Abbott Molecular, Inc.
Stacy Ferguson
Associate Director Regulatory Affairs
1300 E. Touhy
Des Plains, Illinois 60018

April 29, 2022

Re: K202977
Trade/Device Name: Alinity m STI Assay
Regulation Number: 21 CFR 866.3393
Regulation Name: Device to detect nucleic acids from non-viral microorganism(s) causing sexually transmitted infections and associated resistance marker(s)
Regulatory Class: Class II
Product Code: QEP, MKZ, LSL, OUY, LIO, OOI
Dated: February 11, 2022
Received: February 14, 2022

Dear Stacy Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

Table of Contents

5.0 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR Section 807.92(c).

5.1 Submitter

Applicants Name and Address:	Abbott Molecular Inc. 1300 E. Touhy Ave Abbott Molecular Inc.
Contact Person:	Stacy Ferguson Director Regulatory Affairs Abbott Molecular, Inc. 1300 E. Touhy Avenue Des Plaines, IL 60018 Phone: 224-361-7449 Fax: 224-361-7269
Date Prepared:	April 14, 2022

5.2 Device Information

Trade Name	Regulation Name	Product Code	Regulation Number	Class
Alinity m STI Assay	Device to detect nucleic acids from non-viral microorganism(s) causing sexually transmitted infections and associated resistance marker(s)	QEP	866.3393	II

5.3 Predicate Devices

Device Name	Predicate Device	510(k)	Cleared
Alinity m STI Assay	Abbott RealTi*m*e CT/NG (Primary Predicate for CT/NG)	K140354	5/9/14
	Aptima Combo 2 Assay (Primary Predicate for CT/NG)	K190515	5/23/19
	BD Max CT/GC/TV (Primary Predicate for TV)	K151589	9/6/16
	Aptima Mycoplasma genitalium Assay (Primary Predicate for MG)	DEN180047	1/23/19

5.4 Device Description

The Alinity m STI Assay is a real time polymerase chain reaction (PCR) assay for the amplification and detection of *Chlamydia trachomatis* (CT) ribosomal RNA sequences, *Neisseria gonorrhea* (NG) genomic DNA sequences, *Trichomonas vaginalis* (TV) ribosomal RNA sequences, *Mycoplasma genitalium* (MG) ribosomal RNA sequences, and human genomic DNA sequences. The assay can be used with endocervical swab specimens, vaginal swab specimens, male and female urine specimens, gynecological specimens in ThinPrep® PreservCyt® Solution, oropharyngeal swab specimens, and rectal swab specimens. Endocervical swab, vaginal swab, oropharyngeal swab, rectal swab and urine specimens are collected with the Alinity m multi-Collect Specimen Collection Kit. PreservCyt Solution specimens are transferred to an Alinity m Transport Tube for processing on the Alinity m System.

The steps of the Alinity m STI Assay consist of sample preparation, RT-PCR assembly, amplification/detection, and result calculation and reporting. 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. The Alinity m System is designed to be a random-access analyzer that can perform the Alinity m STI Assay in parallel with other Alinity m assays on the same instrument.

The Alinity m STI Assay requires two separate assay specific kits as follows:

- **Alinity m STI AMP Kit, List No. 09N17-095** consisting of multi-well amplification plates containing lyophilized, unit-dose PCR amplification/detection reagents and multi-well activator plates containing liquid, unit-dose activation reagents ($MgCl_2$, TMAC, and KCl). The intended storage condition for the Alinity m STI AMP Kit is 2°C to 8°C.
- **Alinity m STI CTRL Kit, List No. 09N17-085** consisting of negative controls and positive controls, each supplied as liquid in single-use tubes. The intended storage condition for the Alinity m STI Control Kit is -15°C to -25°C.

Nucleic acids from specimens are extracted automatically on-board the Alinity m System 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. The resulting purified nucleic acids are then combined with the liquid unit-dose activator reagent, lyophilized unit-dose Alinity m STI amplification reagents, and Alinity m Vapor Barrier Solution, and transferred by the instrument to an amplification/detection module for reverse transcription, PCR amplification, and real-time fluorescence detection.

Assay controls are tested at or above an established minimum frequency of every 24 hours to help ensure that instrument and reagent performance remain 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. Assay controls are used to demonstrate proper sample processing and assay validity. The controls do not indicate if bacterial cells have been adequately lysed.

The Alinity m STI amplification reagents include primers and a probe that amplify and detect the single copy human gene, β-globin. Amplification and detection of the β-globin gene demonstrates proper sample processing and adequate sample input. In addition, an exogenous internal control (containing an armored RNA sequence) is included in the lyophilized Alinity m STI amplification reagents to assess amplification efficiency and to confirm that no PCR inhibitors are present in the sample. The cellular control and internal control are both used to demonstrate assay validity.

The Alinity m STI Assay also utilizes the following accessories:

- Alinity m STI Assay Application Specification File, List No. 09N17-03A
- Alinity m System and System Software, List No. 08N53-002
- Alinity m Sample Prep Kit 1, List No. 09N18-001
- Alinity m multi-Collect Specimen Collection Kit, List No. 09N19-010
- Alinity m Tubes and Caps, List No. 09N49:
  - Alinity m Transport Tubes Pierceable Capped, List No. 09N49-010
  - Alinity m Transport Tube, List No. 09N49-011
  - Alinity m Pierceable Cap, List No. 09N49-012
- Alinity m System Solutions, List No. 09N20:
  - Alinity m Lysis Solution, List No. 09N20-001
  - Alinity m Ethanol Solution, List No. 09N20-002
  - Alinity m Diluent Solution, List No. 09N20-003
  - Alinity m Vapor Barrier Solution, List No. 09N20-004

5.5 Intended Use

Alinity m STI AMP Kit:

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.

Alinity m multi-Collect Specimen Collection Kit:

The Alinity m multi-Collect Specimen Collection Kit is intended for the collection and transportation of male and female urine specimens, endocervical swab specimens, vaginal swab specimens, oropharyngeal swab specimens, and rectal swab specimens to stabilize nucleic acid for testing with the Alinity m STI Assay. Refer to the Alinity m STI Assay package insert for additional information.

The Alinity m multi-Collect Specimen Collection Kit is not intended for home use.

5.6 Similarities and Differences to Predicate Devices

The primary functional components of the Alinity m STI Assay are substantially equivalent to other legally marketed nucleic acid amplification tests (NAAT) intended for the qualitative detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG).

The Alinity m STI Assay has the same general intended use as the predicate devices. Although there are some technological differences between the Alinity m STI Assay and the predicate devices, these differences do not raise new types of safety or effectiveness questions.

These devices are similar in that they are designed to prepare nucleic acids for amplification, amplify specific CT, NG, TV, and MG sequences, detect the amplified products, and report qualitative results.

The primary similarities and differences between the Alinity m STI Assay and the NAAT predicate devices are shown in **Table 1**. The primary similarities and differences between the Alinity m multi-Collect Specimen Collection Kit and the predicate device are shown in .

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Devices

Feature	Current Application	Predicate Devices			
	Alinity m STI Assay	**Abbott RealTi*me* CT/NG (Predicate for CT/NG)**	**Aptima Combo 2 Assay (Predicate for CT/NG)**	**Becton Dickinson MAX CT/GC/TV (Predicate for TV)**	**Aptima Mycoplasma genitalium Assay (Predicate for MG)**
Intended 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 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	The Abbott RealTi*me* CT/NG assay is an in vitro polymerase chain reaction (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.	The Aptima Combo 2 Assay is a target amplification nucleic acid probe test that 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.	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, gonococcal urogenital disease and/or trichomoniasis in asymptomatic and symptomatic individuals.	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 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.

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Devices					
Feature	**Current Application**	**Predicate Devices**			
	Alinity m STI Assay	**Abbott RealTi*me* CT/NG (Predicate for CT/NG)**	**Aptima Combo 2 Assay (Predicate for CT/NG)**	**Becton Dickinson MAX CT/GC/TV (Predicate for TV)**	**Aptima Mycoplasma genitalium Assay (Predicate for MG)**
	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.				

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Devices					
Feature	**Current Application**	**Predicate Devices**			
	Alinity m STI Assay	**Abbott RealTi*me* CT/NG (Predicate for CT/NG)**	**Aptima Combo 2 Assay (Predicate for CT/NG)**	**Becton Dickinson MAX CT/GC/TV (Predicate for TV)**	**Aptima Mycoplasma genitalium Assay (Predicate for MG)**
Assay Type	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Assay Targets	CT ribosomal RNA	CT cryptic plasmid DNA	CT ribosomal RNA	CT genomic DNA	NA
	NG genomic DNA	NG genomic DNA	NG ribosomal RNA	NG genomic DNA	NA
	TV ribosomal RNA	NA	NA	TV genomic DNA	NA
	MG ribosomal RNA	NA	NA	NA	MG ribosomal RNA
Specimen Types	Endocervical swab	Endocervical swab	Endocervical swab	Endocervical swab	Endocervical swab
	Self-collected vaginal swab	Self-collected vaginal swab	Self-collected vaginal swab	Self-collected vaginal swab	Self-collected vaginal swab
	Clinician-collected vaginal swab	Clinician-collected vaginal swab	Clinician-collected vaginal swab	NA	Clinician-collected vaginal swab
	Male and female urine	Male and female urine	Male and female urine	Male urine (for CT and NG only) and female urine (CT, NG and TV)	Male and female urine
	NA	*Male urethral swabs*	*Male urethral swab*	NA	*Male urethral swab*
	Gynecological specimens in PreservCyt Solution	NA	Gynecological specimens in PreservCyt Solution	NA	NA
	NA	NA	NA	NA	*Self-collected penile meatal swabs (in a clinical setting)*
	Oropharyngeal swab	NA	Oropharyngeal swab	NA	NA
	Rectal swab	NA	Rectal swab	NA	NA

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Devices

Feature	**Current Application**	**Predicate Devices**			
	Alinity m STI Assay	**Abbott RealTi*me* CT/NG (Predicate for CT/NG)**	**Aptima Combo 2 Assay (Predicate for CT/NG)**	**Becton Dickinson MAX CT/GC/TV (Predicate for TV)**	**Aptima Mycoplasma genitalium Assay (Predicate for MG)**
Sample Preparation Procedure	Automated	Automated	Automated	Automated	Automated
Amplification Technology	Real-Time Polymerase Chain Reaction (PCR)	Real-Time PCR	*Target Capture (TC), Transcription-mediated Amplification (TMA), Dual Kinetic Assay (DKA)*	Real-Time PCR	*Target Capture (TC), Transcription-mediated Amplification (TMA), Hybridization Protection Assay (HPA)*
Assay Controls	• Negative Control • Positive Control • Internal Control (IC) • Cellular Control (CC)	• Negative Control • Cutoff Control • Internal Control (IC)	• CT Positive/NG Negative Control • CT Negative/NG Positive Control	• *No Negative Control* • *No Positive Control* • Sample Processing Control	• *No Negative Control* • *No Positive Control* • Internal Control (IC)

5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

5.7.1 Specific Performance Characteristics

5.7.1.1 Analytical Sensitivity

Urogenital Specimens

The limit of detection (LoD) for urogenital specimens was determined by testing dilutions of CT, NG, TV, and MG organisms in pooled negative vaginal swab matrix, pooled negative gynecological PreservCyt matrix, and pooled negative urine matrix. Two different strains were evaluated for each organism in each matrix: serovars D and E for CT (ATCC), strains Z437 and Z433 for NG (Zeptometrix), strains 30001 (ATCC) and MTZ (metronidazole-resistant, Zeptometrix) for TV, and strains SEA-1 and MEGA 216 (azithromycin-resistant) for MG (non-commercial source). For each strain and matrix, a minimum of 6 target levels were evaluated in at least 20 replicates using each of 2 lots. Probit analysis was performed to estimate the LoD for each strain and matrix for each lot. In cases where the probit model did not fit the data, the LoD was determined for each lot to be the target concentration with a detection rate 95% or greater.

The LoD claim for the Alinity m STI Assay is as follows for each of the organisms in urogenital specimen types:

- 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

Extragenital Specimens

The LoD for extragenital specimens was determined by testing dilutions of CT and NG organisms in pooled negative oropharyngeal swab matrix and pooled negative rectal

swab matrix. Two different strains were evaluated for each organism in each matrix: serovars D and E for CT (ATCC) and strains Z437 and Z433 (Zeptometrix) for NG. For each strain and matrix, a minimum of 3 target levels were evaluated in 20 replicates using one reagent lot. The LoD level was determined to be the concentration with a detection rate of 95% or greater where the target level 2-fold below was less than 95%.

The LoD claim for the Alinity m STI Assay is as follows for each of the organisms in extragenital specimen types:

- CT: 17.0 EB/mL
- NG: 7.5 CFU/mL

5.7.1.2 Inclusivity

The analytical sensitivity claim of the Alinity m STI Assay was confirmed by testing at least 20 replicates of the following additional strains:

- CT: Serovars A, B, Ba, C, F, G, H, I, J, K, L1, L2, L3, and E nvCT at 17.0 EB/mL or less. All serovars were detected at ≥ 95.0% across swab and urine matrices.
- NG: 28 additional isolates at 7.5 CFU/mL. All isolates were detected at ≥95.0% across swab, urine, and PreservCyt matrices.
- TV: Strains Z070, Z158, and Z159 at 0.1 TV/mL. All strains were detected at ≥ 95.0% across swab, urine, and PreservCyt matrices.
- MG: Strains MEGA 601, 10008, MEGA 1256, MEGA 1272, MEGA 1404 and SEA-2 at 165 GE/mL. All strains were detected at ≥ 95.0% across swab and urine matrices.

5.7.1.3 Evaluation of Potential Cross Reacting Microorganisms

Urogenital Specimens

A total of 71 potential cross reacting microorganisms that are phylogenetically related to CT, NG, TV, or MG or that may be found in the urogenital tract were evaluated with the Alinity m STI Assay (**Table 2**). 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. No cross reactivity was observed for CT, NG, TV, or MG in the presence of these microorganisms.

A subset of the microorganisms closely related to the STI analytes (asterisk in **Table 2**) was also assessed in CT, NG, TV, and MG positive samples. The positive samples contained CT, NG, TV, and MG 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, NG, TV, and MG in the presence of these microorganisms.

Table 2. Urogenital Microorganisms

Acinetobacter lwoffi	*Lactobacillus vaginalis*
Actinomyces israelii	*Listeria moncytogenes*
Atopobium vaginae	*Mobiluncus curtisii*
Bacteroides fragilis	*Mobiluncus mulieris*
Bacteroides ureolyticus (Campylobacter ureolyticus)	*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 fragilis[a]	*Neisseria meningitidis* Serogroup Y*
Enterococcus 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 I	*Pseudomonas aeruginosa*
Human papilloma virus 16	*Staphylococcus aureus*
Kingella denitrificans	*Staphylococcus epidermidis*
Klebsiella oxytoca	*Streptococcus agalactiae*
Klebsiella pneumoniae	*Streptococcus pyogenes*
Lactobacillus acidophilus	*Tricomonas tenax*
Lactobacillus brevis	*Ureaplasma parvum*
Lactobacillus jensenii	*Ureaplasma urealyticum*
Lactobacillus lactis	

[a]Evaluated using purified genomic DNA

Note: Microorganisms with asterisks were tested with both CT/NG/TV/MG negative and positive samples. Microorganisms without asterisks were tested with only CT/NG/TV/MG negative samples.

Extragenital Specimens

A total of 56 additional potential cross reacting microorganisms that may be found in oropharyngeal or rectal specimens were evaluated with the Alinity m STI Assay (**Table 3**). The microorganisms were tested at 10^5 units/mL for viruses and eukaryotes and 10^6 units/mL for bacteria. No cross reactivity was observed for CT or NG in the presence of these microorganisms.

A subset of the microorganisms (asterisk in **Table 3**) was also assessed in CT and NG positive samples. 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.

Table 3. Extragenital Microorganisms

Adenovirus*	*Moraxella catarrhalis*
Acinetobacter baumannii	*Morganella morganii*
Aggregatibacter actinomycetemcomitans	*Mycoplasma pneumoniae*
Anaerococcus prevotii	Norovirus
Arcanobacterium haemolyticum	*Parvinomas micra*
Bifidobacterium adolescentis	*Plesiomonas shigelloides*
Bordetella pertussis	*Porphyromonas gingivalis*
*Campylobacter jejuni**	*Prevotella oralis*
Campylobacter rectus	*Providencia stuartii*
Citrobacter freundii	Respiratory syncytial virus
Clostridium difficile	*Saccharomyces cerevisiae*
*Corynebacterium diphtheriae**	*Salmonella enterica*
*Entamoeba histolytica**	*Shigella flexneri*
Enterobacter cloacae	*Shigella sonnei*
Enterococcus faecium	*Streptococcus anginosus*
Enterovirus	*Streptococcus dysgalactiae**
Fusobacterium necrophorum	*Streptococcus mitis*
Fusobacterium nucleatum	*Streptococcus mutans*
Giardia lamblia	*Streptococcus pneumoniae*
Haemophilus influenzae	*Streptococcus pyogenes**
Helicobacter pylori	*Streptococcus salivarius*
Human Coronavirus*	*Streptococcus sanguinis*
Human influenza virus A	*Tannerella forsythia*
Human influenza virus B	*Treponema denticola*
Human metapneumovirus	*Veillonella parvula*
Human rhinovirus 57*	*Vibrio cholerae*
Klebsiella oxytoca	*Vibrio parahaemolyticus*
Listeria monocytogenes	*Yersinia enterocolitica*

Note: Microorganisms with asterisks were tested with both CT/NG negative and positive samples. Microorganisms without asterisks were tested with only CT/NG negative samples.

5.7.1.4 Evaluation of Potential Interfering Substances

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 (**Table 4**). 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). No interference was observed in the presence of any of the substances at the concentrations shown in **Table 4** for all positive and negative samples. Assay interference was observed in the presence of seminal fluid at concentrations greater than 3.0% in PreservCyt samples. Cycle number delays were observed for seminal fluid, γ-globulin, and glucose in urine and seminal fluid, mucus, and Preparation H Hemorrhoidal Cream in PreservCyt, which could result in interference at lower target levels.

Table 4. Potentially Interfering Substances in Urogenital Specimens

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

Table 4. Potentially Interfering Substances in Urogenital Specimens

Substance	Matrix[a]	Test Level
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 col*i (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 and seminal fluid, mucus, and Preparation H Hemorrhoidal Cream in PreservCyt, which could result in interference at lower target levels.

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 (**Table 5**). 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 3 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). No interference was observed in the presence of the substances at the concentrations shown in **Table 5** for all positive and negative samples. 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.

Table 5. Potentially Interfering Substances in Oropharyngeal or Rectal Specimens

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.

5.7.1.5 Competitive Interference Study

A competitive interference study was conducted to challenge the performance of the Alinity m STI Assay with swab, PreservCyt, and urine samples containing CT, NG, TV, or MG at 3 times the claimed LoD in the presence of high concentrations of the other three organisms. The high positive targets were prepared with titers of $3.0x10^5$ EB/mL for CT, $1.6x10^4$ CFU/mL for NG, $6.0x10^4$ TV/mL for TV, and $1.1x10^6$ GE/mL for MG. Four conditions were evaluated:

- CT at 3 times the claimed LoD and NG, TV, and MG at high concentrations
- NG at 3 times the claimed LoD and CT, TV, and MG at high concentrations
- TV at 3 times the claimed LoD and CT, NG, and MG at high concentrations
- MG at 3 times the claimed LoD and CT, NG, and TV at high concentrations

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

5.7.1.6 Within Laboratory Precision

Alinity m STI Assay within laboratory precision was evaluated by testing panel members in 3 different sample matrices that represent urogenital specimen types used in the Alinity m STI Assay: urine, swab, and PreservCyt matrix. For each applicable specimen matrix, 13 panel members were prepared with combinations of CT, NG, TV, and MG at sub-LoD (high negative), claimed LoD, low positive (2x claimed LoD), high positive, and negative target levels **(Table 6)**. Each panel member was tested in 2 replicates, twice each day for 12 days, on 3 Alinity m Systems with 3 reagent lots by 3 operators, for a total of 144 replicates. The results for CT, NG, TV, and MG are summarized in **Table 7, Table 8, Table 9,** and **Table 10** respectively.

Table 6. Precision Panel Composition

Panel Member	CT	NG	TV	MG
1	Negative	Negative	Negative	Negative
2	2X LoD Claim	Negative	Negative	Negative
3	Negative	2X LoD Claim	Negative	Negative
4	Negative	Negative	2X LoD Claim	Negative
5	Negative	Negative	Negative	2X LoD Claim
6	2X LoD Claim	2X LoD Claim	2X LoD Claim	2X LoD Claim
7	High Positive [a]	2X LoD Claim	2X LoD Claim	2X LoD Claim
8	2X LoD Claim	High Positive[b]	2X LoD Claim	2X LoD Claim
9	2X LoD Claim	2X LoD Claim	High Positive[c]	2X LoD Claim
10	2X LoD Claim	2X LoD Claim	2X LoD Claim	High Positive[d]
11	High Positive[a]	High Positive[b]	High Positive[c]	High Positive[d]
12	LoD Claim	LoD Claim	LoD Claim	LoD Claim
13	Sub-LoD (High Negative)	Sub-LoD (High Negative)	Sub-LoD (High Negative)	Sub-LoD (High Negative)

[a]Concentration for High CT is 4.4×10^4 IFU/mL or 8.8×10^3 IFU/assay (3.0×10^5 EB/mL or 6.0×10^4 EB/assay)
[b]Concentration for High NG is 1.6×10^4 CFU/mL or 3.2×10^3 CFU/assay
[c]Concentration for High TV is 6.0×10^4 TV/mL or 1.2×10^4 TV/assay
[d]Concentration for High MG is 1.1×10^6 genome copies/mL or 2.2×10^5 genome copies/assay

Table 7. 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.

Table 8. 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.

Table 9. 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.

Table 10. 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.

5.7.1.7 Carryover

The carryover rate for Alinity m STI Assay was determined by testing alternating replicates of STI high positive samples and STI negative samples across multiple runs. The high positive samples were prepared with 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. Of the 548 negative samples tested, 1 sample was reported positive for TV and 1 sample was reported as positive for both CT and TV. All negative samples were reported negative for NG and MG. The overall carryover rate for CT was 0.2% (1/548, 95% CI: 0.0% to 1.0%), the overall carryover rate for TV was 0.4% (2/548, 95% CI: 0.1% to 1.3%), and the overall carryover rate for NG and MG was 0.0% (0/548, 95% CI: 0.0% to 0.7%). The overall sample carryover rate was 0.4% (2/548, 95% CI: 0.1% to 1.3%).

5.7.1.8 Reproducibility Study

Reproducibility performance of the Alinity m STI Assay was evaluated by testing panel members in 3 different sample matrices: urine matrix, swab matrix, and PreservCyt matrix. For each applicable specimen matrix, a 13-member panel was prepared with combinations of CT, NG, TV, and MG at sub-LoD (High Negative), claimed LoD, low positive (2x claimed LoD), high positive, and negative target levels. A total of 3 Alinity m STI AMP Kit lots were used. Each of the 3 clinical sites tested 2 Alinity m STI AMP Kit lots, on 5 non-consecutive days for each lot. A total of 5 replicates of each panel member were tested on each of 5 days. Each of the 3 clinical sites used different lots of Alinity m STI CTRL Kits and Alinity m Sample Prep Kit 1. The reproducibility results for CT, NG, TV, and MG are summarized in **Table 11, Table 12, Table 13,** and **Table 14**, respectively.

Table 11. Reproducibility Analysis: CT 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	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

Table 12 Reproducibility Analysis: NG Results

Matrix	Panel Description	N[a]	n[b]	Agreement (n/N)	Mean CN	Within-Run/Day Component SD	Within-Run/Day Component % CV	Between-Run/Day Component SD	Between-Run/Day Component % CV	Between-Lot Component SD	Between-Lot Component % CV	Between-Site Component SD	Between-Site Component % CV	Total[c] SD	Total[c] % 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

Table 12 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
	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.

Table 13. Reproducibility Analysis: TV 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	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

Table 13. 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
	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.

Table 14. 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.

5.7.2 Clinical Performance

5.7.2.1 Clinical Study Results - Urogenital Specimens

Performance characteristics of the Alinity m STI Assay with urogenital specimens were established in a multicenter clinical study conducted in the United States. Specimens were collected from subjects 14 years of age or older at 33 geographically diverse sites that included but were not limited to STI clinics, primary care offices, and gynecology practices. A total of 7,099 male and female, asymptomatic and symptomatic subjects were enrolled. Study subjects were classified as symptomatic if the subject reported STI related symptoms.

Each female subject provided up to 8 specimens, including 1 urine specimen, 1 self-collected vaginal swab, 3 clinician-collected vaginal swabs, 2 endocervical swabs, and 1 ThinPrep (PreservCyt) cytology specimen. Each male provided 1 urine specimen.

Specimen testing methods included the Alinity m STI Assay and comparator assays for CT, NG, TV, and MG. Alinity m STI testing was performed at 3 external clinical testing sites. Comparator assays for CT and NG included 2 commercially available nucleic acid amplification tests (NAAT) for females (each NAAT tested with 1 swab and 1 urine specimen) and 3 commercially available NAATs for males (each NAAT tested with urine). Comparator assays for TV included 3 NAATs tested with swab specimens and 2 NAATs tested with urine specimens for females and 2 NAATs and culture tested with urine for males. Comparator assays for MG included 3 NAATs for females (each tested with a vaginal swab) and males (each tested with urine).

For each subject, a patient infected status (PIS) was determined based on the combined results from the comparator assays. A female subject was categorized as infected for CT or NG if a minimum of 2 positive results (at least 1 from each comparator NAAT) was reported. For CT, female subjects with positive results on both comparator urine specimens and negative results on both comparator swab specimens (endocervical swab from NAAT 1 and clinician-collected vaginal swab specimens from NAAT 2) were categorized as infected for urine and not infected for swab specimens (there were 2 female subjects that were negative for CT in the swab samples and positive in urine by

both comparator NAATs). A female subject was categorized as not infected for CT or NG if at least 1 of the comparator NAATs reported negative results for all sample types. Refer to **Table 20**, **Table 21**, **Table 24 and Table 25** for the female PIS algorithm**.** A female subject was categorized as infected for TV or MG if the first 2 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 or MG if the first 2 swab comparator NAAT results were both negative or if 2 of the 2 swab comparator NAAT results were negative in cases where 3rd NAAT was used as a tie-breaker. Refer to **Table 28**, **Table 29**, **Table 32** and **Table 33** for the female PIS algorithm.

A male subject was categorized as infected for CT, NG, TV, or MG if a minimum of two comparator positive results was reported. If the comparator TV culture assay result was positive, the subject was categorized as infected for TV regardless of NAAT results. A male subject was categorized as not infected for CT, NG, or MG if two or more comparator NAAT results were negative. For TV, a male subject was categorized as not infected if the TV culture assay result was negative, and if one or more comparator NAATs were negative. Refer to **Table 22**, **Table 23**, **Table 26**, **Table 27**, **Table 30**, **Table 31**, **Table 34** and **Table 35** for the male PIS algorithm.

If a PIS could not be determined due to missing and/or indeterminate results from the comparator assays, the subject was excluded from the analysis for that analyte. Out of 7099 subjects, PIS could not be determined for 1 or more analytes for 171 subjects (42 subjects for CT, 32 subjects for NG, 73 subjects for TV, 93 subjects for MG).

Alinity m STI test results were compared to the PIS for calculation of assay sensitivity and specificity. A total of 12,903 CT, 15,655 NG, 18,843 TV, and 12,829 MG results were used in the analysis. The results were analyzed by gender, specimen type, and the presence of symptoms. CT sensitivity and specificity for female and male subjects by specimen type and by symptom status are presented in **Table 15**. NG sensitivity and specificity for female and male subjects by specimen type and by symptom status are presented in **Table 16**. TV sensitivity and specificity for female and male subjects by

specimen type and by symptom status are presented in **Table 17**. MG sensitivity and specificity for female and male subjects by specimen type and by symptom status are presented in **Table 19.**

For the urogenital study, approximately 4.7% of sample results were invalid on the initial test. Specimens with initial invalid results were retested. Out of a total of 20,145 specimens, the number of specimens with final invalid results for CT, NG, TV and MG were 37, 49, 54 and 38, respectively, or approximately 0.3%.

Table 15. CT Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens

								Sensitivity (%)		Specificity	
Gender	Specimen Type	Symptom Status	N	TP	FP	TN	FN	Estimate (95% CI)	n / N	Estimate (95% CI)	n / N
Female	Clinician-collect Vaginal Swab	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
	Self-collect Vaginal Swab	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.

Table 16. NG Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens

								Sensitivity (%)		Specificity (%)	
Gender	**Specimen Type**	**Symptom Status**	**N**	**TP**	**FP**	**TN**	**FN**	**Estimate (95% CI)**	**n / N**	**Estimate (95% CI)**	**n / N**
Female	Clinician-collect Vaginal Swab	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
	Self-collect Vaginal Swab	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 1 specimen which was collected after 2 other swabs were collected from the cervix (ie, last of the 3 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 of 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.

Table 17. TV Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens

								Sensitivity (%)		Specificity (%)	
Gender	**Specimen Type**	**Symptom Status**	**N**	**TP**	**FP**	**TN**	**FN**	**Estimate (95% CI)**	**n / N**	**Estimate (95% CI)**	**n / N**
Female	Clinician-collect Vaginal Swab	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 (97.6,100.0)	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
	Self-collect Vaginal Swab	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 (86.2,100.0)	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

For female urine, the TV result of the Alinity m STI Assay was compared against a specimen-specific agreement.. A female urine specimen was considered positive for TV if at least 1 comparator NAAT was positive for the urine specimen. A female urine specimen was considered negative if both comparator NAATs were negative for the urine specimen. If a TV specimen-specific status for female urine could not be determined due to missing and/or indeterminate results from the urine comparator assays, the subject was excluded from the analysis for that analyte. The specimen-specific TV status could not be determined for 37 subjects. TV specimen-specific positive and negative agreement for female urine by symptom status are presented in **Table 18.** The TV clinical sensitivity based on the PIS was up to 6.6% lower in female urine than in vaginal swab specimens.

Table 18. TV Specimen-Specific Positive and Negative Agreement for Female Urine by Symptom Status

								PPA		NPA	
Analyte	Specimen Type	Symptom Status	N	Alinity + CCA+	Alinity+ CCA-	Alinity- CCA-	Alinity- CCA+	Estimate (95% CI)	n / N	Estimate (95% CI)	n / N
TV	Female Urine	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

Table 19. MG Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens

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

The numbers of specimens in all combinations of PIS, individual comparator results and Alinity m STI result are summarized. CT results for infected and non-infected female subjects are presented in **Table 20** and **Table 21**, and for infected and non-infected male subjects in **Table 22** and **Table 23**. NG results for infected and non-infected female subjects are presented in **Table 24** and **Table 25**, and for infected and non-infected male subjects in **Table 26** and **Table 27**. TV results for infected and non-infected female subjects are presented in **Table 28** and **Table 29**, and for infected and non- infected male subjects in **Table 30** and **Table 31**. MG results for infected and non-infected female subjects are presented in **Table 32** and **Table 33**, and for infected and non-infected male subjects in **Table 34** and **Table 35**.

Table 20. CT Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI			No. of Subjects		
E	**FU**	**VS**	**FU**	**E**	**SCV**	**CCV**	**Symptomatic**	**Asymptomatic**	**Total**
+	+	+	+	+	+	+	95	65	160
+	+	+	+	N/A	+	+	2	2	4
+	+	+	+	+	N/A	+	0	1	1
+	+	+	+	N/A	N/A	+	0	1	1
+	+	+	+	N/A	+	N/A	1	0	1
+	+	+	+	-	+	+	1	1	2
+	+	+	+	+	+	-	0	1	1
N/A	+	+	+	+	+	+	2	1	3
N/A	+	+	+	N/A	+	+	1	0	1
+	+	N/A	+	+	+	+	1	0	1
+	+	+	N/A	+	+	+	2	2	4
+	N/A	+	N/A	+	+	+	1	0	1
-	+	+	+	+	+	+	3	1	4
-	+	+	+	N/A	+	N/A	1	0	1
-	+	+	+	-	+	+	0	3	3
-	+	+	+	-	+	-	0	1	1
+	-	+	+	+	+	+	2	1	3
+	-	+	+	+	-	+	1	0	1
+	+	+	-	+	+	+	2	1	3
+	+	+	-	N/A	+	N/A	1	0	1
+	+	+	-	-	+	+	1	1	2
-	+	N/A	+	-	-	-	1	0	1
+	N/A	+	-	+	+	+	0	1	1
-	+	+	-	+	+	+	2	0	2
-	+	+	-	-	+	-	1	0	1
+	-	+	-	+	+	+	1	1	2
+	-	+	-	-	+	+	1	0	1
+	-	+	-	+	-	+	1	0	1
-	+	-	+	-	+	-	2	0	2

E = Endocervical Swab, VS = Vaginal Swab, FU = Female Urine, CCV = Clinician-Collected Vaginal Swab, SCV = Self Collected Vaginal Swab, N/A = Not Available

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.

Table 21. CT Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI			No. of Subjects		
E	**FU**	**VS**	**FU**	**E**	**SCV**	**CCV**	**Symptomatic**	**Asymptomatic**	**Total**
-	-	-	-	-	-	-	1267	1405	2672
-	-	-	-	N/A	-	-	16	44	60
-	-	-	-	-	N/A	-	9	22	31
-	-	-	-	-	-	N/A	6	9	15
-	-	-	-	N/A	-	N/A	3	6	9
-	-	-	-	-	N/A	N/A	2	0	2
-	-	-	-	+	-	-	7	8	15
-	-	-	-	-	+	-	4	6	10
-	-	-	-	-	-	+	9	4	13
-	-	-	-	-	+	+	1	0	1
N/A	-	-	-	-	-	-	15	17	32
N/A	-	-	-	N/A	-	-	11	17	28
N/A	-	-	-	-	N/A	-	1	0	1
N/A	-	-	-	N/A	-	N/A	2	3	5
-	N/A	-	-	-	-	-	6	7	13
-	-	N/A	-	-	-	-	8	11	19
-	-	N/A	-	-	-	+	1	0	1
-	-	N/A	-	-	+	+	1	0	1
-	-	-	N/A	-	-	-	10	8	18
N/A	N/A	-	-	-	-	-	9	3	12
N/A	N/A	-	-	N/A	-	-	0	1	1
N/A	N/A	-	-	-	N/A	-	0	1	1
N/A	N/A	-	-	+	-	-	0	1	1
+	-	-	-	-	-	-	6	2	8
+	-	-	-	N/A	-	-	0	1	1
+	-	-	-	-	+	-	1	0	1
+	-	-	-	-	+	+	1	0	1
-	+	-	-	-	-	-	3	2	5
-	+	-	-	-	+	+	1	0	1
-	-	+	-	-	-	-	0	2	2
-	-	+	-	-	N/A	-	1	0	1

Table 21. CT Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI			No. of Subjects		
E	**FU**	**VS**	**FU**	**E**	**SCV**	**CCV**	**Symptomatic**	**Asymptomatic**	**Total**
-	-	+	-	-	+	-	1	0	1
-	-	+	-	-	-	+	2	1	3
-	-	+	-	-	+	+	1	1	2
-	-	+	-	+	+	+	0	1	1
-	-	-	+	N/A	-	N/A	1	0	1
+	+	-	-	+	-	-	1	0	1
-	-	+	+	-	+	+	1	0	1

E = Endocervical Swab, VS = Vaginal Swab, FU = Female Urine, CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, N/A = Not Available

Table 22. CT Analysis Per Patient Infected Status- INFECTED MALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
+	+	+	+	105	131	236
N/A	+	+	+	0	1	1
+	N/A	+	+	3	2	5
+	+	N/A	+	8	15	23
-	+	+	+	2	2	4
+	-	+	+	2	3	5
+	+	-	+	3	1	4
+	+	+	-	2	3	5
+	+	N/A	-	0	2	2
+	-	+	-	1	0	1

MU = Male Urine, N/A = Not Available

Table 23. CT Analysis Per Patient Infected Status- NOT INFECTED MALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
-	-	-	-	874	1665	2539
N/A	-	-	-	3	12	15
-	N/A	-	-	4	11	15
-	-	N/A	-	96	510	606
+	-	-	-	1	4	5
-	+	-	-	1	1	2
-	-	+	-	0	3	3
-	-	-	+	2	12	14
-	+	-	+	0	2	2

MU = Male Urine, N/A = Not Available

Table 24. NG Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				No. of Subjects		
E	**FU**	**VS**	**FU**	**E**	**SCV**	**CCV**	**PreservCyt**	**Symptomatic**	**Asymptomatic**	**Total**
+	+	+	+	+	+	+	+	12	12	24
+	+	+	+	+	+	+	N/A	0	2	2
+	+	+	+	N/A	+	+	N/A	1	0	1
N/A	+	+	+	+	+	+	+	1	0	1
+	+	+	N/A	+	+	+	+	0	2	2
+	+	+	N/A	+	+	+	N/A	1	0	1
+	N/A	+	N/A	+	+	+	+	1	0	1
+	-	+	+	+	+	+	+	3	1	4
+	-	+	+	-	+	+	-	1	0	1
+	+	+	-	-	+	+	-	1	0	1
+	-	+	N/A	+	+	+	+	1	0	1
+	-	+	-	+	+	+	N/A	0	1	1
+	-	+	-	-	+	+	+	1	0	1

E = Endocervical Swab, VS = Vaginal Swab, FU = Female Urine, CCV = Clinician-Collected Vaginal Swab, SCV = Self Collected Vaginal Swab, N/A = Not Available

Table 25. NG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				No. of Subjects		
E	**FU**	**VS**	**FU**	**E**	**SCV**	**CCV**	**PreservCyt**	**Symptomatic**	**Asymptomatic**	**Total**
-	-	-	-	-	-	-	-	1219	1261	2480
-	-	-	-	N/A	-	-	-	7	9	16
-	-	-	-	-	N/A	-	-	10	21	31
-	-	-	-	-	-	N/A	-	6	8	14
-	-	-	-	-	-	-	N/A	169	223	392
-	-	-	-	N/A	N/A	-	-	0	1	1
-	-	-	-	N/A	-	N/A	-	0	1	1
-	-	-	-	N/A	-	-	N/A	10	38	48
-	-	-	-	-	N/A	N/A	-	2	0	2
-	-	-	-	-	N/A	-	N/A	0	2	2
-	-	-	-	N/A	N/A	N/A	-	0	3	3
-	-	-	-	N/A	-	N/A	N/A	7	5	12
-	-	-	-	+	-	-	-	4	1	5
-	-	-	-	-	+	-	-	4	1	5
-	-	-	-	-	-	+	-	3	1	4
-	-	-	-	-	-	-	+	1	0	1
-	-	-	-	+	-	-	N/A	1	0	1
-	-	-	-	-	+	N/A	-	0	1	1
-	-	-	-	-	+	-	N/A	1	0	1
-	-	-	-	-	+	+	-	0	1	1
-	-	-	-	-	+	+	N/A	0	1	1
N/A	-	-	-	-	-	-	-	21	19	40
N/A	-	-	-	N/A	-	-	-	6	6	12
N/A	-	-	-	-	N/A	-	-	1	0	1
N/A	-	-	-	-	-	-	N/A	1	1	2
N/A	-	-	-	N/A	-	N/A	-	2	3	5
N/A	-	-	-	N/A	-	-	N/A	6	11	17
N/A	-	-	-	N/A	N/A	N/A	-	11	2	13
N/A	-	-	-	N/A	N/A	-	N/A	0	1	1
-	N/A	-	-	-	-	-	-	5	6	11
-	N/A	-	-	-	-	-	N/A	1	2	3

Table 25. NG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				No. of Subjects		
E	**FU**	**VS**	**FU**	**E**	**SCV**	**CCV**	**PreservCyt**	**Symptomatic**	**Asymptomatic**	**Total**
-	-	N/A	-	-	-	-	-	4	9	13
-	-	N/A	-	-	-	-	N/A	0	1	1
-	-	N/A	-	N/A	N/A	N/A	-	0	1	1
-	-	-	N/A	-	-	-	-	11	8	19
N/A	N/A	-	-	-	-	-	-	10	4	14
N/A	N/A	-	-	N/A	-	-	-	0	1	1
N/A	N/A	-	-	-	N/A	-	-	0	1	1
-	+	-	-	-	-	-	-	0	1	1
-	-	+	-	-	-	-	-	0	1	1
-	-	+	-	+	+	+	-	0	1	1
+	+	-	-	-	-	-	-	1	0	1

E = Endocervical Swab, VS = Vaginal Swab, FU = Female Urine, CCV = Clinician-Collected Vaginal Swab, SCV = Self Collected Vaginal Swab, N/A = Not Available

Table 26. NG Analysis Per Patient Infected Status- INFECTED MALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
MU	**MU**	**MU**	**MU**	**Symptomatic**	**Asymptomatic**	**Total**
+	+	+	+	69	21	90
N/A	+	+	+	0	1	1
+	N/A	+	+	1	0	1
+	+	N/A	+	3	6	9
+	+	-	+	1	0	1

MU = Male Urine, N/A = Not Available

Table 27. NG Analysis Per Patient Infected Status- NOT INFECTED MALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
-	-	-	-	921	1800	2721
N/A	-	-	-	3	12	15
-	N/A	-	-	4	12	16
-	-	N/A	-	102	525	627
+	-	-	-	1	1	2
-	+	-	-	1	1	2
-	-	+	-	1	2	3
-	-	-	+	2	3	5

MU = Male Urine, N/A = Not Available

Table 28. TV Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI					Number of Subjects		
E	VS	VS	E	SCV	CCV	FU	PreservCyt	Symptomatic	Asymptomatic	Total
+	+	N/A	+	+	+	+	+	113	109	222
+	+	N/A	+	N/A	+	+	+	2	3	5
+	+	N/A	+	+	+	N/A	+	2	1	3
+	+	N/A	+	+	+	+	N/A	19	16	35
+	+	N/A	N/A	+	+	+	N/A	1	2	3
+	+	N/A	N/A	+	N/A	+	N/A	1	0	1
+	+	N/A	N/A	N/A	N/A	+	N/A	0	3	3
+	+	N/A	+	+	+	-	+	5	3	8
+	+	N/A	+	+	+	+	-	0	2	2
+	+	N/A	+	+	+	-	N/A	0	2	2
+	+	N/A	+	+	+	-	-	0	1	1
N/A	+	+	+	+	+	+	+	2	3	5
N/A	+	+	N/A	+	N/A	+	+	1	0	1
N/A	+	+	N/A	+	+	+	N/A	1	1	2
+	N/A	+	+	+	+	+	+	1	1	2
-	+	+	+	+	+	+	+	2	5	7
-	+	+	+	+	+	+	N/A	0	1	1
-	+	+	N/A	+	+	+	N/A	1	0	1
-	+	+	+	+	+	-	+	2	1	3
-	+	+	+	+	+	+	-	1	2	3
-	+	+	-	+	+	+	N/A	2	0	2
-	+	+	+	+	+	-	N/A	0	2	2
-	+	+	-	+	+	-	+	0	1	1
-	+	+	-	+	+	+	-	0	2	2
-	+	+	+	+	+	-	-	2	0	2
-	+	+	-	-	+	-	-	1	1	2
+	-	+	+	+	-	-	+	1	0	1

E = Endocervical Swab, VS = Vaginal Swab, CCV = Clinician-Collected Vaginal Swab, SCV = Self Collected Vaginal Swab, FU = Female Urine, N/A = Not Available

Table 29. TV Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI					Number of Subjects		
E	VS	VS	E	SCV	CCV	FU	PreservCyt	Symptomatic	Asymptomatic	Total
-	-	N/A	-	-	-	-	-	1041	1034	2075
-	-	N/A	N/A	-	-	-	-	7	8	15
-	-	N/A	-	N/A	-	-	-	7	15	22
-	-	N/A	-	-	N/A	-	-	5	8	13
-	-	N/A	-	-	-	N/A	-	14	29	43
-	-	N/A	-	-	-	-	N/A	120	175	295
-	-	N/A	N/A	N/A	-	-	-	0	1	1
-	-	N/A	N/A	-	N/A	-	-	0	1	1
-	-	N/A	N/A	-	-	-	N/A	6	36	42
-	-	N/A	-	N/A	N/A	-	-	2	0	2
-	-	N/A	-	N/A	-	N/A	-	0	2	2
-	-	N/A	-	N/A	-	-	N/A	0	2	2
-	-	N/A	-	-	N/A	N/A	-	1	1	2
-	-	N/A	-	-	-	N/A	N/A	1	4	5
-	-	N/A	N/A	N/A	N/A	-	-	0	1	1
-	-	N/A	N/A	-	N/A	-	N/A	5	5	10
-	-	N/A	N/A	-	-	N/A	N/A	1	0	1
-	-	N/A	N/A	N/A	N/A	N/A	-	0	1	1
-	-	N/A	N/A	N/A	N/A	-	N/A	13	31	44
-	-	N/A	+	-	-	-	-	19	16	35
-	-	N/A	-	+	-	-	-	15	17	32
-	-	N/A	-	-	+	-	-	15	22	37
-	-	N/A	-	-	-	+	-	8	9	17
-	-	N/A	-	-	-	-	+	4	8	12
-	-	N/A	+	-	-	N/A	-	1	0	1
-	-	N/A	+	-	-	-	N/A	14	7	21
-	-	N/A	-	+	-	N/A	-	1	0	1
-	-	N/A	-	+	-	-	N/A	3	7	10
-	-	N/A	N/A	-	+	-	-	0	1	1

-	-	N/A	-	N/A	+	-	-	1	0	1
-	-	N/A	-	-	+	-	N/A	3	3	6
-	-	N/A	-	N/A	-	+	-	0	1	1
-	-	N/A	-	-	-	+	N/A	1	0	1
-	-	N/A	N/A	+	-	-	N/A	1	0	1
-	-	N/A	N/A	-	+	-	N/A	1	0	1
-	-	N/A	+	+	-	-	-	1	0	1
-	-	N/A	+	-	+	-	-	4	6	10
-	-	N/A	-	+	+	-	-	0	3	3
-	-	N/A	-	-	+	-	+	1	0	1
-	-	N/A	+	-	+	-	N/A	1	1	2
-	-	N/A	-	+	+	N/A	-	0	1	1
-	-	N/A	-	+	+	-	N/A	1	0	1
-	-	N/A	+	+	+	-	-	2	2	4
-	-	N/A	+	-	+	-	+	0	1	1

E = Endocervical Swab, VS = Vaginal Swab, CCV = Clinician-Collected Vaginal Swab,
SCV = Self Collected Vaginal Swab, FU = Female Urine, N/A = Not Available

Table 29 Continued. TV Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI					Number of Subjects		
E	VS	VS	E	SCV	CCV	FU	PreservCyt	Symptomatic	Asymptomatic	Total
-	-	N/A	-	+	+	+	-	0	1	1
-	-	N/A	+	+	+	-	N/A	1	2	3
-	-	N/A	+	+	+	+	-	1	0	1
N/A	-	-	-	-	-	-	N/A	1	1	2
N/A	-	-	N/A	-	-	-	N/A	5	9	14
N/A	-	-	N/A	-	-	-	-	6	7	13
N/A	-	-	-	N/A	-	-	-	1	1	2
N/A	-	-	N/A	N/A	-	-	N/A	0	1	1
N/A	-	-	N/A	-	N/A	-	-	1	2	3
-	N/A	-	-	-	-	-	-	6	21	27
-	N/A	-	N/A	-	N/A	-	N/A	1	0	1
-	N/A	-	-	-	-	-	N/A	5	9	14
N/A	-	-	-	-	-	-	-	27	19	46
-	N/A	-	+	-	-	-	-	0	1	1
-	N/A	-	-	-	+	-	-	2	0	2
-	N/A	-	-	-	-	+	-	2	0	2
+	-	-	-	-	-	-	-	2	1	3
+	-	-	+	-	-	-	-	0	1	1
+	-	-	-	-	+	-	-	1	0	1
-	+	-	-	-	-	-	-	2	5	7
-	+	-	-	-	-	-	N/A	1	0	1
-	+	-	-	+	-	-	-	1	0	1
-	+	-	-	-	+	-	-	0	1	1
-	+	-	+	-	-	-	N/A	1	1	2
-	+	-	+	-	+	-	-	1	0	1
-	+	-	-	+	-	+	-	0	2	2
-	+	-	+	N/A	-	+	-	0	1	1

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

Table 30. TV Analysis Per Patient Infected Status- INFECTED MALE Subjects (Urogenital)

Culture	NAAT 1	NAAT 2	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
+	+	+	+	15	32	47
N/A	+	+	+	1	1	2
+	+	N/A	+	0	1	1
-	+	+	+	6	18	24
+	-	+	+	1	0	1
+	+	-	+	0	1	1
+	-	-	+	1	1	2
-	+	+	-	0	1	1

MU = Male Urine, N/A = Not Available

Table 31. TV Analysis Per Patient Infected Status- NOT INFECTED MALE Subjects (Urogenital)

Culture	NAAT 1	NAAT 2	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
-	-	-	-	1047	2211	3258
N/A	-	-	-	17	59	76
-	N/A	-	-	5	19	24
-	-	N/A	-	6	22	28
-	+	-	-	1	0	1
-	-	+	-	0	2	2
-	-	-	+	6	15	21
-	N/A	-	+	1	0	1
-	-	+	+	2	2	4

MU = Male Urine, N/A = Not Available

Table 32. MG Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI			No. of Subjects		
VS	VS	VS	E	SCV	CCV	Symptomatic	Asymptomatic	Total
+	+	N/A	+	+	+	75	58	133
+	+	N/A	N/A	+	+	2	2	4
+	+	N/A	+	N/A	+	0	1	1
+	+	N/A	+	+	N/A	1	0	1
+	+	N/A	-	+	+	6	11	17
+	+	N/A	+	-	+	3	2	5
+	+	N/A	-	+	N/A	1	0	1
N/A	+	+	+	+	+	8	3	11
N/A	+	+	-	+	+	0	1	1
+	N/A	+	+	+	+	1	0	1
+	N/A	+	N/A	+	N/A	0	1	1
+	-	+	+	+	+	34	14	48
+	-	+	N/A	+	+	3	2	5
+	-	+	+	N/A	+	1	0	1
+	-	+	N/A	+	N/A	0	1	1
+	-	+	-	+	+	12	9	21
+	-	+	+	-	+	1	2	3
+	-	+	+	+	-	1	1	2
+	-	+	-	-	+	2	0	2
+	-	+	-	+	-	0	1	1
+	-	+	+	-	-	0	1	1
+	-	+	N/A	-	-	0	1	1

VS = Vaginal Swab, CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, E = Endocervical Swab, N/A = Not Available

Table 33. MG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI			No. of Subjects		
VS	VS	VS	E	SCV	CCV	Symptomatic	Asymptomatic	Total
-	-	N/A	-	-	-	1135	1281	2416
-	-	N/A	N/A	-	-	20	46	66
-	-	N/A	-	N/A	-	8	22	30
-	-	N/A	-	-	N/A	2	7	9
-	-	N/A	N/A	N/A	-	0	1	1
-	-	N/A	N/A	-	N/A	5	4	9
-	-	N/A	-	N/A	N/A	2	0	2
-	-	N/A	+	-	-	2	2	4
-	-	N/A	-	+	-	7	1	8
-	-	N/A	-	-	+	1	1	2
-	-	N/A	+	+	-	0	2	2
-	-	N/A	-	+	+	0	2	2
N/A	-	-	-	-	-	142	111	253
N/A	-	-	N/A	-	-	2	2	4
N/A	-	-	-	N/A	-	2	1	3
N/A	-	-	-	-	N/A	1	0	1
N/A	-	-	-	-	+	1	0	1
N/A	-	-	+	-	+	1	0	1
N/A	-	-	-	+	+	1	0	1
-	N/A	-	-	-	-	13	16	29
-	N/A	-	N/A	-	-	3	10	13
-	N/A	-	-	N/A	-	0	1	1
-	N/A	-	N/A	-	N/A	3	2	5
+	-	-	-	-	-	5	11	16
+	-	-	N/A	-	-	0	1	1
+	-	-	-	-	N/A	1	0	1
+	-	-	+	-	-	2	3	5
+	-	-	-	+	-	4	6	10
+	-	-	-	-	+	2	1	3
+	-	-	N/A	-	+	0	1	1
+	-	-	+	+	-	2	6	8

Table 33. MG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI			No. of Subjects		
VS	VS	VS	E	SCV	CCV	Symptomatic	Asymptomatic	Total
+	-	-	+	-	+	2	0	2
+	-	-	-	+	+	6	2	8
+	-	-	+	+	+	1	1	2
-	+	-	-	-	-	0	3	3
-	-	-	-	-	-	3	0	3

VS = Vaginal Swab, CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, E = Endocervical Swab, FU = Female Urine, N/A = Not Available

Table 34. MG Analysis Per Patient Infected Status- INFECTED MALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
+	+	+	+	56	69	125
N/A	+	+	+	15	8	23
+	N/A	+	+	2	7	9
+	+	N/A	+	3	2	5
-	+	+	+	2	0	2
+	-	+	+	6	9	15
+	+	-	+	15	15	30
+	+	+	-	1	1	2
+	+	-	-	1	1	2

MU = Male Urine, N/A = Not Available

Table 35. MG Analysis Per Patient Infected Status- NOT INFECTED MALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
MU	MU	MU	MU	Symptomatic	Asymptomatic	Total
-	-	-	-	790	1792	2582
N/A	-	-	-	123	187	310
-	N/A	-	-	8	141	149
-	-	N/A	-	24	48	72
+	-	-	-	13	21	34
-	+	-	-	0	1	1
-	-	+	-	0	5	5
-	-	-	+	1	2	3
N/A	-	-	+	3	4	7
+	-	-	+	36	35	71

MU = Male Urine, N/A = Not Available

Expected Values

The prevalence of CT, NG, TV, and MG in this study was dependent on several factors including age, gender, clinic type, presence of symptoms, and the method of testing. A summary of the positivity for CT, NG, TV, and MG, as determined by the Alinity m STI Assay for each specimen type, is presented by collection site and overall in **Table 36** through **Table 39**.

Table 36 Positivity of CT as Determined by the Alinity m STI Assay by Specimen Type and Clinical Site for Urogenital Specimens

	% Positivity (Number Positive / Number Tested with Valid Results)			
Collection Site	**E**	**SCV**	**CCV**	**MU**
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)

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

Table 37 Positivity of NG as Determined by the Alinity m STI Assay by Specimen Type and Clinical Site for Urogenital Specimens

	% Positivity (Number Positive / Number Tested with Valid Results)				
Collection Site	**E**	**SCV**	**CCV**	**PreservCyt**	**MU**
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)

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

Table 38. Positivity of TV as Determined by the Alinity m STI Assay by Specimen Type and Clinical Site for Urogenital Specimens

	% Positivity (Number Positive / Number Tested with Valid Results)					
Collection Site	**E**	**SCV**	**CCV**	**FU**	**PreservCyt**	**MU**
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)

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

Table 39. Positivity of MG as Determined by the Alinity m STI Assay by Specimen Type and Clinical Site for Urogenital Specimens

	% Positivity (Number Positive / Number Tested with Valid Results)			
Collection Site	**E**	**SCV**	**CCV**	**MU**
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)

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

Positive and Negative Predictive Values for Hypothetical Prevalence Rates

The Positive and Negative Predictive Values (PPV and NPV) were calculated using hypothetical prevalence rates and the Alinity m STI Assay sensitivity and specificity determined from the clinical study. Estimates of the PPV and NPV for the Alinity m STI Assay for urogenital specimens are presented in **Table 40** through **Table 43** for CT, NG, TV, and MG, respectively.

Table 40. CT Positive and Negative Predictive Value Using Hypothetical Prevalence for Urogenital Specimens

Specimen Type	Category	0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
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

Table 41. NG Positive and Negative Predictive Value Using Hypothetical Prevalence for Urogenital Specimens

Specimen Type	Category	0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
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

Table 42. TV Positive and Negative Predictive Value Using Hypothetical Prevalence for Urogenital Specimens

Specimen Type	Category	0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
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

Table 43. MG Positive and Negative Predictive Value Using Hypothetical Prevalence for Urogenital Specimens

Specimen Type	Category	0.5%	1.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
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

5.7.2.2 Clinical Study Results - Extragenital Specimens

Performance characteristics of the Alinity m STI Assay with extragenital specimens were established in a multicenter clinical study conducted in the United States. Archived specimens were previously collected with an IRB/IEC approved consent. A total of 2,373 male and female, asymptomatic and symptomatic subjects were enrolled. Three oropharyngeal and 3 rectal specimens were collected from each subject using a common collection device created specifically for the study.

Specimen testing methods included the Alinity m STI Assay and 3 commercially available CT/NG NAAT comparator assays for each oropharyngeal and rectal specimen.

Comparator NAAT results were used to establish an anatomic site-specific composite comparator (CC). A specimen was categorized as infected for CT or NG if a minimum of 2 comparator positive results were reported and as not infected for CT or NG if a minimum of 2 comparator negative results was reported. Refer to **Table 46 through Table 49** for the CC algorithm. If the specimen CC could not be determined for a given analyte (CT or NG) due to missing and/or indeterminate results from the comparator assays, the specimen was excluded from the analysis for that analyte. CC could not be determined for 6 oropharyngeal and 8 rectal specimens for CT, and 10 oropharyngeal and 6 rectal specimens for NG.

Alinity m STI CT and NG test results were compared to the CC for calculation of assay sensitivity and specificity. A total of 2,316 CT and 2,312 NG results from oropharyngeal specimens, and a total of 2,053 CT and 2,049 NG results from rectal specimens were used in the analysis. The results were analyzed by specimen type and the presence of symptoms. Sensitivity and specificity for CT for oropharyngeal and rectal specimens are presented in **Table 44**. Sensitivity and specificity for NG for oropharyngeal and rectal specimens are presented in **Table 45**.

Table 44. 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

Table 45 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

A comparison of CC, individual test results from the comparator assays and Alinity m STI Assay was performed. CT results for infected and non-infected oropharyngeal specimens are presented in **Table 46**, and for infected and non-infected rectal specimens in **Table 47**. NG results for infected and non-infected oropharyngeal specimens are presented in

Table 48, and for infected and non-infected rectal specimens in **Table 49**.

Table 46 CT Analysis per Composite Comparator – Oropharyngeal Specimens

					Number of Subjects		
CC	**NAAT 1**	**NAAT 2**	**NAAT 3**	**Alinity m STI**	**Symptomatic**	**Asymptomatic**	**Total**
Infected	+	+	+	+	8	17	25
	N/A	+	+	+	0	1	1
	-	+	+	+	0	2	2
	+	+	+	-	0	1	1
	-	+	+	-	0	1	1
Not Infected	-	-	-	-	697	1510	2207
	N/A	-	-	-	1	0	1
	-	N/A	-	-	12	16	28
	-	-	N/A	-	7	6	13
	+	-	-	-	13	18	31
	-	+	-	-	1	1	2
	-	-	+	-	2	0	2
	-	-	-	+	0	1	1
	-	+	-	+	0	1	1

N/A = Not Available

Table 47. CT Analysis per Composite Comparator– Rectal Specimens

					Number of Subjects		
CC	**NAAT 1**	**NAAT 2**	**NAAT 3**	**Alinity m STI**	**Symptomatic**	**Asymptomatic**	**Total**
Infected	+	+	+	+	50	79	129
	N/A	+	+	+	1	0	1
	+	N/A	+	+	1	0	1
	-	+	+	+	1	1	2
	+	-	+	+	0	1	1
	+	+	-	+	2	2	4
	+	+	+	-	0	2	2
	-	+	+	-	1	0	1
	+	-	+	-	0	4	4
	+	+	-	-	0	1	1
Not Infected	-	-	-	-	580	1261	1841
	N/A	-	-	-	0	1	1
	-	N/A	-	-	13	8	21
	-	-	N/A	-	8	6	14
	+	-	-	-	4	9	13
	-	+	-	-	1	4	5
	-	-	+	-	4	0	4
	-	-	-	+	2	1	3
	+	-	-	+	0	2	2
	-	+	-	+	0	1	1
	-	-	+	+	0	2	2

N/A = Not Available

Table 48. NG Analysis per Composite Comparator – Oropharyngeal Specimens

					Number of Subjects		
CC	**NAAT 1**	**NAAT 2**	**NAAT 3**	**Alinity m STI**	**Symptomatic**	**Asymptomatic**	**Total**
Infected	+	+	+	+	49	37	86
	N/A	+	+	+	1	0	1
	+	N/A	+	+	0	3	3
	-	+	+	+	0	2	2
	+	-	+	+	3	5	8
	+	+	+	-	1	1	2
	+	-	+	-	2	1	3
Not Infected	-	-	-	-	645	1476	2121
	N/A	-	-	-	2	0	2
	-	N/A	-	-	11	12	23
	-	-	N/A	-	6	6	12
	+	-	-	-	2	2	4
	-	+	-	-	5	12	17
	-	-	+	-	5	8	13
	-	-	-	+	3	4	7
	-	N/A	-	+	0	1	1
	+	-	-	+	2	1	3
	-	+	-	+	1	3	4

N/A = Not Available

Table 49. NG Analysis per Composite Comparator – Rectal Specimens

					Number of Subjects		
CC	**NAAT 1**	**NAAT 2**	**NAAT 3**	**Alinity m STI**	**Symptomatic**	**Asymptomatic**	**Total**
Infected	+	+	+	+	41	53	94
	+	N/A	+	+	0	2	2
	+	-	+	+	4	1	5
	+	+	-	+	1	0	1
	+	-	+	-	2	1	3
Not Infected	-	-	-	-	587	1303	1890
	-	N/A	-	-	14	7	21
	-	-	N/A	-	8	6	14
	+	-	-	-	3	0	3
	-	+	-	-	0	2	2
	-	-	+	-	3	1	4
	-	-	-	+	3	2	5
	+	-	-	+	2	0	2
	-	-	+	+	2	1	3

N/A = Not Available

Expected Values

The prevalence of CT and NG in this study was dependent on several factors including age, gender, clinic type, presence of symptoms, and the method of testing. A summary of the positivity of CT and NG detection, as determined by the Alinity m STI Assay, is presented by collection site and overall in **Table 50**.

Table 50. Positivity Determined by the Alinity m STI Assay for Extragenital Specimens

	% Positivity (Number Positive / Number Tested with Valid Results) for CT		% Positivity (Number Positive / Number Tested with Valid Results) for NG	
Collection Site	**Oropharyngeal**	**Rectal**	**Oropharyngeal**	**Rectal**
01	1.2 (2/170)	4.0 (6/149)	2.9 (5/170)	2.0 (3/149)
02	1.1 (1/91)	3.4 (3/87)	5.6 (5/90)	3.4 (3/87)
03	1.0 (4/385)	14.1 (46/326)	12.6 (48/382)	15.4 (50/324)
04	0.6 (1/168)	2.9 (4/140)	0.6 (1/168)	2.9 (4/138)
05	0.9 (2/227)	6.6 (14/212)	7.9 (18/227)	7.0 (15/213)
06	2.4 (10/413)	9.6 (34/355)	3.1 (13/413)	4.2 (15/354)
07	1.8 (7/396)	4.6 (18/393)	2.5 (10/396)	2.0 (8/394)
08	0.6 (3/466)	5.4 (21/391)	3.2 (15/466)	3.6 (14/390)
All	1.3 (30/2332)	7.1 (146/2053)	5.0 (115/2312)	5.5(112/2049)

Positive and Negative Predictive Values for Hypothetical Prevalence Rates

The Positive and Negative Predictive Values (PPV and NPV) were calculated using hypothetical prevalence rates and the Alinity m STI Assay sensitivity and specificity determined from the clinical study. Estimates of the PPV and NPV for the Alinity m STI Assay for extragenital specimens are presented in **Table 51** and **Table 52** for CT and NG, respectively.

Table 51. 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

Table 52. 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

5.8 Conclusions Drawn from the Studies

The analytical and clinical study results demonstrate that the Alinity m STI Assay on the Alinity m System performs comparably to the predicate devices in detecting *Chlamydia trachomatis*, *Neisseria gonorrhea*, *Trichomonas vaginalis*, and *Mycoplasma genitalium* microorganisms that cause sexually transmitted infections and support a substantial equivalence decision.