.8% to 14.0%.

Two specimens were collected from each eligible subject: one PreservCyt Solution liquid Pap specimen and one endocervical swab specimen. PreservCyt Solution liquid Pap specimens were collected with the spatula/cyto-brush or a broom-like brush cervical sampling device. The distribution of cervical sampling devices is summarized in Table 3 by specimen collection site and overall.

PreservCyt Solution liquid Pap specimens were processed in accordance with the ThinPrep 2000 Processor Operator's Manual and APTIMA Specimen Transfer Kit Package Insert. After processing the PreservCyt Solution liquid Pap specimen with the ThinPrep 2000 Processor, the specimen was transferred into the APTIMA Specimen Transfer Kit for testing with the APTIMA CT Assay.

Sensitivity and specificity of the APTIMA CT Assay in PreservCyt Solution liquid Pap specimens were calculated by comparing results to a patient infected status algorithm. The algorithm included APTIMA Combo 2 Assay and APTIMA CT Assay results in endocervical swab specimens. Both reference NAATs were required to be positive to establish an infected patient status. At least one reference NAAT was required to be negative to establish a non-infected patient status. Table 4 summarizes the frequency of test outcomes for the two reference NAATs.

Table 5 shows the sensitivities and specificities of the APTIMA CT Assay by symptom status and overall. Overall sensitivity was 95.6% (86/90). In symptomatic and asymptomatic subjects, sensitivities were 96.7% (29/30) and 95.0% (57/60), respectively. Overall specificity was 98.8% (1539/1557). In symptomatic and asymptomatic subjects, specificities were 98.8% (325/329) and 98.9% (1214/1228), respectively.

Table 6 shows the sensitivities and specificities of the APTIMA CT Assay by specimen collection site and overall. Sensitivities ranged from 92.9% to 100%. Specificities ranged from 96.5% to 100%.

Table 3: Distribution of Cervical Sampling Device Used for PreservCyt Liquid Pap Specimens

Cervical Sampling Device Used	Clinical Collection Site						Total
	1	2	3	4	5	6	
Spatula/Cytobrush	0	124	475	287	57	364	1307
Broom-Type Device	100	0	0	0	240	0	340

Table 4: PreservCyt Solution Liquid Pap Specimen Analysis for Patient Infected Status

Patient Infected Status	Endocervical Swab			Symptom Status	
	APTIMA COMBO 2 Assay	APTIMA CT Assay		Symptomatic	Asymptomatic
Infected	Positive	Positive		30	60
Non-Infected	Negative	Negative		322	1214
Non-Infected	Negative	Positive		4	12
Non-Infected	Positive	Negative		3	2
Total				359	1288

Table 5: Sensitivity and Specificity of the APTIMA CT Assay Relative to Patient Infected Status by Symptom Status and Overall for PreservCyt Solution Liquid Pap Specimens.

	APTIMA CT PreservCyt Solution result	+/+	+/-	-/+	-/-	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
Symptomatic	Positive	29	0	1	3	96.7 (29/30) (82.8 – 99.9)	98.8 (325/329) (96.9 – 99.7)
	Negative	1	3	3	319		
	Total	30	3	4	322		
Asymptomatic	Positive	57	0	1	13	95.0 (57/60) (86.1 – 99.0)	98.9 (1214/1228) (98.1 –99.4)
	Negative	3	2	11	1201		
	Total	60	2	12	1214		
All	Positive	86	0	2	16	95.6 (86/90) (89.0 – 98.8)	98.8 (1539/1557) (98.2 – 99.3)
	Negative	4	5	14	1520		
	Total	90	5	16	1536		

+/+ = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA CT Assay
+/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Negative endocervical swab specimen result in the APTIMA CT Assay
-/+ = Negative endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA CT Assay
-/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA CT Assay

Table 6: Sensitivity, Specificity and Predictive Values of the APTIMA CT Assay Relative to Patient Infected Status by Clinical Site and Overall for PreservCyt Solution Liquid Pap Specimens

Site	APTIMA CT PreservCyt Solution Result	+/+	+/-	-/+	-/-	Prev (%)	Sensitivity (%) (95% C.I.)	Specificity (%) (95% C.I.)	PPV (%)	NPV (%)
1	Positive	14	0	1	2	14.0	100 (14/14) (76.8 – 100)	96.5 (83/86) (90.1 – 99.3)	82.4	100
	Negative	0	0	0	83					
	Total	14	0	1	85					
2	Positive	4	0	0	0	3.2	100 (4/4) (39.8 – 100)	100 (120/120) (97.0 – 100)	100	100
	Negative	0	0	2	118					
	Total	4	0	2	118					
3	Positive	29	0	0	6	6.5	93.5 (29/31) (78.6 – 99.2)	98.6 (438/444) (97.1 – 99.5)	82.9	99.5
	Negative	2	0	2	436					
	Total	31	0	2	442					
4	Positive	8	0	0	4	2.8	100 (8/8) (63.1 – 100)	98.6 (275/279) (96.4 – 99.6)	66.7	100
	Negative	0	3	1	271					
	Total	8	3	1	275					
5	Positive	13	0	0	3	4.7	92.9 (13/14) (66.1 – 99.8)	98.9 (280/283) (96.9 – 99.8)	81.3	99.6
	Negative	1	1	4	275					
	Total	14	1	4	278					
6	Positive	18	0	1	1	5.2	94.7 (18/19) (74.0 – 99.9)	99.4 (343/345) (97.9 – 99.9)	90.0	99.7
	Negative	1	1	5	337					
	Total	19	1	6	338					
All	Positive	86	0	2	16	5.5	95.6 (86/90) (89.0 – 98.8)	98.8 (1539/ 1557) (98.2 – 99.3)	82.7	99.7
	Negative	4	5	14	1520					
	Total	90	5	16	1536					

+/+ = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA CT Assay
+/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Negative endocervical swab specimen result in the APTIMA CT Assay
-/+ = Negative endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA CT Assay
-/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA CT Assay

Prevalence

The prevalence of CT in patient populations depends on risk factors such as age, gender, the presence of symptoms, the type of clinic, and the test method. A summary of the prevalence of CT, for PreservCyt specimens, is shown in Table 7.

Table 7: Prevalence of *C. trachomatis* by Clinical Site and Overall as Determined by APTIMA CT Assay Results Using PreservCyt Solution Liquid Pap Specimens

Site	% (#positive / #tested)	
1	17.0	(17/100)
2	3.2	(4/124)
3	7.4	(35/475)
4	4.2	(12/287)
5	5.4	(16/297)
6	5.5	(20/364)
All	6.3	(104/1647)

Conclusions from Non-Clinical and Clinical Data

The non-clinical and clinical study results support the use of PreservCyt liquid Pap specimens collected and processed by the Cytyc ThinPrep 2000 Processor in the currently marketed GEN-PROBE APTIMA Assay for *Chlamydia trachomatis*. The currently marketed GEN-PROBE APTIMA Specimen Transfer Kit provides necessary materials and instructions to allow for the testing of PreservCyt liquid Pap specimens in the APTIMA CT Assay.

The results of the clinical study demonstrate reasonable evidence that when the APTIMA CT Assay and the APTIMA Specimen Transfer Kit are labeled as proposed, the APTIMA CT Assay continues to be safe and effective for its stated intended use.

Contraindications and Cautions

There are no contraindications or cautions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 25 2006

Brian Shea, RAC
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10210 Genetic Center Drive
San Diego, CA 92121

Re: k053446
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: June 8, 2006
Received: June 9, 2006

Dear Mr. Shea:

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.

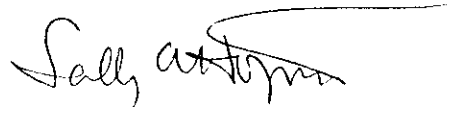
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish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

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 (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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): K053446

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

Indications For 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,[1] and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens collected in the PreservCyt® Solution and processed with the Cytyc ThinPrep® 2000 System. The assay may be used to test specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of chlamydial urogenital disease.

[1] 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.

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K053446