510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K202977

B Applicant

Abbott Molecular, Inc.

C Proprietary and Established Names

Alinity m STI Assay

D Regulatory Information

1. Regulation section

   21 CFR 866.3393: Device to detect nucleic acids from non-viral microorganism(s) causing sexually transmitted infections and associated resistance marker(s)

2. Classification

   Class II

3. Product Codes

QEP:	Nucleic Acid Detection System For Non-Viral Microorganism(s) Causing Sexually Transmitted Infections
LSL:	DNA-Reagents, Neisseria
MKZ:	DNA Probe, Nucleic Acid Amplification, Chlamydia
OUY:	Trichomonas vaginalis nucleic acid assay
OOI:	Instrumentation for clinical multiplex test systems

4. Panel

   Microbiology (83)

II Submission/Device Overview:

A Purpose for Submission:

To obtain market clearance for a new device.

B Measurand:

Chlamydia trachomatis (CT) ribosomal RNA
Neisseria gonorrhoeae (NG) genomic DNA
Trichomonas vaginalis (TV) ribosomal RNA
Mycoplasma genitalium (MG) ribosomal RNA

C Type of Test:

Qualitative, real time polymerase chain reaction (PCR) assay.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Alinity m STI Assay is an *in vitro* polymerase chain reaction (PCR) assay for use with the automated Alinity m System for the direct, qualitative detection and differentiation of ribosomal RNA from *Chlamydia trachomatis* (CT), DNA from *Neisseria gonorrhoeae* (NG), ribosomal RNA from *Trichomonas vaginalis* (TV), and ribosomal RNA from *Mycoplasma genitalium* (MG), to aid in the diagnosis of disease(s) caused by infection from these organisms. The assay may be used to test the following specimens from symptomatic and asymptomatic individuals for the following analytes:

CT: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, male urine, oropharyngeal swabs, and rectal swabs

NG: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, male urine, oropharyngeal swabs, and rectal swabs

TV: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, female urine, and male urine

MG: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, and male urine
A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher clinical sensitivity compared to endocervical swabs. If endocervical swab specimens test negative, testing with a vaginal swab may be indicated, *if M. genitalium* infection is suspected.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Alinity m System

IV Device/System Characteristics:

A Device Description:

The Alinity m System is a fully integrated instrument that can process 300 samples per day (in approximately 8 hours) from first sample aspiration to the last test result. The Alinity m System supports random access to assays as well as continuous loading of samples, reagents and commodities. The system includes a touchscreen where the operator directs the system to execute various tasks, and a barcode scanner for sample identification. Samples can be loaded on the system in any order, and the system will schedule them to be processed based on system defined criteria. The system pipettor robot dispenses and aspirates liquids, as appropriate for each reaction. Sample handling and reagent transport is performed by a handler robot. The instrument performs the following functions automatically:

- Isolation of nucleic acid from specimens
- Amplification of specific nucleic acid targets by PCR
- Detection of the amplified product
- Analysis of the response data to produce qualitative results

The extraction of nucleic acids includes cell lysis and adsorption onto magnetic microparticles, followed by multiple washing cycles and finally elution of the purified nucleic acids. The extracted material is mixed with a master mix for amplification in a PCR reaction which includes target specific probes labelled with different fluorophores allowing for detection of multiple targets in one reaction. The system software analyzes generated signals and reduces the data to determine the final qualitative result for the STI analytes.

All stages of the Alinity m STI Assay procedure are executed automatically by the Alinity m System. No intermediate processing or transfer steps are performed by the user.

<u>Alinity m STI Assay requires the following:</u>

1. AMP Kit, which consists of two distinct reagent plates:
   - Alinity m STI AMP TRAY 1 (4 trays x 96 tests)
   - Alinity m STI ACT TRAY 2 (4 trays x 96 tests)
2. Alinity m Multi-Collect Specimen Collection Kit, with the following components:
   - One Transport Tube filled with 1.4 mL Alinity m Transport Buffer
   - One individually packaged Sterile Specimen Collection Swab
   - One disposable Transfer Pipette
3. Alinity m STI CTRL Kit includes two assay controls in liquid format provided in single-use tubes.

- Alinity STI Negative Control (12 tubes x 0.47mL)
- Alinity STI Positive Control (12 tubes x 0.47mL)

4. Alinity m Sample Prep Kit 1 is used to isolate nucleic acids from biological samples for analysis in PCR tests and consists of:
   - Alinity m Elution Buffer 1 which contains nuclease, protease free molecular grade water, and Tween 20 and preservatives
   - Alinity m Microparticles 1, which contains magnetic microparticles in 6.2 M Guanidine hydrochloride solution
5. Alinity m System Solutions are required to perform the Alinity m STI assay:
   - Alinity m Lysis Solution
   - Alinity m Ethanol Solution
   - Alinity m Diluent Solution
   - Alinity m Vapor Barrier Solution

Specimen Collection

Endocervical, vaginal, oropharyngeal, and rectal swabs, female urine and male urine specimens must be collected using the Alinity m multi-Collect Specimen Collection Kit, according to the instructions for use.

Gynecological specimens in PreservCyt Solution (Hologic Inc.) must be collected and handled according to the manufacturer's instructions. For PreservCyt specimens, only the aliquot taken from the PreservCyt vial prior to cytology processing must be transferred to an Alinity m Transfer Tube for processing on the Alinity m System.

Results

The Alinity m System automatically reports qualitative results for each analyte (CT, NG, TV, or MG) based on the amplification cycle number (CN) after the fluorescent signal is detected by the Alinity m System. Each result is either reported as "Positive", if the CN is less than or equal to a fixed assay cutoff cycle for that signal, or as "Negative", if the CN is not generated, or the CN is greater than the assay cutoff cycle.

Interpretation of Results

Assay	Result	Interpretation
CT	CT Positive	CT Target Detected
CT	CT Negative	CT Target Not Detected
NG	NG Positive	NG Target Detected
NG	NG Negative	NG Target Not Detected
TV	TV Positive	TV Target Detected
TV	TV Negative	TV Target Not Detected
MG	MG Positive	MG Target Detected
MG	MG Negative	MG Target Not Detected

B Principle of Operation:

The Alinity m STI assay utilizes real-time polymerase chain reaction (PCR) to amplify and detect *Chlamydia trachomatis* ribosomal RNA sequences, *Neisseria gonorrhoeae* DNA sequences, *Trichomonas vaginalis* ribosomal RNA sequences, *Mycoplasma genitalium* ribosomal RNA sequences, and human DNA sequences that have been extracted from urogenital specimens, including endocervical swab, vaginal swab, male and female urine, and gynecological specimens preserved in ThinPrep PreservCyt Solution, as well as extragenital specimens, including rectal and oropharyngeal swabs.

Nucleic acids from specimens collected with the Alinity m multi-Collect Specimen Collection Kit, are extracted using the Alinity m Sample Prep Kit 1, Alinity m Lysis Solution, Alinity m Ethanol Solution, and Alinity m Diluent Solution. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash and elution. After multiple washes of the microparticles, the resulting purified nucleic acid is then combined with Alinity m STI activation reagent and Alinity m STI amplification/ detection reagents and transferred into a reaction vessel. Alinity m Vapor Barrier Solution is then added to prevent evaporation during the thermal cycling of the PCR. The reaction vessel is then transferred to an amplification / detection unit for reverse transcription, PCR amplification, and real-time fluorescence detection of CT, NG, TV, and MG amplified target nucleic acids. The Alinity m System's data analysis software processes the generated fluorescence for each assay reaction and automatically calculates and reports assay results.

Internal Controls:

The Alinity m STI assay incorporates an endogenous human DNA sequence, referred to as Cellular Control (CC), by including primers and probes in the amplification reagents to detect and amplify the single copy human gene, β-globin. The CC functions to ensure that the sample was adequate and to monitor the sample extraction and amplification efficiency.

In addition, a defined, consistent quantity of exogenous internal control (IC) is present in each PCR reaction and is measured on the Alinity m System to confirm that no PCR inhibitors are present in the sample. The IC is comprised of an armored RNA sequence unrelated to the Alinity m STI assay target sequences.

The Cellular Control and Internal Control are both used to demonstrate assay validity. If the cycle number (CN) value for either one of these controls exceeds the specified range, a Flag or Message Code is displayed for the associated specimen:

- For Positive Specimens: If the IC CN or CC CN is out of range, but the analyte(s) in that sample is Positive, the sample will yield a Positive result. An IC Flag or CC Flag will be reported next to the positive result.
- For Negative Specimens: If the IC CN or CC CN is out of range and the analyte(s) in that sample is not Positive, no result will be reported for the analyte(s) and a Message Code will be generated.

In addition, the test system is designed to minimize the possibility of nucleic acid contamination on the Alinity m System by the following features:

- Aerosol barrier pipette tips which are used for all pipetting; the pipette tips are discarded after use.
- PCR amplification and detection are carried out automatically in a sealed reaction vessel.
- Disposal of the reaction vessel is performed automatically by the Alinity m System.

External Quality Controls:

The Alinity m STI CTRL Kit includes Negative and Positive assay controls in liquid format provided in single-use tubes. It is recommended that both controls are tested, at the minimum frequency of once every 24 hours to ensure that instrument and reagent performance remains satisfactory. During each control event, a negative control and a positive control are processed through sample preparation and RT-PCR procedures that are identical to those used for specimens. The controls do not indicate if bacterial cells have been adequately lysed, therefore, additional controls, including those for cell lysis, may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and internal quality control policy. Valid results for all control levels must be obtained before specimen results are reported.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Abbott RealTime CT/NG (Predicate for CT/NG)
Hologic Aptima Combo 2 Assay (Predicate for CT/NG in PreservCyt Samples)
Becton Dickinson MAX CT/GC/TV (Predicate for TV)
Hologic Aptima Mycoplasma genitalium Assay (Predicate for MG)

B Predicate 510(k) Number(s):

K140354
K190515
K151589
DEN180047

C Comparison with Predicate(s):

Testing for CT and NG

Device & Predicate Device(s):	**K202977**	**K140354**	**K190515**
Device Trade Name	**Alinity m STI Assay**	**Abbott RealTi*m*e CT/NG**	**Aptima Combo 2 Assay (for Gynecological Specimens)**
General Device Characteristic Similarities and Differences			
Intended Use/Indications For Use	The Alinity m STI Assay is an *in vitro* polymerase chain reaction (PCR) assay for use	The Abbott RealTi*m*e CT/NG assay is an in vitro polymerase chain reaction	The Aptima Combo 2 Assay is a target amplification nucleic acid probe test that

	with the automated Alinity m System for the direct, qualitative detection and differentiation of ribosomal RNA from *Chlamydia trachomatis* (CT), DNA from *Neisseria gonorrhoeae* (NG), ribosomal RNA from *Trichomonas vaginalis* (TV), and ribosomal RNA from *Mycoplasma genitalium* (MG) to aid in the diagnosis of urogenital disease(s) caused by infection from these organisms. The assay may be used to test the following specimens from symptomatic and asymptomatic individuals for the following analytes: CT: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, male urine, oropharyngeal swabs, and rectal swabs NG: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, male urine, oropharyngeal swabs, and rectal swabs TV: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, female urine, and male urine MG: vaginal swabs (clinician collected and self-collected in a clinical	(PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae.* The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab and patient-collected vaginal swab specimens; female and male urine specimens.	utilizes target capture for the *in vitro* qualitative detection and differentiation of ribosomal RNA (rRNA) from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of chlamydial and/or gonococcal disease using the Panther System as specified. On the Panther System, the assay may be used to test the following specimens from symptomatic and asymptomatic individuals: clinician-collected endocervical, vaginal, throat, rectal, and male urethral swab specimens, clinician-collected gynecological specimens collected in the PreservCyt Solution, patient-collected vaginal swab specimens,[1] and female and male urine specimens. [1]Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection kit has not been evaluated for home use.

	settings), endocervical swabs, and male urine A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher clinical sensitivity compared to endocervical swabs. If endocervical swab specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected.		
Assay Type	Qualitative Nucleic acid amplification	Qualitative Nucleic acid amplification	Qualitative Nucleic acid amplification
Amplification Technology	Real Time RT-PCR	Real Time PCR	Target Capture (TC), Transcription-mediated Amplification (TMA), Dual Kinetic Assay (DKA)
Assay Targets	CT ribosomal RNA NG genomic DNA TV ribosomal RNA MG ribosomal RNA	CT cryptic plasmid DNA NG genomic DNA	CT ribosomal RNA NG ribosomal RNA
Specimen Types	Endocervical swabs Self-collected vaginal swabs Clinician- collected vaginal swabs Male and female urine Gynecological specimens in PreservCyt Solution Oropharyngeal swabs Rectal swabs	Endocervical swabs Self-collected vaginal swabs Clinician- collected vaginal swabs Male and female urine Male urethral swabs	Endocervical swabs Self-collected vaginal swabs Clinician- collected vaginal swabs Male and female urine Male urethral swabs Gynecological specimens in PreservCyt Solution Oropharyngeal swabs Rectal swabs
Sample Preparation	Automated extraction and purification	Automated extraction and purification	Automated extraction and purification
Assay Controls	• External Negative and Positive Controls • Internal Processing Control (IC) • Sample Adequacy Cellular Control (CC)	• External Negative and Positive Control • Internal Cutoff Control • Internal Processing Control	• External Negative and Positive Controls
Specimen Collection Kit(s)	Alinity m multi-Collect Specimen Collection Kit	Abbott multi-Collect Specimen Collection Kit	• Aptima Multitest Swab Specimen Collection Kit

			• Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens • Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens

Testing for TV and MG

Device & Predicate Device(s):	**K202977**	**K151589**	**DEN180047**
Device Trade Name	Alinity m STI	BD Max CT/GC/TV	Aptima Mycoplasma genitalium Assay
General Device Characteristic Similarities and Differences			
Intended Use/Indications For Use	The Alinity m STI Assay is an *in vitro* polymerase chain reaction (PCR) assay for use with the automated Alinity m System for the direct, qualitative detection and differentiation of ribosomal RNA from *Chlamydia trachomatis* (CT), DNA from *Neisseria gonorrhoeae* (NG), ribosomal RNA from *Trichomonas vaginalis* (TV), and ribosomal RNA from *Mycoplasma genitalium* (MG) to aid in the diagnosis of urogenital disease(s) caused by infection from these organisms. The assay may be used to test the following specimens from symptomatic and asymptomatic individuals for the following analytes: CT: vaginal swabs (clinician-collected and self-collected in a	The BD MAX CT/GC/TV assay, as performed using the BD MAX System incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC) and/or *Trichomonas vaginalis* (TV). The assay may be used for detection of CT and/or GC DNA in male urine specimens, and the detection of CT, GC and/or TV DNA in female urine specimens, clinician-collected female endocervical swab specimens and patient-collected vaginal swab specimens (in a clinical setting). The assay is indicated for use to aid in the diagnosis of chlamydial urogenital disease,	The Aptima Mycoplasma genitalium assay is an *in vitro* nucleic acid amplification test (NAAT) for the qualitative detection of ribosomal RNA (rRNA) from *Mycoplasma genitalium* on the fully automated Panther system. It is intended for use as an aid in the diagnosis of *M. genitalium* urogenital infections in male and female patients suspected of *M. genitalium* infection. The assay may be used to test the following specimens: clinician-collected and self-collected vaginal swabs (in a clinical setting), clinician-collected endocervical swabs, female and male urine, clinician-collected male urethral swabs, and self-collected penile meatal

	clinical settings), endocervical swabs, male urine, oropharyngeal swabs, and rectal swabs NG: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, male urine, oropharyngeal swabs, and rectal swabs TV: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, female urine, and male urine MG: vaginal swabs (clinician collected and self-collected in a clinical settings), endocervical swabs, and male urine A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher clinical sensitivity compared to endocervical swabs. If endocervical swab specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected.	gonococcal urogenital disease and/or trichomoniasis in asymptomatic and symptomatic individuals.	swabs (in a clinical setting). For females, a vaginal swab is the preferred specimen type due to higher clinical sensitivity for detecting *M. genitalium* than other specimen types; however, female urine or clinician-collected endocervical swabs may be used as alternative specimens when vaginal swab specimens are not available. If female urine or clinician-collected endocervical swab specimens test negative, testing with a vaginal swab may be indicated, if *M. genitalium* infection is suspected.

Assay Type	Qualitative Nucleic acid amplification	Qualitative Nucleic acid amplification	Qualitative Nucleic acid amplification
Amplification Technology	Real Time PCR	Real Time PCR	Target Capture (TC), Transcription-mediated Amplification (TMA), Hybridization Protection Assay (HPA)
Assay Targets	CT ribosomal RNA NG genomic DNA TV ribosomal RNA MG ribosomal RNA	CT genomic DNA NG genomic DNA TV genomic DNA	MG ribosomal RNA (16s rRNA)
Specimen Types	Endocervical swabs Self-collected vaginal swabs Clinician- collected vaginal swabs Male and female urine Gynecological specimens in PreservCyt Solution Oropharyngeal swabs Rectal swabs	Endocervical swabs Self-collected vaginal swabs Male and female urine	Endocervical swabs Self-collected vaginal swabs Clinician- collected vaginal swabs Male and female urine Male urethral swabs Self-collected penile meatal swabs
Sample Preparation	Automated extraction and purification	Automated extraction and purification	Automated extraction and purification
Assay Controls	• External Negative and • Positive Controls • Internal processing Control (IC) • Sample adequacy Cellular Control (CC)	• Internal Processing Control	• Internal Processing Control
Specimen Collection Kit(s)	• Alinity m multi-Collect Specimen Collection Kit	• BD MAX Urine Transport Kit • BD MAX 3-in-1 Swab Collection Kit	• Aptima Multitest Swab Specimen Collection Kit • Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens • Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens

VI Standards/Guidance Documents Referenced:

AMMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

I/ANSI/ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

CLSI Guideline EP12-A2, "User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline." Second Edition.

CLSI Guideline EP15-A3, "User Verification of Precision and Estimation of Bias;Approved Guideline." Third edition.

FDA Guidance Document, "Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of Trichomonas vaginalis, 2015."

VII Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

Within Laboratory Precision

The within-laboratory precision of the Alinity m STI assay was evaluated by testing 13 panel members prepared in three different sample matrices that represent urogenital specimen types: urine and two contrived matrices described in section B.2. For each specimen matrix, the 13 panel members were prepared by spiking with quantified stocks of whole organisms in combinations of the four target organisms CT, NG, TV, and MG. The following target concentrations were evaluated for each organism: LoD (targeting the limit of detection), low positive (targeting 2x claimed LoD), high positive (targeting ≥ 5x LoD), and a high negative (targeting 0.3x LoD); a negative panel member consisted of unspiked matrix. Each panel member was tested in two replicates, twice each day for 12 days, on three Alinity m Systems with three reagent lots, for a total of 144 replicates. Three operators performed the testing. The results were evaluated for
% agreement with expected results. Additionally, the mean, standard deviation and % CV were calculated for each component of variability (within-run, between run, between day, between lot/instrument, and overall/total) for each panel member, for each matrix, and for each of the four target organisms.

Precision Panel Composition

Panel Member	CT	NG	TV	MG
1	Negative	Negative	Negative	Negative
2	Low Positive	Negative	Negative	Negative
3	Negative	Low Positive	Negative	Negative

4	Negative	Negative	Low Positive	Negative
5	Negative	Negative	Negative	Low Positive
6	Low Positive	Low Positive	Low Positive	Low Positive
7	High Positive	Low Positive	Low Positive	Low Positive
8	Low Positive	High Positive	Low Positive	Low Positive
9	Low Positive	Low Positive	High Positive	Low Positive
10	Low Positive	Low Positive	Low Positive	High Positive
11	High Positive,	High Positive	High Positive	High Positive
12	Near LoD	Near LoD	Near LoD	Near LoD
13	High Negative	High Negative	High Negative	High Negative

Data Analysis

The data was analyzed for percent agreement with expected results (positive or negative); the summary of the qualitative analysis is as follows.

For CT:

- For the panel members with CT concentration at near LoD or above (Panel Member 2, 6-12), the positive percent agreement with expected results was 100% (3456/3456), 95% CI: (99.9%-100%) across instruments, lots and matrices.
- For the High Negative Panel Member 13, the CT positivity rate ranged from 27.8% to 61.1% across instruments, lots and matrices.
- For the panel members without CT Target (Panel Member 1, 3-5), 1726 samples returned the expected negative results, for the overall negative percent agreement of 99.9% (1726/1728), 95% CI (99.6%-100%), across instruments, lots and matrices.

For NG:

- For the panel members with NG concentration at near LoD or above (Panel Member 3, 6-12), the positive percent agreement with expected results was 100% (3456/3456), 95% CI: (99.9%-100%), across instruments, lots and matrices.
- For the High Negative Panel Member 13, the NG positivity rate ranged from 45.1% to 84.7% across instruments, lots and matrices.
- For the panel members without NG target (Panel Member 1, 2, 4, 5), all samples returned the expected negative results, for the overall negative percent of 100% (1728/1728), 95% CI: (99.8%-100%), across instruments, lots and matrices.

For TV:

- For the panel members with TV concentration at near LoD or above (Panel Member 4, 6-12), the positive percent agreement with expected results was 99.97% (3455/3456), 95% CI: (99.8%-100%), across instruments, lots and matrices.
- For the High Negative Panel Member 13, the TV positivity rate ranged from 23.6% to 93.8% across instruments, lots and matrices.
- For the panel members without TV target (Panel Member 1, 2, 3, 5), the negative percent agreement was 99.8% (1724/1728), 95% CI: (99.4%-99.9%), across instruments, lots and matrices.

For MG:

- For the panel members with MG concentration at near LoD or above (Panel Member 5-12), the positive percent agreement with expected results was 100% (3456/3456), 95% CI: (99.9%-100%), across instruments, lots and matrices.
- For the High Negative Panel Member 13, the MG positivity rate ranged from 45.1% to 77.1% across instruments, lots and matrices.
- For the panel members without MG target (Panel Member 1, 2, 3, 5), the negative percent agreement was 100% (1728/1728), 95% CI: (99.8%-100%), across instruments, lots and matrices.

Additionally, the analysis of each variance component was performed for each positive target (near LoD and above) based on the generated signal (CN), using the random effects ANOVA model. The point estimates of the means, standard deviations (SD), and percent coefficient of variation (%CV) were reported. The SD and %CV were calculated for each component of variability. The total assay variability was defined as the sum of the within-run (residual error) component, the between-run component, the between-day component and between-instrument component estimates of variability.

The summary of the within-laboratory precision data is shown below.

Within-lab Precision: CT Results

						Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Instrument/Lot Component		Total[d]	
Matrix	**Panel Description**	**N[a]**	**n[b]**	**Agreement (n/N)**	**Mean CN**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Urine	CT High Pos (NG, TV & MG High Pos)	144	144	100.0%	16.62	0.191	1.2	0.133	0.8	0.133	0.8	0.655	3.9	0.094	0.6	0.662	4.0
	CT High Pos (NG, TV & MG at 2X LOD Claim)	144	144	100.0%	17.03	0.162	1.0	0.138	0.8	0.138	0.8	0.457	2.7	0.229	1.3	0.511	3.0
	CT at 2X LOD Claim (TV High Pos, NG & MG at 2X LOD Claim)	144	144	100.0%	30.18	0.246	0.8	0.121	0.4	0.121	0.4	0.613	2.0	0.160	0.5	0.634	2.1
	CT at 2X LOD Claim (NG High Pos, TV & MG at 2X LOD Claim)	144	144	100.0%	30.65	0.171	0.6	0.125	0.4	0.125	0.4	0.352	1.1	0.232	0.8	0.422	1.4
	CT at 2 X LOD Claim (MG High Pos, NG & TV at 2X LOD Claim)	144	144	100.0%	30.37	0.213	0.7	0.069	0.2	0.069	0.2	0.311	1.0	0.231	0.8	0.388	1.3
	CT at 2X LOD Claim (NG, TV & MG at 2X LOD Claim)	144	144	100.0%	30.80	0.380	1.2	0.079	0.3	0.079	0.3	0.489	1.6	0.321	1.0	0.585	1.9
	CT at 2X LOD Claim (CT only)	144	144	100.0%	30.23	0.180	0.6	0.165	0.5	0.165	0.5	0.287	0.9	0.177	0.6	0.337	1.1
	CT at LOD Claim	144	144	100.0%	31.73	0.164	0.5	0.112	0.4	0.112	0.4	0.404	1.3	0.204	0.6	0.453	1.4
	CT at Sub-LOD (High Negative)	144	76	52.8%	37.08	0.522	1.4	0.101	0.3	0.101	0.3	0.630	1.7	0.240	0.6	0.675	1.8
	CT Negative[e]	576	575	99.8%	....	....	....	....	....	....	....	....	....	....	....	....	....
Swab	CT High Pos (NG, TV & MG High Pos)	144	144	100.0%	16.94	0.219	1.3	1.645	9.7	1.645	9.7	1.659	9.8	0.253	1.5	1.679[f]	9.9[f]
	CT High Pos (NG, TV & MG at 2X LOD Claim)	144	144	100.0%	16.97	0.083	0.5	0.046	0.3	0.046	0.3	0.103	0.6	0.109	0.6	0.150	0.9
	CT at 2X LOD Claim (TV High Pos, NG & MG at 2X LOD Claim)	144	144	100.0%	29.58	0.102	0.3	0.000	0.0	0.000	0.0	0.116	0.4	0.113	0.4	0.162	0.5
	CT at 2X LOD Claim (NG High Pos, TV & MG at 2X LOD Claim)	144	144	100.0%	29.53	0.102	0.3	0.037	0.1	0.037	0.1	0.125	0.4	0.140	0.5	0.188	0.6
	CT at 2 X LOD Claim (MG High Pos, NG & TV at 2X LOD Claim)	144	144	100.0%	29.62	0.113	0.4	0.027	0.1	0.027	0.1	0.119	0.4	0.137	0.5	0.181	0.6
	CT at 2X LOD Claim (NG, TV & MG at 2X LOD Claim)	144	144	100.0%	29.60	0.163	0.5	0.071	0.2	0.071	0.2	0.183	0.6	0.170	0.6	0.249	0.8
	CT at 2X LOD Claim (CT only)	144	144	100.0%	29.71	0.084	0.3	0.022	0.1	0.022	0.1	0.090	0.3	0.105	0.4	0.138	0.5
	CT at LOD Claim	144	144	100.0%	30.51	0.230	0.8	0.036	0.1	0.036	0.1	0.236	0.8	0.117	0.4	0.264	0.9
	CT at Sub-LOD (High Negative)	144	88	61.1%	36.60	0.543	1.5	0.193	0.5	0.193	0.5	0.576	1.6	0.298	0.8	0.649	1.8
	CT Negative[e]	576	575	99.8%	....	....	....	....	....	....	....	....	....	....	....	....	....

[a] N:Total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Within-Laboratory includes Within-Run, Between-Run and Between-Day Components.

[d] Total includes Within-Run, Between-Run, Between-Day and Between-Instrument/Lot Components.

[e] The negative panel included 4 panel members negative for CT

[f] Two samples had cellular control (CC) failures and very late target CNs. Because the Alinity m STI assay reports positive results even if the CC fails, the CNs from these replicates were included in the total SD and %CV. Without those samples, the total SD was 0.143 and the total %CV was 0.9.

Within-lab Precision: NG Results

Matrix	Panel Description	N[a]	N[b]	Agreement (n/N)	Mean CN	Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Instrument/Lot Component		Total[d]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Urine	NG High Pos (CT, TV & MG High Pos)	144	144	100.0%	21.89	0.183	0.8	0.138	0.6	0.138	0.6	0.322	1.5	0.209	1.0	0.384	1.8
	NG High Pos (CT, TV & MG at 2X LOD Claim)	144	144	100.0%	22.41	0.230	1.0	0.206	0.9	0.206	0.9	0.416	1.9	0.193	0.9	0.458	2.0
	NG at 2X LOD Claim (MG High Pos, CT & TV at 2X LOD Claim)	144	144	100.0%	30.95	0.287	0.9	0.044	0.1	0.044	0.1	0.391	1.3	0.140	0.5	0.415	1.3
	NG at 2X LOD Claim (TV High Pos, CT & MG at 2X LOD Claim)	144	144	100.0%	30.72	0.245	0.8	0.000	0.0	0.000	0.0	0.318	1.0	0.197	0.6	0.374	1.2
	NG at 2X LOD Claim (CT, TV & MG at 2X LOD Claim)	144	144	100.0%	31.37	0.291	0.9	0.207	0.7	0.207	0.7	0.433	1.4	0.022	0.1	0.434	1.4
	NG at 2X LOD Claim (CT High Pos, TV & MG at 2X LOD Claim)	144	144	100.0%	31.24	0.212	0.7	0.144	0.5	0.144	0.5	0.346	1.1	0.093	0.3	0.359	1.1
	NG at 2X LOD Claim (NG only)	144	144	100.0%	31.23	0.189	0.6	0.000	0.0	0.000	0.0	0.241	0.8	0.083	0.3	0.255	0.8
	NG at LOD Claim	144	144	100.0%	32.32	0.217	0.7	0.149	0.5	0.149	0.5	0.384	1.2	0.126	0.4	0.404	1.3
	NG at Sub-LOD (High Negative)	144	119	82.6%	37.80	0.849	2.2	0.191	0.5	0.191	0.5	0.870	2.3	0.527	1.4	1.017	2.7
	NG Negative[e]	576	576	100.0%	....	....	....	....	....	....	....	....	....	....	....	....	....
Swab	NG High Pos (CT, TV & MG High Pos)	144	144	100.0%	21.31	0.135	0.6	0.117	0.6	0.117	0.6	0.194	0.9	0.232	1.1	0.303	1.4
	NG High Pos (CT, TV & MG at 2X LOD Claim)	144	144	100.0%	22.07	0.165	0.7	0.184	0.8	0.184	0.8	0.342	1.5	0.134	0.6	0.367	1.7
	NG at 2X LOD Claim (MG High Pos, CT & TV at 2X LOD Claim)	144	144	100.0%	31.45	0.179	0.6	0.092	0.3	0.092	0.3	0.238	0.8	0.126	0.4	0.270	0.9
	NG at 2X LOD Claim (TV High Pos, CT & MG at 2X LOD Claim)	144	144	100.0%	31.32	0.159	0.5	0.166	0.5	0.166	0.5	0.289	0.9	0.136	0.4	0.319	1.0
	NG at 2X LOD Claim (CT, TV & MG at 2X LOD Claim)	144	144	100.0%	31.40	0.173	0.5	0.258	0.8	0.258	0.8	0.323	1.0	0.000	0.0	0.323	1.0
	NG at 2X LOD Claim (CT High Pos, TV & MG at 2X LOD Claim)	144	144	100.0%	31.33	0.192	0.6	0.119	0.4	0.119	0.4	0.276	0.9	0.171	0.5	0.324	1.0
	NG at 2X LOD Claim (NG only)	144	144	100.0%	31.49	0.173	0.6	0.096	0.3	0.096	0.3	0.205	0.6	0.196	0.6	0.283	0.9
	NG at LOD Claim	144	144	100.0%	32.16	0.201	0.6	0.103	0.3	0.103	0.3	0.243	0.8	0.127	0.4	0.274	0.9
	NG at Sub-LOD (High Negative)	144	122	84.7%	36.76	0.730	2.0	0.198	0.5	0.198	0.5	0.757	2.1	0.266	0.7	0.802	2.2
	NG Negative[e]	576	576	100.0%	....	....	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	NG High Pos (CT, TV & MG High Pos)	144	144	100.0%	21.28	0.147	0.7	0.177	0.8	0.177	0.8	0.230	1.1	0.162	0.8	0.281	1.3
	NG High Pos (CT, TV & MG at 2X LOD Claim)	144	144	100.0%	24.04	0.191	0.8	0.063	0.3	0.063	0.3	0.205	0.9	0.232	1.0	0.310	1.3
	NG at 2X LOD Claim (MG High Pos, CT & TV at 2X LOD Claim)	144	144	100.0%	30.66	0.181	0.6	0.082	0.3	0.082	0.3	0.199	0.6	0.129	0.4	0.237	0.8
	NG at 2X LOD Claim (TV High Pos, CT & MG at 2X LOD Claim)	144	144	100.0%	30.91	0.164	0.5	0.086	0.3	0.086	0.3	0.198	0.6	0.220	0.7	0.296	1.0
	NG at 2X LOD Claim (CT, TV & MG at 2X LOD Claim)	144	144	100.0%	31.80	0.253	0.8	0.081	0.3	0.081	0.3	0.278	0.9	0.134	0.4	0.309	1.0
	NG at 2X LOD Claim (CT High Pos, TV & MG at 2X LOD Claim)	144	144	100.0%	31.35	0.219	0.7	0.103	0.3	0.103	0.3	0.242	0.8	0.195	0.6	0.311	1.0
	NG at 2X LOD Claim (NG only)	144	144	100.0%	31.18	0.224	0.7	0.109	0.4	0.109	0.4	0.266	0.9	0.250	0.8	0.365	1.2
	NG at LOD Claim	144	144	100.0%	32.87	0.272	0.8	0.185	0.6	0.185	0.6	0.329	1.0	0.153	0.5	0.363	1.1
	NG at Sub-LOD (High Negative)	144	65	45.1%	37.31	0.613	1.6	0.332	0.9	0.332	0.9	0.698	1.9	0.232	0.6	0.735	2.0
	NG Negative[e]	576	576	100.0%	....	....	....	....	....	....	....	....	....	....	....	....	....

[a] N: total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Within-Laboratory includes Within-Run, Between-Run and Between-Day Components.

[d] Total includes Within-Run, Between-Run, Between-Day and Between-Instrument/Lot Components.

[e] The negative panel included 4 panel members negative for NG

Within-lab Precision: TV Results

Matrix	Panel Description	N[a]	N[b]	Agreement (n/N)	Mean CN	Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Instrument/Lot Component		Total[d]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Urine	TV High Pos (CT, NG & MG High Pos)	144	144	100.0%	9.85	0.274	2.8	0.178	1.8	0.178	1.8	0.706	7.2	0.256	2.6	0.751	7.6
	TV High Pos (CT, NG & MG at 2X LOD Claim)	144	144	100.0%	9.85	0.353	3.6	0.204	2.1	0.204	2.1	0.758	7.7	0.357	3.6	0.837	8.5
	TV at 2X LOD Claim (MG High Pos, CT & NG at 2X LOD Claim)	144	144	100.0%	27.30	0.245	0.9	0.101	0.4	0.101	0.4	0.360	1.3	0.295	1.1	0.465	1.7
	TV at 2X LOD Claim (NG High Pos, CT & MG at 2X LOD Claim)	144	144	100.0%	27.60	0.186	0.7	0.175	0.6	0.175	0.6	0.397	1.4	0.353	1.3	0.531	1.9
	TV at 2X LOD Claim (CT High Pos, NG & MG at 2X LOD Claim)	144	144	100.0%	27.58	0.224	0.8	0.061	0.2	0.061	0.2	0.461	1.7	0.297	1.1	0.548	2.0
	TV at 2X LOD Claim (CT, NG & MG at 2X LOD Claim)	144	143	99.3%	27.84	0.210	0.8	0.000	0.0	0.000	0.0	0.368	1.3	0.341	1.2	0.502	1.8
	TV at 2X LOD Claim (TV only)	144	144	100.0%	27.22	0.266	1.0	0.000	0.0	0.000	0.0	0.393	1.4	0.375	1.4	0.543	2.0
	TV at LOD Claim	144	144	100.0%	28.73	0.355	1.2	0.190	0.7	0.190	0.7	0.520	1.8	0.321	1.1	0.611	2.1
	TV at Sub-LOD (High Negative)	144	34	23.6%	33.89	0.956	2.8	0.000	0.0	0.000	0.0	0.978	2.9	0.355	1.0	1.041	3.1
	TV Negative[e]	576	574	99.7%	....	....	....	....	....	....	....	....	....	....	....	....	....
Swab	TV High Pos (CT, NG & MG High Pos)	144	144	100.0%	10.44	0.267	2.6	1.679	16.1	1.679	16.1	1.704	16.3	0.583	5.6	1.801[f]	17.3[f]
	TV High Pos (CT, NG & MG at 2X LOD Claim)	144	144	100.0%	10.13	0.170	1.7	0.025	0.2	0.025	0.2	0.221	2.2	0.371	3.7	0.432	4.3
	TV at 2X LOD Claim (MG High Pos, CT & NG at 2X LOD Claim)	144	144	100.0%	29.31	0.376	1.3	0.159	0.5	0.159	0.5	0.409	1.4	0.295	1.0	0.504	1.7
	TV at 2X LOD Claim (NG High Pos, CT & MG at 2X LOD Claim)	144	144	100.0%	29.11	0.192	0.7	0.093	0.3	0.093	0.3	0.265	0.9	0.330	1.1	0.423	1.5
	TV at 2X LOD Claim (CT High Pos, NG & MG at 2X LOD Claim)	144	144	100.0%	29.24	0.200	0.7	0.161	0.6	0.161	0.6	0.280	1.0	0.298	1.0	0.409	1.4
	TV at 2X LOD Claim (CT, NG & MG at 2X LOD Claim)	144	144	100.0%	28.94	0.338	1.2	0.165	0.6	0.165	0.6	0.402	1.4	0.275	0.9	0.487	1.7
	TV at 2X LOD Claim (TV only)	144	144	100.0%	26.99	0.190	0.7	0.054	0.2	0.054	0.2	0.207	0.8	0.264	1.0	0.336	1.2
	TV at LOD Claim	144	144	100.0%	29.75	0.334	1.1	0.055	0.2	0.055	0.2	0.352	1.2	0.259	0.9	0.437	1.5
	TV at Sub-LOD (High Negative)	144	135	93.8%	33.55	0.378	1.1	0.000	0.0	0.000	0.0	0.411	1.2	0.151	0.5	0.438	1.3
	TV Negative[e]	576	575	99.8%	....	....	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	TV High Pos (CT, NG & MG High Pos)	144	144	100.0%	9.11	0.182	2.0	0.152	1.7	0.152	1.7	0.238	2.6	0.394	4.3	0.460	5.1
	TV High Pos (CT, NG & MG at 2X LOD Claim)	144	144	100.0%	8.54	0.166	1.9	0.099	1.2	0.099	1.2	0.193	2.3	0.356	4.2	0.405	4.7
	TV at 2X LOD Claim (MG High Pos, CT & NG at 2X LOD Claim)	144	144	100.0%	26.98	0.291	1.1	0.126	0.5	0.126	0.5	0.317	1.2	0.368	1.4	0.486	1.8
	TV at 2X LOD Claim (NG High Pos, CT & MG at 2X LOD Claim)	144	144	100.0%	27.41	0.216	0.8	0.206	0.8	0.206	0.8	0.304	1.1	0.376	1.4	0.483	1.8
	TV at 2X LOD Claim (CT High Pos, NG & MG at 2X LOD Claim)	144	144	100.0%	26.59	0.166	0.6	0.063	0.2	0.063	0.2	0.180	0.7	0.315	1.2	0.363	1.4
	TV at 2X LOD Claim (CT, NG & MG at 2X LOD Claim)	144	144	100.0%	28.11	0.289	1.0	0.124	0.4	0.124	0.4	0.314	1.1	0.248	0.9	0.401	1.4
	TV at 2X LOD Claim (TV only)	144	144	100.0%	27.88	0.128	0.5	0.101	0.4	0.101	0.4	0.201	0.7	0.331	1.2	0.388	1.4
	TV at LOD Claim	144	144	100.0%	29.01	0.452	1.6	0.000	0.0	0.000	0.0	0.466	1.6	0.247	0.9	0.527	1.8
	TV at Sub-LOD (High Negative)	144	85	59.0%	33.95	0.352	1.0	0.000	0.0	0.000	0.0	0.373	1.1	0.096	0.3	0.385	1.1

TV Negative[e]	576	575	99.8%	....	....	....	....	....	....	....	....	....	....	....	....	....	....

[a] N: Total number of replicates,

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Within-Laboratory includes Within-Run, Between-Run and Between-Day Components.

[d] Total includes Within-Run, Between-Run, Between-Day and Between-Instrument/Lot Components.

[e] The negative panel included 4 panel members negative for TV.

[f] Two samples had cellular control (CC) failures and very late target CNs. Because the Alinity m STI Assay reports positive results even if the CC fails, the CNs from these replicates were included in the total SD and %CV. Without those samples, the total SD was 0.402 and the total %CV was 3.9

Within-lab Precision: MG Results

Matrix	Panel Description	N[a]	n[b]	Agreement (n/N)	Mean CN	Within-Run Component		Between-Run Component		Between-Day Component		Within-Laboratory[c]		Between-Instrument/Lot Component		Total[d]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Urine	MG High Pos (CT, NG & TV High Pos)	144	144	100.0%	20.57	0.199	1.0	0.149	0.7	0.149	0.7	0.660	3.2	0.423	2.1	0.784	3.8
	MG High Pos (CT, NG & TV at 2X LOD Claim)	144	144	100.0%	21.63	0.219	1.0	0.098	0.5	0.098	0.5	0.352	1.6	0.472	2.2	0.589	2.7
	MG at 2X LOD Claim (TV High Pos, CT & NG at 2X LOD Claim)	144	144	100.0%	31.39	0.315	1.0	0.148	0.5	0.148	0.5	0.692	2.2	0.443	1.4	0.822	2.6
	MG at 2X LOD Claim (NG High Pos, CT & TV at 2X LOD Claim)	144	144	100.0%	31.76	0.242	0.8	0.182	0.6	0.182	0.6	0.438	1.4	0.498	1.6	0.663	2.1
	MG at 2X LOD Claim (CT High Pos, NG & TV at 2X LOD Claim)	144	144	100.0%	31.74	0.242	0.8	0.112	0.4	0.112	0.4	0.517	1.6	0.440	1.4	0.679	2.1
	MG at 2X LOD Claim (CT, NG & TV at 2X LOD Claim)	144	144	100.0%	31.77	0.672	2.1	0.000	0.0	0.000	0.0	0.758	2.4	0.559	1.8	0.942	3.0
	MG at 2X LOD Claim (MG only)	144	144	100.0%	31.73	0.139	0.4	0.087	0.3	0.087	0.3	0.305	1.0	0.376	1.2	0.484	1.5
	MG at LOD Claim	144	144	100.0%	32.90	0.317	1.0	0.126	0.4	0.126	0.4	0.589	1.8	0.530	1.6	0.792	2.4
	MG at Sub-LOD (High Negative)	144	111	77.1%	38.85	1.084	2.8	0.125	0.3	0.125	0.3	1.364	3.5	0.000	0.0	1.364	3.5
	MG Negative[e]	576	576	100.0%	....	....	....	....	....	....	....	....	....	....	....	....	....
Swab	MG High Pos (CT, NG & TV High Pos)	144	144	100.0%	19.85	0.404	2.0	1.826	9.2	1.826	9.2	1.870	9.4	0.574	2.9	1.956[f]	9.9[f]
	MG High Pos (CT, NG & TV at 2X LOD Claim)	144	144	100.0%	20.58	0.141	0.7	0.081	0.4	0.081	0.4	0.163	0.8	0.382	1.9	0.415	2.0
	MG at 2X LOD Claim (TV High Pos, CT & NG at 2X LOD Claim)	144	144	100.0%	30.90	0.141	0.5	0.017	0.1	0.017	0.1	0.153	0.5	0.337	1.1	0.370	1.2
	MG at 2X LOD Claim (NG High Pos, CT & TV at 2X LOD Claim)	144	144	100.0%	30.76	0.158	0.5	0.038	0.1	0.038	0.1	0.182	0.6	0.324	1.1	0.371	1.2
	MG at 2X LOD Claim (CT High Pos, NG & TV at 2X LOD Claim)	144	144	100.0%	30.86	0.123	0.4	0.072	0.2	0.072	0.2	0.147	0.5	0.307	1.0	0.340	1.1
	MG at 2X LOD Claim (CT, NG & TV at 2X LOD Claim)	144	144	100.0%	30.72	0.199	0.6	0.130	0.4	0.130	0.4	0.243	0.8	0.327	1.1	0.407	1.3
	MG at 2X LOD Claim (MG only)	144	144	100.0%	31.31	0.137	0.4	0.079	0.3	0.079	0.3	0.160	0.5	0.252	0.8	0.298	1.0
	MG at LOD Claim	144	144	100.0%	31.55	0.248	0.8	0.000	0.0	0.000	0.0	0.248	0.8	0.270	0.9	0.367	1.2
	MG at Sub-LOD (High Negative)	144	94	65.3%	35.95	0.409	1.1	0.263	0.7	0.263	0.7	0.487	1.4	0.171	0.5	0.516	1.4
	MG Negative[e]	576	576	100.0%	....	....	....	....	....	....	....	....	....	....	....	....	....

[a] N: Total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Within-Laboratory includes Within-Run, Between-Run and Between-Day Components.

[d] Total includes Within-Run, Between-Run, Between-Day and Between-Instrument/Lot Components

[e] The negative panel included 4 panel members negative for MG.

[f] Two samples had cellular control (CC) failures and very late target CNs. Because the Alinity m STI Assay reports positive results even if the CC fails, the CNs from these replicates were included in the total SD and %CV. Without those samples, the total SD was 0.361 and the total %CV was 1.8.

Reproducibility

The Alinity m STI Assay Reproducibility panel consisted of 13 primary panel members, prepared in urine and other matrices, as described above for the Within-laboratory Precision study. The reproducibility testing was conducted at three clinical sites over five days of testing, using two lots of Alinity m STI reagents, with each sample tested in 5 replicates. The summary of the results is shown below.

Reproducibility Analysis: CT Results

Matrix	Panel Description	N[a]	n[b]	Agreement (n/N)	Mean CN	Within-Run/Day Component		Between-Run/Day Component		Between-Lot Component		Between-Site Component		Total[c]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Urine	CT High Pos (NG, TV & MG High Pos)	150	150	100.0%	19.31	0.405	2.1	0.278	1.4	0.144	0.7	0.956	5.0	1.084	5.6
	CT High Pos (NG, TV & MG at 2X LOD Claim)	150	150	100.0%	19.18	0.224	1.2	0.272	1.4	0.143	0.7	0.697	3.6	0.794	4.1
	CT at 2X LOD Claim (MG High Pos, NG & TV at 2X LOD Claim)	150	150	100.0%	31.50	0.243	0.8	0.209	0.7	0.114	0.4	0.592	1.9	0.683	2.2
	CT at 2X LOD Claim (TV High Pos, NG & MG at 2X LOD Claim)	150	150	100.0%	31.81	0.285	0.9	0.272	0.9	0.128	0.4	0.774	2.4	0.878	2.8
	CT at 2X LOD Claim (NG High Pos, TV & MG at 2X LOD Claim)	150	150	100.0%	31.47	0.189	0.6	0.270	0.9	0.000	0.0	0.609	1.9	0.692	2.2
	CT at 2X LOD Claim (NG, TV & MG at 2X LOD Claim)	150	150	100.0%	31.34	0.200	0.6	0.262	0.8	0.063	0.2	0.561	1.8	0.654	2.1
	CT at 2X LOD Claim (CT only)	150	150	100.0%	31.29	0.182	0.6	0.244	0.8	0.148	0.5	0.402	1.3	0.526	1.7
	CT at LOD Claim	150	149	99.3%	32.05	0.344	1.1	0.157	0.5	0.245	0.8	0.464	1.4	0.647	2.0
	CT at Sub-LOD (High Negative)	150	54	36.0%	36.85	0.543	1.5	0.016	0.0	0.572	1.6	0.550	1.5	0.962	2.6
	CT Negative[d]	600	600	100.0%	....	....	....	....	....	....	....	....	....	....	....
Swab	CT High Pos (NG, TV & MG High Pos)	150	150	100.0%	16.80	0.185	1.1	0.075	0.4	0.151	0.9	0.000	0.0	0.250	1.5
	CT High Pos (NG, TV & MG at 2X LOD Claim)	150	150	100.0%	16.95	0.120	0.7	0.049	0.3	0.123	0.7	0.000	0.0	0.179	1.1
	CT at 2X LOD Claim (MG High Pos, NG & TV at 2X LOD Claim)	150	150	100.0%	29.59	0.147	0.5	0.097	0.3	0.133	0.4	0.000	0.0	0.221	0.7
	CT at 2X LOD Claim (TV High Pos, NG & MG at 2X LOD Claim)	150	150	100.0%	29.71	0.428	1.4	0.000	0.0	0.115	0.4	0.000	0.0	0.443	1.5
	CT at 2X LOD Claim (NG High Pos, TV & MG at 2X LOD Claim)	150	150	100.0%	29.53	0.159	0.5	0.104	0.4	0.130	0.4	0.000	0.0	0.230	0.8
	CT at 2X LOD Claim (NG, TV & MG at 2X LOD Claim)	150	150	100.0%	29.57	0.130	0.4	0.091	0.3	0.111	0.4	0.000	0.0	0.193	0.7
	CT at 2X LOD Claim (CT only)	150	150	100.0%	29.45	0.129	0.4	0.088	0.3	0.133	0.5	0.000	0.0	0.206	0.7
	CT at LOD Claim	150	150	100.0%	30.47	0.222	0.7	0.069	0.2	0.169	0.6	0.000	0.0	0.288	0.9
	CT at Sub-LOD (High Negative)	150	54	36.0%	36.94	0.900	2.4	0.000	0.0	0.940	2.5	0.000	0.0	1.301	3.5
	CT Negative[d]	600	595	99.2%	....	....	....	....	....	....	....	....	....	....	....

[a] N: Total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Total includes Within-Run/Day, Between-Run/Day, Between-Lot and Between-Site Components.

[d] The negative panel included 4 panel members negative for CT

Reproducibility Analysis: NG Results

Matrix	Panel Description	N[a]	n[b]	Agreement (n/N)	Mean CN	Within-Run/Day Component		Between-Run/Day Component		Between-Lot Component		Between-Site Component		Total[c]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Urine	NG High Pos (CT, TV & MG High Pos)	150	150	100.0%	24.85	0.513	2.1	1.162	4.7	0.547	2.2	0.448	1.8	1.453	5.8
	NG High Pos (CT, TV & MG at 2X LOD Claim)	150	150	100.0%	26.05	0.436	1.7	1.136	4.4	0.594	2.3	0.974	3.7	1.668	6.4
	NG at 2X LOD Claim (MG High Pos, CT & TV at 2X LOD Claim)	150	148	98.7%	35.29	0.764	2.2	1.073	3.0	0.540	1.5	1.058	3.0	1.774	5.0
	NG at 2X LOD Claim (TV High Pos, CT & MG at 2X LOD Claim)	150	150	100.0%	34.70	0.735	2.1	1.089	3.1	0.160	0.5	0.760	2.2	1.526	4.4
	NG at 2X LOD Claim (CT High Pos, TV & MG at 2X LOD Claim)	150	149	99.3%	34.68	0.662	1.9	1.018	2.9	0.401	1.2	0.911	2.6	1.570	4.5
	NG at 2X LOD Claim (CT, TV & MG at 2X LOD Claim)	150	147	98.0%	35.37	1.004	2.8	1.093	3.1	0.679	1.9	1.037	2.9	1.934	5.5
	NG at 2X LOD Claim (NG only)	150	145	96.7%	35.84	0.767	2.1	0.677	1.9	0.796	2.2	1.025	2.9	1.652	4.6
	NG at LOD Claim	150	141	94.0%	36.20	0.931	2.6	1.110	3.1	0.526	1.5	0.870	2.4	1.770	4.9
	NG at Sub-LOD (High Negative)	150	14	9.3%	37.82	0.000	0.0	0.735	1.9	0.617	1.6	0.443	1.2	1.056	2.8
	NG Negative[d]	600	600	100.0%	....	....	....	....	....	....	....	....	....	....	....
Swab	NG High Pos (CT, TV & MG High Pos)	150	150	100.0%	21.77	0.259	1.2	0.172	0.8	0.112	0.5	0.000	0.0	0.331	1.5
	NG High Pos (CT, TV & MG at 2X LOD Claim)	150	150	100.0%	22.51	0.289	1.3	0.268	1.2	0.000	0.0	0.197	0.9	0.440	2.0
	NG at 2X LOD Claim (MG High Pos, CT & TV at 2X LOD Claim)	150	150	100.0%	31.63	0.316	1.0	0.159	0.5	0.155	0.5	0.139	0.4	0.411	1.3
	NG at 2X LOD Claim (TV High Pos, CT & MG at 2X LOD Claim)	150	150	100.0%	31.44	0.275	0.9	0.159	0.5	0.147	0.5	0.000	0.0	0.350	1.1
	NG at 2X LOD Claim (CT High Pos, TV & MG at 2X LOD Claim)	150	150	100.0%	31.68	0.294	0.9	0.262	0.8	0.000	0.0	0.136	0.4	0.417	1.3
	NG at 2X LOD Claim (CT, TV & MG at 2X LOD Claim)	150	150	100.0%	31.54	0.306	1.0	0.246	0.8	0.000	0.0	0.111	0.4	0.408	1.3
	NG at 2X LOD Claim (NG only)	150	150	100.0%	31.78	0.285	0.9	0.180	0.6	0.117	0.4	0.108	0.3	0.373	1.2
	NG at LOD Claim	150	150	100.0%	32.49	0.336	1.0	0.185	0.6	0.053	0.2	0.116	0.4	0.405	1.2
	NG at Sub-LOD (High Negative)	150	80	53.3%	36.95	0.934	2.5	0.000	0.0	0.126	0.3	0.163	0.4	0.956	2.6
	NG Negative[d]	600	600	100.0%	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	NG High Pos (CT, TV & MG High Pos)	150	150	100.0%	21.64	0.322	1.5	0.182	0.8	0.086	0.4	0.169	0.8	0.415	1.9
	NG High Pos (CT, TV & MG at 2X LOD Claim)	150	150	100.0%	25.30	0.239	0.9	0.198	0.8	0.055	0.2	0.097	0.4	0.329	1.3
	NG at 2X LOD Claim (MG High Pos, CT & TV at 2X LOD Claim)	150	150	100.0%	31.08	0.285	0.9	0.231	0.7	0.142	0.5	0.000	0.0	0.394	1.3
	NG at 2X LOD Claim (TV High Pos, CT & MG at 2X LOD Claim)	150	150	100.0%	31.16	0.271	0.9	0.176	0.6	0.000	0.0	0.085	0.3	0.334	1.1
	NG at 2X LOD Claim (CT High Pos, TV & MG at 2X LOD Claim)	150	150	100.0%	30.39	0.328	1.1	0.163	0.5	0.137	0.5	0.000	0.0	0.392	1.3
	NG at 2X LOD Claim (CT, TV & MG at 2X LOD Claim)	150	150	100.0%	32.06	0.376	1.2	0.309	1.0	0.225	0.7	0.000	0.0	0.536	1.7
	NG at 2X LOD Claim (NG only)	150	150	100.0%	30.48	0.318	1.0	0.245	0.8	0.240	0.8	0.128	0.4	0.485	1.6

NG at LOD Claim	150	150	100.0%	33.10	0.413	1.2	0.166	0.5	0.193	0.6	0.000	0.0	0.486	1.5
NG at Sub-LOD (High Negative)	150	63	42.0%	37.46	0.742	2.0	0.000	0.0	0.323	0.9	0.000	0.0	0.810	2.2
NG Negative[d]	600	598	99.7%	....	....	....	....	....	....	....	....	....	....	....

[a] N: total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Total includes Within-Run/Day, Between-Run/Day, Between-Lot and Between-Site Components.

[d] The negative panel included 4 panel members negative for NG.

Reproducibility Analysis: TV Results

Matrix	Panel Description	N[a]	n[b]	Agreement (n/N)	Mean CN	Within-Run/Day Component		Between-Run/Day Component		Between-Lot Component		Between-Site Component		Total[c]	
						SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
Urine	TV High Pos (CT, NG & MG High Pos)	150	150	100.0%	11.58	0.606	5.2	0.387	3.3	0.000	0.0	0.979	8.5	1.215	10.5
	TV High Pos (CT, NG & MG at 2X LOD Claim)	150	150	100.0%	11.45	0.328	2.9	0.409	3.6	0.000	0.0	0.780	6.8	0.940	8.2
	TV at 2X LOD Claim (MG High Pos, CT & NG at 2X LOD Claim)	150	150	100.0%	31.61	0.364	1.2	0.251	0.8	0.253	0.8	0.687	2.2	0.855	2.7
	TV at 2X LOD Claim (NG High Pos, CT & MG at 2X LOD Claim)	150	149	99.3%	31.38	0.445	1.4	0.369	1.2	0.076	0.2	0.568	1.8	0.814	2.6
	TV at 2X LOD Claim (CT High Pos, NG & MG at 2X LOD Claim)	150	150	100.0%	31.56	0.397	1.3	0.206	0.7	0.321	1.0	0.692	2.2	0.884	2.8
	TV at 2X LOD Claim (CT, NG & MG at 2X LOD Claim)	150	150	100.0%	31.09	0.315	1.0	0.278	0.9	0.103	0.3	0.642	2.1	0.775	2.5
	TV at 2X LOD Claim (TV only)	150	150	100.0%	31.34	0.465	1.5	0.087	0.3	0.307	1.0	0.205	0.7	0.600	1.9
	TV at LOD Claim	150	149	99.3%	31.75	0.357	1.1	0.156	0.5	0.229	0.7	0.521	1.6	0.690	2.2
	TV at Sub-LOD (High Negative)	150	56	37.3%	34.88	0.937	2.7	0.227	0.7	0.485	1.4	0.314	0.9	1.124	3.2
	TV Negative[d]	600	596	99.3%	....	....	....	....	....	....	....	....	....	....	....
Swab	TV High Pos (CT, NG & MG High Pos)	150	150	100.0%	10.43	0.312	3.0	0.145	1.4	0.322	3.1	0.000	0.0	0.472	4.5
	TV High Pos (CT, NG & MG at 2X LOD Claim)	150	150	100.0%	10.47	0.715	6.8	0.131	1.2	0.275	2.6	0.000	0.0	0.778	7.4
	TV at 2X LOD Claim (MG High Pos, CT & NG at 2X LOD Claim)	150	150	100.0%	29.29	0.494	1.7	0.283	1.0	0.116	0.4	0.000	0.0	0.581	2.0
	TV at 2X LOD Claim (NG High Pos, CT & MG at 2X LOD Claim)	150	150	100.0%	29.22	0.336	1.1	0.234	0.8	0.364	1.2	0.000	0.0	0.548	1.9
	TV at 2X LOD Claim (CT High Pos, NG & MG at 2X LOD Claim)	150	150	100.0%	29.33	0.349	1.2	0.134	0.5	0.364	1.2	0.000	0.0	0.522	1.8
	TV at 2X LOD Claim (CT, NG & MG at 2X LOD Claim)	150	150	100.0%	29.05	0.200	0.7	0.142	0.5	0.273	0.9	0.000	0.0	0.367	1.3
	TV at 2X LOD Claim (TV only)	150	150	100.0%	29.69	0.269	0.9	0.173	0.6	0.222	0.7	0.064	0.2	0.394	1.3
	TV at LOD Claim	150	150	100.0%	29.77	0.395	1.3	0.658	2.2	0.000	0.0	0.000	0.0	0.767	2.6
	TV at Sub-LOD (High Negative)	150	74	49.3%	34.22	1.272	3.7	0.918	2.7	0.522	1.5	0.000	0.0	1.653	4.8
	TV Negative[d]	600	596	99.3%	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	TV High Pos (CT, NG & MG High Pos)	150	150	100.0%	9.53	0.235	2.5	0.112	1.2	0.371	3.9	0.000	0.0	0.453	4.8
	TV High Pos (CT, NG & MG at 2X LOD Claim)	150	150	100.0%	8.96	0.233	2.6	0.137	1.5	0.300	3.3	0.000	0.0	0.404	4.5
	TV at 2X LOD Claim (MG High Pos, CT & NG at 2X LOD Claim)	150	150	100.0%	27.32	0.419	1.5	0.166	0.6	0.226	0.8	0.000	0.0	0.505	1.8
	TV at 2X LOD Claim (NG High Pos, CT & MG at 2X LOD Claim)	150	150	100.0%	27.61	0.207	0.7	0.170	0.6	0.114	0.4	0.066	0.2	0.299	1.1
	TV at 2X LOD Claim (CT High Pos, NG & MG at 2X LOD Claim)	150	150	100.0%	26.77	0.559	2.1	0.262	1.0	0.229	0.9	0.000	0.0	0.658	2.5
	TV at 2X LOD Claim (CT, NG & MG at 2X LOD Claim)	150	150	100.0%	28.39	0.380	1.3	0.213	0.7	0.152	0.5	0.000	0.0	0.461	1.6
	TV at 2X LOD Claim (TV only)	150	150	100.0%	28.37	0.327	1.2	0.070	0.2	0.167	0.6	0.000	0.0	0.374	1.3

TV at LOD Claim	150	150	100.0%	29.32	0.599	2.0	0.000	0.0	0.184	0.6	0.081	0.3	0.632	2.2
TV at Sub-LOD (High Negative)	150	44	29.3%	34.77	1.045	3.0	0.178	0.5	0.222	0.6	0.000	0.0	1.083	3.1
TV Negative[d]	600	581	96.8%	....	....	....	....	....	....	....	....	....	....	....

[a] N: Total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Total includes Within-Run/Day, Between-Run/Day, Between-Lot and Between-Site Components.

[d] The negative panel included 4 panel members negative for TV.

Reproducibility Analysis: MG Results

						Within-Run/Day Component		Between-Run/Day Component		Between-Lot Component		Between-Site Component		Total[c]	
Matrix	**Panel Description**	**N[a]**	**n[b]**	**Agreement (n/N)**	**Mean CN**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Urine	MG High Pos (CT, NG & TV High Pos)	150	150	100.0%	22.66	0.428	1.9	0.228	1.0	0.329	1.5	0.906	4.0	1.079	4.8
	MG High Pos (CT, NG & TV at 2X LOD Claim)	150	150	100.0%	22.67	0.292	1.3	0.266	1.2	0.231	1.0	0.708	3.1	0.843	3.7
	MG at 2X LOD Claim (TV High Pos, CT & NG at 2X LOD Claim)	150	150	100.0%	33.73	0.497	1.5	0.309	0.9	0.341	1.0	0.945	2.8	1.163	3.4
	MG at 2X LOD Claim (NG High Pos, CT & TV at 2X LOD Claim)	150	150	100.0%	33.18	0.382	1.2	0.304	0.9	0.033	0.1	0.825	2.5	0.959	2.9
	MG at 2X LOD Claim (CT High Pos, NG & TV at 2X LOD Claim)	150	150	100.0%	33.18	0.368	1.1	0.257	0.8	0.353	1.1	0.704	2.1	0.907	2.7
	MG at 2X LOD Claim (CT, NG & TV at 2X LOD Claim)	150	150	100.0%	32.85	0.312	0.9	0.292	0.9	0.267	0.8	0.734	2.2	0.890	2.7
	MG at 2X LOD Claim (MG only)	150	150	100.0%	33.01	0.274	0.8	0.199	0.6	0.295	0.9	0.340	1.0	0.564	1.7
	MG at LOD Claim	150	150	100.0%	33.71	0.645	1.9	0.118	0.4	0.362	1.1	0.723	2.1	1.041	3.1
	MG at Sub-LOD (High Negative)	150	55	36.7%	40.29	1.021	2.5	0.076	0.2	0.854	2.1	0.000	0.0	1.333	3.3
	MG Negative[d]	600	600	100.0%	....	....	....	....	....	....	....	....	....	....	....
Swab	MG High Pos (CT, NG & TV High Pos)	150	150	100.0%	19.73	0.225	1.1	0.101	0.5	0.292	1.5	0.000	0.0	0.382	1.9
	MG High Pos (CT, NG & TV at 2X LOD Claim)	150	150	100.0%	20.64	0.186	0.9	0.127	0.6	0.320	1.6	0.000	0.0	0.391	1.9
	MG at 2X LOD Claim (TV High Pos, CT & NG at 2X LOD Claim)	150	150	100.0%	31.03	0.471	1.5	0.000	0.0	0.196	0.6	0.000	0.0	0.511	1.6
	MG at 2X LOD Claim (NG High Pos, CT & TV at 2X LOD Claim)	150	150	100.0%	30.80	0.189	0.6	0.121	0.4	0.250	0.8	0.000	0.0	0.336	1.1
	MG at 2X LOD Claim (CT High Pos, NG & TV at 2X LOD Claim)	150	150	100.0%	30.87	0.159	0.5	0.046	0.1	0.236	0.8	0.000	0.0	0.288	0.9
	MG at 2X LOD Claim (CT, NG & TV at 2X LOD Claim)	150	150	100.0%	30.69	0.165	0.5	0.124	0.4	0.225	0.7	0.000	0.0	0.305	1.0
	MG at 2X LOD Claim (MG only)	150	150	100.0%	31.40	0.180	0.6	0.083	0.3	0.238	0.8	0.000	0.0	0.310	1.0
	MG at LOD Claim	150	150	100.0%	31.58	0.244	0.8	0.034	0.1	0.304	1.0	0.000	0.0	0.391	1.2
	MG at Sub-LOD (High Negative)	150	102	68.0%	36.54	0.571	1.6	0.151	0.4	0.048	0.1	0.164	0.4	0.614	1.7
	MG Negative[d]	600	599	99.8%	....	....	....	....	....	....	....	....	....	....	....

[a] N: total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used for the Mean and SD calculation.

[c] Total includes Within-Run/Day, Between-Run/Day, Between-Lot and Between-Site Components

[d] The negative panel included 4 panel members negative for MG.

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Cross-reactivity in Urogenital Specimens

The specificity of the Alinity m STI assay was evaluated for cross-reactivity with microorganisms potentially present at the sample collection site. The test samples were prepared by spiking microorganisms into Alinity m transport buffer containing cultured HeLa cells (see matrix equivalence study below). The microorganisms were tested at 10^5 units/mL for viruses and eukaryotes and 10^6 units/mL for bacteria. The unit of measure was specific to each microorganism. In cases where the organisms could not be procured, purified nucleic acid was used as an alternate (see footnote below). Each sample was tested in three replicates. All samples returned expected results; no cross-reactivity was observed with the organisms tested.

Microorganisms Tested in the Specificity Studies

Acinetobacter lwoffi	*Lactobacillus lactis*
Actinomyces israelii	*Lactobacillus vaginalis*
Atopobium vaginae	*Listeria monocytogenes*
Bacteroides fragilis	*Mobiluncus curtisii*
Bacteroides ureolyticus (Campylobacter ureolyticus)	*Mobiluncus mulieris*
	*Mycoplasma hominis**
Bifidobacterium longum	*Mycoplasma pneumoniae*
Candida albicans	*Neisseria cinerea**
Candida glabrata	*Neisseria elongata**
Candida parapsilosis	*Neisseria flava**
Candida tropicalis	*Neisseria flavescens**
*Chlamydia pneumoniae**	*Neisseria lactamica**
*Chlamydia psittaci**	*Neisseria mucosa**
Clostridium difficile	*Neisseria meningitidis Serogroup A**
Clostridium perfringens	*Neisseria meningitidis Serogroup B**
Corynebacterium genitalium	*Neisseria meningitidis Serogroup C**
Corynebacterium xerosis	*Neisseria meningitidis Serogroup D**
Cryptococcus neoformans	*Neisseria meningitidis Serogroup W135**
Dientamoeba fragilisa	*Neisseria meningitidis Serogroup Y**
Entercoccus faecalis	*Neisseria perflava**
Enterobacter aerogenes	*Neisseria polysaccharea**
Enterobacter cloacae	*Neisseria sicca**
Escherichia coli	*Neisseria subflava**
Fusobacterium nucleatum	*Pentatrichomonas hominis*
Gardnerella vaginalis	*Peptostreptococcus anaerobius*
Haemophilus ducreyi[a]	*Prevotella bivia*
Herpes simplex virus I	*Propionibacterium acnes*

Herpes simplex virus II	*Proteus mirabilis*
Human Immunodeficiency virus 1	*Pseudomonas aeruginosa*
Human papilloma virus 16	*Staphylococcus aureus*
Kingella denitrificans	*Staphylococcus epidermidis*
Klebsiella oxytoca	*Streptococcus agalactiae*
Klebsiella pneumoniae	*Streptococcus pyogenes*
Lactobacillus acidophilus	*Trichomonas tenax*
Lactobacillus brevis	*Ureaplasma parvum*
Lactobacillus jensenii	*Ureaplasma urealyticum*

[a]*Haemophilus ducreyi* testing performed with purified genomic DNA
*Indicates microorganism tested in both target-negative and target positive samples

Microbial Interference in Urogenital Specimens

The Alinity m STI assay was also evaluated for interference with a subset of the organisms used in the cross-reactivity study above (as denoted by an asterisk in the table above), by testing samples prepared with target organisms (CT, NG, TV, MG) at low positive concentrations in the presence of the potentially interfering organisms spiked at high concentrations (10^5 units/mL for viruses and eukaryotes and 10^6 units/mL for bacteria). The selected organisms were those that are closely related to the STI target organisms and thus have the greatest potential for primer binding at homologous targets. All positive samples reported the expected positive results for CT, NG, TV, and MG in the presence of these microorganisms; no interference was observed.

Cross-reactivity and Microbial Interference in Extragenital Specimens

Additional testing for CT and NG was performed to evaluate potential cross-reactivity and microbial interference with organisms that may be encountered in extragenital anatomic sites (i.e., oropharynx and rectum). No cross-reactivity was observed for CT or NG with the tested organisms.

A subset of the microorganisms was also assessed for interference in CT and NG positive samples, as denoted by an asterisk in the table below. The positive samples contained CT and NG organisms at 2 times the claimed LoD. The potential cross-reacting microorganisms were tested at 10^5 units/mL for viruses and eukaryotes, and 10^6 units/mL for bacteria. All positive samples reported positive results for CT and NG in the presence of these microorganisms.

Potential Cross-Reacting Microorganisms in Extragenital Specimens

Adenovirus*	*Haemophilus influenzae*	*Saccharomyces cerevisiae*
Acinetobacter baumannii	*Helicobacter pylori*	*Salmonella enterica*
Aggregatibacter actinomycetemcomitans	Human Coronavirus*	*Shigella flexneri*
Anaerococcus prevotii	Human influenza virus A	*Shigella sonnei*
Arcanobacterium haemolyticum	Human influenza virus B	*Streptococcus anginosus*
Bifidobacterium adolescentis	Human metapneumovirus	*Streptococcus dysgalactiae**

Bordetella pertussis	Human rhinovirus 57*	*Streptococcus mitis*
*Campylobacter jejuni**	*Klebsiella oxytoca*	*Streptococcus mutans*
Campylobacter rectus	*Listeria monocytogenes*	*Streptococcus pneumoniae*
Citrobacter freundii	*Moraxella catarrhalis*	*Streptococcus pyogenes**
Clostridium difficile	*Morganella morganii*	*Streptococcus salivarius*
*Corynebacterium diphtheriae**	*Mycoplasma pneumoniae*	*Streptococcus sanguinis*
*Entamoeba histolytica**	Norovirus	*Tannerella forsythia*
Enterobacter cloacae	*Parvinomas micra*	*Treponema denticola*
Enterococcus faecium	*Plesiomonas shigelloides*	*Veillonella parvula*
Enterovirus	*Porphyromonas gingivalis*	*Vibrio cholerae*
Fusobacterium necrophorum	*Prevotella oralis*	*Vibrio parahaemolyticus*
Fusobacterium nucleatum	*Providencia stuartii*	*Yersinia enterocolitica*
Giardia lamblia	Respiratory syncytial virus	

*Indicates microorganism tested in both CT/NG-negative and CT/NG positive samples

Potential Interferents-Urogenital Specimens

The potential for interference in the Alinity m STI Assay was assessed with 35 substances that may be found in urine, vaginal swab, endocervical swab, and/or PreservCyt samples. Substances were diluted into pooled vaginal swab, pooled gynecological PreservCyt, and/or pooled urine matrices. For each substance and matrix, both CT, NG, TV, and MG positive and negative samples were tested. The positive matrices contained CT, NG, TV, and MG organisms at 3 times the claimed assay LoD. Two different strains of each organism were used in this study (CT serovars D and E, NG strains Z433 and Z437, TV strains 30001 and MTZ, and MG strains SEA-1 and MEGA 216). Although expected positive results were obtained with all the substances at the concentrations shown in the table below, cycle number delays were observed for several substances, as indicated below, which could result in interference at lower target levels.

Potential Interferents (Urogenital)

Substance	Matrix[a]	Test Level
Blood	U, S, P	5.0% v/v
Norforms Deodorant Suppositories	U, S, P	0.25% w/v
Progesterone	U, S, P	20 ng/mL
Beta Estradiol	U, S, P	1.2 ng/mL
Leukocytes	U, S, P	10^6 cells/mL
Mucus	U	0.2 % v/v
	S, P[b]	0.8 % v/v
Seminal Fluid	U[b], S	5.0% v/v
	P[b]	3.0% v/v
Azithromycin	U	12.0 µg/mL
Doxycycline	U	31.2 µg/mL
Acetaminophen	U	196.5 µg/mL

Aspirin	U	652.2 µg/mL
Vagisil Feminine Powder	U	0.25% w/v
Albumin	U	60 mg/mL
γ-globulin	U[b]	60 mg/mL
Glucose	U[b]	1.2 mg/mL
Acidic urine	U	pH 4.0
Alkaline urine	U	pH 9.0
Bilirubin	U	72.5 µg/mL
Candida albicans (Urinary tract infection organism)	U	$3x10^4$ CFU/mL
Staphylococcus saprophyticus (Urinary tract infection organism)	U	$3x10^4$ CFU/mL
Escherichia coli (Urinary tract infection organism)	U	$3x10^4$ CFU/mL
Ibuprofen	U	495.1 µg/mL
Phenazopyridine Hydrochloride	U	80 µg/mL
Clotrimazole Vaginal Cream	S, P	0.25% w/v
KY Jelly Personal Lubricant	S, P	0.25% w/v
Metronidazole	S, P	40.1 µg/mL
Miconazole-3	S, P	0.25% w/v
Monistat-1	S, P	0.25% w/v
Terconazole Vaginal Cream	S, P	0.25% w/v
Preparation H Hemorroidal Cream	S, P[b]	0.25% w/v
Vagisil Anti-Itch Cream	S, P	0.25% w/v
Vagisil Moisturizing Gel	S, P	0.25% w/v
Povidone-Iodine Medicated Douche	S, P	0.25% w/v
Yeast Gard Douche	S, P	0.25% w/v
Vaginal Contraceptive Foam	S, P	0.25% w/v

[a] U = Urine, S = Swab, P = PreservCyt

[b] Cycle number delays were observed for seminal fluid, γ-globulin, and glucose in urine; cycle delays were observed for seminal fluid, mucus, and Preparation H Hemorrhoidal Cream in PreservCyt.

Potential Interferents-Extragenital Specimens

The potential for interference in the Alinity m STI Assay was assessed with 18 substances that may be found in oropharyngeal or rectal swab samples. Substances were diluted into pooled oropharyngeal swab or pooled rectal swab matrices. For each substance and matrix, both CT and NG positive and negative samples were tested. The positive matrices contained CT and NG at three times the claimed LoD. Two different strains of CT and NG were used in this study (CT serovars D and E and NG strains Z433 and Z437). The study results are shown below.

Potential Interferents (Extragenital)

Substance	Matrix[a]	Test Level
Blood	O	5.0% v/v
Mucus	O	25 mg/mL
Listerine Antiseptic Mouthwash	O	5.0% v/v
Mucinex Dextromethorphan Cough Suppressant	O	100 ug/mL
Chloraseptic Sore Throat Spray, Menthol	O	5.0% v/v
Abreva Cold Sore Medication	O	5.0% w/v
Colgate Total Whitening Toothpaste	O	0.25% w/v
Arm & Hammer PeroxiCare Deep Clean Toothpaste	O	0.25% w/v
Sensodyne Repair & Protect Sensitive Toothpaste	O[b]	0.25% w/v
Preparation H Hemorrhoidal Cream	R	0.25% w/v
Barium Sulfate	R	0.25% w/v
Dulcolax Laxative Suppository	R	0.25% w/v
K-Y Jelly Personal Lubricant	R	0.25% w/v
Phillips' Milk of Magnesia Liquid Laxative	R	0.25% w/v
Pepto-Bismol	R	0.25% w/v
Imodium	R	0.25% w/v
Feces	R[b]	1.0% w/v
Lotrimin	R	0.25% w/v

[a]O = Oropharyngeal, R = Rectal

[b]Cycle number delays were observed for Sensodyne Repair & Protect Sensitive Toothpaste in oropharyngeal specimens and feces in rectal specimens, which could result in interference at lower target levels.

Competitive Interference

A competitive interference study was conducted to evaluate the potential for interference in cases of co-infection, when one or more targets are present at high concentrations, and another target is present at a low concentration. Four panels of test samples were prepared to represent specimen types used in the Alinity m STI assay: urine matrix, swab matrix, and PreservCyt matrix. The urine matrix consisted of CT, NG, TV, and MG negative urine added to the Alinity m multi-Collect transport buffer in a 3:2 ratio (as performed in clinical use). The study was performed in two contrived matrices described in section B.2. One serovar of CT, one isolate of NG, one strain of TV, and one strain of MG was evaluated in the study. The concentrations for the high organism level were targeted to meet or exceed 95% of the results obtained from specimens of diseased patients in the intended use population. Each sample was tested in 20 replicates. The following table shows the targeted analyte concentrations for each panel.

Competitive Interference Test Panel

Panel Member	CT	NG	TV	MG
Panel 1	3X claimed LOD	High[b]	High[c]	High[d]
Panel 2	High[a]	3X claimed LOD	High[c]	High[d]
Panel 3	High[a]	High[b]	3X claimed LOD	High[d]
Panel 4	High[a]	High[b]	High[c]	3X claimed LOD

[a]Concentration for High CT is 3.0 x 10^5 EB/mL

[b]Concentration for High NG is 1.6 x 10^4 CFU/mL

[c]Concentration for High TV is 6.0 x 10^4 TV/mL

[d]Concentration for High MG is 1.1 x 10^6genome equivalents/mL

For each analyte at the low concentration, 100% (20/20) of replicates were detected in each matrix.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Specimen Stability (urogenital)

   Specimen stability under storage was evaluated in 3 different clinical matrices:
   - Urine matrix (negative urine pooled from unique donors and added to the Alinity m multi-Collect transport buffer in a 3:2 ratio, as in actual use),
   - Swab matrix (pooled negative vaginal swab specimens collected with the Alinity m multi-Collect Specimen Collection kit), and
   - PreservCyt matrix (pooled negative gynecological specimens collected in PreservCyt Solution).

   One serovar of CT, one isolate of NG, one strain of TV, and one strain of MG were spiked to a target low positive concentration, i.e., 2x claimed LoD.

   Seven replicates of each sample were tested immediately (control condition) and then after the specimen stability conditions (test conditions). The following storage conditions were evaluated:

Storage Conditions

Baseline	Immediately	

2 to 8°C	7 days	Each storage condition was followed by a minimum 4 hr on-board storage
	14 days	
	15 days	
30°C	7 days	
	14 days	
	15 days	
-20°C ±5°C	30 days	
	31 days	
	60 days	
	61days	

For each matrix type, each analyte and each condition, the qualitative results were summarized. The number of the samples with "Positive" result, the number of the samples with "Negative" result, the total number of the samples tested, and the percentage of samples with "Positive" result were reported. There was 100% positivity rate observed for all samples.

In addition, the mean CN and SD were calculated for CT, NG, TV, and MG for each matrix type and each condition.

Specimen Stability in Urogenital Specimens

		Matrix											
	Condition	**Urine**				**Swab**				**PreservCyt**			
C. trachomatis													
		T=0	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**
	Control		28.15	0.181	N/A		29.56	0.120	N/A	N/A	N/A	N/A	N/A
	7 days	28.15	27.84	0.173	-0.31	29.56	29.46	0.108	-0.10	N/A	N/A	N/A	N/A
	14 days	28.15	27.99	0.053	-0.16	29.56	29.52	0.150	-0.04	N/A	N/A	N/A	N/A
	15 days	28.15	27.99	0.062	-0.16	29.56	29.52	0.066	-0.04	N/A	N/A	N/A	N/A
30°C (+/- 5°C)	7 days	28.15	27.91	0.108	-0.24	29.56	29.35	0.086	-0.21	N/A	N/A	N/A	N/A
	14 days	28.15	28.02	0.048	-0.13	29.56	29.58	0.058	0.02	N/A	N/A	N/A	N/A
	15 days	28.15	28.03	0.060	-0.12	29.56	29.55	0.076	-0.01	N/A	N/A	N/A	N/A
-20°C (+/- 5°C)	30 days	28.15	28.27	0.079	0.12	29.56	29.53	0.078	-0.03	N/A	N/A	N/A	N/A
	31 days	28.15	28.22	0.130	0.07	29.56	29.62	0.097	0.06	N/A	N/A	N/A	N/A
	60 days	28.15	28.10	0.100	-0.05	29.56	29.54	0.053	-0.02	N/A	N/A	N/A	N/A
	61 days	28.15	28.15	0.143	0.00	29.56	29.50	0.128	-0.06	N/A	N/A	N/A	N/A
N. gonorrhoeae													
		T=0	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**
	Control		30.53	1.592	N/A		29.46	0.202	N/A		29.65	0.391	N/A
2°C to 8°C	7 days	30.53	28.94	0.118	-1.59	29.46	29.29	0.206	-0.17	29.65	28.55	0.103	-1.10
	14 days	30.53	28.92	0.120	-1.61	29.46	29.30	0.263	-0.16	29.65	28.53	0.110	-1.12
	15 days	30.53	28.78	0.113	-1.75	29.46	29.41	0.199	-0.05	29.65	28.49	0.168	-1.16
	7 days	30.53	28.73	0.154	-1.80	29.46	29.12	0.103	-0.34	29.65	28.77	0.111	-0.88

30°C (+/- 5°C)	14 days	30.53	28.85	0.091	-1.68	29.46	29.02	0.114	-0.44	29.65	28.72	0.126	-0.93
	15 days	30.53	28.88	0.084	-1.65	29.46	29.01	0.104	-0.45	29.65	28.75	0.051	-0.90
-20°C (+/- 5°C)	30 days	30.53	30.14	1.066	-0.39	29.46	29.74	0.200	0.28	29.65	29.39	0.187	-0.26
	31 days	30.53	29.33	0.311	-1.20	29.46	29.39	0.184	-0.07	29.65	29.87	0.603	0.22
	60 days	30.53	29.04	0.127	-1.49	29.46	29.42	0.089	-0.04	29.65	28.90	0.113	-0.75
	61 days	30.53	29.52	1.015	-1.01	29.46	29.31	0.155	-0.15	29.65	28.90	0.123	-0.75
T. vaginalis													
		T=0	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**
	Control		27.46	0.193	N/A		29.09	0.186	N/A		27.52	0.195	N/A
2°C to 8°C	7 days	27.46	27.38	0.227	-0.08	29.09	28.85	0.173	-0.24	27.52	27.42	0.109	-0.10
	14 days	27.46	27.27	0.094	-0.19	29.09	29.08	0.406	-0.01	27.52	27.37	0.249	-0.15
	15 days	27.46	27.19	0.088	-0.27	29.09	28.98	0.122	-0.11	27.52	27.36	0.168	-0.16
30°C (+/- 5°C)	7 days	27.46	27.31	0.086	-0.15	29.09	28.61	0.629	-0.48	27.52	27.75	0.250	0.23
	14 days	27.46	27.41	0.164	-0.05	29.09	29.22	0.104	0.13	27.52	27.76	0.157	0.24
	15 days	27.46	27.49	0.171	0.03	29.09	29.30	0.090	0.21	27.52	27.94	0.146	0.42
-20°C (+/- 5°C)	30 days	27.46	27.77	0.266	0.31	29.09	29.00	0.177	-0.09	27.52	27.78	0.323	0.26
	31 days	27.46	27.77	0.231	0.31	29.09	29.16	0.177	0.07	27.52	27.72	0.401	0.20
	60 days	27.46	27.69	0.312	0.23	29.09	28.97	0.171	-0.12	27.52	27.72	0.335	0.20
	61 days	27.46	27.64	0.200	0.18	29.09	29.02	0.184	-0.07	27.52	27.50	0.458	-0.02
M. genitalium													
		T=0	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**	**T=0**	**Avg. CN**	**SD**	**Change (CN)**
	Control		30.85	0.196	N/A		31.99	0.193	N/A	N/A	N/A	N/A	N/A
2°C to 8°C	7 days	30.85	30.53	0.165	-0.32	31.99	31.95	0.221	-0.04	N/A	N/A	N/A	N/A
	14 days	30.85	30.63	0.163	-0.22	31.99	31.91	0.180	-0.08	N/A	N/A	N/A	N/A
	15 days	30.85	30.68	0.133	-0.17	31.99	31.91	0.101	-0.08	N/A	N/A	N/A	N/A
30°C (+/- 5°C)	7 days	30.85	30.57	0.186	-0.28	31.99	32.06	0.118	0.07	N/A	N/A	N/A	N/A
	14 days	30.85	30.74	0.140	-0.11	31.99	32.13	0.057	0.14	N/A	N/A	N/A	N/A
	15 days	30.85	30.74	0.114	-0.11	31.99	32.10	0.214	0.11	N/A	N/A	N/A	N/A
-20°C (+/- 5°C)	30 days	30.85	30.95	0.116	0.10	31.99	31.96	0.169	-0.03	N/A	N/A	N/A	N/A
	31 days	30.85	30.91	0.134	0.06	31.99	32.04	0.189	0.05	N/A	N/A	N/A	N/A
	60 days	30.85	30.80	0.139	-0.05	31.99	31.98	0.192	-0.01	N/A	N/A	N/A	N/A
	61 days	30.85	30.93	0.205	0.08	31.99	32.03	0.211	0.04	N/A	N/A	N/A	N/A

Specimen Stability (extragenital)

Specimen stability, on-board stability, and storage were evaluated in 2 different clinical matrices that represent extragenital specimen types used in the Alinity m STI assay: oropharyngeal swab matrix and rectal swab matrix. Clinical oropharyngeal swab matrix was prepared by pooling CT/NG-negative oropharyngeal swab specimens collected with the Alinity m multi-Collect Specimen Collection Kit. Clinical rectal swab matrix was prepared by pooling CT/NG-negative rectal swab specimens collected with the Alinity m multi-Collect Specimen Collection Kit. For each matrix, one CT serovar and one NG isolate were spiked to a target low positive concentration (2x LoD).

Seven replicates of each sample were tested immediately (control condition) and then after the specimen stability conditions (test conditions). The following storage conditions were evaluated.

Storage Conditions

Baseline	Immediately	
2 to 8°C	7 days	Each storage condition was followed by a minimum 4 hr on-board storage
	14 days	
	15 days	
30°C (±5°C)	7 days	
	14 days	
	15 days	
-20°C (±5°C)	30 days	
	31 days	
	60 days	
	61 days	

For each matrix type, each analyte and each condition, the qualitative results were summarized. The number of the samples with "Positive" results, the number of the samples with "Negative" results, the total number of the samples tested, and the percentage of samples with 'Positive' results were reported. There was 100% positivity rate observed for all samples.

In addition, the mean CN and SD were calculated for CT, NG, TV, and MG for each matrix type and each condition.

Specimen Stability for CT in Extragenital Specimens

	Condition	Oropharyngeal			Rectal		
C. trachomatis							
		Avg. CN	**SD**	**Change (CN)**	**Avg. CN**	**SD**	**Change (CN)**
	Control T=0	29.32	0.086	N/A	29.37	0.053	N/A
2°C to 8°C	7 days	29.75	0.070	-0.31	29.74	0.063	0.37
	14 days	29.82	0.066	-0.16	29.89	0.148	0.52
	15 days	29.73	0.114	-0.16	29.89	0.121	0.52
30°C (±5°C)	7 days	29.56	0.068	-0.24	30.45	0.070	1.08
	14 days	29.62	0.054	-0.13	30.75	0.091	1.38
	15 days	29.53	0.085	-0.12	30.74	0.171	1.37
-20°C (±5°C)	30 days	29.66	0.091	0.12	29.78	0.127	0.41
	31 days	29.66	0.141	0.07	29.78	0.114	0.41
	60 days	29.64	0.114	0.32	29.87	0.279	0.50
	61 days	29.58	0.109	0.26	29.93	0.555	0.56
N. gonorrhoeae							

		Avg. CN	SD	Change (CN)	Avg. CN	SD	Change (CN)
	Control T=0	29.24	0.142	N/A	28.76	0.196	N/A
2°C to 8°C	7 days	29.25	0.054	0.01	28.74	0.116	-0.02
	14 days	29.16	0.115	-0.08	28.75	0.208	-0.01
	15 days	29.14	0.103	-0.10	28.75	0.221	-0.01
30°C (±5°C)	7 days	28.90	0.130	-0.34	28.76	0.060	0.00
	14 days	28.73	0.083	-0.51	28.64	0.182	-0.12
	15 days	28.70	0.113	-0.54	28.61	0.184	-0.15
-20°C (±5°C)	30 days	29.23	0.126	-0.01	28.96	0.144	0.20
	31 days	29.15	0.196	-0.09	28.89	0.116	0.13
	60 days	29.32	0.146	0.08	29.04	0.113	0.28
	61 days	29.27	0.073	0.03	29.10	0.210	0.34

The results indicated there was no target deterioration for any of the tested conditions for each of the matrices tested. The data support specimen stability for all specimen types (i.e., endocervical and/vaginal swabs, PreservCyt specimens, urine, and oropharyngeal and rectal swabs) when stored for 14 days at 2°C to 30°C and up to 60 days at -20°C (±5°C).

Specimen Freeze-Thaw Stability (urogenital)

Freeze thaw stability of urogenital specimens was evaluated in two different clinical matrices:

- Urine matrix (negative urine pooled from unique donors and added to the Alinity m multi-Collect transport buffer in a 3:2 ratio), and
- Swab matrix (pooled negative vaginal swab specimens collected with the Alinity m multi-Collect Specimen Collection kit).

One serovar of CT, one isolate of NG, one strain of TV, and one strain of MG were spiked to a target low positive concentration (2x LoD).

The samples were tested immediately after preparation to establish baseline. Subsequently, the samples were frozen at -20°C (±5°C), then thawed at room temperature (~15-30°C). The process was repeated three times, for a total of four F/T cycles. Following the fourth cycle, the samples were stored at 30°C for a minimum of 15 days. Because samples are allowed to be stored on-board for 4 hours prior to processing, the samples were stored on-board of the instrument for an additional 4 hours before analysis. There were 30 replicates of each sample tested in the study. All samples tested returned positive results, demonstrating that urine and vaginal swab specimens stored in Alinity m multi-Collect Specimen Collection Kit transport buffer are stable after undergoing up to 4 freeze-thaws, followed by 15-day storage at 30°C, plus 4 hours on-board of the instrument, prior to testing with the Alinity m STI Assay.

The data was also evaluated based on the generated signal in comparison with baseline data. The difference between the mean CN values at baseline and after storage ranged from -0.61 to 0.19 CN. The summary of the data is presented below.

4 F/T Stability Summary Data for Urogenital Specimens

Analyte	Matrix	Test Condition	N	Baseline	Mean CN	SD	Change from Baseline (CN)
CT	Urine	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	28.18	28.00	0.097	-0.18
	Swab	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	29.52	29.48	0.101	-0.04
NG	Urine	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	29.46	28.85	0.166	-0.61
	Swab	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	29.29	29.01	0.131	-0.28
TV	Urine	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	27.49	27.54	0.223	0.05
	Swab	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	29.14	29.17	0.259	0.03
MG	Urine	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	30.92	30.88	0.137	-0.04
	Swab	4 F/T, followed by 15 days at 30°C, plus 4 hrs on-board	30	31.92	32.11	0.200	0.19

Specimen Freeze-Thaw Stability (Extragenital)

A similar study as above was conducted to evaluate the effect of repeated freeze-thaw on extragenital specimens, testing for CT and NG. The study utilized two clinical matrices: oropharyngeal swab and rectal swab matrix. Clinical oropharyngeal swab matrix was prepared by pooling CT/NG-negative oropharyngeal swab specimens collected with the Alinity m multi-Collect Specimen Collection Kit. Clinical rectal swab matrix was prepared by pooling CT/NG-negative rectal swab specimens collected with the Alinity m multi-Collect Specimen Collection Kit. For each matrix, one CT serovar and one NG isolate were spiked to a target low positive concentration (2x LoD). As described above, samples were subjected to at least 4 freeze/thaw cycles, followed by 15-day storage at 30°C, plus 4 hours left on-board of the instrument.

There were at least 60 replicates of each sample tested in the study. All samples tested returned positive results demonstrating that oropharyngeal and rectal swab specimens stored in Alinity m multi-Collect Specimen Collection Kit transport buffer remain stable after undergoing 4 freeze-thaws, followed by 15-day storage at 30°C, plus 4 hours left on-board of the instrument, prior to testing with the Alinity m STI Assay.

The data was also evaluated based on the generated signal in comparison with baseline data. The difference between the mean CN values at baseline and after storage ranged from -0.29 to 0.95 CN. The summary of the data is presented below.

4 F/T Stability Summary Data for Extragenital Specimens

Analyte	Matrix	Test Condition	No. of Replicates	Baseline CN	Mean CN	SD	Change (CN)
CT	Oroph.	4 F/T cycles, plus 15 days at 30°C, plus 4 hrs on-board	62	29.33	29.68	0.138	0.35
	Rectal	4 F/T cycles, plus 15 days at 30°C, plus 4 hrs on-board	62	29.68	30.63	0.132	0.95
NG	Oropharyngeal	4 F/T cycles, plus 15 days at 30°C, plus 4 hrs on-board	62	29.00	28.86	0.172	-0.14
	Rectal	4 F/T cycles, plus 15 days at 30°C, plus 4 hrs on-board	62	29.04	28.75	0.188	-0.29

6. Detection Limit:

The limit of detection (LoD) for urogenital specimens was determined by testing dilutions of cultured and quantified CT, NG, TV, and MG organisms in pooled negative vaginal swab matrix (collected in the Alinity m multi-Collect Specimen Collection Kit), pooled negative gynecological PreservCyt matrix, and pooled negative urine matrix. Two different strains of each organism were evaluated in each matrix: serovars D and E for CT, strains Z437 and Z433 for NG, strains 30001 ND and MTZ (metronidazole-resistant) for TV, and strains SEA-1 and MEGA 216 (azithromycin-resistant) for MG. For each strain and matrix, a minimum of 6 target levels were evaluated in at least 20 replicates using each of two lots. Probit analysis was performed for each strain and matrix for each lot, where three or more panel members were targeted to detection rates between 10% and 90% and at least one panel member was targeted to a detection rate exceeding 95%. The CT organisms were quantified in Elementary Bodies (EB/mL), the NG organisms were quantified in colony forming units (CFU/mL), the TV organisms were quantified in trophozoites/mL (TV/mL), and the MG organisms were quantified in genome copies (GE/mL). The study was conducted over three days and included two reagent lots and four instruments. Each sample was tested for a total of 24 replicates, to ensure a minimum of 20 valid results.

A second study was conducted to determine the LoD of the assay in rectal and oropharyngeal specimens. The study was conducted by testing dilution series of titered CT and NG cultures. Two CT serovars (D-UW3 and VR-348B) and two NG strains (Z437 and Z433) were diluted in rectal and oropharyngeal clinical matrices. The oropharyngeal swab matrix consisted of pooled CT/NG-negative oropharyngeal swab specimens collected with the Alinity m multi-Collect Specimen Collection Kit. The rectal swab matrix consisted of pooled CT/NG-negative rectal swab specimens collected with the Alinity m multi-Collect Specimen Collection Kit. For each strain, a minimum of three panel members were prepared for each sample matrix, where one panel member was targeted to the approximate LoD target level (≥95% detection rate), one panel member was targeted at 2-fold greater than the approximate LoD target level, and one panel member was targeted at 2-fold less than the approximate LoD target level. For each strain and each matrix, a total of 24 replicates of each target level were tested using one reagent lot, testing over three days. For each panel member, a total of 8 replicates were tested each day, which yields a total of 24 replicates (8 replicates × 3 days). This ensured a minimum of 20 replicates per target level for each strain and each matrix

Based on the study data, the claimed LoD for Alinity m STI assay, applicable to all claimed matrices is:

- CT: 17.0 Elementary Bodies (EB)/mL
- NG: 7.5 Colony Forming Units (CFU)/mL
- TV: 0.1 TV/mL
- MG: 165 Genome Equivalents (GE)/mL

7. Strain Inclusivity

The analytical reactivity of the Alinity m STI Assay was evaluated by testing at least 20 replicates of additional strains, each spiked into urine, swab, and PreservCyt matrices, at concentrations targeting the claimed LoD.

- For CT, additional serovars A, B, Ba, C, F, G, H, I, J, K, L1, L2, L3, and E nvCT were tested at 17.0 EB/mL or less; all serovars were detected in ≥95.0% replicates across the matrices (swab and urine).
- For NG, 28 additional isolates were tested at 7.5 CFU/mL; all isolates were detected in ≥95.0% replicates across the matrices (swab, urine, and PreservCyt).
- For TV, additional strains Z070, Z158, and Z159 were tested at 0.1 TV/mL; all strains were detected in ≥95.0% replicates across the matrices (swab, urine, and PreservCyt).
- For MG: additional strains MEGA 601, 10008, MEGA 1256, MEGA 1272, MEGA1404, and SEA-2 were tested at 165 GE/mL; all strains were detected in ≥95.0% replicates across the matrices (swab and urine).

8. Assay Cut-Off:

The Alinity m STI assay is performed for a total of 45 thermal cycles, referred to as CN. The assay cutoffs for CT, NG and TV were initially evaluated with remnant positive and negative clinical swab and urine specimens, as determined by FDA cleared NAATs detecting CT, NG and TV. For NG, the remnant clinical samples were supplemented with swab, urine and PreservCyt samples spiked with cultured NG organisms at low titers (between 0.01 and 0.0005 CFU/mL). For MG, positive samples were prepared by spiking cultured MG at titers between 0.64 and 5.16 genome equivalents/mL in contrived swab matrix. A total of 36 samples at these low levels were tested on the Alinity m STI assay. The CN values from these samples were normally distributed. The cutoffs were set by maximizing the positive agreement while maintaining high negative agreement. Additionally, the cutoffs were further evaluated by data analysis employing a Receiver Operator Characteristic (ROC) method, testing endocervical swabs, vaginal swabs, and urine specimens obtained from 398 female and 411 males subjects through a prospective collection. The overall positive and negative agreements for the prospective samples were calculated across specimen types against the matched specimen result from the above-mentioned comparator assays. A ROC plot was generated by varying the cutoff from approximately cycle 15 to cycle 45 for each target.

The final CN cutoffs were set at 39.0, 41.0, 34.5, and 42.6 for CT, NG, TV and MG, respectively.

9. Carry-Over:

Two analytical studies were conducted to evaluate potential carryover contamination from high-positive samples into negative samples. High-positive samples were prepared at titers greater than or equal to $3.0x10^5$ EB/mL for CT, $1.6x10^4$ CFU/mL for NG, $2.3x10^4$ TV/mL for TV, and $1.1x10^6$ GE/mL for MG.

Study 1 was designed to evaluate potential carryover at the sample input rack and during sample preparation phase. High-positive and negative sample replicates were placed in alternating positions within the sample input rack, so that each negative sample replicate was processed adjacent to a positive sample replicate during sample preparation and RT-PCR processes. The Alinity m instrument can process 48 samples through sample preparation (12 positions for each of the four Assay Processing Units). Therefore, a run size of 24 high-positive samples and 24 negative samples occupied all positions during a run. Testing was conducted in 11 runs.

Study 2 was designed to evaluate potential carryover at the AMP reagent trays where eluate, activator, and AMP reagents are combined. The negative and high positive samples were placed in the sample input racks such that each negative sample replicate was processed adjacent to a positive sample replicate at the AMP reagent tray. The Alinity m STI AMP plate is 96 total samples. Therefore, a run size of 48 high-positive samples and 48 negative samples occupied all positions in the AMP plate during a run. The study was conducted across three instruments with two runs on each, for a total of six runs (288 negative samples in total).

The carryover rate for each target analyte was defined as the percentage of negative samples that report a detectable "Positive" result for the specific target being analyzed.

Of the 264 replicates of the negative sample tested in Study 1, all were reported as Negative for all targets, for the calculated carryover rate of 0.0% (0/264), with the 95% CI: 0.0% - 1.4%.

Of the 284 valid replicates (4 negative samples were excluded due to instrument error) of the negative samples tested in Study 2, one sample generated a positive result for CT and another sample was positive for CT and TV, for the calculated carryover rate of 0.7% (2/284), with the 95% CI: 0.2%-2.53%.

Combining the results from both studies resulted in a calculated carryover rate of 0.4% (2/548), with the 95% CI: 0.1%-1.3%.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See Clinical Studies below.

2. Matrix Equivalence Studies:

The following studies were designed to demonstrate equivalence in performance when using contrived matrix in place of natural clinical matrix in certain analytical studies.

Urogenital Specimens

Contrived Matrix vs. Clinical Swab and Contrived Matrix vs. Clinical PreservCyt

Clinical swab matrix consisted of vaginal swab specimens collected from CT/NG/TV/MG negative donors using the Alinity m multi-Collect Specimen Collection Kit. All vaginal swab specimens were pooled to obtain a "clinical vaginal background matrix."

Contrived matrix was prepared by spiking human cultured cervical cells into Alinity m multi-Collect transport buffer.

PreservCyt Matrix
Clinical PreservCyt matrix consisted of gynecological specimens collected from CT/NG/TV/MG negative donors in PreservCyt Solution. All clinical PreservCyt specimens were pooled to obtain a "clinical PreservCyt background matrix."

Contrived matrix was prepared by spiking human cultured cervical cells into PreservCyt Solution.

For each clinical and contrived matrix, 14 panel members were prepared with different combinations of cultured *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis,* and *M. genitalium* organisms at the concentrations shown below.

Concentrations of the Test Samples

Conc. Level	CT (EB/mL)	NG (CFU/mL)	TV (TV/mL)	MG (GE/mL)
Low Positive	34.0	15.0	0.2	330
Mid Positive	1700.0	750.0	10.0	16500
High Positive	300,000	16,000	60,000	1,100,000
Near LoD	17.0	7.5	0.1	165
High Negative (swab)	0.05	0.06	0.0002	2.3
High Negative (PreservCyt)	0.03	0.10	0.0002	5.2
Negative	N/A	N/A	N/A	N/A

The make-up of the Matrix Equivalence test panel is shown below.

Matrix Equivalence Test Panel (Urogenital)

Panel Member	CT	NG	TV	MG
1	Negative	Negative	Negative	Negative
2	Low Positive	Negative	Negative	Negative
3	Negative	Low Positive	Negative	Negative
4	Negative	Negative	Low Positive	Negative
5	Negative	Negative	Negative	Low Positive
6	Low Positive	Low Positive	Low Positive	Low Positive
7	High Positive	Low Positive	Low Positive	Low Positive
8	Low Positive	High Positive	Low Positive	Low Positive
9	Low Positive	Low Positive	High Positivec	Low Positive
10	Low Positive	Low Positive	Low Positive	High Positive
11	High Positive	High Positive	High Positive	High Positive
12	Mid Positive	Mid Positive	Mid Positive	Mid Positive
13	Near LOD	Near LOD	Near LOD	Near LOD
14	High Negative	High Negative	High Negative	High Negative

For each matrix, 10 replicates of each panel member were tested (10 replicates x 14 panel members = 140 clinical/contrived pairs). Each target was expected to be positive in 9 of the 14 panel members, excluding the High Negative level. Each target was expected to be negative in 4 of the 14 panel members, excluding the High Negative level.

The matrix is considered equivalent when the demonstrated agreement for the positive and the negative panel members is ≥95% (excluding the High Negative panel member).

All 40 of the CT/NG/TV/MG negative contrived and clinical sample pairs generated negative results in both swab and PreservCyt matrices. All 90 of the CT/NG/TV/MG positive contrived and clinical sample pairs were detected in both swab and PreservCyt matrices. All 130 of the CT/NG/TV/MG contrived and clinical total sample pairs were matched in both swab and PreservCyt matrices. All panel members 1-13 returned expected results for all targets in all matrices, thus there was 100% agreement. As expected, Panel Member #14 generated positive results <100% of the time.

The overall calculated agreement for all 14 panel members, for each analyte and for each matrix pair, is shown below.

Agreement Analysis For All Targets

Analyte	Matrix	Both Positive	Both Negative	Point Estimate (Ratio)	95% CI
CT	Swab	92	44	97.1% (136/140)	(92.9 - 98.9)
	PreservCyt	92	48	100.0% (140/140)	(97.3 - 100.0)
NG	Swab	93	45	98.6% (138/140)	(94.9 - 99.6)
	PreservCyt	92	42	95.7% (134/140)	(91.0 - 98.0)
TV	Swab	93	43	97.1% (136/140)	(92.9 - 98.9)
	PreservCyt	96	43	99.3% (139/140)	(96.1- 99.9)
MG	Swab	96	41	97.9% (137/140)	(93.9 - 99.3)
	PreservCyt	95	42	97.9% (137/140)	(93.9 - 99.3)

Additionally, the observed difference in the signal (i.e., CN values) generated by the samples prepared in clinical matrix vs. the contrived matrix was assessed; the range of these differences is shown below for each target.

Range of CN Differences (Urogenital)

Diff. in CN Values	CT	NG	TV	MG
MIN	-1.87	-0.98	-1.67	-2.23
MAX	0.39	1.89	0.13	-0.27

Extragenital Specimens

Contrived Matrix vs. Clinical Oropharyngeal Swab and Contrived Matrix vs. Clinical Rectal Swab

Clinical oropharyngeal swab matrix consisted of oropharyngeal swab specimens collected from CT/NG negative donors using the Alinity m multi-Collect Specimen Collection Kit. All oropharyngeal swab specimens were pooled to obtain a "clinical oropharyngeal swab matrix."

Clinical rectal swab matrix consisted of rectal swab specimens collected from CT/NG negative donors using the Alinity m multi-Collect Specimen Collection Kit. All rectal swab specimens were pooled to obtain a "clinical rectal swab matrix."

Contrived matrix for this study was prepared by spiking human cultured cells into Alinity m multi-Collect transport buffer.

For each clinical and contrived matrix, 9 panel members were prepared with different combinations of cultured *C. trachomatis* and *N. gonorrhoeae* organisms at the concentrations shown below.

Matrix Equivalence Test Panel (Extragenital)

Panel Member	CT	NG
1	Negative	Negative
2	Low Positive	Negative
3	Negative	Low Positive
4	Low Positive	Low Positive
5	High Positive	Low Positive
6	Low Positive	High Positive
7	Mid Positive	Mid Positive
8	Near LOD	Near LOD
9	High Negative	High Negative

Concentrations of Test Samples

Conc. Level	CT (EB/mL)	NG (CFU/mL)
Low Positive	34.0	15.0
Mid Positive	1700.0	750.0
Near LoD	17.0	7.5
High Negative	0.17	0.03
Negative	N/A	N/A

For each matrix, 10 replicates of each panel member were tested (10 replicates x 9 panel members = 90 clinical/contrived pairs). Each target was expected to be positive in 6 of the 9 panel members, excluding the High Negative level. Each target was expected to be negative in 2 of the 9 panel members, excluding the High Negative level.

The matrix is considered equivalent when the demonstrated agreement for the positive and the negative panel members is ≥95% (excluding High Negative panel member).

All 20 of the CT/NG negative contrived and clinical sample pairs generated negative results in both oropharyngeal and rectal matrices. All 60 of the CT/NG positive contrived and clinical sample pairs were detected in both oropharyngeal and rectal matrices. All 80 of the CT/NG contrived and clinical total sample pairs were matched in both matrices. All panel members 1-8 returned expected results for all targets in all matrices, thus there was 100% agreement. As expected, Panel Member #9 generated positive results <100% of the time.

The overall calculated agreement for all 9 panel members, for each analyte and for each matrix pair, is shown below.

Agreement Analysis For Both Targets

Analyte	Matrix	Both Positive	Both Negative	Point Estimate (Ratio)	95% CI
CT	Oropharyngeal	63	23	95.6% (86/90)	(89.1 - 98.3)
	Rectal	63	23	95.6% (86/90)	(89.1 - 98.3)
NG	Oropharyngeal	65	23	97.8% (88/90)	(92.3 - 99.4)
	Rectal	65	25	100% (90/90)	(95.9 - 100)

Additionally, the observed difference in the signal (i.e., CN values) generated by the samples prepared in clinical matrix vs. the contrived matrix was assessed; the range of these differences is shown below for each organism.

Range of CN Differences (Extragenital)

Diff. in CN	CT	NG
MIN	-0.81	-0.03
MAX	0.24	1.04

The data from the above studies demonstrated matrix equivalence between the clinical matrix and the respective contrived matrix for all specimen types included in the studies for all target analytes tested.

Clinical Equivalency of Performance for Extragenital Specimens: Study-specific Collection in PreservCyt Media vs. the Alinity m multi-Collect Specimen Collection Media

An additional study was conducted to demonstrate equivalence between the PreservCyt collection media used for extragenital specimens in the collaborative study vs. the Alinity m Collection Media used in actual clinical practice.

For the collaborative study, three extragenital specimens (either rectal or oropharyngeal) from each patient were added to a single tube containing 10 mL of PreservCyt Solution, which was then added to the Alinity m transport buffer (0.5 ml to 0.9 mL). To determine equivalence between the two types of specimen collection methods, analytical sensitivity study was conducted. Test samples were contrived (a) in the same manner as during the clinical study, and (b) in pooled negative clinical matrix (i.e., rectal or oropharyngeal swab specimens collected from CT/NG negative donors using the Alinity m multi-Collect Specimen Collection Kit). The study included two strains of CT and NG organisms, spiked at a minimum of 3 concentration levels targeting the previously determined LoD, and levels 2-fold above and 2-fold below the LoD. Each sample was tested in at least 20 replicates using one lot of reagents over three days. The results from the study were acceptable and demonstrated equivalence in performance for extragenital swabs collected in the study-specific PreservCyt media vs. swabs collected in the Alinity m multi-Collect Collection media; the summary of results is shown below.

LoD Comparison for Extragenital Swabs Collected in PreservCyt vs. Swabs Collected in Alinity m multi-Collect Media

Analyte	Specimen Type	Strain	PreservCyt Matrix LOD	Multi-collect Matrix LOD	Fold Change
CT	Oropharyngeal Swab	Strain 1	0.030	0.060	-2.00
		Strain 2	0.050	0.130	-2.60
	Rectal Swab	Strain 1	0.030	0.140	-4.67
		Strain 2	0.060	0.060	1.00
NG	Oropharyngeal Swab	Strain 1	0.110	0.055	2.00
		Strain 2	0.060	0.030	2.00
	Rectal Swab	Strain 1	0.100	0.100	1.00
		Strain 2	0.050	0.050	1.00

Note: The LoD for CT is expressed in IFU/mL; the LoD for NG is expressed in CFU/mL

C Clinical Studies:

Urogenital Specimens

Clinical performance of the Alinity m STI assay with urogenital specimens was established in a multicenter clinical study conducted in the United States. The specimens for the urogenital evaluation were prospectively collected from subjects 14 years of age or older, at 33 geographically diverse sites that included STD clinics, Planned Parenthood clinics, primary care and gynecology practices. The duration of study enrollment was approximately 10 months. The study population consisted of 7,099 subjects (3,401 females and 3,698 males), seeking testing for sexually transmitted infections (STI), both symptomatic and asymptomatic of STIs. Study subjects were classified as symptomatic if the subject reported STI related symptoms.

Each female subject provided up to 8 specimens, including 1 first-catch urine specimen, 1 self-collected vaginal swab, 3 clinician-collected vaginal swabs, 2 endocervical swabs, and 1 ThinPrep (PreservCyt) cytology specimen. All specimens for comparator testing were collected in the appropriate collection media, as specified in the respective assays' IFU.

Each male provided first-catch urine specimen, collected into a sterile collection cup. The urine was divided into aliquots which were then transferred into the appropriate collection media, as specified in the respective assays' IFU, including one aliquot for the Alinity m Multi-Collect Specimen Collection Kit.

The following testing methods were utilized during the study:

- Testing with the Alinity m STI assay was performed at 3 external clinical testing sites.
- The comparator testing was conducted at six clinical facilities.
- Comparator testing for CT and NG in female patients was performed with two NAATs, testing urine and swab specimens from each female subject.
- Comparator testing for CT and NG in males consisted of testing urine with three NAATs.
- Comparator testing for TV in females included three NAATs.

- Comparator testing for TV in males consisted of testing urine with two NAATs, and In-pouch TV culture.
- Comparator testing for MG included three NAATs for both females and males.

Determination of Comparator Results (Subject's Infection Status)

The Alinity m STI assay was compared to a composite algorithm of test results from the comparator assays, defining a Patient Infected Status (PIS) for each analyte (CT, NG, TV, and MG), as defined below.

C. trachomatis (CT) and *N. gonorrhoeae* (NG) Patient Infected Status

For females, urine specimens and swab specimens were tested on two separate comparator NAATs to establish PIS.

Female subjects were considered "infected" if there were one or more positive results for each NAAT comparator assay. When calculating sensitivity and specificity estimates, in cases where the swabs were negative by both assays and the urine specimens were positive in both assays, the PIS comparator for the swab results was defined as "not infected" and the PIS comparator for the urine results was defined as "infected" (there were two female subjects that were negative for CT in the swab samples and positive in urine only by both NAATs). A female subject was categorized as "not infected" for CT or NG if at least one of the comparators reported negative results for all sample types. The PIS was defined as "indeterminate" (IND) if missing results (N/A) from a comparator assay(s) precluded the ability to determine if one or more positive results could have been obtained by at least two NAAT comparator assays.

For males, urine specimens were tested with three comparator NAATs were used to establish PIS for CT and NG. A male subject was considered "infected" if two or more positive results from each of the NAAT comparator assays were obtained. The PIS was defined as "not infected" if two or more comparator assays were negative. The PIS was defined as "indeterminate" (IND) if missing results from the NAAT comparator assays precluded the ability to conclusively determine the infection status.

T. vaginalis (TV) Patient Infected Status

For females, three comparator NAATs for the detection of TV were used for testing of vaginal swab specimens to establish TV PIS. A female subject was categorized as "infected" for TV if the first two swab comparator NAAT results were both positive, or if 2 of the 3 swab comparator NAAT results were positive in cases where the 3rd NAAT was used as a tie-breaker. A female subject was categorized as "not infected" for TV if the first two swab comparator NAAT results were both negative, or if 2 of the 3 swab comparator NAAT results were negative in cases where the 3rd NAAT was used as a tie-breaker. The PIS was defined as "indeterminate" (IND) if both swab comparator assays were missing or a required tie-breaker assay precluded the ability to determine the PIS.

For males, the TV PIS algorithm utilized two comparator NAATs for TV. Additionally, the In-Pouch TV culture kit was used as a third comparator. The PIS was defined as "infected" if the TV culture result was positive (regardless of NAAT results), or if both NAATs were positive. If the TV culture result was negative, the PIS was defined as "not infected" if one or more comparator NAATs were negative. The PIS was defined as IND if missing results from the comparator assays precluded the ability to determine the PIS. Subjects with an IND PIS were excluded from analyses.

M. genitalium (MG) Patient Infected Status

For females, three comparator NAATs were used for testing of vaginal swab specimens to establish MG PIS. A female subject was categorized as "infected" for MG if the first two swab comparator NAAT results were both positive, or if 2 of the 3 swab comparator NAAT results were positive in cases where the 3rd NAAT was used as a tie-breaker. A female subject was categorized as "not infected" for MG if the first two swab comparator NAAT results were both negative, or if 2 of the 3 swab comparator NAAT results were negative in cases where the 3rd NAAT was used as a tie-breaker.

For males, three comparator NAATs were used to test the urine specimens for MG. Two or more positive results from each of the comparator assays were defined as "infected." The PIS was defined as "not infected" if two or more comparator assays were negative. The PIS was defined as "indeterminate" (IND) if missing results from NAAT comparator assays precluded the ability to determine the PIS. Subjects with an IND PIS were excluded from analyses.

Prevalence of Infections Observed during Clinical Study

The prevalence of the infections observed during the clinical study, as determined by the comparator results (PIS), is presented below by site and overall.

Prevalence of Infections in Females (determined by PIS)

	% Positive (No. Positive/No. Tested)			
Site	**CT+**	**NG+**	**TV+**	**MG+**
1	4.9 (2/41)	0.0 (0/41)	12.2 (5/41)	22.5 (9/40)
2	3.7 (22/587)	0.7 (4/588)	12.9 (76/588)	6.8 (40/586)
3	3.8 (9/235)	0.8 (2/236)	13.6 (32/236)	6.0 (14/234)
4	21.1 (4/19)	0.0 (0/20)	15.0 (3/20)	10.0 (2/20)
5	6.7 (18/270)	0.0 (0/270)	6.3 (16/256)	7.9 (21/266)
6	0.0 (0/4)	0.0 (0/4)	0.0 (0/4)	0.0 (0/4)
7	3.4 (17/500)	1.0 (5/499)	12.9 (61/473)	6.4 (30/468)
8	2.8 (3/106)	2.8 (3/106)	16.2 (17/105)	5.7 (6/106)
9	6.4 (7/109)	0.0 (0/109)	7.3 (8/110)	13.1 (14/107)
10	3.8 (4/106)	4.8 (5/105)	6.6 (7/106)	9.5 (10/105)
11	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	5.6 (1/18)
12	4.2 (2/48)	0.0 (0/48)	10.4 (5/48)	4.2 (2/48)

13	7.7 (4/52)	0.0 (0/52)	11.5 (6/52)	3.8 (2/52)
14	0.0 (0/39)	2.5 (1/40)	5.0 (2/40)	10.5 (4/38)
15	8.1 (3/37)	5.4 (2/37)	5.4 (2/37)	11.1 (4/36)
16	11.8 (2/17)	0.0 (0/17)	0.0 (0/16)	5.9 (1/17)
17	0.0 (0/43)	0.0 (0/43)	9.3 (4/43)	18.6 (8/43)
18	0.0 (0/5)	0.0 (0/5)	0.0 (0/6)	0.0 (0/6)
19	11.1 (1/9)	0.0 (0/9)	10.0 (1/10)	30.0 (3/10)
20	9.0 (12/133)	1.5 (2/134)	1.5 (2/134)	6.7 (9/134)
21	2.9 (1/35)	0.0 (0/35)	0.0 (0/35)	8.3 (3/36)
22	8.9 (11/124)	3.2 (4/124)	4.1 (5/122)	7.4 (9/121)
23	5.3 (2/38)	2.6 (1/38)	5.4 (2/37)	10.5 (4/38)
24	11.8 (6/51)	0.0 (0/51)	0.0 (0/51)	0.0 (0/50)
25	6.9 (2/29)	6.9 (2/29)	6.9 (2/29)	6.9 (2/29)
26	4.7 (4/85)	1.2 (1/85)	4.7 (4/85)	15.3 (13/85)
27	13.0 (30/231)	2.6 (6/231)	7.4 (17/231)	9.1 (21/230)
28	8.0 (7/87)	1.1 (1/87)	3.4 (3/87)	5.7 (5/87)
29	20.0 (13/65)	3.1 (2/65)	20.0 (13/65)	9.2 (6/65)
30	11.1 (8/72)	0.0 (0/72)	25.0 (18/72)	14.1 (10/71)
31	9.8 (5/51)	0.0 (0/51)	11.8 (6/51)	11.8 (6/51)
32	29.8 (14/47)	6.4 (3/47)	10.6 (5/47)	17.4 (8/46)
All	**6.5 (213/3293)**	**1.3 (44/3296)**	**9.9 (322/3255)**	**8.2 (267/3247)**

Prevalence of Infections in Males (determined by PIS)

	% Positive (No. Positive/No. Tested)			
Site	**CT+**	**NG+**	**TV+**	**MG+**
1	15.3 (9/59)	20.3 (12/59)	5.3 (3/57)	22.4 (13/58)
2	4.4 (39/889)	0.3 (3/889)	2.1 (19/890)	4.7 (42/890)
3	3.5 (9/260)	0.4 (1/260)	1.2 (3/260)	2.7 (7/259)
4	16.4 (19/116)	7.8 (9/116)	2.6 (3/116)	11.3 (13/115)
5	3.9 (9/233)	0.9 (2/233)	1.3 (3/230)	4.3 (10/233)
6	0.0 (0/24)	0.0 (0/24)	0.0 (0/24)	8.3 (2/24)
7	3.6 (22/606)	0.8 (5/608)	3.6 (22/609)	4.4 (25/574)
8	13.9 (11/79)	13.9 (11/79)	5.1 (4/79)	13.9 (11/79)
9	2.1 (1/47)	0.0 (0/47)	0.0 (0/47)	10.4 (5/48)
10	12.7 (14/110)	3.6 (4/111)	0.0 (0/112)	3.6 (4/110)
11	6.3 (1/16)	0.0 (0/16)	6.3 (1/16)	18.8 (3/16)
12	5.6 (2/36)	8.3 (3/36)	5.4 (2/37)	2.8 (1/36)
13	18.8 (6/32)	6.3 (2/32)	0.0 (0/33)	6.1 (2/33)
14	8.0 (2/25)	0.0 (0/25)	0.0 (0/25)	0.0 (0/22)
15	13.2 (9/68)	4.4 (3/68)	2.9 (2/68)	11.8 (8/68)
16	16.7 (1/6)	0.0 (0/6)	0.0 (0/7)	0.0 (0/5)
17	8.3 (2/24)	4.2 (1/24)	4.2 (1/24)	20.8 (5/24)
18	0.0 (0/1)	0.0 (0/1)	0.0 (0/1)	0.0 (0/1)

19	7.7 (1/13)	15.4 (2/13)	7.7 (1/13)	23.1 (3/13)
20	0.0 (0/1)	0.0 (0/1)	0.0 (0/1)	0.0 (0/1)
21	15.6 (12/77)	3.9 (3/77)	0.0 (0/77)	3.9 (3/77)
22	19.2 (5/26)	0.0 (0/26)	0.0 (0/26)	4.0 (1/25)
23	4.4 (2/45)	6.7 (3/45)	0.0 (0/45)	8.9 (4/45)
24	9.8 (6/61)	0.0 (0/61)	6.6 (4/61)	8.2 (5/61)
25	4.1 (2/49)	0.0 (0/49)	0.0 (0/49)	2.0 (1/49)
26	15.2 (5/33)	15.2 (5/33)	0.0 (0/33)	3.0 (1/33)
27	7.3 (4/55)	1.8 (1/56)	1.8 (1/56)	7.3 (4/55)
28	14.7 (20/136)	7.2 (10/138)	1.4 (2/138)	4.4 (6/135)
29	16.0 (19/119)	8.4 (10/119)	0.0 (0/119)	5.0 (6/119)
30	25.4 (15/59)	6.8 (4/59)	1.7 (1/59)	11.9 (7/59)
31	16.9 (10/59)	3.4 (2/59)	5.1 (3/59)	8.5 (5/59)
32	19.6 (10/51)	2.0 (1/51)	5.9 (3/51)	10.4 (5/48)
33	26.4 (19/72)	6.9 (5/72)	1.4 (1/72)	15.1 (11/73)
All	**8.2 (286/3487)**	**2.9 (102/3493)**	**2.3 (79/3494)**	**6.2 (213/3447)**

Clinical Study Results (Urogenital Specimens)

The clinical sensitivity and specificity of the Alinity m STI assay with urogenital specimens is shown below for each target pathogen, shown by gender and symptom status.

Sensitivity and Specificity for CT

Clinical Performance for *C. trachomatis* in Urogenital Specimens against PIS

								Sensitivity (95% CI)		Specificity (95% CI)	
Gender	**Specimen Type**	**Symptom Status**	**N**	**TP**	**FP**	**TN**	**FN**	**Estimate**	**n / N**	**Estimate**	**n / N**
Female	Vaginal Swab Clinician-collected	Symptomatic	1517	119	18	1378	2	98.3 (94.2,99.5)	119/121	98.7 (98.0,99.2)	1378/1396
		Asymptomatic	1649	82	7	1558	2	97.6 (91.7,99.3)	82/84	99.6 (99.1,99.8)	1558/1565
		All	3166	201	25	2936	4	98.0 (95.1,99.2)	201/205	99.2 (98.8,99.4)	2936/2961
	Vaginal Swab Self-collect	Symptomatic	1521	121	14	1383	3	97.6 (93.1,99.2)	121/124	99.0 (98.3,99.4)	1383/1397
		Asymptomatic	1642	82	8	1552	0	100.0 (95.5,100.0)	82/82	99.5 (99.0,99.7)	1552/1560
		All	3163	203	22	2935	3	98.5 (95.8,99.5)	203/206	99.3 (98.9,99.5)	2935/2957
	Endocervical Swab	Symptomatic	1495	113	8	1369	5	95.8 (90.5,98.2)	113/118	99.4 (98.9,99.7)	1369/1377
		Asymptomatic	1592	75	10	1501	6	92.6 (84.8,96.6)	75/81	99.3 (98.8,99.6)	1501/1511
		All	3087	188	18	2870	11	94.5 (90.4,96.9)	188/199	99.4 (99.0,99.6)	2870/2888

Male	Male Urine	Symptomatic	1107	123	2	979	3	97.6 (93.2,99.2)	123/126	99.8 (99.3,99.9)	979/981
		Asymptomatic	2380	155	14	2206	5	96.9 (92.9,98.7)	155/160	99.4 (98.9,99.6)	2206/2220
		All	3487	278	16	3185	8	97.2 (94.6,98.6)	278/286	99.5 (99.2,99.7)	3185/3201

Two subjects tested negative for CT by both comparators in the swab specimens and positive by both comparators in urine specimens. For calculations of performance, these samples were considered PIS CT Negative for swab samples and PIS CT Positive for urine samples.

Sensitivity and Specificity for NG

Clinical Performance for *N. gonorrhoeae* in Urogenital Specimens against PIS

								Sensitivity (95% CI)		Specificity (95% CI)	
Gender	**Specimen Type**	**Symptom Status**	**N**	**TP**	**FP**	**TN**	**FN**	**Estimate**	**n / N**	**Estimate**	**n / N**
Female	Vaginal Swab Clinician-collected	Symptomatic	1519	23	3	1493	0	100.0 (85.7,100.0)	23/23	99.8 (99.4,99.9)	1493/1496
		Asymptomatic	1651	18	4	1629	0	100.0 (82.4,100.0)	18/18	99.8 (99.4,99.9)	1629/1633
		All	3170	41	7	3122	0	100.0 (91.4,100.0)	41/41	99.8 (99.5,99.9)	3122/3129
	Vaginal Swab Self-collect	Symptomatic	1523	23	5	1495	0	100.0 (85.7,100.0)	23/23	99.7 (99.2,99.9)	1495/1500
		Asymptomatic	1643	18	5	1620	0	100.0 (82.4,100.0)	18/18	99.7 (99.3,99.9)	1620/1625
		All	3166	41	10	3115	0	100.0 (91.4,100.0)	41/41	99.7 (99.4,99.8)	3115/3125
	Endocervical Swab	Symptomatic	1497	19	5	1470	3[a]	86.4 (66.7,95.3)	19/22	99.7 (99.2,99.9)	1470/1475
		Asymptomatic	1593	18	2	1573	0	100.0 (82.4,100.0)	18/18	99.9 (99.5,100.0)	1573/1575
		All	3090	37	7	3043	3[a]	92.5 (80.1,97.4)	37/40	99.8 (99.5,99.9)	3043/3050
	PreservCyt	Symptomatic	1349	19	1	1327	2	90.5 (71.1,97.3)	19/21	99.9 (99.6,100.0)	1327/1328
		Asymptomatic	1387	15	0	1372	0	100.0 (79.6,100.0)	15/15	100.0 (99.7,100.0)	1372/1372
		All	2736	34	1	2699	2	94.4 (81.9,98.5)	34/36	100.0 (99.8,100.0)	2699/2700
Male	Male Urine	Symptomatic	1109	74	2	1033	0	100.0 (95.1,100.0)	74/74	99.8 (99.3,99.9)	1033/1035
		Asymptomatic	2384	28	3	2353	0	100.0 (87.9,100.0)	28/28	99.9 (99.6,100.0)	2353/2356
		All	3493	102	5	3386	0	100.0 (96.4,100.0)	102/102	99.9 (99.7,99.9)	3386/3391

[a]A false negative test result was obtained on one specimen which was collected after two other swabs were collected from the cervix (i.e., last of the three swabs). Based on the CN values from the Cellular Control, the false negative result was likely due to insufficient cellular material collected. Without this sample, the overall sensitivity for NG is 94.9% (37/39) with a 95% confidence interval of (83.1%, 98.6%). Refer to the limitations section for caution when collecting multiple cervical specimens.

Note on Performance of Alinity m STI for NG in Endocervical Swabs

The sensitivity of the Alinity m STI assay for NG with endocervical specimens was below the FDA expectation of 95%, at 92.5%. In total, there were 40 comparator-positive NG specimens, of which 3 specimens tested negative (false negative). The sponsor evaluated the potential causes for this outcome by examining the CN values for the Cellular Control (CC) associated with the NG positive endocervical swab specimens. The review of the data showed that, while the CN values for the Cellular Control ranged from 20.6 to 27.3 for 39 of the 40 NG-positive endocervical specimens, one of the false negative specimens (from a symptomatic female) had a CC CN value of 32.55, indicating very low cellularity. By comparison, the CC CN from the PreservCyt specimen from this same subject (same anatomic site) was 26.81, suggesting that the endocervical swab specimen which was NG-Negative on Alinity m STI, was not collected effectively. Looking back at the order in which the samples were collected from this particular Subject, it was determined that the endocervical specimen designated for the Alinity m STI testing was collected 7th out of the 8 specimens collected. Further, the review of the CN values for the NG target detected for the other specimens from the same subject suggests that this subject had a low bacterial load to begin with when compared to the mean Ct at LoD, as evidenced by the NG target CN value of 32.25 for the vaginal swab and 35.36 for the PreservCyt sample. The CN values for IC, CC and NG target generated for all samples from that particular subject, which were run on the Alinity m, are shown below.

Subject 250027, Asymptomatic Female

Specimen Type	**Internal Control CN**	**Cellular Control CN**	**NG Target CN**	**Alinity m STI Result**
Urine	30.92	30.69	-1	NG Negative
Self-collected Vaginal Swab	31.48	24.61	32.25	NG Positive
Clinician-collect Vaginal Swab 1*	N/A	N/A	N/A	N/A
Clinician-collect Vaginal Swab2	30.86	26.16	31.37	NG Positive
Clinician-collect Vaginal Swab 3*	N/A	N/A	N/A	N/A
Endocervical Swab 1*	N/A	N/A	N/A	N/A
Endocervical Swab 2	30.83	**32.55**	-1	NG Negative
PreservCyt (endocervical)	31.17	26.81	35.36	NG Positive

*Specimen collected for comparator testing; not run on the Alinity m STI

Although FDA expects the sensitivity point estimate of for tests detecting STI pathogens to be 95%, the demonstrated sensitivity of the Alinity m STI for NG in endocervical swabs at 92.5% (without excluding the one sample discussed above) was found acceptable for clearance based on the following considerations:

a. The inclusion of the cellular control in the assay design afforded the ability to examine the sample adequacy and to draw conclusions about the effectiveness of the sample collection.

b. The low bacterial load of the subject in question, as evidenced by the elevated NG-target CN value in the other samples from the same individual, suggest that an ineffective endocervical swab collection could have resulted in the false negative result.
c. The sponsor conducted a well-designed study enrolling > 7,000 subjects at 33 clinical sites, however, the observed prevalence of gonorrhea in females was < 1.2%; enrolling additional subjects would be unlikely to alter the performance estimates.
d. Were the endocervical swab from this particular Subject excluded from performance calculations due to potentially inadequate sample collection, NG sensitivity for the Alinity m STI with endocervical swab specimens would have been 94.9% (37/39), with the 95% CI of 83.1% - 98.6%, which is similar to other cleared assays for the detection of NG.
e. Sensitivity of the assay for detection of NG was 100% in other claimed specimens such as vaginal specimens, both self-collected and clinician-collected, as well as in male urine, suggesting that the performance of the Alinity m STI assay is comparable to the other similar assays previously cleared by the FDA.
f. In clinical practice, it is unlikely that multiple swabs will be collected from the cervix from a single patient.

For the reasons above, and in an effort to avoid imposing additional burden of supplemental data collection, while remaining consistent with our decisions for other sponsors' submissions, FDA has accepted the data by adding a limitation to the labeling to caution the user that: *False negative results for Neisseria gonorrhoeae were observed from endocervical samples when multiple endocervical swabs were collected from one patient. If multiple endocervical samples are collected from the same patient, and the NG test result is negative, further testing may be indicated if infection with N. gonorrhoeae is strongly suspected.*

Sensitivity and Specificity for TV

Clinical Performance for *T. vaginalis* in Urogenital Specimens against PIS

								Sensitivity		Specificity	
Gender	**Specimen Type**	**Symptom Status**	**N**	**TP**	**FP**	**TN**	**FN**	**Estimate (95% CI)**	**n / N**	**Estimate (95% CI)**	**n / N**
Female	Vaginal Swab Clinician-collected	Symptomatic	1518	157	35	1325	1	99.4 (96.5,99.9)	157/158	97.4 (96.4,98.1)	1325/1360
		Asymptomatic	1654	159	44	1451	0	100.0 (97.6,100)	159/159	97.1 (96.1,97.8)	1451/1495
		All	3172	316	79	2776	1	99.7 (98.2,99.9)	316/317	97.2 (96.6,97.8)	2776/2855
	Vaginal Swab Self-collected	Symptomatic	1522	157	27	1337	1	99.4 (96.5,99.9)	157/158	98.0 (97.1,98.6)	1337/1364
		Asymptomatic	1644	155	35	1453	1	99.4 (96.5,99.9)	155/156	97.6 (96.7,98.3)	1453/1488
		All	3166	312	62	2790	2	99.4 (97.7,99.8)	312/314	97.8 (97.2,98.3)	2790/2852
	Endocervical Swab	Symptomatic	1496	152	46	1295	3	98.1 (94.5,99.3)	152/155	96.6 (95.5,97.4)	1295/1341

		Asymptomatic	1597	152	39	1402	4	97.4 (93.6,99.0)	152/156	97.3 (96.3,98.0)	1402/1441
		All	3093	304	85	2697	7	97.7 (95.4,98.9)	304/311	96.9 (96.2,97.5)	2697/2782
	PreservCyt	Symptomatic	1337	131	5	1197	4	97.0 (92.6,98.8)	131/135	99.6 (99.0,99.8)	1197/1202
		Asymptomatic	1386	127	9	1242	8	94.1 (88.7,97.0)	127/135	99.3 (98.6,99.6)	1242/1251
		All	2723	258	14	2439	12	95.6 (92.4,97.4)	258/270	99.4 (99.0,99.7)	2439/2453
Male	Male Urine	Symptomatic	1109	24	9	1076	0	100.0 (86.2,100)	24/24	99.2 (98.4,99.6)	1076/1085
		Asymptomatic	2385	54	17	2313	1	98.2 (90.4,99.7)	54/55	99.3 (98.8,99.5)	2313/2330
		All	3494	78	26	3389	1	98.7 (93.2,99.8)	78/79	99.2 (98.9,99.5)	3389/3415

Specimen Specific Agreement for TV in Female Urine

The performance of the Alinity m STI for detection of TV in female urine was assessed by testing the urine samples from the enrolled female subjects with two FDA cleared NAATs for detection of TV. A composite comparator algorithm (CCA) was used to determine the female urine-specific TV status, where a specimen was considered TV positive if at least one NAAT was positive. The TV specimen specific PPA and NPA of Alinity m TV results in female urine specimens, against two FDA cleared NAATs for TV, are shown below.

TV Specimen Specific Agreement for Female Urine

Symptom Status		Alinity+	Alinity+	Alinity-	Alinity-	Positive Percent Agreement		Negative Percent Agreement	
	N	CCA+	CCA-	CCA-	CCA+	PPA (95% CI)	n / N	NPA (95% CI)	n / N
Symptomatic	1507	141	16	1346	4	97.2% (93.1,98.9)	141/145	98.8% (98.1,99.3)	1346/1362
Asymptomatic	1651	154	10	1484	3	98.1% (94.5,99.3)	154/157	99.3 (98.8,99.6)	1484/1494
All	3158	295	26	2830	7	97.7% (95.3,98.9)	295/302	99.1% (98.7,99.4)	2830/2856

The performance of the Alinity m STI for detection of TV in female urine was also assessed as compared to the PIS (as described earlier). The data showed that the detection of TV infection in females using urine specimens is up to 6.6% lower than when using vaginal swab specimens.

Sensitivity and Specificity for MG

Clinical Performance for *M. genitallium* in Urogenital Specimens against PIS

								Sensitivity		Specificity	
Gender	Specimen Type	Symptom Status	N	TP	FP	TN	FN	Estimate (95% CI)	n / N	Estimate (95% CI)	n / N
Female		Symptomatic	1514	148	15	1350	1	99.3 (96.3,99.9)	148/149	98.9 (98.2,99.3)	1350/1365

	Vaginal Swab Clinician-collected	Asymptomatic	1643	105	8	1526	4	96.3 (90.9,98.6)	105/109	99.5 (99.0,99.7)	1526/1534
		All	3157	253	23	2876	5	98.1 (95.5,99.2)	253/258	99.2 (98.8,99.5)	2876/2899
	Vaginal Swab Self-collected	Symptomatic	1517	144	21	1346	6	96.0 (91.5,98.2)	144/150	98.5 (97.7,99.0)	1346/1367
		Asymptomatic	1632	104	20	1502	6	94.5 (88.6,97.5)	104/110	98.7 (98.0,99.1)	1502/1522
		All	3149	248	41	2848	12	95.4 (92.1,97.3)	248/260	98.6 (98.1,99.0)	2848/2889
	Endocervical Swab	Symptomatic	1492	125	10	1336	21	85.6 (79.0,90.4)	125/146	99.3 (98.6,99.6)	1336/1346
		Asymptomatic	1584	82	14	1466	22	78.8 (70.0,85.6)	82/104	99.1 (98.4,99.4)	1466/1480
		All	3076	207	24	2802	43	82.8 (77.6,87.0)	207/250	99.2 (98.7,99.4)	2802/2826
Male	Male Urine	Symptomatic	1099	99	40	958	2	98.0 (93.1,99.5)	99/101	96.0 (94.6,97.0)	958/998
		Asymptomatic	2348	110	41	2195	2	98.2 (93.7,99.5)	110/112	98.2 (97.5,98.6)	2195/2236
		All	3447	209	81	3153	4	98.1 (95.3,99.3)	209/213	97.5 (96.9,98.0)	3153/3234

Expected Values

The positivity rate of the Alinity m STI assay for CT, NG, TV, and MG observed during the study is shown for each specimen type, by collection site and overall.

Positivity Rates Obtained with Alinity m STI for *C. trachomatis*

Collection Site	Endocervical Swabs	Self-Collected Vaginal Swabs	Clinician Collected Vaginal Swabs	Male Urine
01	2.4 (1/41)	2.4 (1/41)	5.1 (2/39)	15.3 (9/59)
02	4.0 (22/552)	4.6 (26/568)	4.2 (24/567)	4.7 (42/889)
03	2.7 (6/225)	4.1 (9/222)	4.3 (10/232)	3.5 (9/260)
04	21.1 (4/19)	15.8 (3/19)	21.1 (4/19)	17.2 (20/116)
05	7.2 (17/237)	7.1 (18/254)	7.2 (18/251)	3.9 (9/233)
06	0.0 (0/4)	0.0 (0/3)	0.0 (0/4)	0.0 (0/24)
07	3.5 (14/395)	3.4 (15/438)	3.2 (14/433)	3.6 (22/606)
08	2.9 (3/103)	2.9 (3/105)	2.9 (3/104)	15.2 (12/79)
09	6.6 (7/106)	7.5 (8/107)	6.6 (7/106)	4.3 (2/47)
10	4.8 (5/105)	3.8 (4/105)	4.8 (5/104)	12.7 (14/110)
11	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	6.3 (1/16)
12	4.2 (2/48)	4.2 (2/48)	4.2 (2/48)	5.6 (2/36)
13	7.7 (4/52)	9.8 (5/51)	7.7 (4/52)	18.8 (6/32)
14	0.0 (0/39)	2.6 (1/38)	0.0 (0/39)	8.0 (2/25)
15	8.1 (3/37)	10.8 (4/37)	8.1 (3/37)	14.7 (10/68)
16	11.8 (2/17)	12.5 (2/16)	12.5 (2/16)	16.7 (1/6)
17	0.0 (0/43)	0.0 (0/43)	0.0 (0/43)	8.3 (2/24)
18	0.0 (0/5)	0.0 (0/5)	0.0 (0/5)	0.0 (0/1)
19	11.1 (1/9)	11.1 (1/9)	12.5 (1/8)	7.7 (1/13)
20	-	-	-	0.0 (0/1)
21	7.5 (10/133)	9.9 (13/131)	9.8 (13/133)	14.3 (11/77)

22	5.9 (2/34)	5.7 (2/35)	8.6 (3/35)	19.2 (5/26)
23	7.6 (9/118)	9.2 (11/120)	10.7 (13/121)	4.4 (2/45)
24	5.3 (2/38)	5.4 (2/37)	8.1 (3/37)	8.2 (5/61)
25	12.0 (6/50)	12.0 (6/50)	15.7 (8/51)	4.1 (2/49)
26	10.3 (3/29)	6.9 (2/29)	10.3 (3/29)	18.2 (6/33)
27	6.0 (5/84)	4.7 (4/85)	4.7 (4/85)	7.3 (4/55)
28	12.9 (29/225)	13.4 (31/231)	13.4 (31/231)	14.7 (20/136)
29	9.2 (8/87)	9.2 (8/87)	8.1 (7/86)	16.8 (20/119)
30	20.0 (13/65)	25.0 (16/64)	21.9 (14/64)	25.4 (15/59)
31	14.1 (10/71)	12.9 (9/70)	12.5 (9/72)	18.6 (11/59)
32	9.8 (5/51)	10.0 (5/50)	10.0 (5/50)	19.6 (10/51)
33	27.7 (13/47)	29.8 (14/47)	29.8 (14/47)	26.4 (19/72)
All	**6.7 (206/3087)**	**7.1 (225/3163)**	**7.1 (226/3166)**	**8.4 (294/3487)**

Positivity Rates Obtained with Alinity m STI for *N. gonorrhoeae*

Collection Site	Endocervical Swabs	Self-Collected Vaginal Swabs	Clinician Collected Vaginal Swabs	PreservCyt	Male Urine
01	0.0 (0/41)	2.4 (1/41)	2.6 (1/39)	0.0 (0/36)	20.3 (12/59)
02	0.9 (5/553)	1.1 (6/569)	0.9 (5/568)	0.4 (1/268)	0.4 (4/889)
03	0.9 (2/225)	0.9 (2/222)	0.9 (2/233)	0.9 (2/224)	0.4 (1/260)
04	0.0 (0/20)	5.0 (1/20)	0.0 (0/20)	0.0 (0/20)	8.6 (10/116)
05	0.4 (1/237)	0.0 (0/254)	0.0 (0/251)	0.0 (0/263)	0.9 (2/233)
06	0.0 (0/4)	0.0 (0/3)	0.0 (0/4)	0.0 (0/4)	0.0 (0/24)
07	0.3 (1/395)	0.5 (2/438)	0.7 (3/433)	0.0 (0/310)	1.0 (6/608)
08	3.9 (4/103)	2.9 (3/105)	2.9 (3/104)	2.9 (3/105)	13.9 (11/79)
09	0.0 (0/106)	0.0 (0/107)	0.0 (0/106)	0.9 (1/108)	0.0 (0/47)
10	3.8 (4/104)	6.7 (7/104)	5.8 (6/103)	3.8 (4/105)	3.6 (4/111)
11	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	0.0 (0/16)
12	2.1 (1/48)	0.0 (0/48)	0.0 (0/48)	0.0 (0/48)	8.3 (3/36)
13	0.0 (0/52)	0.0 (0/51)	0.0 (0/52)	0.0 (0/44)	6.3 (2/32)
14	2.5 (1/40)	2.6 (1/39)	2.5 (1/40)	2.5 (1/40)	0.0 (0/25)
15	2.7 (1/37)	5.4 (2/37)	5.4 (2/37)	5.4 (2/37)	4.4 (3/68)
16	0.0 (0/17)	0.0 (0/16)	0.0 (0/16)	0.0 (0/17)	0.0 (0/6)
17	0.0 (0/43)	0.0 (0/43)	0.0 (0/43)	0.0 (0/41)	8.3 (2/24)
18	0.0 (0/5)	0.0 (0/5)	0.0 (0/5)	0.0 (0/5)	0.0 (0/1)
19	0.0 (0/9)	0.0 (0/9)	0.0 (0/8)	0.0 (0/9)	15.4 (2/13)
20	-	-	-	-	0.0 (0/1)
21	2.2 (3/134)	1.5 (2/132)	1.5 (2/134)	1.5 (2/133)	3.9 (3/77)
22	0.0 (0/34)	0.0 (0/35)	0.0 (0/35)	0.0 (0/34)	0.0 (0/26)
23	3.4 (4/118)	3.3 (4/120)	3.3 (4/121)	3.3 (4/122)	6.7 (3/45)
24	0.0 (0/38)	2.7 (1/37)	2.7 (1/37)	0.0 (0/38)	0.0 (0/61)
25	0.0 (0/50)	0.0 (0/50)	0.0 (0/51)	0.0 (0/47)	0.0 (0/49)
26	6.9 (2/29)	6.9 (2/29)	6.9 (2/29)	7.4 (2/27)	15.2 (5/33)
27	1.2 (1/84)	2.4 (2/85)	2.4 (2/85)	1.2 (1/83)	1.8 (1/56)
28	2.7 (6/225)	2.6 (6/231)	2.6 (6/231)	2.6 (6/230)	7.2 (10/138)
29	1.1 (1/87)	1.1 (1/87)	1.2 (1/86)	1.2 (1/86)	8.4 (10/119)
30	3.1 (2/65)	3.1 (2/64)	4.7 (3/64)	3.1 (2/65)	6.8 (4/59)
31	2.8 (2/71)	1.4 (1/70)	1.4 (1/72)	0.0 (0/71)	5.1 (3/59)
32	0.0 (0/51)	2.0 (1/50)	0.0 (0/50)	0.0 (0/51)	2.0 (1/51)
33	6.4 (3/47)	8.5 (4/47)	6.4 (3/47)	6.4 (3/47)	6.9 (5/72)
All	**1.4 (44/3090)**	**1.6 (51/3166)**	**1.5 (48/3170)**	**1.3 (35/2736)**	**3.1 (107/3493)**

Positivity Rates Obtained with Alinity m STI for *T. vaginalis*

Collection Site	Endocervical Swabs	Self-Collected Vaginal Swabs	Clinician Collected Vaginal Swabs	Female Urine	PreservCyt	Male Urine
01	12.2 (5/41)	12.2 (5/41)	15.4 (6/39)	12.2 (5/41)	11.1 (4/36)	7.0 (4/57)
02	21.8 (121/554)	16.8 (96/570)	17.8 (101/569)	12.9 (75/581)	14.9 (40/269)	3.1 (28/890)
03	14.2 (32/225)	14.4 (32/222)	14.2 (33/233)	13.7 (32/233)	14.3 (32/224)	2.3 (6/260)
04	15.0 (3/20)	15.0 (3/20)	15.0 (3/20)	15.0 (3/20)	15.0 (3/20)	2.6 (3/116)
05	8.4 (20/237)	7.5 (19/253)	9.6 (24/251)	7.9 (20/254)	6.0 (15/249)	1.3 (3/230)
06	25.0 (1/4)	0.0 (0/3)	0.0 (0/4)	25.0 (1/4)	0.0 (0/4)	0.0 (0/24)
07	15.4 (61/395)	16.0 (70/438)	16.6 (72/433)	11.8 (55/466)	15.2 (47/310)	4.1 (25/609)
08	16.5 (17/103)	19.2 (20/104)	22.3 (23/103)	16.7 (17/102)	16.2 (17/105)	8.9 (7/79)
09	8.4 (9/107)	10.3 (11/107)	10.3 (11/107)	7.7 (8/104)	7.3 (8/109)	0.0 (0/47)
10	6.7 (7/105)	7.6 (8/105)	10.6 (11/104)	6.6 (7/106)	6.6 (7/106)	0.0 (0/112)
11	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	0.0 (0/18)	6.3 (1/16)
12	10.4 (5/48)	10.4 (5/48)	10.4 (5/48)	8.3 (4/48)	10.4 (5/48)	5.4 (2/37)
13	13.5 (7/52)	13.7 (7/51)	11.5 (6/52)	13.2 (5/38)	13.6 (6/44)	0.0 (0/33)
14	5.0 (2/40)	5.1 (2/39)	7.5 (3/40)	5.1 (2/39)	5.0 (2/40)	0.0 (0/25)
15	16.2 (6/37)	10.8 (4/37)	10.8 (4/37)	5.4 (2/37)	5.4 (2/37)	4.4 (3/68)
16	0.0 (0/16)	0.0 (0/15)	0.0 (0/15)	0.0 (0/16)	0.0 (0/16)	0.0 (0/7)
17	9.3 (4/43)	11.6 (5/43)	11.6 (5/43)	9.3 (4/43)	9.8 (4/41)	4.2 (1/24)
18	0.0 (0/6)	0.0 (0/6)	0.0 (0/6)	0.0 (0/5)	0.0 (0/6)	0.0 (0/1)
19	10.0 (1/10)	10.0 (1/10)	11.1 (1/9)	11.1 (1/9)	10.0 (1/10)	7.7 (1/13)
20	-	-	-	-	-	0.0 (0/1)
21	1.5 (2/134)	3.8 (5/132)	2.2 (3/134)	3.0 (4/134)	1.5 (2/133)	0.0 (0/77)
22	2.9 (1/34)	2.9 (1/35)	0.0 (0/35)	0.0 (0/34)	0.0 (0/34)	0.0 (0/26)
23	4.2 (5/118)	4.2 (5/120)	4.1 (5/121)	5.8 (7/121)	5.8 (7/120)	0.0 (0/45)
24	5.4 (2/37)	5.6 (2/36)	8.3 (3/36)	5.6 (2/36)	5.4 (2/37)	8.2 (5/61)
25	0.0 (0/50)	2.0 (1/50)	0.0 (0/51)	2.2 (1/45)	0.0 (0/47)	0.0 (0/49)
26	6.9 (2/29)	6.9 (2/29)	6.9 (2/29)	7.1 (2/28)	7.4 (2/27)	0.0 (0/33)
27	7.1 (6/84)	4.7 (4/85)	4.7 (4/85)	4.8 (4/84)	4.8 (4/83)	1.8 (1/56)
28	10.2 (23/225)	7.4 (17/231)	9.5 (22/231)	7.8 (18/230)	8.3 (19/230)	1.4 (2/138)
29	3.4 (3/87)	3.4 (3/87)	4.7 (4/86)	3.5 (3/85)	2.3 (2/86)	0.8 (1/119)
30	21.5 (14/65)	23.4 (15/64)	20.3 (13/64)	20.0 (13/65)	20.0 (13/65)	3.4 (2/59)
31	26.8 (19/71)	25.7 (18/70)	27.8 (20/72)	25.0 (18/72)	23.9 (17/71)	8.5 (5/59)
32	11.8 (6/51)	14.0 (7/50)	12.0 (6/50)	10.0 (5/50)	9.8 (5/51)	5.9 (3/51)
33	10.6 (5/47)	12.8 (6/47)	10.6 (5/47)	10.6 (5/47)	12.8 (6/47)	1.4 (1/72)
All	**12.6 (389/3093)**	**11.8 (374/3166)**	**12.5 (395/3172)**	**10.1 (323/3195)**	**10.0 (272/2723)**	**3.0 (104/3494)**

Positivity Rates Obtained with Alinity m STI for *M. genitalium*

Collection Site	Endocervical Swabs	Self-Collected Vaginal Swabs	Clinician Collected Vaginal Swabs	Male Urine
01	17.5 (7/40)	22.5 (9/40)	23.7 (9/38)	29.3 (17/58)
02	6.5 (36/551)	7.1 (40/567)	7.8 (44/566)	6.7 (60/890)
03	5.8 (13/224)	5.4 (12/221)	5.6 (13/231)	4.6 (12/259)
04	15.0 (3/20)	15.0 (3/20)	15.0 (3/20)	19.1 (22/115)
05	7.6 (18/236)	9.1 (23/252)	9.2 (23/251)	4.3 (10/233)
06	0.0 (0/4)	0.0 (0/3)	0.0 (0/4)	12.5 (3/24)
07	7.1 (28/392)	7.4 (32/434)	6.0 (26/430)	5.1 (29/574)
08	5.8 (6/103)	5.7 (6/105)	6.7 (7/104)	19.0 (15/79)
09	10.5 (11/105)	14.3 (15/105)	13.2 (14/106)	10.4 (5/48)
10	8.7 (9/104)	13.5 (14/104)	11.7 (12/103)	6.4 (7/110)
11	5.6 (1/18)	11.1 (2/18)	5.6 (1/18)	25.0 (4/16)
12	4.2 (2/48)	4.2 (2/48)	4.2 (2/48)	2.8 (1/36)
13	0.0 (0/52)	3.9 (2/51)	3.8 (2/52)	12.1 (4/33)
14	7.9 (3/38)	10.8 (4/37)	10.5 (4/38)	0.0 (0/22)
15	13.9 (5/36)	16.7 (6/36)	11.1 (4/36)	20.6 (14/68)
16	5.9 (1/17)	0.0 (0/16)	6.3 (1/16)	0.0 (0/5)
17	11.6 (5/43)	16.3 (7/43)	18.6 (8/43)	25.0 (6/24)
18	0.0 (0/6)	0.0 (0/6)	0.0 (0/6)	0.0 (0/1)
19	20.0 (2/10)	30.0 (3/10)	33.3 (3/9)	30.8 (4/13)
20	-	-	-	0.0 (0/1)
21	7.5 (10/134)	9.1 (12/132)	7.5 (10/134)	5.2 (4/77)
22	5.7 (2/35)	11.1 (4/36)	8.3 (3/36)	4.0 (1/25)
23	6.8 (8/117)	8.4 (10/119)	8.3 (10/120)	8.9 (4/45)
24	10.5 (4/38)	13.5 (5/37)	10.8 (4/37)	9.8 (6/61)
25	0.0 (0/49)	0.0 (0/49)	0.0 (0/50)	6.1 (3/49)
26	6.9 (2/29)	6.9 (2/29)	6.9 (2/29)	6.1 (2/33)
27	16.7 (14/84)	20.0 (17/85)	15.3 (13/85)	9.1 (5/55)
28	6.7 (15/224)	9.1 (21/230)	9.1 (21/230)	7.4 (10/135)
29	4.6 (4/87)	6.9 (6/87)	7.0 (6/86)	7.6 (9/119)
30	9.2 (6/65)	10.9 (7/64)	12.5 (8/64)	11.9 (7/59)
31	10.0 (7/70)	15.9 (11/69)	12.7 (9/71)	8.5 (5/59)
32	3.9 (2/51)	10.0 (5/50)	12.0 (6/50)	14.6 (7/48)
33	15.2 (7/46)	19.6 (9/46)	17.4 (8/46)	19.2 (14/73)
All	**7.5 (231/3076)**	**9.2 (289/3149)**	**8.7 (276/3157)**	**8.4 (290/3447)**

Positive and Negative Predictive Values for Hypothetical Prevalence Rates for Urogenital Samples

The Positive and Negative Predictive Values (PPV and NPV) of the Alinity m STI assay were calculated based on the demonstrated sensitivity and specificity during the clinical study, using hypothetical prevalence rates. Estimates of the PPV and NPV for the Alinity m STI Assay for urogenital specimens are presented for each target organism by specimen type.

Positive and Negative Predictive Values for Alinity m STI when Testing for *C. trachomatis*

Specimen Type	Category	Hypothetical Prevalence								
		0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
		Predictive Values								
CCV	PPV (%)	36.9	54.0	70.3	85.9	92.8	95.3	96.7	97.5	98.0
	NPV (%)	100.0	100.0	100.0	99.9	99.8	99.7	99.5	99.3	99.2
SCV	PPV (%)	40.0	57.2	73.0	87.5	93.6	95.9	97.1	97.8	98.3
	NPV (%)	100.0	100.0	100.0	99.9	99.8	99.7	99.6	99.5	99.4
E	PPV (%)	43.2	60.5	75.6	88.9	94.4	96.4	97.4	98.1	98.5
	NPV (%)	100.0	99.9	99.9	99.7	99.4	99.0	98.6	98.2	97.7
MU	PPV (%)	49.4	66.3	79.9	91.1	95.6	97.2	98.0	98.5	98.8
	NPV (%)	100.0	100.0	99.9	99.9	99.7	99.5	99.3	99.1	98.8

CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, E = Endocervical Swab, MU = Male Urine

Positive and Negative Predictive Values for Alinity m STI for *N. gonorrhoeae*

Specimen Type	Category	Hypothetical Prevalence								
		0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
		Predictive Values								
CCV	PPV (%)	69.2	81.9	90.1	95.9	98.0	98.7	99.1	99.3	99.5
	NPV (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
SCV	PPV (%)	61.1	75.9	86.4	94.3	97.2	98.2	98.7	99.0	99.3
	NPV (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
E	PPV (%)	66.9	80.3	89.2	95.5	97.8	98.6	99.0	99.3	99.4
	NPV (%)	100.0	99.9	99.8	99.6	99.2	98.7	98.2	97.6	96.9
PreservCyt	PPV (%)	92.8	96.3	98.1	99.3	99.6	99.8	99.8	99.9	99.9
	NPV (%)	100.0	99.9	99.9	99.7	99.4	99.0	98.6	98.2	97.7
MU	PPV (%)	77.3	87.3	93.3	97.3	98.7	99.2	99.4	99.6	99.7
	NPV (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, E = Endocervical Swab, MU = Male Urine

Positive and Negative Predictive Values for Alinity m STI for *T. Vaginalis*

Specimen Type		Hypothetical Prevalence								
		0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
		Predictive Values								
CCV	PPV (%)	15.3	26.7	42.4	65.5	80.0	86.4	90.0	92.3	93.9
	NPV (%)	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
SCV	PPV (%)	18.7	31.6	48.3	70.6	83.5	89.0	92.0	93.8	95.1
	NPV (%)	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.7
E	PPV (%)	13.9	24.4	39.5	62.7	78.0	85.0	88.9	91.4	93.2

	NPV (%)	100.0	100.0	100.0	99.9	99.7	99.6	99.4	99.2	99.0
PreservCyt	PPV (%)	45.7	62.8	77.4	89.8	94.9	96.7	97.7	98.2	98.6
	NPV (%)	100.0	100.0	99.9	99.8	99.5	99.2	98.9	98.5	98.1
FU	PPV (%)	34.1	51.0	67.8	84.4	92.0	94.8	96.3	97.2	97.8
	NPV (%)	100.0	99.9	99.9	99.6	99.2	98.8	98.3	97.7	97.1
MU	PPV (%)	39.5	56.7	72.6	87.2	93.5	95.8	97.0	97.7	98.2
	NPV (%)	100.0	100.0	100.0	99.9	99.9	99.8	99.7	99.6	99.5

CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, E = Endocervical Swab, FU=Female Urine, MU = Male Urine

Positive and Negative Predictive Values for Alinity m STI for *M. genitalium*

Specimen Type		Hypothetical Prevalence								
		0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
		Predictive Values								
CCV	PPV (%)	38.3	55.5	71.6	86.7	93.2	95.6	96.9	97.6	98.1
	NPV (%)	100.0	100.0	100.0	99.9	99.8	99.7	99.5	99.4	99.2
SCV	PPV (%)	25.2	40.4	57.8	78.0	88.2	92.2	94.4	95.7	96.6
	NPV (%)	100.0	100.0	99.9	99.8	99.5	99.2	98.8	98.5	98.0
E	PPV (%)	32.9	49.6	66.6	83.7	91.5	94.5	96.1	97.0	97.7
	NPV (%)	99.9	99.8	99.6	99.1	98.1	97.0	95.8	94.5	93.1
MU	PPV (%)	16.4	28.4	44.4	67.3	81.3	87.4	90.7	92.9	94.4
	NPV (%)	100.0	100.0	100.0	99.9	99.8	99.7	99.5	99.4	99.2

CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, E = Endocervical Swab, MU = Male Urine

Extragenital Specimens Study

The performance of the Alinity m STI test for the detection of CT and NG infections in extragenital specimens (i.e., oropharyngeal and anorectal swab specimens) was evaluated by testing residual samples prospectively collected in a clinical study, performed in collaboration between academic institutions under an IRB/IEC approved protocol. The study was uniquely designed to facilitate the evaluation of assay performance for the detection of CT and NG infections in extragenital specimens by simultaneous comparison of the performance among three previously FDA-cleared NAATs for the detection of CT and NG in urogenital specimens.

Eight diverse clinic sites (STD, HIV, Family Planning, and STD Research Clinics), located at geographically distributed locations, were utilized for sample collection. There were 2390 subjects available for testing, representing sexually active men and women, ranging in age from 15 to 77 years old. The study population consisted of 1226 males, 1092 females, and 26 transgender individuals. Both symptomatic and asymptomatic individuals were included in the study population following informed consent.

In that study, three oropharyngeal and three rectal specimens were collected from each enrolled subject, using a common collection device consisting of 10 mL of the PreservCyt solution. All three oropharyngeal swabs were broken at the score mark and placed into a single tube

containing 10 mL of PreservCyt solution. Similarly, for the rectal collection, the three rectal swabs were broken at the score mark and placed into a single tube containing 10 mL of PreservCyt solution. Prior to testing, 0.5 mL of each sample was placed in an Alinity m transport tube containing 0.9 ml Alinity m transport buffer.

Results obtained with three comparator NAATs were used to construct a Composite Comparator (CC) to determine the anatomic site-specific infection status of each oropharyngeal and rectal specimen for CT and NG in order to calculate estimates of clinical sensitivity and specificity. A specimen that generated positive results by at least 2 of the 3 comparators was classified as "infected" at that anatomic site. A specimen that generated negative results by at least 2 of 3 comparators was classified as "not infected" at that anatomic site (oropharyngeal and rectal specimens were evaluated individually). The specimen CC was defined as "indeterminate" (IND) if missing results from the comparator assays precluded the ability to determine if two or more comparator results were concordant.

Prevalence of Infections Observed during Clinical Study

Collection Site	**Oropharyngeal % Prevalence (No. Infected/No. Tested)**		**Rectal % Prevalence (No. Infected/No. Tested)**	
	CT+	**NG+**	**CT+**	**NG+**
1	1.2 (2/170)	2.4 (4/170)	4.0 (6/149)	2.0 (3/149)
2	1.1 (1/91)	6.7 (6/90)	3.4 (3/87)	2.3 (2/87)
3	1.3 (5/385)	11.3 (43/382)	14.1 (46/326)	14.5 (47/324)
4	0.6 (1/171)	0.0 (0/171)	2.8 (4/143)	2.1 (3/141)
5	0.8 (2/240)	7.1 (17/240)	6.6 (15/226)	6.6 (15/227)
6	2.2 (9/413)	2.9 (12/413)	9.3 (33/355)	4.0 (14/354)
7	1.5 (6/396)	2.3 (9/396)	4.3 (17/393)	2.0 (8/394)
8	0.9 (4/466)	3.0 (14/466)	5.6 (22/391)	3.6 (14/390)
All	**1.3 (30/2332)**	**4.5 (105/2328)**	**7.1 (146/2070)**	**5.1 (106/2066)**

Clinical Study Results (Extragenital Specimens)

The following tables show the clinical performance estimates for CT and NG in oropharyngeal and rectal swab specimens, by symptom status.

CT Clinical Sensitivity and Specificity by Specimen Type and Symptom Status for Extragenital Specimens

							Sensitivity (%)		Specificity (%)	
Specimen Type	Symptom Status	N	TP	FP	TN	FN	Estimate (95% CI)	n / N	Estimate (95% CI)	n / N
Oropharyngeal	Symptomatic	741	8	0	733	0	100.0 (67.6,100.0)	8/8	100.0 (99.5,100.0)	733/733
	Asymptomatic	1575	20	2	1551	2	90.9 (72.2,97.5)	20/22	99.9 (99.5,100.0)	1551/1553
	All	2316	28	2	2284	2	93.3 (78.7, 98.2)	28/30	99.9 (99.7, 100.0)	2284/2286
Rectal	Symptomatic	668	55	2	610	1	98.2 (90.6,99.7)	55/56	99.7 (98.8,99.9)	610/612
	Asymptomatic	1385	83	6	1289	7	92.2 (84.8,96.2)	83/90	99.5 (99.0,99.8)	1289/1295
	All	2053	138	8	1899	8	94.5 (89.6, 97.2)	138/146	99.6 (99.2, 99.8)	1899/1907

NG Clinical Sensitivity and Specificity by Specimen Type and Symptom Status for Extragenital Specimens

							Sensitivity (%)		Specificity (%)	
Specimen Type	Symptom Status	N	TP	FP	TN	FN	Estimate (95% CI)	n / N	Estimate (95% CI)	n / N
Oropharyngeal	Symptomatic	738	53	6	676	3	94.6 (85.4,98.2)	53/56	99.1 (98.1,99.6)	676/682
	Asymptomatic	1574	47	9	1516	2	95.9 (86.3,98.9)	47/49	99.4 (98.9,99.7)	1516/1525
	All	2312	100	15	2192	5	95.2 (89.3,98.2)	100/105	99.3 (98.9,99.6)	2192/2207
Rectal	Symptomatic	670	46	7	615	2	95.8 (86.0,98.8)	46/48	98.9 (97.7,99.5)	615/622
	Asymptomatic	1379	56	3	1319	1	98.2 (90.7,99.7)	56/57	99.8 (99.3,99.9)	1319/1322
	All	2049	102	10	1934	3	97.1 (91.9,99.0)	102/105	99.5 (99.1, 99.7)	1934/1944

The following table shows the prevalence of extragenital CT and NG infections encountered during the clinical study, by the collection site, as determined by the comparator result.

Expected Values

The following table shows the positivity rate of the Alinity m STI assay when testing subjects for extragenital CT and NG infections, based on the observed results in the clinical study.

Alinity m STI Assay Positivity Observed in Clinical Study (Extragenital)

Collection Site	Oropharyngeal		Rectal	
	CT+	NG+	CT+	NG+
1	1.2 (2/170)	4.0 (6/149)	2.9 (5/170)	2.0 (3/149)
2	1.1 (1/91)	3.4 (3/87)	5.6 (5/90)	3.4 (3/87)
3	1.0 (4/385)	14.1 (46/326)	12.6 (48/382)	15.4 (50/324)
4	0.6 (1/171)	2.8 (4/143)	0.6 (1/171)	2.8 (4/141)
5	0.8 (2/240)	6.2 (14/226)	7.5 (18/240)	7.0 (16/227)
6	2.4 (10/413)	9.6 (34/355)	3.1 (13/413)	4.2 (15/354)
7	1.8 (7/396)	4.6 (18/393)	2.5 (10/396)	2.0 (8/394)
8	0.6 (3/466)	5.4 (21/391)	3.2 (15/466)	3.6 (14/390)
All	1.3 (30/2332)	7.1 (146/2070)	4.9 (115/2328)	5.5 (113/2066)

Positive and Negative Predictive Values for Hypothetical Prevalence Rates for Extragenital Samples

The Positive and Negative Predictive Values (PPV and NPV) of the Alinity m STI assay were calculated based on the demonstrated sensitivity and specificity during the clinical study, using hypothetical prevalence rates. Estimates of the PPV and NPV for the Alinity m STI Assay for extragenital specimens are presented for each target organism.

Positive and Negative Predictive Values for Alinity m STI for *C. trichomonas* (Extragenital Specimens)

CT Positive and Negative Predictive Value Using Hypothetical Prevalence for Extragenital Specimens										
Specimen Type	**Category**	**0.5%**	**1.0%**	**2.0%**	**5.0%**	**10.0%**	**15.0%**	**20.0%**	**25.0%**	**30.0%**
Oropharyngeal	PPV (%)	84.3	91.5	95.6	98.3	99.2	99.5	99.6	99.7	99.8
	NPV (%)	100.0	99.9	99.9	99.7	99.3	98.8	98.4	97.8	97.2
Rectal	PPV (%)	53.1	69.5	82.1	92.2	96.2	97.5	98.3	98.7	99.0
	NPV (%)	100.0	99.9	99.9	99.7	99.4	99.0	98.6	98.2	97.7

Positive and Negative Predictive Values for Alinity m STI for *N. gonorrhoeae* (Extragenital Specimens)

NG Positive and Negative Predictive Value Using Hypothetical Prevalence for Extragenital Specimens										
Specimen Type	**Category**	**0.5%**	**1.0%**	**2.0%**	**5.0%**	**10.0%**	**15.0%**	**20.0%**	**25.0%**	**30.0%**
Oropharyngeal	PPV (%)	41.3	58.6	74.1	88.1	94.0	96.1	97.2	97.9	98.4
	NPV (%)	100.0	100.0	99.9	99.7	99.5	99.2	98.8	98.4	98.0
Rectal	PPV (%)	48.7	65.6	79.4	90.9	95.5	97.1	97.9	98.4	98.8
	NPV (%)	100.0	100.0	99.9	99.8	99.7	99.5	99.3	99.1	98.8

D Clinical Cut-Off:

Not applicable.

E Other Supportive Instrument Performance Characteristics Data:

Quality Control

There were six lots of QC material utilized during the testing of the urogenital samples across the testing sites. The cumulative statistics from the QC testing, based on the generated CN (cycle number) values are shown below.

Target	N	Mean CN	SD	%CV	Invalid	Instr. Error
CT	165	29.44	0.404	1.37	5	5
NG	169	29.04	0.345	1.19	1	5
TV	169	28.26	0.458	1.62	1	5
MG	169	28.98	0.318	1.10	1	5

Two lots of QC material were utilized during the testing of the extragenital samples. The cumulative statistics from the QC testing are shown below.

Target	N	Mean CN	SD	%CV	Invalid	Instr. Error
CT	30	29.39	0.2705	0.92	0	1
NG	30	29.57	0.2595	0.88	0	1

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.