



Food and Drug Administration
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Cepheid
Scott Campbell, Ph.D., MBA
Vice President, Clinical Affairs
904 Caribbean Drive
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October 16, 2015

Re: K151565

Trade/Device Name: Xpert[®] TV Assay on the Cepheid GeneXpert Instrument Systems (GeneXpert Dx, GeneXpert Infinity-48, GeneXpert Infinity-48s, and GeneXpertInfinity-80 systems), Xpert Vaginal/Endocervical Specimen Collection Kit, and Xpert Urine Specimen Collection Kit

Regulation Number: 21 CFR 866.3860

Regulation Name: *Trichomonas vaginalis* nucleic acid assay

Regulatory Class: II

Product Code: OUY, OOI

Dated: September 11, 2015

Received: September 14, 2015

Dear Dr. Campbell:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tamara V. Feldblyum -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151565

Device Name

Xpert® TV

Indications for Use (Describe)

The Cepheid Xpert TV Assay, performed on the GeneXpert® Instrument Systems, is a qualitative in vitro diagnostic test for the detection of *Trichomonas vaginalis* genomic DNA. The test utilizes automated real-time polymerase chain reaction (PCR) to detect *Trichomonas vaginalis* genomic DNA. The Xpert TV Assay uses female urine specimens, endocervical swab specimens, or patient-collected vaginal swab specimens (collected in a clinical setting). The Xpert TV Assay is intended to aid in the diagnosis of trichomoniasis in symptomatic or asymptomatic individuals.

Ancillary Collection Kits:

Xpert Vaginal/Endocervical Specimen Collection Kit

The Cepheid® Xpert® Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.

Xpert Urine Specimen Collection Kit

The Cepheid® Xpert® Urine Specimen Collection Kit is designed to preserve and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in first-catch urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay. The Xpert Urine Specimen Collection Kit is intended for use with male (Xpert CT/NG Assay) and female (Xpert CT/NG Assay and Xpert TV Assay) urine.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

As required by 21 CFR Section 807.92(c).

Submitted by: Cepheid
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Contact: Scott A. Campbell, Ph.D, MBA

Date of Preparation: October 12, 2015

Device:

Trade name: Xpert[®] TV

Common name: Xpert TV Assay

Type of Test: Real-Time Polymerase Chain Reaction (PCR) for the detection of *Trichomonas vaginalis*

Regulation number/
Classification name/
Product code: 866.3860/ *Trichomonas vaginalis* nucleic acid amplification test system /OUY
862.2570/Instrumentation for clinical multiplex test systems/OOI

Classification
Advisory Panel: Microbiology (83)

Prescription Use: Yes

Predicate Device
Assay: Gen-Probe[®] Aptima *Trichomonas vaginalis* Assay
[510(k) #K122062]

Predicate Device
Assay: Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit
[510(k) #K121710]
Xpert CT/NG Urine Specimen Collection Kit
[510(k) #K121710]

Device Description:

The Xpert TV Assay is an automated real-time polymerase chain reaction (PCR) in vitro diagnostic test for qualitative detection of genomic DNA from *Trichomonas vaginalis*. The Xpert TV Assay is intended as an aid in the diagnosis of trichomoniasis.

The Xpert TV Assay is performed on the Cepheid GeneXpert[®] Instrument Systems (GeneXpert Dx, GeneXpert Infinity-48, GeneXpert Infinity-48s, and GeneXpert Infinity-80 systems). The GeneXpert Instrument System platform automates sample preparation, amplification and real-time detection.

The GeneXpert Instrument Systems require the use of single-use, disposable cartridges (the Xpert TV cartridges) that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained and specimens never come into contact with working parts of the instrument modules, cross-contamination between samples is minimized.

The Xpert TV Assay cartridges contain reagents for the detection of genomic DNA from *T. vaginalis* for use with the following specimens collected from symptomatic and asymptomatic individuals: female urine, endocervical swab and patient-collected vaginal swab (collected in a clinical setting). A Sample Processing Control (SPC), Sample Adequacy Control (SAC), and a Probe Check Control (PCC) are controls utilized by the GeneXpert Instrument System platform. The SPC, SAC, and PCC are controls utilized by the GeneXpert Instrument System platform. The SPC is present to control for adequate processing of the target trichomonads and to monitor the presence of inhibitors in the real-time PCR reaction to reduce the possibility of false negative results. The SAC reagents detect the presence of a single copy human gene and monitor whether the specimen contains human cells. The PCC verifies reagent rehydration, real-time PCR tube filling in the cartridge, probe integrity, and dye stability.

The single-use, multi-chambered fluidic cartridges are designed to complete sample preparation and real-time PCR for the detection of genomic DNA from *T. vaginalis* in 70 minutes or less. The GeneXpert Instrument Systems, comprised of the GeneXpert Dx Systems and the GeneXpert Infinity Systems, have 1 to 80 randomly accessible modules, depending upon the instrument, that are each capable of performing separate sample preparation and real-time PCR and RT-PCR tests. Each module contains a syringe drive for dispensing fluids (i.e., the syringe drive activates the plunger that works in concert with the rotary valve in the cartridge to move fluids between chambers), an ultrasonic horn for lysing cells or spores¹, and a proprietary I-CORE[®] thermocycler for performing real-time PCR and RT-PCR and detection.

The swab and/or urine specimens are collected from asymptomatic or symptomatic patients and placed into a specimen transport tube containing preservative. The specimen is transferred to the sample chamber of the disposable fluidic cartridge (the Xpert TV cartridge). The user initiates a test from the system user interface and places the cartridge into the GeneXpert instrument platform, which performs hands-off real-time, multiplex

¹ Although sonication is a fundamental capability of every GeneXpert module, sonication is not used in the Xpert TV Assay.

PCR for detection of DNA. The results are automatically generated at the end of the process in a report that can be viewed and printed.

The ancillary specimen collection kits for use with the Xpert TV Assay are the Cepheid Xpert Vaginal/Endocervical Specimen Collection Kit and the Cepheid Xpert Urine Specimen Collection Kit.

Device Intended Use:

The Cepheid Xpert TV Assay, performed on the GeneXpert Instrument Systems, is a qualitative *in vitro* diagnostic test for the detection of *Trichomonas vaginalis* genomic DNA. The test utilizes automated real-time polymerase chain reaction (PCR) to detect *Trichomonas vaginalis* genomic DNA. The Xpert TV Assay uses female urine specimens, endocervical swab specimens, or patient-collected vaginal swab specimens (collected in a clinical setting). The Xpert TV Assay is intended to aid in the diagnosis of trichomoniasis in symptomatic or asymptomatic individuals.

Ancillary Collection Kits:

Xpert Vaginal/Endocervical Specimen Collection Kit

The Cepheid[®] Xpert[®] Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.

Xpert Urine Specimen Collection Kit

The Cepheid[®] Xpert[®] Urine Specimen Collection Kit is designed to preserve and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in first-catch urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay. The Xpert Urine Specimen Collection Kit is intended for use with male (Xpert CT/NG Assay) and female (Xpert CT/NG Assay and Xpert TV Assay) urine.

Substantial Equivalence:

The Xpert TV Assay is substantially equivalent to the Gen-Probe[®] Aptima *Trichomonas vaginalis* Assay [510(k) # K122062]. The Xpert TV Assay and the Gen-Probe Aptima *Trichomonas vaginalis* Assay both detect *T. vaginalis* from endocervical swab, patient-collected vaginal swab (collected in a clinical setting), and female urine specimens using nucleic acid-based technology. The performance of the Xpert TV Assay was evaluated in a multi-site clinical study in which the performance of the Xpert TV Assay was compared to a patient-infected status (PIS). The results of the study demonstrated that the performance of the Xpert TV Assay is substantially equivalent to the predicate device.

Table 5-1 shows the similarities and differences between the Xpert TV Assay and the predicate device.

Table 5-1: Comparison of Similarities and Differences of the Xpert TV Assay with the Predicate Device

Similarities		
Item	Device	Predicate Device
	Cepheid Xpert TV Assay	Gen-Probe Aptima <i>Trichomonas vaginalis</i> Assay
510(k) Number	K151565	K122062
Regulation	866.3860	866.3860
Product Code	OYU	OYU
Device Class	Same	II
Intended Use	<p>The Cepheid Xpert TV Assay, performed on the GeneXpert® Instrument Systems, is a qualitative <i>in vitro</i> diagnostic test for the detection of <i>Trichomonas vaginalis</i> genomic DNA. The test utilizes automated real-time polymerase chain reaction (PCR) to detect <i>Trichomonas vaginalis</i> genomic DNA. The Xpert TV Assay uses female urine specimens, endocervical swab specimens, or patient-collected vaginal swab specimens (collected in a clinical setting). The Xpert TV Assay is intended to aid in the diagnosis of trichomoniasis in symptomatic or asymptomatic individuals.</p> <p>Ancillary Collection Kits:</p> <p>Xpert Vaginal/Endocervical Specimen Collection Kit</p> <p>The Cepheid® Xpert®</p>	<p>The APTIMA <i>Trichomonas vaginalis</i> Assay is an <i>in vitro</i> qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from <i>Trichomonas vaginalis</i> 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.</p>

Similarities		
Item	Device	Predicate Device
	Cepheid Xpert TV Assay	Gen-Probe Aptima <i>Trichomonas vaginalis</i> Assay
	<p>Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport <i>Chlamydia trachomatis</i>, <i>Neisseria gonorrhoeae</i>, and <i>Trichomonas vaginalis</i> DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.</p> <p>Xpert Urine Specimen Collection Kit</p> <p>The Cepheid® Xpert® Urine Specimen Collection Kit is designed to preserve and transport <i>Chlamydia trachomatis</i>, <i>Neisseria gonorrhoeae</i>, and <i>Trichomonas vaginalis</i> DNA in first-catch urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay. The Xpert Urine Specimen Collection Kit is intended for use with male (Xpert CT/NG Assay) and female (Xpert CT/NG Assay and Xpert TV Assay) urine.</p>	
Assay Targets	<i>T. vaginalis</i> genomic DNA	<i>T. vaginalis</i> ribosomal RNA

Similarities		
Item	Device	Predicate Device
	Cepheid Xpert TV Assay	Gen-Probe Aptima <i>Trichomonas vaginalis</i> Assay
Specimen Types	<i>Endocervical Swabs</i> <i>Vaginal Swabs</i> <i>Female Urine</i>	<i>Endocervical Swabs</i> <i>Vaginal Swabs</i> <i>Female Urine</i>
Nucleic Acid Extraction	Yes	Yes
Assay Results	Same	Qualitative
Collection Kit	Same	Urine collection kit Swab collection kit

Primary Differences		
Item	New Device	Predicate Device
	Cepheid Xpert TV Assay	Gen-Probe Aptima <i>Trichomonas vaginalis</i> Assay
Technology/ Detection	Multiplex real-time polymerase chain reaction (PCR)	Transcription-mediated amplification (TMA)
Specimen Types	Endocervical Swabs Vaginal Swabs Female Urine	Endocervical Swabs Vaginal Swabs Female Urine
Instrument System	Cepheid GeneXpert Instrument System	TIGRIS DTS System
Laboratory Users	Operators in Moderate and High Complexity labs	CLIA High Complexity
Early assay termination function	Yes (for positive samples)	No

The Xpert TV Assay has the same general intended use as the predicate device and has the same technological characteristics as the predicate device. The differences between the Xpert TV Assay and the predicate device do not raise different questions of safety and effectiveness. The clinical study demonstrates that the Xpert TV Assay is acceptable

for its intended use with inexperienced lab users and is substantially equivalent to the predicate device described above.

Ancillary Collection Kits:

Xpert Vaginal/Endocervical Specimen Collection Kit and Xpert Urine Specimen Collection Kit

The predicate devices for the ancillary specimen collection kits, the Cepheid Xpert® Vaginal/Endocervical Specimen Collection Kit and Cepheid Xpert Urine Specimen Collection Kit, are the Cepheid Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit and the Cepheid Xpert CT/NG Urine Specimen Collection Kit [510(k) #K121710]. The similarities and differences are shown in Tables 5-2 and 5-3.

Table 5-2: Comparison of Similarities and Differences of the Xpert Vaginal/Endocervical Specimen Collection Kit with the Predicate Device

Similarities		
Item	Device	Predicate
	Cepheid Xpert Vaginal/Endocervical Specimen Collection Kit	Cepheid Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit
Intended Use (Similarities)	Same	The collection kit is used for the collection of endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) and is designed to collect, preserve and transport patient <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA in endocervical and vaginal specimens.
Single-use Device	Yes	Yes
Transport Medium pH	Same	8.15-8.55

Similarities		
Item	Device	Predicate
	Cepheid Xpert Vaginal/Endocervical Specimen Collection Kit	Cepheid Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit
Description	Same	Contains an individually packaged sterile large cleaning swab (for endocervical samples) and a package containing an individually packaged sterile collection swab (for vaginal and endocervical sampling) and a swab transport reagent tube. The collection swab is placed into the transport reagent tube after swab sampling to stabilize the nucleic acid until sample preparation.

Differences		
Item	Device	Predicate
Intended Use (differences)	Specimen storage and transport when testing for the presence of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , and <i>Trichomonas vaginalis</i> in vaginal and endocervical swab specimens.	Specimen storage and transport when testing for the presence of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in vaginal and endocervical swab specimens.

Table 5-3: Comparison of Similarities and Differences of the Xpert Urine Specimen Collection Kit with the Predicate Device

Similarities		
Item	Device	Predicate
	Cepheid Xpert Urine Specimen Collection Kit	Cepheid Xpert CT/NG Urine Specimen Collection Kit
Intended Use (Similarities)	The collection kit is designed to preserve and transport <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA in first-catch female urine specimens from symptomatic and asymptomatic individuals prior to analysis.	The collection kit is designed to preserve and transport <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA in first-catch male and female urine specimens from symptomatic and asymptomatic individuals prior to analysis.
Single-use Device	Yes	Yes
Transport Medium pH	Same	7.95 – 8.35
Description	Same	Contains one individually packaged sterile disposable transfer pipette and one urine transport reagent tube. Approximately 7 mL of a first-catch urine specimen is transferred to the Urine Transport Reagent tube to preserve and transport the specimen prior to analysis with the assay.

Similarities		
Item	Device	Predicate
	Cepheid Xpert Urine Specimen Collection Kit	Cepheid Xpert CT/NG Urine Specimen Collection Kit
Differences		
Item	Device	Predicate
Intended Use (differences)	Specimen storage and transport when testing for the presence of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , and <i>Trichomonas vaginalis</i> in urine specimens.	Specimen storage and transport when testing for the presence of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in urine specimens.

Non-Clinical Studies:

Analytical Sensitivity (Limit of Detection)

The analytical sensitivity or limit of detection (LoD) of the Xpert TV Assay was assessed using two *Trichomonas vaginalis* strains, one metronidazole susceptible (*T. vaginalis* ATCC® 30001™), and one metronidazole resistant (*T. vaginalis* ATCC® 30238™). Both strains were tested individually in clinical *T. vaginalis*-negative pooled urine matrix in Cepheid Xpert Urine Transport Reagent and clinical *T. vaginalis*-negative pooled vaginal swab matrix (VS) in Cepheid Xpert Swab Transport Reagent.

T. vaginalis was cultured and incubated at 35°C. Visual examination of the cultures for white precipitate (indicating growth) was conducted every 24 hours for 3 to 5 days. Cell pellets were resuspended in growth medium and enumerated visually using light microscopy. The concentration of isolates was expressed as the number of cells per milliliter (cells/mL). Cultures were diluted in culture medium to 1 x10⁴ cells/mL and stored at -20°C. Cells were thawed on ice for use in the study.

The limit of detection (LoD) was estimated by testing replicates of 20 at five concentrations for each strain and sample type over three days. The LoD for each strain was estimated by probit analysis. The claimed LoDs were confirmed by analyzing at least 20 replicates with *T. vaginalis* cells diluted to the estimated LoD concentrations. The LoD is defined as the lowest number of cells/mL that can be reproducibly distinguished from negative samples with 95% confidence or the lowest concentration at which 19 of 20 replicates were positive. The study was performed with two different lots of Xpert TV reagents and the claimed LoD for each strain is the higher of the two determinations (Table 5-4). The claimed LoD for *T. vaginalis* strains ATCC 30001 and ATCC 30238 in vaginal swab matrix is 2 cells/mL. The claimed LoD for *T. vaginalis* strain ATCC 30001 in urine matrix is 3 cells/mL. The claimed LoD for *T. vaginalis* strain ATCC 30238 in urine matrix is 2 cells/mL.

The LoD point estimates and confirmed LoD for each genogroup tested are summarized in Table 5-4.

Table 5-4: LoD of Two *T. vaginalis* Strains in Pooled Vaginal Swab Matrix and Urine Matrix

<i>Trichomonas vaginalis</i> strain and matrix	LoD Estimates by Probit Analysis (cells/mL)		Verified LoD (cells/mL)	Verification (Positives/20)	Mean TV Ct	Mean SAC Ct	Mean SPC Ct	LoD Claim (cells/mL)
	Reagent Lot 1	Reagent Lot 2						
ATCC 30001 in Vaginal Swab	2.0	1.6	2.0	20/20	39.1	21.4	33.9	2
ATCC 30238 in Vaginal Swab	1.7	2.1	2.1	20/20	37.5	21.4	33.7	2
ATCC 30001 in Urine	2.2	2.5	2.5	20/20	38.2	29.3	34.1	3
ATCC 30238 in Urine	2.1	1.7	2.1	20/20	38.2	29.2	33.8	2

Analytical Specificity (Cross-reactivity and Competitive Interference)

A panel of 124 microorganisms, including bacteria, fungi, and viruses commonly found in the urogenital tract, as well as other protozoans closely related to *T. vaginalis* were tested with the Xpert TV Assay. The microorganisms were tested in the presence (competitive interference) and absence (cross-reactivity) of 3X LoD *T. vaginalis* ATCC 30001 cells. The microorganisms were seeded into either pooled *Trichomonas vaginalis*-negative urine matrix (patient urine added to Cepheid Urine Transport Reagent) or pooled *Trichomonas vaginalis*-negative vaginal swab matrix (vaginal swabs collected into Cepheid Swab Transport Reagent).

Each bacterial or fungal strain was tested at 1×10^6 CFU/mL or greater or at 1×10^6 genomes/mL. Viral strains were tested at 1×10^5 U/mL or 10^5 genomes/mL or greater. Protozoans were cultured in growth media, visually enumerated by light microscopy and tested at 1×10^5 cells/mL or greater or 10^5 genomes/mL. All microorganisms were tested in triplicate. Positive and negative controls were included in the study. One organism, *Trichomonas tenax*, demonstrated cross-reactivity (result of **TV DETECTED** in the absence of TV) at 1×10^5 cells/mL for the urine and vaginal swab matrix samples. *Trichomonas tenax* was subjected to repeat analysis at various other concentrations until a result of **TV NOT DETECTED** was obtained (at 1×10^2 cells/mL). This is addressed in Limitations in the package insert. For the other 123 microorganisms, all TV positive samples remained positive and all TV negative samples remained negative, indicating that there was no interference or cross-reactivity with the results of the Xpert TV Assay for these microorganisms. Results are shown in Table 5-5 and Table 5-6 for urine and vaginal swab matrix, respectively.

Table 5-5. Analytical Specificity/Competitive Interference Determination for Xpert TV Assay in Urine Matrix

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Achromobacter xerosis</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Acinetobacter calcoaceticus</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Acinetobacter lwoffii</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Actinomyces israelii</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Actinomyces pyogenes</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Aerococcus viridans</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Aeromonas hydrophila</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Alcaligenes faecalis</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Atopobium vaginae</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bacillus subtilis</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bacteroides fragilis</i> ^b	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bacteroides ureolyticus</i> ^b	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bifidobacterium adolescentis</i> ^b	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bifidobacterium breve (breve)</i> ^b	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Blastocystis hominis</i> ^c	1 x 10 ^{5d}	TV NOT DETECTED	TV DETECTED
<i>Branhamella catarrhalis</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Brevibacterium linens</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Campylobacter jejuni</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Candida albicans</i> ^e	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida glabrata</i> ^e	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida parapsilosi</i> ^e	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida tropicalis</i> ^e	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Chlamydia trachomatis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Chromobacterium violaceum</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Citrobacter freundii</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Clostridium difficile</i> ^b	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Clostridium perfringens</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Corynebacterium genitalium</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Corynebacterium xerosis</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Cryptococcus neoformans</i> ^e	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Cryptosporidium parvum</i> ^c	1 x 10 ^{5d}	TV NOT DETECTED	TV DETECTED
Cytomegalovirus ^f	5 x 10 ⁵	TV NOT DETECTED	TV DETECTED
<i>Deinococcus radiodurans</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Derxia gummosa</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Eikenella corrodens</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Entamoeba histolytica</i> ^c	1 x 10 ^{5d}	TV NOT DETECTED	TV DETECTED
<i>Enterobacter aerogenes</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterobacter cloacae</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterococcus avium</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterococcus faecalis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterococcus faecium</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Erysipelothrix rhusiopathiae</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Escherichia coli</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Flavobacterium meningosepticum</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Fusobacterium nucleatum</i> ^b	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Gardnerella vaginalis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Gemella haemolysans</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Giardia intestinalis</i> ^c	1 x 10 ^{5d}	TV NOT DETECTED	TV DETECTED
<i>Haemophilus ducreyi</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Haemophilus influenzae</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
Herpes simplex virus I ^f	1 x 10 ⁵	TV NOT DETECTED	TV DETECTED
Herpes simplex virus II ^f	1 x 10 ⁵	TV NOT DETECTED	TV DETECTED
HIV-1 ^f	2 x 10 ⁵	TV NOT DETECTED	TV DETECTED
Human papilloma virus 16 ^f	6 x 10 ⁵	TV NOT DETECTED	TV DETECTED
<i>Kingella dentrificans</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Kingella kingae</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Klebsiella oxytoca</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Klebsiella pneumoniae</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus acidophilus</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus brevis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus crispatus</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus jensonii</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Lactobacillus lactis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus vaginalis</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Legionella pneumophila</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Leuconostoc paramensenteroides</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Listeria monocytogenes</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Micrococcus luteus</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Mobiluncus curtisi</i> ^b	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Moraxella lacunata</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Moraxella osloensis</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Morganella morganii</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Mycobacterium smegmatis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Mycoplasma genitalium</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Mycoplasma hominis</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Neisseria cinerea</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria dentrificans</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria elongata</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria flava</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria flavescens</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria gonorrhoeae</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria lactamica</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria mucosa</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria perflava</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria polysaccharea</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria sicca</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria subflava</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pantoea agglomerans</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Paracoccus denitrificans</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pentatrichomonis hominis</i> ^c	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Peptostreptococcus anaerobius</i> ^b	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Peptostreptococcus productus</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Plesiomonas shigelloides</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Prevotella bivia</i> ^b	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Propionibacterium acnes</i> ^b	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Proteus mirabilis</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Proteus vulgaris</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Providencia stuartii</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Pseudomonas aeruginosa</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pseudomonas fluorescens</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pseudomonas putida</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Rahnella aquatilis</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Rhodospirillum rubrum</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Saccharomyces cerevisiae</i> ^e	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Salmonella minnesota</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Salmonella typhimurium</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Serratia marcescens</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Staphylococcus aureus</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Staphylococcus epidermidis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Staphylococcus saprophyticus</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus agalactiae</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Streptococcus bovis</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus mitis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus mutans</i>	2 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Streptococcus pneumoniae</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus pyogenes</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus salivarius</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus sanguis</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptomyces griseinus</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Trichomonas tenax</i> ^c	1 x 10 ⁵	TV DETECTED	TV DETECTED
<i>Trichomonas tenax</i> ^c	1 x 10 ³	TV DETECTED	TV DETECTED
<i>Trichomonas tenax</i> ^c	1 x 10 ²	TV NOT DETECTED	TV DETECTED
<i>Ureaplasma parvum</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Ureaplasma urealyticum</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Vibrio parahaemolyticus</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Yersinia enterocolitica</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED

a. Tests run $\geq 10^6$ CFU/mL for bacteria and fungi, $\geq 10^6$ genomes/mL for yeast, $\geq 10^5$ U/mL or $\geq 10^5$

genomes/mL for viruses and $\geq 10^5$ cells/mL for protozoans.

- b. Anaerobic organism
- c. Protozoan
- d. Genome equivalents tested (DNA)
- e. Fungal organism
- f. Virus

Table 5-6. Analytical Specificity/Competitive Interference Determination for Xpert TV Assay in Vaginal Swab Matrix

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Achromobacter xerosis</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Acinetobacter calcoaceticus</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Acinetobacter lwoffii</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Actinomyces israelii</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Actinomyces pyogenes</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Aerococcus viridans</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Aeromonas hydrophila</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Alcaligenes faecalis</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Atopobium vaginae</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bacillus subtilis</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bacteroides fragilis</i> ^b	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bacteroides ureolyticus</i> ^b	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bifidobacterium adolescentis</i> ^b	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Bifidobacterium breve (breve)</i> ^b	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Blastocystis hominis</i> ^c	1 x 10 ⁵ ^d	TV NOT DETECTED	TV DETECTED
<i>Branhamella catarrhalis</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Brevibacterium linens</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Campylobacter jejuni</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida albicans</i> ^e	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida glabrata</i> ^e	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida parapsilosi</i> ^e	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Candida tropicalis</i> ^e	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Chlamydia trachomatis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Chromobacterium violaceum</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Citrobacter freundii</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Clostridium difficile</i> ^b	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Clostridium perfringens</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Corynebacterium genitalium</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Corynebacterium xerosis</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Cryptococcus neoformans</i> ^e	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Cryptosporidium parvum</i> ^c	1 x 10 ^{5 d}	TV NOT DETECTED	TV DETECTED
Cytomegalovirus ^f	5 x 10 ⁵	TV NOT DETECTED	TV DETECTED
<i>Deinococcus radiodurans</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Derxia gummosa</i>	1 x 10 ^{6 d}	TV NOT DETECTED	TV DETECTED
<i>Eikenella corrodens</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Entamoeba histolytica</i> ^c	1 x 10 ^{5 d}	TV NOT DETECTED	TV DETECTED
<i>Enterobacter aerogenes</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterobacter cloacae</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterococcus avium</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterococcus faecalis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Enterococcus faecium</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Erysipelothrix rhusiopathiae</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Escherichia coli</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Flavobacterium meningosepticum</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Fusobacterium nucleatum</i> ^b	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Gardnerella vaginalis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Gemella haemolysans</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Giardia intestinalis</i> ^c	1 x 10 ^{5 d}	TV NOT DETECTED	TV DETECTED
<i>Haemophilus ducreyi</i>	1 x 10 ^{6 d}	TV NOT DETECTED	TV DETECTED
<i>Haemophilus influenzae</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
Herpes simplex virus I ^f	1 x 10 ⁵	TV NOT DETECTED	TV DETECTED
Herpes simplex virus II ^f	1 x 10 ⁵	TV NOT DETECTED	TV DETECTED
HIV-1 ^f	2 x 10 ⁵	TV NOT DETECTED	TV DETECTED
Human papilloma virus 16 ^f	6 x 10 ⁵	TV NOT DETECTED	TV DETECTED
<i>Kingella dentrificans</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Kingella kingae</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Klebsiella oxytoca</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Klebsiella pneumoniae</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus acidophilus</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus brevis</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus crispatus</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus jensenii</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus lactis</i>	1 x 10 ⁷	TV NOT DETECTED	TV DETECTED
<i>Lactobacillus vaginalis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Legionella pneumophila</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Leuconostoc paramensenteroides</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Listeria monocytogenes</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Micrococcus luteus</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Mobiluncus curtisii</i> ^b	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Moraxella lacunata</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Moraxella osloensis</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Morganella morganii</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Mycobacterium smegmatis</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Mycoplasma genitalium</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Mycoplasma hominis</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Neisseria cinerea</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria dentrificans</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria elongata</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria flava</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria flavescens</i>	8 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria gonorrhoeae</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria lactamica</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria mucosa</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria perflava</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria polysaccharea</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria sicca</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Neisseria subflava</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pantoea agglomerans</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Paracoccus denitrificans</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Pentatrichomonis hominis</i> ^c	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Peptostreptococcus anaerobius</i> ^b	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Peptostreptococcus productus</i> ^b	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Plesiomonas shigelloides</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Prevotella bivia</i> ^b	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Propionibacterium acnes</i> ^b	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Proteus mirabilis</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Proteus vulgaris</i>	7 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Providencia stuartii</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pseudomonas aeruginosa</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pseudomonas fluorescens</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Pseudomonas putida</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Rahnella aquatilis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Rhodospirillum rubrum</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Saccharomyces cerevisiae</i> ^e	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Salmonella minnesota</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Salmonella typhimurium</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Serratia marcescens</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Staphylococcus aureus</i>	9 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Staphylococcus epidermidis</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Staphylococcus saprophyticus</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus agalactiae</i>	6 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus bovis</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus mitis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus mutans</i>	5 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus pneumoniae</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus pyogenes</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus salivarius</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptococcus sanguis</i>	2 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Streptomyces griseinus</i>	4 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Trichomonas tenax</i> ^c	1 x 10 ⁵	TV DETECTED	TV DETECTED
<i>Trichomonas tenax</i> ^c	1 x 10 ³	TV DETECTED	TV DETECTED

Microorganism	Concentration Tested ^a	Xpert TV Assay Result	
		Cross-Reactivity (- <i>T. vaginalis</i>)	Competitive Interference (+ <i>T. vaginalis</i>)
<i>Trichomonas tenax</i> ^c	1 x 10 ²	TV NOT DETECTED	TV DETECTED
<i>Ureaplasma parvum</i>	1 x 10 ^{6d}	TV NOT DETECTED	TV DETECTED
<i>Ureaplasma urealyticum</i>	1 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Vibrio parahaemolyticus</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED
<i>Yersinia enterocolitica</i>	3 x 10 ⁶	TV NOT DETECTED	TV DETECTED

a. Tests run $\geq 10^6$ CFU/mL for bacteria and fungi, $\geq 10^6$ genomes/mL for yeast, $\geq 10^5$ U/mL or $\geq 10^5$ genomes/mL for viruses and $\geq 10^5$ cells/mL for protozoans.

b. Anaerobic organism

c. Protozoan

d. Genome equivalents tested (DNA)

e. Fungal organism

f. Virus

Additional three microorganisms, *Dientamoeba fragilis*, *Agrobacterium radiobacter*, and *Erwinia herbicola*, were not available for direct testing. An *in silico* analysis was conducted using the Basic Local Alignment Search Tool (BLAST) to compare the Xpert TV Assay primer and probe sequences with all available sequences associated with these three microorganisms in the GenBank database. Available sequence data for *D. fragilis* was examined and showed a maximum of 7% homology to the Xpert TV primer and probe sequences. Available sequence data for *A. radiobacter* was examined and showed a maximum of 38% homology to the Xpert TV primer and probe sequences. Available sequence data for *E. herbicola* was examined and showed a maximum of 10% homology to the Xpert TV primer and probe sequences. Results are shown in Table 5-7.

Table 5-7. *In silico* Analytical Specificity Determination for Xpert TV Assay

Strain	Accession Number	% Homology
<i>Dientamoeba fragilis</i>	KC967121.1	7%
<i>Agrobacterium radiobacter</i>	CP000629.1	38%
<i>Erwinia herbicola</i>	NG_035384.1	10%

Analytical Reactivity (Inclusivity)

The analytical inclusivity of the Xpert TV Assay was evaluated by testing 17 *T. vaginalis* strains diluted in either negative pooled vaginal swab matrix in Cepheid Xpert Swab Transport Reagent or negative pooled urine in Cepheid Xpert Urine Transport Reagent. All *T. vaginalis* strains were tested in triplicate at a concentration of 3X the analytical LoD for the respective specimen type (6 cells/mL for vaginal swabs and 7.5 cells/mL for urine). All strains tested were reported as **TV DETECTED**. Results are shown in Table 5-8. Positive and negative controls were included in the study. The inclusivity for the 17 *T. vaginalis* strains tested was 100%.

Table 5-8: Analytical Reactivity (Inclusivity) of Xpert TV Assay

Isolate ATCC #	Isolation Source	Results Vaginal Swab	Results Urine
30001	Vaginal exudate	TV DETECTED	TV DETECTED
30184	Vaginal swab	TV DETECTED	TV DETECTED
30187	Endocervical swab	TV DETECTED	TV DETECTED
30188	Vagina	TV DETECTED	TV DETECTED
30236	Endocervical swab	TV DETECTED	TV DETECTED
30240	Vaginal pool	TV DETECTED	TV DETECTED
30245	Vaginal and Endocervical material	TV DETECTED	TV DETECTED
30247	Vagina	TV DETECTED	TV DETECTED
50138	human	TV DETECTED	TV DETECTED
50139	human	TV DETECTED	TV DETECTED
50141	human	TV DETECTED	TV DETECTED
50143	human	TV DETECTED	TV DETECTED
50147	human	TV DETECTED	TV DETECTED
50167	Vagina	TV DETECTED	TV DETECTED
50183	Prostatic fluid	TV DETECTED	TV DETECTED
PRA-95	Vaginal exudate	TV DETECTED	TV DETECTED
PRA-98	human	TV DETECTED	TV DETECTED

Interfering Substances Study

The performance of the Xpert TV Assay was evaluated with potentially interfering endogenous and exogenous substances that may be present in the urogenital tract.

All substances were tested in the presence and absence of 3X LoD *T. vaginalis* (ATCC strain 30001) to determine if there was interference with the Xpert TV Assay. Substances were individually diluted into either pooled *Trichomonas vaginalis*-negative urine matrix (patient urine added to Cepheid Urine Transport Reagent) or pooled *Trichomonas vaginalis*-negative vaginal swab matrix (vaginal swabs collected into Cepheid Swab Transport Reagent). Positive and negative controls were included in the study.

For each interfering substance, eight replicates were tested for each set of samples (either *T. vaginalis* negative or *T. vaginalis* positive in clinical matrix). Tables 5-9 and 5-10 show the substances that were tested, the test concentrations, and the matrix in which they were diluted. One substance, blood at > 60% v/v demonstrated interference (result of **TV NOT DETECTED** in the presence of TV) in the vaginal swab matrix samples. Blood was subjected to repeat analysis at various lower concentrations until a result of **TV DETECTED** was obtained (50% v/v). For the other conditions and substances tested, all TV positive samples remained positive and all TV negative samples remained negative, indicating that there was no interference causing false negative or false positive results with the Xpert TV Assay for these substances.

Table 5-9: Potentially Interfering Substances in Urine Samples

Class/Substance	Active Ingredient	Concentration Tested
Blood	Blood	0.3% v/v, 1% v/v
Mucus	Mucin	0.8% w/v
Analgesics & Antibiotics	Acetylsalicylic Acid 500mg	40 mg/mL
	Acetaminophen	3.2 mg/mL
	Azithromycin	1.8 mg/mL
	Doxycycline	3.6 mg/mL
OTC Deodorant & Powders	PEG-20; PEG-32; PEG-20 Stearate	0.25% w/v
	Nanoxynol-9	0.25% w/v
Albumin	BSA	10 mg/ml
Glucose	Glucose	10 mg/ml
Bilirubin	Bilirubin	1 mg/ml
Acidic Urine (pH 4.0)	Urine + N-Acetyl-L-Cysteine	pH 4.0
Alkaline Urine (pH 9.0)	Urine + Ammonium Citrate	pH 9.0
Leukocytes	Leukocytes	10 ⁵ cells/mL
Intravaginal Hormones	Progesterone; Estradiol	7 mg/mL Progesterone + 0.07 mg/mL Beta Estradiol

Table 5-10: Potentially Interfering Substances in Swab Samples

Class/Substance	Active Ingredient	Concentration Tested
Blood ^a	Blood	10%, 50%, 60% v/v
Seminal Fluid	Seminal Fluid	5.0% v/v
Mucus	Mucin	0.8% w/v
Over the counter (OTC) Vaginal Products; Contraceptives; Vaginal treatments	Benzocaine 5%; Resorcinol 2%	0.25% w/v
	Clotrimazole 2%	0.25% w/v
	Miconazole Nitrate 2%	0.25% w/v
	Tioconazole	0.25% w/v
	5% w/w Aciclovir	0.25% w/v
	Glycerin, Propylene glycol	0.25% w/v
	Glycerin; Carbomer	0.12% w/v
	Glycerin, Hydroxyethyl cellulose	0.25% w/v
	Goldenseal 3X HPUS; Kreosotum 12X HPUS	0.25% w/v
	Povidone-iodine 10%	0.25% v/v
Nonoxynol-9 12.5%	0.25% w/v	
Hemorrhoidal Cream	Glycerin 14%; Pramoxine HCl 1%	0.25% w/v
Leukocytes	Leukocytes	10 ⁵ cells/mL
Intravaginal Hormones	Progesterone; Estradiol	7 mg/mL Progesterone + 0.07 mg/mL Beta Estradiol

a. In tests with substances diluted into pooled *T. vaginalis*-positive swab matrix, assay interference was observed in tests with blood at 60% v/v. No assay interference was observed in tests with blood at 50% v/v. This is addressed in Limitations in the package insert.

Carry-Over Contamination

This study was conducted to demonstrate that single-use, self-contained GeneXpert cartridges prevent carry-over contamination in negative samples run after very high positive samples in the same GeneXpert module. A negative sample (*T. vaginalis* negative vaginal swabs in Cepheid Xpert Swab Transport Reagent) was run followed by 20 rounds of high positive sample (*T. vaginalis* ATCC 30001 at 10⁶ cells/mL diluted in vaginal swab matrix) alternated with negative sample in two separate GeneXpert modules for a total of 40 high positive and 42 negative samples for each module. This testing scheme resulted in a total of 82 runs (40 positive + 42 negative single-use samples). There was no evidence of carry-over contamination as all 40 positive samples were correctly reported as **TV DETECTED** and all 42 negative samples were correctly reported as **TV NOT DETECTED**.

Linearity

Not applicable, the Xpert TV Assay is a qualitative assay.

Clinical Studies

Clinical Performance

Performance characteristics of the Xpert TV Assay were determined in a multi-site prospective investigational study by comparing the results from the Xpert TV Assay to a patient infected status (PIS) algorithm comprised of an FDA cleared NAAT test and culture.

Study participants included consenting asymptomatic and symptomatic, sexually active females seen at locations including, but not limited to: OB/GYN, sexually transmitted disease (STD), and family planning clinics. The average age among eligible study participants was 33.5 years (range = 18 to 78 years).

The study specimens consisted of prospectively collected urine, endocervical swabs and patient-collected vaginal swabs (collected in a clinical setting). Clinician-collected vaginal swabs were collected for testing by the reference NAAT test and culture. Samples were collected from 17 clinical sites and tested at 11 sites. Reference testing was performed at 3 central laboratories.

A study participant was considered to be infected by PIS if either of the reference test (NAAT and culture) results were positive. The subject was considered to be not infected by PIS when both reference test results were negative.

Performance of the Xpert TV Assay was calculated relative to the PIS for each of the three specimen types (endocervical swabs, patient-collected vaginal swabs and urine).

Specimens with discrepant results between the Xpert TV Assay and the PIS were analyzed by validated bi-directional Sanger sequencing and results are footnoted in Table 5-11 for informational purposes only.

Among the 5391 tests performed, 85 had initial ERROR, INVALID or NO RESULT outcomes (1.58%, 95% CI 1.26-1.95). Of those, 77 specimens yielded valid results upon repeat assay (2 specimens were not retested). The overall valid reporting rate of the assay was 99.9% (5383/5391).

Results of the Xpert TV Assay were compared to the PIS algorithm for determination of sensitivity, specificity, and predictive values. Sensitivity and specificity for TV by specimen type and symptom status are presented in Table 5-11.

Table 5-11: Xpert TV vs. PIS by Symptomatic Status

Sample Type	Status	Total (n)	Sens	95% CI	Spec	95% CI	Prev (%)	PPV (%)	NPV (%)
ES	Symp	685	100% (71/71)	94.9%-100%	98.5% (605/614)	97.2%-99.3%	10.4%	88.8%	100%
	Asymp	1114	98.1% (104/106)	93.4%-99.8%	99.1% (999/1008)	98.3%-99.6%	9.5%	92.0%	99.8%
	Overall	1799	98.9% (175/177) ^a	96.0%-99.9%	98.9% (1604/1622) ^b	98.3%-99.3%	9.8%	90.7%	99.9%
	Difference	P-Value	P=0.517	-0.70%, 4.48%	P=0.331	-1.69%, 0.54%			
PC-VS	Symp	682	98.6% (73/74)	92.7%-100%	99.5% (605/608)	98.6%-99.9%	10.9%	96.1%	99.8%
	Asymp	1109	95.0% (113/119)	89.3%-98.1%	99.6% (986/990)	99.0%-99.9%	10.7%	96.6%	99.4%
	Overall	1791	96.4% (186/193) ^c	92.7%-98.5%	99.6% (1591/1598) ^d	99.1%-99.8%	10.8%	96.4%	99.6%
	Difference	P-Value	P=0.254	-1.04%, 8.42%	P=1.000	-0.77%, 0.59%			
UR	Symp	688	98.6% (71/72)	92.5%-100%	99.8% (615/616)	99.1%-100%	10.5%	98.6%	99.8%
	Asymp	1105	98.2% (109/111)	93.6%-99.8%	99.6% (990/994)	99.0%-99.9%	10.0%	96.5%	99.8%
	Overall	1793	98.4% (180/183) ^e	95.3%-99.7%	99.7% (1605/1610) ^f	99.3%-99.9%	10.2%	97.3%	99.8%
	Difference	P-Value	P=1.000	-3.25%, 4.08%	P=0.655	-0.27%, 0.75%			

TP=true positive, **FP**=false positive, **TN**=true negative, **FN**=false negative, ES=endocervical swab, PC-VS=patient-collected vaginal swab, UR= urine

a. Testing results by sequencing: 1 of 2 FN was TV positive; 1 of 2 was TV negative.

b. Testing results by sequencing: 8 of 18 FP were TV positive; 10 of 18 were TV negative.

c. Testing results by sequencing: 3 of 7 FN were TV positive; 4 of 7 were TV negative.

d. Testing results by sequencing: 5 of 7 FP were TV positive; 2 of 7 were TV negative.

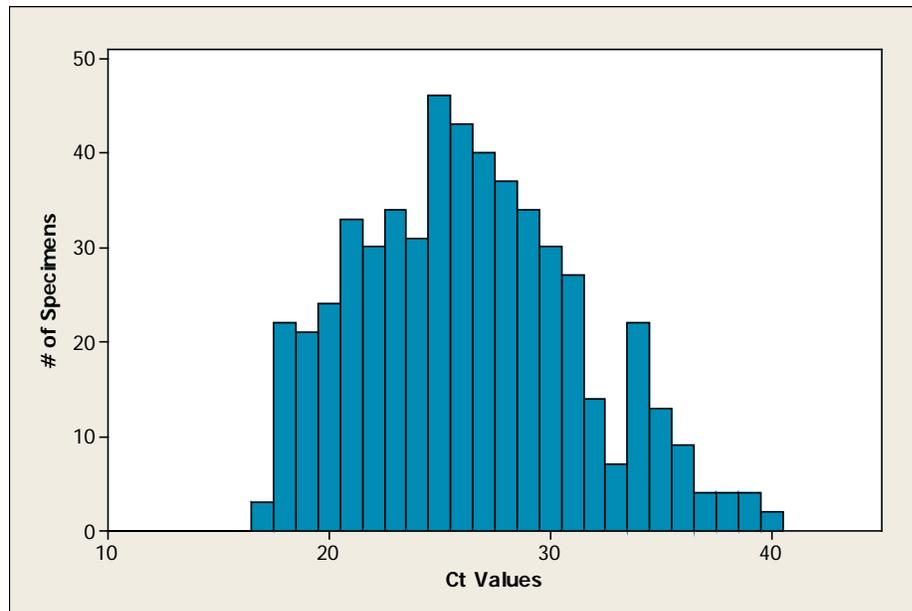
e. Testing results by sequencing: 3 of 3 FN were TV negative.

f. Testing results by sequencing: 5 of 5 FP were TV negative.

Cycle Threshold (Ct) Frequency Distribution

Patient-collected vaginal swabs, endocervical swabs and urine specimens were collected from 1867 females at 17 collection sites in the US. The frequency distribution of Xpert TV Assay positive results for the 197 *Trichomonas vaginalis* infected study subjects are shown in Figure 5-1.

Figure 5-1. Ct Distribution of Patients Designated as Positive for TV Based on PIS Algorithm



Reproducibility Study

Intra-site reproducibility of the Xpert TV Assay was evaluated at three sites (two external, one in-house). Site 1 used an Infinity-80 instrument. Sites 2 and 3 used GeneXpert Dx instruments. Specimens were created by spiking *Trichomonas vaginalis* (ATCC[®] 30001[™]) into pooled, *Trichomonas vaginalis* negative urine (patient urine added to Cepheid Urine Transport Reagent) or vaginal swab matrix (vaginal swabs collected into Cepheid Swab Transport Reagent). The specimens were prepared at concentration levels representing high negative (below LoD), LoD (~1X LoD, moderate positive (~3X LoD), and negative (*Trichomonas vaginalis* negative clinical matrix). A panel of 8 specimens (4 in urine and 4 in vaginal swab matrix) was tested twice per day, on 12 different days, by two different operators, at each of three sites (8 specimens x 2 replicates x 12 days x 2 operators x 3 sites = 1,152 observations total). Three lots of Xpert TV Assay cartridges were used at each of the 3 testing sites, with each lot used for 4 days of testing. Positive and negative controls were included in the study. The Xpert TV Assay was performed according to the Xpert TV Assay procedure. The rate of agreement with expected results is shown by site in Table 5-12.

Table 5-12: Summary of Reproducibility Results

Sample ^a	Site 1 (Infinity-80)			Site 2 (GeneXpert Dx)			Site 3 (GeneXpert Dx)			Total Agreement by Sample
	Op 1	Op 2	Site	Op 1	Op 2	Site	Op 1	Op 2	Site	
FS-Neg	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
FS-Mod Pos (~3X LoD; ~6 cells/mL)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
FS-LoD (~1X LoD; ~2 cells/mL)	95.8% (23/24)	100% (24/24)	97.9% (47/48)	87.5% (21/24)	95.8% (23/24)	91.7% (44/48)	100% (24/24)	95.8% (23/24)	97.9% (47/48)	95.8% (138/144)
FS-High Neg (below LoD; < 2 cells/mL)	87.5% (21/24)	75.0% (18/24)	81.3% (39/48)	66.7% (16/24)	79.2% (19/24)	72.9% (35/48)	79.2% (19/24)	70.8% (17/24)	75.0% (36/48)	76.4% (110/144)
UR-Neg	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
UR-Mod Pos (~3X LoD; ~9 cells/mL)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
UR-LoD (~1X LoD; ~3 cells/mL)	75.0% (18/24)	91.7% (22/24)	83.3% (40/48)	83.3% (20/24)	91.3% (21/23) ^b	87.2% (41/47)	91.7% (22/24)	100% (24/24)	95.8% (46/48)	88.8% (127/143)
UR-High Neg (below LoD; < 3 cells/mL)	75.0% (18/24)	75.0% (18/24)	75.0% (36/48)	70.8% (17/24)	54.2% (13/24)	62.5% (30/48)	75.0% (18/24)	75.0% (18/24)	75.0% (36/48)	70.8% (102/144)

a. FS=female swab matrix; UR= urine matrix.

b. One sample indeterminate on initial and retest.

The reproducibility of the Xpert TV Assay was also evaluated in terms of the fluorescence signal expressed in Ct values for each target detected. The mean, standard deviation (SD), and coefficient of variation (CV) between-sites, between-lots, between-days, between-operators, and residual variability for each panel member are presented in Table 5-13.

Table 5-13: Summary of Reproducibility Data

Sample ^a	Assay Channel (Analyte)	N ^b	Mean Ct	Between-Site		Between-Lot		Between-Day		Between-Operator		Residual		Total	
				SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c
FS-Neg	SPC	144	33.7	0.0	0.0	0.1	23.2	0.1	8.9	0.0	0.0	0.4	67.9	0.4	1.2
FS-Mod Pos (~3X LoD; ~6 cells/mL)	TV	144	35.4	0.1	7.9	0.0	0.0	0.0	0.0	0.1	12.5	0.8	79.7	0.8	2.3
FS-LoD (~1X LoD; ~2 cells/mL)	TV	138	38.5	0.0	0.0	0.0	0.0	0.5	28.0	0.0	0.0	1.2	72.0	1.3	3.5
FS-High Neg (below LoD; < 2 cells/mL)	TV	110	39.4	0.0	0.0	0.0	0.0	0.4	17.6	0.0	0.0	1.7	82.4	1.8	4.5
UR-Neg	SPC	144	33.9	0.1	8.6	0.0	0.0	0.1	9.0	0.1	18.5	0.4	63.9	0.4	1.2
UR-Mod Pos (~3X LoD; ~9 cells/mL)	TV	144	35.5	0.2	22.3	0.1	9.6	0.0	0.0	0.0	0.0	0.6	67.9	0.7	1.9
UR-LoD (~1X LoD; ~3 cells/mL)	TV	127	39.3	0.0	0.0	0.4	24.4	0.0	0.0	0.0	0.0	1.2	75.6	1.3	3.4
UR-High Neg (below LoD; < 3 cells/mL)	TV	102	39.0	0.0	0.0	0.3	14.4	0.7	29.5	0.3	11.6	1.0	44.6	1.3	3.3

- a. FS=female swab matrix; UR= urine matrix.
- b. Results with non-zero Ct values out of 144.
- c. (%) is contribution of variance component to overall CV.

Instrument System Precision

An in-house precision study was conducted to compare the performance of the GeneXpert Dx and the GeneXpert Infinity Instrument Systems using specimens comprised of *Trichomonas vaginalis* (ATCC[®] 30001[™]) spiked into negative urine (patient urine added to Cepheid Urine Transport Reagent) or vaginal swab matrix (vaginal swabs collected into Cepheid Swab Transport Reagent). The specimens were prepared at concentration levels representing low positive (below LoD), LoD (~1X LoD), moderate positive (~3X LoD), and negative (*Trichomonas vaginalis* negative clinical matrix). A panel of 8 specimens (4 in urine matrix and 4 in vaginal swab matrix) was tested on 12 different days by two operators. Each operator conducted four runs of each panel specimen per day on each of the three instrument systems (8 specimens x 4 times/day x 12 days x 2 operators x 3 instrument systems = 2,304 observations total). Three lots of Xpert TV Assay cartridges were used for the study, with each lot used for 4 days of testing. Positive and negative controls were included in the study. The Xpert TV

Assay was performed according to the Xpert TV Assay procedure. The rate of agreement with expected results is shown by instrument in Table 5-14.

Table 5-14: Summary of Precision Results

Sample ^a	GeneXpert Dx			Infinity-48			Infinity-80			% Total Agreement by Sample
	Op 1	Op 2	Inst	Op 1	Op 2	Inst	Op 1	Op 2	Inst	
FS-Neg	100% (48/48)	100% (48/48)	100% (96/96)	97.9% (47/48)	100% (48/48)	99.0% (95/96)	100% (48/48)	100% (48/48)	100% (96/96)	99.7% (287/288)
FS-Mod Pos (~3X LoD; ~6 cells/mL)	100% (48/48)	100% (48/48)	100% (96/96)	100% (48/48)	100% (48/48)	100% (96/96)	100% (48/48)	100% (48/48)	100% (96/96)	100% (288/288)
FS-LoD (~1X LoD; ~ 2 cells/mL)	93.8% (45/48)	87.5% (42/48)	90.6% (87/96)	93.8% (45/48)	89.6% (43/48)	91.7% (88/96)	95.8% (46/48)	89.6% (43/48)	92.7% (89/96)	91.7% (264/288)
FS-High Neg (below LoD; < 2 cells/mL)	74.5% (35/47)	75.0% (36/48)	74.7% (71/95)	77.1% (37/48)	75.0% (36/48)	76.0% (73/96)	83.3% (40/48)	68.8% (33/48)	76.0% (73/96)	75.6% (217/287) ^b
UR-Neg	100% (48/48)	100% (48/48)	100% (96/96)	100% (48/48)	100% (48/48)	100% (96/96)	100% (48/48)	100% (47/47)	100% (95/95)	100% (287/287) ^b
UR-Mod Pos (~3X LoD; ~9 cells/mL)	100% (48/48)	100% (48/48)	100% (96/96)	100% (48/48)	100% (48/48)	100% (96/96)	100% (48/48)	100% (48/48)	100% (96/96)	100% (288/288)
UR-LoD (~1X LoD; ~3 cells/mL)	93.8% (45/48)	93.8% (45/48)	93.8% (90/96)	95.8% (46/48)	89.6% (43/48)	92.7% (89/96)	95.8% (46/48)	95.8% (46/48)	95.8% (92/96)	94.1% (271/288)
UR-High Neg (below LoD; < 3 cells/mL)	72.9% (35/48)	77.1% (37/48)	75.0% (72/96)	70.8% (34/48)	79.2% (38/48)	75.0% (72/96)	81.3% (39/48)	85.4% (41/48)	83.3% (80/96)	77.8% (224/288)

a. FS=female swab matrix; UR= urine matrix.

b. One FS-Low Pos and one UR-Neg sample indeterminate and not retested.

The precision of the Xpert TV Assay was also evaluated in terms of the fluorescence signal expressed in Ct values for each target detected. The mean, standard deviation (SD), and coefficient of variation (CV) between-instruments, between-lots, between-days, between-operators, and residual variability for each panel member are presented in Table 5-15.

Table 5-15: Summary of Precision Data

Sample ^a	Assay Channel (Analyte)	N ^b	Mean Ct	Between-Instrument		Between-Lot		Between-Day		Between-Operator		Residual		Total	
				SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c	SD	CV (%) ^c
FS-Neg	SPC	288	31.9	0.0	0.0	0.3	53.5	0.0	0.0	0.1	1.9	0.2	44.6	0.4	1.1
FS-Mod Pos (~3X LoD; ~6 cells/mL)	TV	288	35.2	0.0	0.0	0.3	22.4	0.0	0.0	0.1	4.5	0.4	73.1	0.5	1.5
FS-LoD (~1X LoD; ~2 cells/mL)	TV	264	39.0	0.2	3.3	0.1	0.4	0.2	1.3	0.0	0.0	1.3	95.0	1.3	3.4
FS-High Neg (below LoD; < 2 cells/mL)	TV	217	39.4	0.0	0.0	0.0	0.0	0.0	0.0	0.2	1.6	1.3	98.4	1.3	3.2
UR-Neg	SPC	287	32.4	0.0	0.0	0.3	47.2	0.1	2.9	0.0	0.0	0.3	49.9	0.4	1.2
UR-Mod Pos (~3X LoD; ~9 cells/mL)	TV	288	35.4	0.0	0.0	0.4	30.4	0.0	0.0	0.2	11.3	0.5	58.3	0.6	1.8
UR-LoD (~1X LoD; ~3 cells/mL)	TV	271	38.2	0.0	0.0	0.5	13.6	0.6	16.2	0.3	3.6	1.2	66.5	1.4	3.7
UR-High Neg (below LoD; < 3 cells/mL)	TV	224	38.9	0.0	0.0	0.3	5.4	0.0	0.0	0.3	4.2	1.2	90.3	1.3	3.3

- a. FS=female swab matrix; UR=urine matrix.
b. Results with non-zero Ct values out of 288.
c. (%) is contribution of variance component to overall CV.

Conclusions

The results of the nonclinical analytical and clinical performance studies summarized above demonstrate that the Xpert TV Assay is substantially equivalent to the predicate device.