510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K102911

B. Purpose for Submission:

Evaluation of automatic Class III designation for the Aptima *Trichomonas vaginalis* (ATV) assay

C. Measurand:

Ribosomal RNA from *T. vaginalis*

D. Type of Test:

Nucleic acid amplification test

E. Applicant:

Gen Probe Inc.

F. Proprietary and Established Names:

Aptima *Trichomonas vaginalis* assay

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.3860

2. Classification:

   Class II

3. Product code:

   OUY – *Trichomonas vaginalis* nucleic acid amplification test system

4. Panel:

   83 – Microbiology

H. Intended Use:

1. Intended use:

   The APTIMA Trichomonas vaginalis Assay is an *in vitro* qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis using the TIGRIS DTS System.

   The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, female urine specimens, and specimens collected in PreservCyt solution.

2. Indications for use:

   The APTIMA Trichomonas vaginalis Assay is an *in vitro* qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis using the TIGRIS DTS System.

   The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, female urine specimens, and specimens collected in PreservCyt solution.

3. Special conditions for use statement:

   For prescription use

4. Special instrument requirements:

   The automated TIGRIS DTS System

I. Device Description:

The ATV assay is a nucleic acid amplification test intended for the *in vitro* qualitative detection of ribosomal RNA from *T. vaginalis* in patient-collected first catch urine and clinician collected vaginal swabs, endocervical swab and ThinPrep Pap Test specimens collected in Cytyc Preservcyt solution. The assay may be used to test specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of trichomoniasis using the TIGRIS DTS System automated analyzer.

There are 4 kits (1 master and 3 ancillary) that are required to perform the ATV assay on the TIGRIS DTS System. The Master Kit contains 9 reagents and 2 controls and is made up of 3 boxes. Box 1 – the Refrigerated box contains ATV amplification reagent, ATV enzyme reagent, ATV probe reagent and ATV Target Capture reagent-B. Box 2 – the Room Temperature box contains ATV amplification reconstitution solution, ATV enzyme reconstitution reagent, ATV probe reconstitution reagent, ATV selection reagent and ATV target capture reagent. Box 3 – the Controls kit box contains ATV positive and negative controls. The three ancillary kits consist of the APTIMA Assay Fluids kit, the APTIMA Auto Detect Reagents kit and APTIMA System Fluids Preservative kit. In addition to the reagents provided in the kit, the assay utilizes four specimen collection kits – the APTIMA unisex swab specimen collection kit for endocervical and male urethral swab specimens, APTIMA

vaginal swab specimen collection kit, APTIMA urine specimen collection kit for male and female urine specimens and the APTIMA specimen transfer kit.

J. Substantial Equivalence Information:

1. Predicate device name:
   In Pouch Trichomonas vaginalis

2. Predicate 510(k) number:
   K896296

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	NAAT test for detection of *T. vaginalis* ribosomal RNA (rRNA)	Accurate system for early microscopic identification and culture confirmation of *T. vaginalis* from female and male urogenital sites

Differences		
Item	Device	Predicate
Specimen types	Urine, vaginal swab, endocervical swab, Thin Prep in PreservCyt solution	Vaginal swab ,seminal fluid, urine
Assay type	Target capture, transcription mediated amplification assay	Culture media
Detection	Direct microscopic observation, then inoculation for culture	Hybridization protection assay, providing relative light units (RLUs)

K. Standard/Guidance Document Referenced (if applicable):

EP5-A2, 2004: Evaluation of Precision Performance of Quantitative Measurement Methods, CLSI Approved Guideline

EP 15-A2, 2006: User Verification of Performance For Precision and Trueness, CLSI approved Guideline

Format for Traditional and Abbreviated 510(k)s; Guidance for Industry and Staff, Aug.2005

General Principles of Software Validation; final guidance for Industry and FDA Staff, Jan. 2002

Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, May 2005

L. Test Principle:

The Aptima TV assay involves 3 main steps which take place in a single tube: target capture (TC), target amplification by Transcription Mediated Amplification (TMA) and detection of the amplification products (amplicon) by Hybridization Protection Assay (HPA). Specimens to be tested are collected and transferred into their respective specimen transport tubes. The transport solutions in the specimen transport tubes release the rRNA targets and protect them from degradation. When the TV assay is performed, the target rRNA is isolated from the specimen by use of capture oligomers via target capture that utilizes magnetic particles. When target capture is complete, the TV rRNA is amplified via TMA. Detection of the amplicon is achieved by HPA using single stranded nucleic acid probes with chemiluminescent labels that are complimentary to the amplicon. During the detection step, light emitted from the labeled RNA: DNA hybrids is measured as photon signals in a luminometer and are reported as Relative Light Units (RLU).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility was evaluated at 3 external US labs using the TIGRIS DTS System. Six operators, 2 at each site, performed reproducibility testing using 3 reagent kit lots. At each site, testing was performed over 6 days. Each site performed 2 runs per day. Each run contained 3 replicates of an 8 member reproducibility panel. The panels consisted of *Trichomonas vaginalis* negative and positive specimens prepared in either a urine or PreservCyt solution. For each sample matrix, there was a high negative, moderate positive, high positive and negative sample. Results are shown in the chart below.

Reproducibility Study: Signal Variability of the ATV Assay by Panel Member, Including Samples With Discordant Test Results

						Between Sites		Between Operators		Between Lots		Between Worklists		Within Worklists		Total	
PM	Matrix	Conc Level	Target Conc[1]	N	Mean RLU	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
A	P	Neg	N/A	106	2.0	1.1	56.8	0.0	0.0	0.0	0.0	0.4	21.3	0.8	42.5	1.5	74.1
B	P	HNeg	0.01	106	58.3	17.2	29.4	0.0	0.0	11.1	19.1	0.0	0.0	22.2	38.0	30.2	51.7
C	P	MPos	0.1	108	367.0	32.8	8.9	0.0	0.0	57.5	15.7	51.0	13.9	140.6	38.3	163.6	44.6
D	P	HPos	1	107	1110.4	53.9	4.9	0.0	0.0	109.6	9.9	60.9	5.5	77.1	6.9	156.8	14.1
E	U	Neg	N/A	108	2.1	1.0	45.7	0.0	0.0	0.0	0.0	0.0	0.0	1.3	62.4	1.7	77.3
F	U	HNeg	0.006	107	60.2	11.2	18.7	0.0	0.0	9.6	15.9	9.8	16.2	12.0	19.9	21.4	35.6
G	U	MPos	0.1	107	781.6	53.2	6.8	0.0	0.0	66.6	8.5	56.0	7.2	83.7	10.7	131.9	16.9
H	U	HPos	1	108	1122.8	49.5	4.4	15.0	1.3	119.3	10.6	109.2	9.7	106.9	9.5	200.7	17.9

Conc=concentration, HNeg=high negative, HPos=high positive, MPos=moderate positive, Neg=negative, P=PreservCyt, PM=panel member, U=Urine

[1] Concentration units = trichomonads/mL

Note: The RLU value reported by the software is the total measured RLU divided by 1000 with the digits after the decimal point truncated. Variability from some factors may be numerically negative. This can occur if the variability due to those factors is very small. In these cases, SD and CV are shown as 0.

b. Linearity/assay reportable range:

The ATV Assay is designed for and validated on the TIGRIS DTS System. The assay test results are automatically interpreted by the TIGRIS DTS System APTIMA Trichomonas vaginalis Software. A test result may be negative, positive or invalid as determined by the total RLU in the detection step. A test result may be invalid due to RLU values outside the normal expected ranges. Initial invalid results should be retested.

Test Interpretation	**Total RLU (x 1000)**
Negative	0* to <100
Positive	100 to <2400
Invalid	0* or >/= 2400

*If the RLU measured on the TIGRIS DTS System in between 0 and 999, a result of "0" is reported in the "Total RLU (000s)" column in the run report. Measured RLU values less than 690 are reported as invalid. RLU values between 690 and 999 are reported as valid.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Data to support the recommended shipping and storage conditions for the vaginal swab, PreservCyt liquid Pap and urine specimens were generated with negative clinical specimens spiked with *T. vaginalis* to a final concentration of 250 TV/mL. Greater than 95% positivity was observed in all matrices (vaginal swab, PreservCyt liquid Pap, and urine) at all times and temperatures tested confirming the validity of the claimed maximum storage times and temperatures.

Quality Control Results and Acceptability

The APTIMA Negative Control for Trichomonas and APTIMA Positive Control for Trichomonas act as controls for the target capture, amplification and detection steps of the assay. The Positive Control contains non-infectious Trichomonas vaginalis trichomonads rRNA.

The APTIMA Trichomonas vaginalis Controls must produce the following test results:

Control	**Total RLU (x1000)**	**Trichomonas vaginalis Result**
Negative Control	0* and <20	Negative
Positive Control	>/=500 and < 2400	Positive

**If the RLU measured on the TIGRIS DTS System in between 0 and 999, a result of "0" is reported in the "Total RLU (000s)" column in the run report. Measured RLU values less than 690 are reported as invalid. RLU values between 690 and 999 are reported as valid.*

d. Detection limit:

Panel samples containing 0.1 TV/mL in urine specimen matrix, PreservCyt liquid Pap specimen matrix, and vaginal swab matrix (90 replicates per matrix) were prepared with two strains of *T. vaginalis* (one Metronidazole-susceptible strain and one Metronidazole-resistant strain). Testing showed 100% positivity in all specimen matrices and in both *T. vaginalis* strains.

e. Analytical specificity:

Analytical specificity of the APTIMA Trichomonas vaginalis Assay was evaluated by testing various microorganisms, including common flora of the female genitourinary tract, opportunistic organisms, and closely related organisms. Testing was conducted in vaginal swab, PreservCyt liquid Pap, and urine matrices with 25 replicates of each isolate per matrix. The list of organisms and the concentrations tested are provided in **Table 7**. No cross-reactivity or significant effect on APTIMA Trichomonas vaginalis Assay specificity was observed with any of the organisms tested.

The APTIMA Trichomonas vaginalis Assay was also evaluated by testing the same organisms (**Table 7**) in vaginal swab, PreservCyt liquid Pap, and urine matrices spiked with *T. vaginalis* lysate to a final concentration of 2.5 TV/mL (25 replicates of each isolate per matrix). The APTIMA Trichomonas vaginalis Assay was not significantly affected by the presence of the microorganisms tested, except in the presence of *Trichomonas tenax* and *Pentatrichomonas hominis* (where lower signal outputs were observed). *T. tenax* is a commensal of the oral cavity and *Pentatrichomonas hominis* is a commensal of the large intestine.

Table 7: Microorganisms Tested in the APTIMA Trichomonas vaginalis Assay

Microorganism	Concentration Tested		
	STM	**PreservCyt**	**Urine**
Acinetobacter lwoffi	$4.6x10^7$ CFU/mL	$4.6x10^7$ CFU/mL	$2.3x10^7$ CFU/mL
Actinomyces israelii	$2.1x10^8$ CFU/mL	$2.1x10^8$ CFU/mL	$1.1x10^8$ CFU/mL
Atopobium vaginae	$6.2x10^6$ CFU/mL	$6.2x10^6$ CFU/mL	$6.2x10^6$ CFU/mL
Bacteroides fragilis	$6.4x10^8$ CFU/mL	$6.4x10^8$ CFU/mL	$3.2x10^8$ CFU/mL
Bifidobacterium adolescentis	$7.2x10^7$ CFU/mL	$7.2x10^7$ CFU/mL	$3.6x10^7$ CFU/mL
Campylobacter jejuni	$7.2x10^7$ CFU/mL	$7.2x10^7$ CFU/mL	$3.6x10^7$ CFU/mL
Candida albicans	$1.2x10^8$ CFU/mL	$1.2x10^8$ CFU/mL	$5.9x10^7$ CFU/mL
Candida glabrata	$1.3x10^8$ CFU/mL	$1.4x10^8$ CFU/mL	$6.4x10^7$ CFU/mL
Candida parapsilosis	$9.2x10^7$ CFU/mL	$9.2x10^7$ CFU/mL	$4.6x10^7$ CFU/mL
Candida tropicalis	$1.8x10^7$ CFU/mL	$1.8x10^7$ CFU/mL	$9.1x10^6$ CFU/mL
Chlamydia trachomatis	$2.0x10^4$ TCID 50/mL	$2.0x10^4$ TCID 50/mL	$2.0x10^4$ TCID 50/mL
Clostridium difficile	$2.6x10^7$ CFU/mL	$2.6x10^7$ CFU/mL	$1.3x10^7$ CFU/mL
Clostridium perfringens	$1.9x10^8$ CFU/mL	$1.9x10^8$ CFU/mL	$9.4x10^7$ CFU/mL
Corynebacterium genitalium	$2.8x10^7$ CFU/mL	$2.8x10^7$ CFU/mL	$1.4x10^7$ CFU/mL
Cryptococcus neoformans	$5.8x10^7$ CFU/mL	$5.8x10^7$ CFU/mL	$2.9x10^7$ CFU/mL
Enterobacter aerogenes	$1.5x10^9$ CFU/mL	$1.5x10^9$ CFU/mL	$1.0x10^8$ CFU/mL
Enterococcus faecalis	$9.2x10^7$ CFU/mL	$9.2x10^7$ CFU/mL	$9.2x10^7$ CFU/mL
Escherichia coli	$2.2x10^8$ CFU/mL	$2.2x10^8$ CFU/mL	$2.2x10^8$ CFU/mL
Fusobacterium nucleatum	$1.3x10^8$ CFU/mL	$1.3x10^8$ CFU/mL	$6.4x10^7$ CFU/mL
Gardnerella vaginalis	$8.2x10^6$ CFU/mL	$8.2x10^6$ CFU/mL	$4.1x10^6$ CFU/mL
Haemophilus ducreyi	$2.1x10^9$ CFU/mL	$2.1x10^9$ CFU/mL	$3.1x10^9$ CFU/mL
Herpes simplex virus I	$2.0x10^5$ TCID 50/mL	$2.0x10^5$ TCID 50/mL	$2.0x10^5$ TCID 50/mL
Herpes simplex virus II	$2.0x10^5$ TCID 50/mL	$2.0x10^5$ TCID 50/mL	$2.0x10^5$ TCID 50/mL
HIV-1	$3.0x10^7$ copies/mL	$3.0x10^7$ copies/mL	$3.0x10^7$ copies/mL
HPV 16 (SiHa)	$1.0x10^5$ cell/mL	$1.0x10^5$ cells/mL	$1.0x10^5$ cells/mL
Klebsiella oxytoca	$9.6x10^8$ CFU/mL	$9.6x10^8$ CFU/mL	$4.8x10^8$ CFU/mL
Lactobacillus acidophilus	$1.0x10^8$ CFU/mL	$1.0x10^8$ CFU/mL	$5.2x10^7$ CFU/mL
Lactobacillus jensenii	$1.6x10^9$ CFU/mL	$1.6x10^9$ CFU/mL	$8.2x10^8$ CFU/mL
Lactobacillus vaginalis	$4.6x10^8$ CFU/mL	$4.6x10^8$ CFU/mL	$2.3x10^8$ CFU/mL
Listeria monocytogenes	$2.1x10^9$ CFU/mL	$2.1x10^9$ CFU/mL	$1.0x10^9$ CFU/mL

Mobiluncus curtisii	$4.1x10^7$ CFU/mL	$4.1x10^7$ CFU/mL	$4.1x10^7$ CFU/mL
Mycoplasma hominis	$1.0x10^8$ CFU/mL	$1.0x10^8$ CFU/mL	$1.0x10^8$ CFU/mL
Neisseria gonorrhoeae	$2.7x10^8$ CFU/mL	$2.7x10^8$ CFU/mL	$1.4x10^8$ CFU/mL
Pentatrichomonas hominis	$2.2x10^6$ CFU/mL	$2.2x10^6$ CFU/mL	$1.3x10^6$ CFU/mL
Peptostreptococcus anaerobius	$2.2x10^8$ CFU/mL	$2.2x10^8$ CFU/mL	$1.1x10^8$ CFU/mL
Prevotella bivia	$5.2x10^8$ CFU/mL	$5.2x10^8$ CFU/mL	$2.6x10^8$ CFU/mL
Propionibacterium acnes	$1.6x10^8$ CFU/mL	$1.6x10^8$ CFU/mL	$1.6x10^8$ CFU/mL
Proteus mirabilis	$1.2x10^9$ CFU/mL	$1.2x10^9$ CFU/mL	$6.0x10^8$ CFU/mL
Pseudomonas aeruginosa	$1.5x10^8$ CFU/mL	$1.5x10^8$ CFU/mL	$1.5x10^8$ CFU/mL
Staphylococcus aureus	$2.8x10^8$ CFU/mL	$2.8x10^8$ CFU/mL	$2.8x10^8$ CFU/mL
Staphylococcus epidermidis	$3.0x10^8$ CFU/mL	$3.0x10^8$ CFU/mL	$1.5x10^8$ CFU/mL
Streptococcus pyogenes	$1.0x10^8$ CFU/mL	$1.0x10^8$ CFU/mL	$8.9x10^7$ CFU/mL
Streptococcus agalactiae	$1.0x10^8$ CFU/mL	$1.0x10^8$ CFU/mL	$1.0x10^8$ CFU/mL
Trichomonas tenax	$2.7x10^5$ CFU/mL	$2.7x10^5$ CFU/mL	$1.3x10^5$ CFU/mL
Ureaplasma urealyticum	$1.6x10^8$ CFU/mL	$1.4x10^8$ CFU/mL	$1.3x10^8$ CFU/mL

Interference Studies

The following substances (at a concentration of 1% vol/vol or wt/vol) were individually spiked into vaginal swab, PreservCyt liquid Pap, and urine matrices and tested in the APTIMA Trichomonas vaginalis Assay: over-the-counter personal lubricants, spermicides, deodorant sprays/powders, anti-fungal/anti-itch medications, intravaginal hormones, porcine gastric mucus, glacial acetic acid, vinegar, and seminal fluid. Whole blood was tested at 10% vol/vol and KOVA-Trol I High Abnormal w/ Urobilinogen Urinalysis Control was substituted for urine to test for high levels of protein, glucose, ketones, bilirubin, nitrite, and urobilinogen. No interference was observed with any of the tested substances in the APTIMA Trichomonas vaginalis Assay with the exception of porcine gastric mucus, which exhibited lower signal output when present at a final concentration of 1% (V/V or W/V).

f. Assay cut-off:

The ATV Assay is designed for and validated on the TIGRIS DTS System. The assay test results are automatically interpreted by the TIGRIS DTS System APTIMA Trichomonas vaginalis Software. A test result may be negative, positive or invalid as determined by the total RLU in the detection step. A test result may be invalid due to RLU values outside the normal expected ranges. Initial invalid results should be retested.

Test Interpretation	**Total RLU (x 1000)**
Negative	0* to <100
Positive	100 to <2400
Invalid	0* or >/= 2400

*If the RLU measured on the TIGRIS DTS System in between 0 and 999, a result of "0" is reported in the "Total RLU (000s)" column in the run report. Measured RLU values less than 690 are reported as invalid. RLU values between 690 and 999 are reported as valid.

2. <u>Comparison studies:</u>

a. Method comparison with predicate device:

See 3 (a) below

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

A pivotal prospective multicenter clinical trial was conducted with 1025 symptomatic and asymptomatic women enrolled from 9 US clinical sites, including obstetric and gynecology, family planning and STD clinics. Up to 6 specimens were collected from each subject (1 first catch urine, 3 vaginal swabs, 1 endocervical swab and 1 PreservCyt solution liquid Pap specimen). All specimens were clinician-collected except urine specimens. 2 of the vaginal swab specimens were tested with a commercially available culture system and wet mount microscopic exam to establish infected status. The remaining 4 specimens were tested with the ATV assay at 3 external labs. Performance characteristics of the ATV assay were determined by comparing results to a patient infected status algorithm. Each subject was designated as infected or non-infected based on vaginal swab specimen results tested by culture and/or wet mount microscopic exam. At least one positive reference result established an infected patient status. Both reference tests were required to be negative to establish a non-infected patient status. Of the evaluable specimens, a total of 738 urines, 877 vaginal swabs, 922 endocervical swabs and 813 PreservCyt solution liquid Pap specimens were tested with the assay. There were 3 urines, 2 vaginal and 2 endocervical swabs with final invalid results due to hardware errors or specimen issues. Results below show the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the APTIMA Trichomonas vaginalis Assay and the prevalence of *T. vaginalis* (based on the infected status) in each specimen type. Performance was similar across specimen types.

Performance characteristics of the APTIMA *Trichomonas vaginalis* Assay

Specimen Type	N	TP	FP	TN	FN	Prev %	Sensitivity% (95% CI)	Specificity% (95%CI)	PPV% (95%CI)	NPV% (95%CI)
Urine	735	80	7	644	4	11.4	95.2 (88.4-98.1)	98.9 (97.8-99.5)	92.0 (1-96.4)	99.4(98.5-99.8)
Clinician collected vaginal swab	875	111	8	756	0	12.7	100 (96.7-100)	99.0(97.9-99.5)	93.3(87.6-97.0)	100(99.5-100)
Endocervical swab	920	114	5	801	0	12.4	100 (96.7-100)	99.4(98.6-99.7)	95.8(90.7-98.6)	100(99.6-100)

PreservCyt	813	93	3	717	0	11.4	100 (96.0-100)	99.6 (98.8-99.9)	96.9(91.4-99.3)	100(99.5-100)

The sensitivity, specificity, PPV, and NPV of the APTIMA Trichomonas vaginalis Assay and the prevalence of *T. vaginalis* (based on the infected status) in each specimen type were also evaluated by symptom status. Subjects were classified as symptomatic if symptoms were reported by the subject. Subjects were classified as asymptomatic if the subject did not report symptoms. For each specimen type, performance was similar in symptomatic and asymptomatic women. Prevalence was higher in symptomatic women.

Table 3: Performance Characteristics of the APTIMA Trichomonas vaginalis Assay by Symptom Status

Specimen Type	Symptom Status	n	TP	FP	TN	FN	Prev %	Sensitivity % (95% CI)[1]	Specificity % (95% CI)[1]	PPV % (95% CI)[2]	NPV % (95% CI)[2]
Urine	Asymptomatic	324	21	3	299	1	6.8	95.5 (78.2-99.2)	99.0 (97.1-99.7)	87.5 (71.4-96.9)	99.7 (98.4-100)
	Symptomatic	411	59	4	345	3	15.1	95.2 (86.7-98.3)	98.9 (97.1-99.6)	93.7 (85.7-98.1)	99.1 (97.7-99.8)
CVS	Asymptomatic	345	24	4	317	0	7.0	100 (86.2-100)	98.8 (96.8-99.5)	85.7 (70.3-95.6)	100 (98.9-100)
	Symptomatic	530	87	4	439	0	16.4	100 (95.8-100)	99.1 (97.7-99.6)	95.6 (89.5-98.8)	100 (99.2-100)
ES	Asymptomatic	372	26	1	345	0	7.0	100 (87.1-100)	99.7 (98.4-99.9)	96.3 (82.4-99.9)	100 (99.0-100)
	Symptomatic	548	88	4	456	0	16.1	100 (95.8-100)	99.1 (97.8-99.7)	95.7 (89.6-98.8)	100 (99.2-100)
PCyt	Asymptomatic	353	23	0	330	0	6.5	100 (85.7-100)	100 (98.8-100)	100 (86.2-NC)	100 (99.0-100)
	Symptomatic	460	70	3	387	0	15.2	100 (94.8-100)	99.2 (97.8-99.7)	95.9 (88.9-99.1)	100 (99.1-100)

CI = confidence interval, CVS = clinician-collected vaginal swab, ES = endocervical swab, FN = false negative, FP = false positive, NC = not calculable, PCyt = PreservCyt Solution liquid Pap, Prev = prevalence, TN = true negative, TP = true positive.

[1]Score confidence interval.

[2]PPV 95% confidence interval computed from the exact 95% confidence interval for the positive likelihood ratio, NPV 95% confidence interval computed from the exact 95% confidence interval from the negative likelihood ratio. Some confidence limits could not be calculated due to undefined results in the formulas.

*b. Clinical specificity**:***

See 3(a) above

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off**:**

N/A

5. Expected values/Reference range:

The prevalence of *T. vaginalis* in different populations depends on patient risk factors such as age, lifestyle, the presence or absence of symptoms, and the sensitivity of the test in detecting the infection. A summary of the prevalence of *T. vaginalis*, by specimen type, as determined by the APTIMA Trichomonas vaginalis Assay in the clinical trial is described below.

The positivity rate for the Aptima *TV* assay by specimen type, collection site and overall was 11.8% (87/735) for urines, 11.8% (96/813) for PreservCyt solution Pap specimens, 12.9% (119/920) for endocervical swab specimens and 13.6% (119/875) for vaginal swab specimens.

N. Instrument Name:

The TIGRIS DTS System

O. System Descriptions:

1. Modes of Operation:

   The TIGRIS DTS System is an integrated hardware and software system that fully automates all steps of nucleic acid testing necessary to perform Gen-Probe assays. The system automates the following steps: sample processing/ target capture, amplification, detection and results processing. The 2 main components of the system are the computer work station and the analyzer. The assay software in the computer work station directs the analyzer modules to perform each sequential assay step. The analyzer holds all of the fluids, reagents and consumables needed to perform the assay.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes _X_____ or No _____

3. Specimen Identification:

   See Section L, Test Principle. A complete description is included in theTIGRIS DTS System Operator's Manual for system procedural information

4. Specimen Sampling and Handling:

   See #3 above

5. Calibration:

   N/A

6. Quality Control:

   See #3 above

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

N/A

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports reclassification into Class II