Alinity m

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STI

REF 09N17-095
53-608012/R3

Rx ONLY

IVD

STI AMP Kit

Revised August 2023

REF 09N17-095
53-608012/R3
NOTE: Changes Highlighted

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Abbott

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CUSTOMER SERVICE: 1-800-553-7042
CUSTOMER SERVICE INTERNATIONAL: CALL YOUR ABBOTT REPRESENTATIVE

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NAME

Alinity m STI Assay

- Alinity m STI AMP Kit (09N17-095)
- Alinity m STI CTRL Kit (09N17-085)

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 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, gynecological specimens in ThinPrep PreservCyt Solution, female urine, 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, female urine, 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.

SUMMARY AND EXPLANATION OF THE TEST

The Alinity m STI Assay uses PCR technology with homogenous real-time fluorescence detection. The Alinity m STI Assay is used for the detection and differentiation of sexually transmitted pathogens, *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG).

Chlamydia trachomatis

Chlamydiae are non-motile, Gram-negative, obligate intracellular parasites of eukaryotic cells. *Chlamydia trachomatis* (CT) is the causative agent of chlamydia. Chlamydial infections of the urogenital tract are associated with salpingitis, ectopic pregnancies and tubal factor infertility in women as well as non-gonococcal urethritis and epididymitis in men.[1-3] The genital site most commonly affected in women is the cervix, but the infection can be asymptomatic and, if untreated, is likely to ascend to the uterus, fallopian tubes and ovaries causing pelvic inflammatory disease (PID).[4] Neonates born of infected mothers can contract inclusion conjunctivitis, nasopharyngeal infections, and pneumonia due to CT.[5] Infection by CT in men is also often asymptomatic and, if untreated, may lead to epididymitis, a major complication.[3]

CT may also infect the oropharynx and rectum in men and women, which can serve as a reservoir for infection in partners who engage in oral or anal sexual activity.[6] Rectal CT infection may also lead to proctitis.[7]

Since a specific diagnosis of chlamydia may improve treatment compliance and enhance partner notification, the use of a nucleic acid amplification test is strongly recommended.[8]

Neisseria gonorrhoeae

Neisseria gonorrhoeae, a Gram-negative, oxidase-positive diplococcus without flagellae, is the causative agent of gonorrhea.[9] Gonorrhea is one of the most common sexually transmitted infections (STIs) in the United States (US). Over 1.57 million new infections of NG are estimated to occur each year.[10] In men, gonococcal infection usually results in acute anterior urethritis accompanied by a purulent exudate.[11,12] In women, the infection is most often found in the cervix, but the vagina and uterus also may be infected. The infection is frequently asymptomatic, especially in women. Without treatment, local complications of gonococcal infection can occur including PID or acute salpingitis for women and epididymitis for men.[11,12]

Rarely, disseminated gonococcal infection (DGI) may occur in untreated patients.[13]

NG can infect the rectum and oropharynx of both men and women. Rectal infection may result in discharge, itching, soreness, bleeding, or cause painful bowel movements, while oropharyngeal infections can cause a sore throat.[14,15] Infection of both sites are often asymptomatic and can serve as a reservoir for future infection.[16]

Trichomonas vaginalis

Trichomonas vaginalis is an anaerobic, protozoan parasite and the causative agent of trichomoniasis. TV is the most common curable sexually transmitted infection in the US.[17] In women, infection with TV can cause vaginitis, urethritis, and cervicitis and is associated with PID, tubal infertility, preterm delivery, low birth weight, and premature rupture of membranes.[17,18] Women with TV infection are more susceptible to being infected by HIV and are at a higher risk of transmitting HIV to sexual partners.[19,20] In men, TV infection can cause non-gonococcal urethritis (NGU), epididymitis, or prostatitis.[17] Between 70-85% of patients infected with TV are asymptomatic. Because of the adverse events associated with infection, screening can be considered for asymptomatic patients at high risk for infection, including those with multiple sex partners, illicit drug use, or a history of STI.[17]

Microscopic evaluation of wet mounts and TV culture are often used to diagnose TV infection. However, nucleic acid amplification tests (NAATs) have become the preferred method of TV detection due to their superior sensitivity.[17]

Mycoplasma genitalium

Mycoplasma genitalium is a small, sexually-transmitted bacterium that colonizes the urogenital tract of both men and women. It has been recognized as a cause of male urethritis, being responsible for 15 - 20% of NGU and 20 - 25% of non-chlamydial NGU.[17] In women, MG infection is detected in 10-30% of cervicitis cases, with infection being more common in women with cervicitis than without.[17,21,22] Recent evidence also indicates an association between MG infection and PID, preterm birth, and infertility.[23] Identifying MG infections is often a challenge; most cases are asymptomatic or cause symptoms that resemble other sexually transmitted infections (STIs). However, recommended treatment regimens that are effective against other STIs, typically have lower efficacy for MG infections.[17] Due to the fastidious growth requirements of MG for cell culture, the CDC recommends the use of NAATs for detecting MG infections.[17]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The Alinity m STI Assay requires 2 separate assay specific kits:

- Alinity m STI AMP Kit (09N17-095) consisting of 2 types of multi-well assay trays. The amplification trays (AMP Trays) contain lyophilized, unit-dose PCR amplification/detection reagents. The activation trays (ACT Trays) contain liquid unit-dose activation reagent. The intended storage condition for the Alinity m STI AMP Kit is 2°C to 8°C.
- Alinity m STI CTRL Kit (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 CTRL Kit is −25°C to −15°C.

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

Endocervical swab, vaginal swab, oropharyngeal swab, rectal swab and urine specimens are collected with the Alinity m multi-Collect Specimen Collection Kit (09N19-015). 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, 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.

The Alinity m System is a random access analyzer that can perform the Alinity m STI Assay in parallel with other Alinity m assays on the same instrument.

Nucleic acids from specimens are extracted using the Alinity m Sample Prep Kit 1, Alinity m Lysis Solution, Alinity m Ethanol Solution or Alinity m Bottle for Ethanol Use (filled with customer supplied 190 Proof Ethanol, ACS, Denaturant free), 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 acid is then combined with the liquid unit-dose Alinity m STI activation reagent and lyophilized unit-dose Alinity m STI amplification/detection reagents and transferred into a reaction vessel. Alinity m Vapor Barrier Solution is then added to the reaction vessel which is then transferred to an amplification/detection unit for PCR amplification, and real-time fluorescence detection of CT, NG, TV, and MG.

The Alinity m STI amplification/detection reagents include primers and probes that amplify and detect an endogenous human DNA sequence (CC: Cellular Control) as a sample validity control for sample adequacy, sample extraction, and amplification efficiency. In addition, an exogenous internal control (IC), containing an armored RNA sequence, is included in the lyophilized Alinity m STI amplification reagents, and is used to confirm that no PCR inhibitors are present in the sample. The cellular control and internal control are both used to demonstrate assay validity.

Assay controls are tested at or above an established minimum frequency to help ensure that instrument and reagent performance remains satisfactory. During each control event, a negative control and a positive control are processed through sample preparation and PCR procedures that are identical to those used for specimens.

The possibility of nucleic acid contamination on the Alinity m System is minimized because:

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

For additional information on system and assay technology, refer to the Alinity m System Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity m STI AMP Kit List No. 09N17-095

The Alinity m STI AMP Kit is comprised of 2 types of multi-well trays: Alinity m STI AMP TRAY 1 and Alinity m STI ACT TRAY 2.

Each Alinity m STI AMP TRAY 1 (individually packed in a foil pouch with a desiccant bag) contains 96 unit-dose lyophilized amplification reagent wells. One well is used per test.

- Amplification reagent wells consist of synthetic oligonucleotides, DNA Polymerase, Reverse Transcriptase, excipient, dNTPs, and Internal Control Armored RNA® in negative human plasma. Negative human plasma was tested and found to be nonreactive for HBsAg, HIV-1 antigen, Syphilis, HIV-1 RNA, HCV RNA, HBV DNA, anti-HIV-1/HIV-2, and anti-HCV.

Each Alinity m STI ACT TRAY 2 (individually packed in a foil pouch without a desiccant bag) contains 96 unit-dose liquid activation reagent wells. One reagent well is used per test.

- Activation reagent wells consist of magnesium chloride, potassium chloride, and tetramethyl ammonium chloride. Preservative: 0.15% ProClin® 950.

	Quantity
Σ	384 tests
Alinity m STI AMP TRAY 1	4 trays / 96 tests each
Alinity m STI ACT TRAY 2	4 trays / 96 tests each

WARNINGS AND PRECAUTIONS

IVD

- **For In Vitro Diagnostic Use**

Safety Precautions

The following warnings and precautions apply to:
Alinity m STI AMP TRAY 1.

CAUTION: This preparation contains human-sourced and/or potentially infectious components. Refer to the **REAGENTS** section of this package insert. Components sourced from human blood have been tested and found to be non-reactive by appropriate FDA-licensed, approved, or cleared tests for antibody to HCV, antibody to HIV-1, antibody to HIV-2, HBsAg, HIV-1 antigen, and Syphilis. The material is also tested and found to be negative by appropriate FDA-licensed, approved, or cleared PCR methods for HIV-1 RNA, HCV RNA, and HBV DNA. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. These reagents and human specimens should be handled as if infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories,[24] OSHA Standard on Bloodborne Pathogens,[25] CLSI Document M29-A4,[26] and other appropriate biosafety practices.[27] Therefore all human sourced materials should be considered infectious.

These precautions include, but are not limited to, the following:

- Wear gloves when handling specimens or reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectant.[24]

Decontaminate and dispose of all potentially infectious materials in accordance with local, state and federal regulations.[27]

The following warnings and precautions apply to:
Alinity m STI ACT TRAY 2.

DANGER	Contains Tetramethylammonium chloride, and 2-Methyl-4-isothiazolin-3-one
H302	Harmful if swallowed.
H316	Causes mild skin irritation.[a]
H317	May cause an allergic skin reaction.
H370	Causes damage to organs.
H412	Harmful to aquatic life with long lasting effects.
Prevention	
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P308+P311	IF exposed or concerned: Call a POISON CENTER/ doctor.

P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Storage	
P405	Store locked up.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

[a] Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29CFR 1910/1200 (HCS) 2012 have been implemented.

Important information regarding the safe handling, transport and disposal of this product is contained in the Safety Data Sheet.

Safety Data Sheets are available from your Abbott Representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity m System Operations Manual, Section 7 and Section 8.

Reagent Shipment

	Shipment Condition
Alinity m STI AMP Kit	On dry ice

Reagent Storage

In order to minimize damage to foil pouches, it is recommended that the Alinity m STI AMP TRAY 1 (AMP TRAY 1) and Alinity m STI ACT TRAY 2 (ACT TRAY 2) are stored in the original kit packaging. Open the foil pouch for the reagent trays just prior to loading onto the instrument. Onboard storage time begins when reagents are loaded on the Alinity m System.

	Storage Temperature	Maximum Storage Time
Unopened	2°C to 8°C	Until expiration date
Onboard	System Temperature	30 days (not to exceed expiration date)

Reagent Handling

- Do not use reagents that have been damaged.
- Minimize contact with the surface of reagent trays during handling.
- Up to 2 sets of assay trays (AMP TRAY 1 and ACT TRAY 2) can be loaded on each Alinity m Assay Tray Carrier. AMP Kit lots can be different between the 2 sets of assay trays. However, AMP TRAY 1 and ACT TRAY 2 within each set must be from the same AMP Kit lot.
- The Alinity m System will track the onboard storage time of AMP TRAY 1 and ACT TRAY 2 while on the instrument. The Alinity m System will not allow the use of AMP TRAY 1 and ACT TRAY 2 if the maximum onboard storage time has been exceeded.
- For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity m System Operations Manual, Section 8.

Indications of Reagent Deterioration

- Deterioration of the reagents may be indicated when a control error occurs or control values are repeatedly out of the specified ranges.
- Reagents are shipped on dry ice and stored at 2°C to 8°C upon arrival. If reagents arrive in a condition contrary to this recommendation or are damaged, immediately contact your Abbott Representative.
- For troubleshooting information, refer to the Alinity m System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity m STI Assay application specification file must be installed on the Alinity m System prior to performing the assay.

For a detailed description of system operating instructions, refer to the Alinity m System Operations Manual, Section 5.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Collection

Endocervical, vaginal, oropharyngeal, and rectal swabs, female urine and male urine specimens must be collected using the Alinity m multi-Collect Specimen Collection Kit (List No. 09N19-015).

Users must follow the instructions in the Alinity m multi-Collect Specimen Collection Kit (List No. 09N19-015) for collecting endocervical, vaginal, oropharyngeal, and rectal swabs, female urine, and male urine specimens.

For swab specimen collections, only the orange shaft swab provided in the Alinity m multi-Collect Specimen Collection Kit should be used.

A transport tube containing multiple swabs or a combination of swab and urine cannot be used in the Alinity m STI Assay.

A new endocervical, vaginal, oropharyngeal, or rectal swab specimen should be collected if the specimen is received without a swab or with multiple swabs.

For urine specimen collections, ensure that the urine level falls within the clear fill window of the Specimen Transport Tube label.

Do not use specimens collected with the Alinity m multi-Collect Specimen Collection Kit if the tube is damaged or if buffer has leaked from the tube.

Gynecological specimens in PreservCyt Solution (Hologic Inc.) must be collected and handled according to the manufacturer's instructions. For PreservCyt specimens, only the aliquot taken from the PreservCyt vial prior to cytology processing can be used for Alinity m STI Assay testing.

Specimen Type

The specimen types listed below can be used with this assay on the Alinity m System. Alinity m STI Assay performance with other collection devices or specimen types has not been evaluated. Refer to the Intended Use for the analytes that can be evaluated for each specimen type.

Collection Device	Specimen Types[a]
Alinity m multi-Collect Specimen Collection Kit	Endocervical Swab Vaginal Swab Oropharyngeal Swab Rectal Swab Female Urine Male Urine
PreservCyt Solution	Gynecological

[a] The Alinity m System does not provide the capability to verify specimen types. It is the responsibility of the operator to use the correct specimen types in the assay.

Specimen Storage

Alinity m multi-Collect Specimens

Specimen Type	Temperature	Maximum Storage Time
Endocervical Swab, Vaginal Swab, Oropharyngeal Swab, Rectal Swab, Female Urine, Male Urine	2°C to 30°C	14 days
	−25°C to −15°C	60 days[a]

[a] Avoid more than 4 freeze thaw cycles.

PreservCyt Specimens

Specimen Type	Temperature	Maximum Storage Time
Gynecological	2°C to 30°C	14 days
	−25°C to −15°C	60 days

Specimen Shipping

Ship specimens at 2°C to 30°C or frozen. Specimens must not exceed the maximum storage time listed in the **Specimen Storage** section prior to testing. Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens.

Preparation for Analysis

When handling Alinity m multi-Collect specimens or specimens in Alinity m Transport Tubes, do not touch the top of pierceable caps to avoid contamination.

For an endocervical, vaginal, oropharyngeal, and rectal swab specimen, do not remove the swab from the Specimen Transport Tube. The swab does not interfere with the instrument's ability to aspirate sample.

For a urine specimen that is received in a urine specimen collection cup, transfer the urine to an Alinity m multi-Collect Specimen Collection Kit transport tube. Follow the instructions for urine specimen collection in the Alinity m multi-Collect Specimen Collection Kit package insert before performing the Alinity m STI Assay.

If precipitate is observed in urine specimens in Alinity m multi-Collect Specimen Collection tubes, heat the specimens at 37°C for 10 minutes and mix thoroughly to ensure uniformity.

PreservCyt specimens need to be transferred to an Alinity m Transport Tube for processing on the Alinity m System.

- Vortex each specimen for 15 to 20 seconds. Ensure that the contents in the PreservCyt vial are on the bottom by tapping the vial on the bench.
- Immediately transfer a minimum of 0.35 mL and a maximum of 2.0 mL of each specimen to an Alinity m Transport Tube (List No. 09N49-010 or 09N49-011) and cap with an Alinity m Pierceable Cap (List No. 09N49-012).

Only PreservCyt specimens that have been aliquoted prior to cytology processing can be used.

Frozen Specimens:

If the urine, endocervical, vaginal, oropharyngeal, or rectal swab specimen collected in Alinity m multi-Collect Specimen Collection tubes is stored frozen, it must be completely thawed prior to sample preparation.

- Thaw specimens at 15°C to 30°C or at 2°C to 8°C. Specimens should not undergo more than 4 freeze/thaw cycles.
- Vortex each specimen for a minimum of 2 to 3 seconds. Do not touch the top of pierceable caps to avoid cross-contamination.
- Visually inspect each specimen.
  - In swab specimens, if layering, stratification, or precipitation is observed, continue to mix specimens thoroughly to ensure uniformity.
  - In urine specimens, if precipitation is observed, heat the specimens at 37°C for 10 minutes. Mix specimens thoroughly to ensure uniformity.

All specimen tubes must be labeled with specimen ID barcodes, or must be identified with a specimen ID and rack and position.

PROCEDURE

Materials Provided

09N17-095 Alinity m STI AMP Kit

Materials Required but not Provided

- 09N17-085 Alinity m STI CTRL Kit
- 09N18-001 Alinity m Sample Prep Kit 1
- 09N20-001 Alinity m Lysis Solution
- 09N20-002 Alinity m Ethanol Solution or 09N20-012 Alinity m Bottle for Ethanol Use (filled with customer supplied 190 Proof Ethanol, ACS, Denaturant free)
- 09N20-003 Alinity m Diluent Solution
- 09N20-004 Alinity m Vapor Barrier Solution
- 09N49-010 Alinity m Transport Tube Pierceable Capped
- 09N49-011 Alinity m Transport Tubes
- 09N49-012 Alinity m Pierceable Caps
- 09N17-03B (v2.00) or higher Alinity m STI Application Specification File
- Vortex mixer
- Calibrated pipettes capable of delivering 100 to 1000 µL
- Aerosol barrier pipette tips for 100 to 1000 µL pipettes
- Plate adapter for 384 well plates (eg, Eppendorf Catalog No. 022638955)
- Centrifuge with swing plate rotor capable of accommodating the plate adapter and capable of ≥100 *g*

For information on materials required for operation of the instrument, refer to the Alinity m System Operations Manual, Section 1.

For general operating procedures, refer to the Alinity m System Operations Manual, Section 5.

For optimal performance, it is important to perform routine maintenance as described in the Alinity m System Operations Manual, Section 9.

Procedural Precautions

- Read the instructions in this package insert carefully before processing samples.
- When handling specimens, do not touch the top of pierceable caps to avoid cross-contamination. Specimens can contain extremely high levels of organisms. Change gloves if they come in contact with specimen.
- Do not use specimens collected with the Alinity m multi-Collect Specimen Collection Kit if the tube is damaged or if buffer has leaked from the tube. Discard unused, damaged, or leaking kits in accordance with local, state, and federal regulations.
- Use aerosol barrier pipette tips or disposable pipettes only one time when pipetting specimens. To prevent contamination to the pipette barrel while pipetting, care should be taken to avoid touching the pipette barrel to the inside of the sample tube or container. The use of extended aerosol barrier pipette tips is recommended.
- Work area and instrument platforms must be considered potential sources of contamination.
- Ensure the Alinity m STI AMP TRAY 1 is tapped prior to loading on the Alinity m System per instructions in the **Assay Procedure** section.
- Ensure the Alinity m STI ACT TRAY 2 is centrifuged prior to loading on the Alinity m System per instructions in the **Assay Procedure** section.
- Monitoring procedures for the presence of amplification product can be found in the Alinity m System Operations Manual, Section 9.
- To reduce the risk of nucleic acid contamination, clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectant.
- Clean the retention bar after each use.
- To prevent contamination, change to new gloves before handling the Alinity m Sample Prep Kit 1, assay trays, system solutions, Integrated Reaction Unit (IRU) sleeves, and pipette tips. Also change to new gloves whenever they are contaminated by a specimen, a control, or a reagent. Always use powder-free gloves.
- The use of the Alinity m STI CTRL Kit is integral to the performance of the Alinity m STI Assay. Refer to the **QUALITY CONTROL PROCEDURES** section of this package insert for details. Refer to the Alinity m STI CTRL Kit package insert for preparation and usage.
- The Alinity m STI CTRL reagents are contained in single-use tubes with pierceable caps. Avoid contamination or damage to the caps after removal from their original packaging. Discard tubes after use.

Assay Procedure

Prior to loading on the Alinity m System, hold the Alinity m STI AMP TRAY 1 by the edges with the label facing up and tap 3 times on the bench.

Prior to loading onto the Alinity m System, Alinity m STI ACT TRAY 2 must be centrifuged as follows:

1. Load ACT TRAY 2 onto the plate adapter (eg, Eppendorf Catalog No. 022638955).
2. Load the plate adapter (with ACT TRAY 2) on a swing plate centrifuge capable of accommodating the plate adapter. Spin at 100 – 800 *g* for 1 to 5 minutes to remove potential bubbles.
3. Immediately following centrifugation, carefully transfer the ACT TRAY 2 to the Alinity m Assay Tray Carriers. Take care to minimize disturbance to the ACT TRAY 2. Load the tray carriers per Alinity m System Operations Manual, Section 5.
4. If disturbance occurs during transfer that could potentially introduce bubbles (eg, dropping, bumping, inversion of ACT TRAY 2), re-centrifuge the ACT TRAY 2.
5. Proceed with the **Reagent and sample inventory management** procedure per the Alinity m System Operations Manual, Section 5.

For a detailed description of how to run an assay, refer to the Alinity m System Operations Manual, Section 5.

Prior to testing specimens, check control status. If control testing is required refer to **QUALITY CONTROL PROCEDURES** section. Controls may be tested separately or with specimens. For preparation of samples, refer to the instructions under **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS: Preparation for Analysis** section.

From the Create Order screen, select the assay (CT, NG, TV, and/or MG) being tested.

- For endocervical swab, vaginal swab, and male urine, any combination of the four assays can be selected for a given specimen.
- For gynecological specimens in PreservCyt, and female urine, only CT, NG and/or TV should be selected.
- For oropharyngeal swab and rectal swab specimens, only CT and/or NG should be selected.

One PCR reaction can detect one or more pathogens with the STI Assay. Therefore, only one patient specimen aliquot is required for detection of the selected assay(s).

The Alinity m System will track the onboard storage time of amplification reagents, controls and specimens while on the instrument. The Alinity m System will not allow the use of amplification reagents, controls, or process specimens that have exceeded the allowable onboard storage time.

Alinity m multi-Collect specimens or PreservCyt specimens, may be placed on the Alinity m Universal Sample Rack (sample rack) onboard the system for up to 4 hours.

Requirements for minimum sample volume and cap requirements for specimen tubes allowable on the Alinity m System are summarized in the following table:

Tube Type	List No.	Minimum Volume Required
Alinity m multi-Collect Specimen Collection Kit Transport Tube	09N19-015	0.35 mL
Alinity m Transport Tube Pierceable Capped	09N49-010	0.35 mL
Alinity m Transport Tube Alinity m Pierceable Cap	09N49-011 09N49-012	0.35 mL

It is recommended that specimen tubes containing a swab are capped when tested. Specimens without a swab may be capped or uncapped when tested.

Post Processing Procedure

Upon completion of Alinity m sample preparation, specimens can be recapped using new, unused Alinity m Pierceable Caps (List No. 09N49-012) and stored at 2°C to 30°C for up to 14 days from date of collection.

If longer storage is needed, store at −25°C to −15°C for up to 60 days from date of collection.

When recapping, take care not to touch the top of new pierceable caps to avoid cross-contamination. Change gloves if they come in contact with specimen liquid.

QUALITY CONTROL PROCEDURES

Negative and Positive Controls

One Alinity m STI Negative CTRL and one Alinity m STI Positive CTRL are recommended to be tested, at or above the minimum frequency of once every 24 hours to monitor the assay performance and Alinity m System. The controls are processed through sample preparation and PCR procedures that are identical to those used for specimens. Valid results for all control levels must be obtained before specimen results are reported.

The controls do not indicate if bacterial cells have been adequately lysed. Additional controls, including those for cell lysis, may be tested in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

If quality control results do not meet the acceptance criteria, refer to the Alinity m System Operations Manual, Section 10, for troubleshooting information.

A Flag is displayed for specimens when a control result is invalid. If the controls for a given target analyte (CT, NG, TV, or MG) are invalid, all of the specimens for that target analyte processed following an invalid assay control must be retested.

If control results are invalid, refer to the Alinity m System Operations Manual, Section 5 for a description of quality control flags, and Section 10 for troubleshooting information.

The presence of CT, NG, TV, or MG must not be detected in the negative control. CT, NG, TV, or MG detected in the negative control is indicative of contamination by other samples or by amplified product. To avoid contamination, clean the Alinity m System and repeat sample processing for controls and specimens following the Alinity m System Operations Manual, Section 9.

The retention bar should be cleaned after each use, according to Alinity m System Operations Manual, Section 9.

If negative controls are persistently reactive, follow Monitoring procedures for the presence of amplification product, as indicated in the Alinity m System Operations Manual, Section 9. If the issue is not resolved, contact your Abbott Representative.

Detection of Inhibition and/or Cell Inadequacy

A defined, consistent quantity of IC is present in each PCR reaction and measured on the Alinity m System to assess amplification efficiency and to confirm that no PCR inhibitors are present in the sample. The IC is comprised of an RNA sequence unrelated to the Alinity m STI Assay target sequences.

The Alinity m STI Assay also detects an endogenous human DNA sequence (CC: Cellular Control) from the specimen to evaluate sample adequacy, sample extraction, and amplification efficiency.

A Flag or Message Code is displayed when the IC CN value or the CC CN value of a specimen or control exceeds the established range:

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

Refer to the Alinity m System Operations Manual, Section 5 for an explanation of the corrective actions for Flags.

Refer to the Alinity m System Operations Manual, Section 10 for an explanation of the corrective actions for Message Codes.

RESULTS

Calculation

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

Interpretation of Results

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

The results displayed on the workstation will only contain those requested in the order.

Flags, Result Codes, and Message Codes

Some results may contain information in the Flags and Codes fields. For a description of the flags and result codes that may appear in these fields, refer to the Alinity m System Operations Manual, Section 5.

For a description of Message Codes refer to the Alinity m System Operations Manual, Section 10.

If a patient specimen received a flag or message code for any of the individual assays, then the patient specimen can be retested by creating an order only for those assays that did not give results.

LIMITATIONS OF THE PROCEDURE

1. For females, 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.
2. False negative results for *Neisseria gonorrhoeae* were observed from endocervical samples in the clinical study when multiple endocervical samples were collected from one patient. If multiple endocervical samples are necessary from the same patient, and the NG test result is negative, further testing may be indicated if infection with *N. gonorrhoeae* is strongly suspected.
3. Performance of the assay for the detection of MG has not been established in gynecological specimens in PreservCyt or in female urine.
4. Performance of the assay for the detection of TV and MG has not been established in oropharyngeal or rectal swab specimens.
5. Gynecological specimens in PreservCyt are acceptable for detection of CT, but may detect up to 10.7% fewer CT infections when compared with vaginal swab specimens.
6. First-catch female urine specimens are acceptable for the detection of CT, NG, and TV, but may detect up to 12.3% fewer CT infections, 9.8% fewer NG infections, and 6.6% fewer TV infections when compared with vaginal swab specimens.
7. The Alinity m STI Assay has not been evaluated for patients younger than 14 years of age.
8. Assay interference may cause false negative or invalid results. Assay interference may be observed in the presence of seminal fluid at concentrations greater than 3.0% in PreservCyt samples.
9. Cycle number delays were observed for mucus, seminal fluid, γ-globulin, glucose, Preparation H Hemorrhoidal Cream, feces and Sensodyne Repair & Protect Sensitive Toothpaste, which could result in interference at lower target levels (refer to **Table 3** and **Table 4**).
10. Performance with specimens collected with other collection media than those specified in this package insert has not been evaluated.
11. Only PreservCyt specimens that have been aliquoted prior to cytology have been evaluated with the Alinity m STI Assay. The use of residual specimens post cytology has not been evaluated.
12. A negative test result does not preclude the possibility of infection and can be caused by improper specimen collection, technical error, specimen mix-up, or target levels below the assay limit of detection (LoD).

13. As with any diagnostic test, results from the Alinity m STI Assay should be interpreted in conjunction with other clinical and laboratory findings.
14. Reliable results are dependent on appropriate specimen collection and handling (refer to the **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** section of this package insert).
15. The Alinity m STI Assay has not been validated for use with vaginal swab specimens collected by patients at home. The patient-collected vaginal swab specimen application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.
16. Use of this assay is limited to personnel who have been trained in the procedure. Failure to follow the instructions given in this insert may result in erroneous results.
17. Nucleic acid contamination from the positive controls or specimens must be monitored by good laboratory practice and careful adherence to the procedures specified in this package insert.
18. A positive result for the presence of CT, NG, TV, and MG nucleic acids does not establish the causative agent for salpingitis or PID. A negative result for CT, NG, TV, and MG nucleic acids does not exclude related infection as a cause of ascending infection.
19. The Alinity m STI Assay has not been evaluated with patients who are currently being treated with antimicrobial agents active against CT, NG, TV, and MG.
20. The Alinity m STI Assay should not be used to determine therapeutic success or failure as nucleic acids may persist after appropriate antimicrobial therapy.
21. The Alinity m STI Assay for male and female urine testing must be performed on first-catch urine specimens (defined as the first 20-30 mL of the urine stream). The effects of other variables such as first-catch vs. mid-stream, post douching, etc. have not been determined.
22. The Alinity m STI Assay is not intended to replace other methods (eg, cervical exam) for diagnosis of urogenital infection. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
23. Use of the Alinity m STI Assay is not approved for the evaluation of suspected sexual abuse contact tracings as well as for other medico-legal indications.
24. The effects of factors such as vaginal discharge, use of tampons, douching, or other specimen collection variables have not been determined.
25. Though rare, mutations within the highly-conserved regions covered by the primers and/or probes of the Alinity m STI Assay may result in failure to detect the presence of the organism(s).

SPECIFIC PERFORMANCE CHARACTERISTICS

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[28, 29]). 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 for NG (Zeptometrix). 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

Inclusivity

The analytical sensitivity claim for 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, urine and PreservCyt 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, MEGA1404, and SEA-2 at 165 GE/mL. All strains were detected at ≥95.0% across swab and urine matrices.

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 1**). 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 1**) 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 1. Urogenital Microorganisms

Acinetobacter lwoffi	*Listeria monocytogenes*
Actinomyces israelii	*Mobiluncus curtisii*
Atopobium vaginae	*Mobiluncus mulieris*
Bacteroides fragilis	*Mycoplasma hominis**
Bacteroides ureolyticus	*Mycoplasma pneumoniae*
(Campylobacter ureolyticus)	*Neisseria cinerea**
Bifidobacterium longum	*Neisseria elongata**
Candida albicans	*Neisseria flava**
Candida glabrata	*Neisseria flavescens**
Candida parapsilosis	*Neisseria lactamica**
Candida tropicalis	*Neisseria mucosa**
*Chlamydia pneumoniae**	*Neisseria meningitidis* Serogroup A*
*Chlamydia psittaci**	*Neisseria meningitidis* Serogroup B*
Clostridium difficile	*Neisseria meningitidis* Serogroup C*
Clostridium perfringens	*Neisseria meningitidis* Serogroup D*
Corynebacterium genitalium	*Neisseria meningitidis* Serogroup W135*
Corynebacterium xerosis	*Neisseria meningitidis* Serogroup Y*
Cryptococcus neoformans	*Neisseria perflava**
Dientamoeba fragilis[a]	*Neisseria polysaccharea**
Entercoccus faecalis	*Neisseria sicca**
Enterobacter aerogenes	*Neisseria subflava**
Enterobacter cloacae	*Pentatrichomonas hominis*
Escherichia coli	*Peptostreptococcus anaerobius*
Fusobacterium nucleatum	*Prevotella bivia*
Gardnerella vaginalis	*Propionibacterium acnes*
Haemophilus ducreyi[a]	*Proteus mirabilis*
Herpes simplex virus I	*Pseudomonas aeruginosa*
Herpes simplex virus II	*Staphylococcus aureus*
Human Immunodeficiency virus 1	*Staphylococcus epidermidis*
Human papilloma virus 16	*Streptococcus agalactiae*
Kingella denitrificans	*Streptococcus pyogenes*
Klebsiella oxytoca	*Trichomonas tenax*
Klebsiella pneumoniae	*Ureaplasma parvum*
Lactobacillus acidophilus	*Ureaplasma urealyticum*
Lactobacillus brevis	
Lactobacillus jensenii	
Lactobacillus lactis	
Lactobacillus vaginalis	

[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 2**). 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 2**) 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 2. 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.

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 3**). 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 3** 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 3. 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
Albumin	U	60 mg/mL
γ-globulin	U[b]	60 mg/mL
Glucose	U[b]	1.2 mg/mL
Acidic urine	U	pH 4.0
Alkaline urine	U	pH 9.0
Bilirubin	U	72.5 µg/mL
Candida albicans (Urinary tract infection organism)	U	$3x10^4$ CFU/mL
Staphylococcus saprophyticus (Urinary tract infection organism)	U	$3x10^4$ CFU/mL
Escherichia coli (Urinary tract infection organism)	U	$3x10^4$ CFU/mL
Ibuprofen	U	495.1 µg/mL
Phenazopyridine Hydrochloride	U	80 µg/mL
Clotrimazole Vaginal Cream	S, P	0.25% w/v
KY Jelly Personal Lubricant	S, P	0.25% w/v
Metronidazole	S, P	40.1 µg/mL
Miconazole-3	S, P	0.25% w/v
Monistat-1	S, P	0.25% w/v
Terconazole Vaginal Cream	S, P	0.25% w/v
Preparation H Hemorrhoidal 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 4**). 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 any of the substances at the concentrations shown in **Table 4** 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 4. 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 µg/mL
Chloraseptic Sore Throat Spray, Menthol	O	5.0% v/v
Abreva Cold Sore Medication	O	5.0% w/v
Colgate Total Whitening Toothpaste	O	0.25% w/v
Arm & Hammer PeroxiCare Deep Clean Toothpaste	O	0.25% w/v
Sensodyne Repair & Protect Sensitive Toothpaste	O[b]	0.25% w/v
Preparation H Hemorrhoidal Cream	R	0.25% w/v
Barium Sulfate	R	0.25% w/v
Dulcolax Laxative Suppository	R	0.25% w/v
K-Y Jelly Personal Lubricant	R	0.25% w/v
Phillips' Milk of Magnesia Liquid Laxative	R	0.25% w/v
Pepto-Bismol	R	0.25% w/v
Imodium	R	0.25% w/v
Feces	R[b]	1.0% w/v
Lotrimin	R	0.25% w/v

[a] O = Oropharyngeal, R = Rectal

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

Competitive Interference 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.

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 5**). 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 **Tables 6, 7, 8**, and **9**, respectively.

Table 5. 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	Sub-LoD	Sub-LoD	Sub-LoD

[a] Concentration for High CT is $4.4x10^4$ IFU/mL or $8.8x10^3$ IFU/assay ($3.0x10^5$ EB/mL or $6.0x10^4$ EB/assay)

[b] Concentration for High NG is $1.6x10^4$ CFU/mL or $3.2x10^3$ CFU/assay.

[c] Concentration for High TV is $6.0x10^4$ TV/mL or $1.2x10^4$ TV/assay.

[d] Concentration for High MG is $1.1x10^6$ genome equivalents/mL or $2.2x10^5$ genome equivalents/assay.

Table 6. Within Laboratory 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	0.612	3.7	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	0.404	2.4	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	0.548	1.8	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	0.281	0.9	0.352	1.1	0.232	0.8	0.422	1.4
	CT at 2X 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	0.216	0.7	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	0.298	1.0	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	0.151	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	0.352	1.1	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	0.339	0.9	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	0.000	0.0	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	0.040	0.2	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	0.055	0.2	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	0.062	0.2	0.125	0.4	0.140	0.5	0.188	0.6
	CT at 2X 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	0.025	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	0.044	0.1	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	0.023	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	0.038	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	0.000	0.0	0.576	1.6	0.298	0.8	0.649	1.8
	CT Negative[e]	576	575	99.8%	....	....	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	CT High Pos (NG, TV & MG High Pos)	144	144	100.0%	17.21	0.181	1.0	0.095	0.6	0.024	0.1	0.205	1.2	0.089	0.5	0.224	1.3
	CT High Pos (NG, TV & MG at 2X LoD Claim)	144	144	100.0%	17.66	0.102	0.6	0.073	0.4	0.000	0.0	0.125	0.7	0.113	0.6	0.169	1.0
	CT at 2X LoD Claim (TV High Pos, NG & MG at 2X LoD Claim)	144	144	100.0%	29.77	0.102	0.3	0.049	0.2	0.036	0.1	0.118	0.4	0.082	0.3	0.144	0.5
	CT at 2X LOD (NG High Pos, TV & MG at 2X LoD Claim)	144	144	100.0%	30.77	0.162	0.5	0.144	0.5	0.000	0.0	0.216	0.7	0.196	0.6	0.292	0.9
	CT at 2X LoD Claim (MG High Pos, NG & TV at 2X LoD Claim)	144	144	100.0%	29.83	0.220	0.7	0.032	0.1	0.000	0.0	0.222	0.7	0.149	0.5	0.268	0.9
	CT at 2X LoD Claim (NG, TV & MG at 2X LoD Claim)	144	144	100.0%	30.33	0.607	2.0	0.000	0.0	0.126	0.4	0.620	2.0	0.000	0.0	0.620	2.0
	CT at 2X LoD Claim (CT only)	144	144	100.0%	31.09	0.402	1.3	0.141	0.5	0.000	0.0	0.426	1.4	0.180	0.6	0.462	1.5
	CT at LoD Claim	144	144	100.0%	31.22	0.721	2.3	0.000	0.0	0.300	1.0	0.781	2.5	0.000	0.0	0.781	2.5
	CT at Sub-LoD (High Negative)	144	40	27.8%	37.36	0.228	0.6	0.348	0.9	0.125	0.3	0.434	1.2	0.224	0.6	0.489	1.3
	CT 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 in 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 7. Within Laboratory 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	0.227	1.0	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	0.279	1.2	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	0.262	0.8	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	0.203	0.7	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	0.245	0.8	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	0.233	0.7	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	0.150	0.5	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	0.280	0.9	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	0.000	0.0	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	0.076	0.4	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	0.236	1.1	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	0.127	0.4	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	0.175	0.6	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	0.091	0.3	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	0.158	0.5	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	0.052	0.2	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	0.090	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	0.000	0.0	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	0.000	0.0	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	0.038	0.2	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	0.000	0.0	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	0.071	0.2	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	0.084	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	0.000	0.0	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	0.092	0.3	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	0.000	0.0	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	0.000	0.0	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 in 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 8. Within Laboratory Precision: TV Results

Matrix	Panel Description	N[a]	n[b]	Agreement (n/N)	Mean CN	Within-Run Component SD	Within-Run Component % CV	Between-Run Component SD	Between-Run Component % CV	Between-Day Component SD	Between-Day Component % CV	Within-Laboratory[c] SD	Within-Laboratory[c] % CV	Between-Instrument/Lot Component SD	Between-Instrument/Lot Component % CV	Total[d] SD	Total[d] % CV
Urine	TV High Pos (CT, NG & MG High Pos)	144	144	100.0%	9.85	0.274	2.8	0.178	1.8	0.626	6.4	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	0.638	6.5	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	0.243	0.9	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	0.305	1.1	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	0.398	1.4	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	0.302	1.1	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	0.289	1.1	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	0.329	1.1	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	0.205	0.6	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	0.121	1.2	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	0.139	1.4	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	0.000	0.0	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	0.157	0.5	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	0.113	0.4	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	0.141	0.5	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	0.063	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	0.096	0.3	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	0.160	0.5	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	0.000	0.0	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	0.000	0.0	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	0.000	0.0	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	0.054	0.2	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	0.030	0.1	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	0.000	0.0	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	0.118	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	0.115	0.4	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	0.124	0.4	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 in 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 9. Within Laboratory Precision: MG 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	MG High Pos (CT, NG & TV High Pos)	144	144	100.0%	20.57	0.199	1.0	0.149	0.7	0.612	3.0	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	0.257	1.2	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	0.598	1.9	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	0.317	1.0	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	0.443	1.4	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	0.352	1.1	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	0.257	0.8	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	0.479	1.5	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	0.819	2.1	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	0.000	0.0	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	0.000	0.0	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	0.057	0.2	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	0.082	0.3	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	0.037	0.1	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	0.048	0.2	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	0.023	0.1	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	0.011	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	0.000	0.0	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.

Carryover

The carryover rate for Alinity m STI assay was determined in two studies. Study 1 evaluated the carryover rate in the Sample Input Rack and Sample Processing Unit by analyzing 360 valid replicates of STI negative panel processed from alternating positions in the sample input rack with 360 valid replicates of high concentration STI positive panel consisting of all assay analytes (at $6.2x10^5$ EB/mL CT, $1.6x10^4$ CFU/mL NG, $6.0x10^4$ TV/mL TV and $1.1x\ 10^6$ Genome Copies/mL MG) across multiple runs. None of the analyte was detected in any of the STI negative samples, resulting in a carryover rate of 0.0% (95% CI: 0.0% to 1.1%).

Study 2 evaluated the carryover rate in the AMP tray by evaluating 362 valid replicates of STI negative panel processed from alternating positions at the AMP tray with 362 valid replicates of high concentration STI positive panel consisting of all assay analytes (at $6.2x10^5$ EB/mL CT, $1.6x10^4$ CFU/mL NG, $6.0x10^4$ TV/mL TV and $1.1x\ 10^6$ Genome Copies/mL MG) across multiple runs. None of the analyte was detected in any of the STI negative samples, resulting in a carryover rate of 0.0% (95% CI: 0.0% to 1.1%).

None of the STI analyte was detected in any of the total 722 STI negative samples, resulting in an overall Alinity m STI carryover rate of 0.0% (95% CI: 0.0% to 0.5%).

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 **Tables 10, 11, 12,** and **13**, respectively.

Table 10. 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%	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	CT High Pos (NG, TV & MG High Pos)	150	150	100.0%	17.40	0.212	1.2	0.105	0.6	0.081	0.5	0.080	0.5	0.263	1.5
	CT High Pos (NG, TV & MG at 2X LoD Claim)	150	150	100.0%	17.64	0.333	1.9	0.175	1.0	0.197	1.1	0.000	0.0	0.424	2.4
	CT at 2X LoD Claim (MG High Pos, NG & TV at 2X LoD Claim)	150	150	100.0%	30.07	0.216	0.7	0.141	0.5	0.162	0.5	0.000	0.0	0.305	1.0
	CT at 2X LoD Claim (TV High Pos, NG & MG at 2X LoD Claim)	150	150	100.0%	29.92	0.153	0.5	0.097	0.3	0.071	0.2	0.047	0.2	0.200	0.7
	CT zat 2X LoD Claim (NG High Pos, TV & MG at 2X LoD Claim)	150	150	100.0%	31.14	0.223	0.7	0.152	0.5	0.095	0.3	0.124	0.4	0.312	1.0
	CT at 2X LoD Claim (NG, TV & MG at 2X LoD Claim)	150	150	100.0%	30.57	0.650	2.1	0.321	1.1	0.000	0.0	0.137	0.4	0.738	2.4
	CT at 2X LoD Claim (CT only)	150	150	100.0%	31.63	0.779	2.5	0.184	0.6	0.457	1.4	0.000	0.0	0.921	2.9
	CT at LoD Claim	150	150	100.0%	31.73	0.935	2.9	0.163	0.5	0.000	0.0	0.158	0.5	0.962	3.0
	CT at Sub-LoD (High Negative)	150	37	24.7%	37.33	0.646	1.7	0.215	0.6	0.740	2.0	0.000	0.0	1.005	2.7
	CT 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 in 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 11. Reproducibility Analysis: NG 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	NG High Pos (CT, TV & MG High Pos)	150	150	100.0%	24.85	0.513	2.1	1.162	4.7	0.547	2.2	0.448	1.8	1.453	5.8
	NG High Pos (CT, TV & MG at 2X LoD Claim)	150	150	100.0%	26.05	0.436	1.7	1.136	4.4	0.594	2.3	0.974	3.7	1.668	6.4
	NG at 2X LoD Claim (MG High Pos, CT & TV at 2X LoD Claim)	150	148	98.7%	35.29	0.764	2.2	1.073	3.0	0.540	1.5	1.058	3.0	1.774	5.0
	NG at 2X LoD Claim (TV High Pos, CT & MG at 2X LoD Claim)	150	150	100.0%	34.70	0.735	2.1	1.089	3.1	0.160	0.5	0.760	2.2	1.526	4.4
	NG at 2X LoD Claim (CT High Pos, TV & MG at 2X LoD Claim)	150	149	99.3%	34.68	0.662	1.9	1.018	2.9	0.401	1.2	0.911	2.6	1.570	4.5
	NG at 2X LoD Claim (CT, TV & MG at 2X LoD Claim)	150	147	98.0%	35.37	1.004	2.8	1.093	3.1	0.679	1.9	1.037	2.9	1.934	5.5
	NG at 2X LoD Claim (NG only)	150	145	96.7%	35.84	0.767	2.1	0.677	1.9	0.796	2.2	1.025	2.9	1.652	4.6
	NG at LoD Claim	150	141	94.0%	36.20	0.931	2.6	1.110	3.1	0.526	1.5	0.870	2.4	1.770	4.9
	NG at Sub-LoD (High Negative)	150	14	9.3%	37.82	0.000	0.0	0.735	1.9	0.617	1.6	0.443	1.2	1.056	2.8
	NG Negative[d]	600	600	100.0%	....	....	....	....	....	....	....	....	....	....	....
Swab	NG High Pos (CT, TV & MG High Pos)	150	150	100.0%	21.77	0.259	1.2	0.172	0.8	0.112	0.5	0.000	0.0	0.331	1.5
	NG High Pos (CT, TV & MG at 2X LoD Claim)	150	150	100.0%	22.51	0.289	1.3	0.268	1.2	0.000	0.0	0.197	0.9	0.440	2.0
	NG at 2X LoD Claim (MG High Pos, CT & TV at 2X LoD Claim)	150	150	100.0%	31.63	0.316	1.0	0.159	0.5	0.155	0.5	0.139	0.4	0.411	1.3
	NG at 2X LoD Claim (TV High Pos, CT & MG at 2X LoD Claim)	150	150	100.0%	31.44	0.275	0.9	0.159	0.5	0.147	0.5	0.000	0.0	0.350	1.1
	NG at 2X LoD Claim (CT High Pos, TV & MG at 2X LoD Claim)	150	150	100.0%	31.68	0.294	0.9	0.262	0.8	0.000	0.0	0.136	0.4	0.417	1.3
	NG at 2X LoD Claim (CT, TV & MG at 2X LoD Claim)	150	150	100.0%	31.54	0.306	1.0	0.246	0.8	0.000	0.0	0.111	0.4	0.408	1.3
	NG at 2X LoD Claim (NG only)	150	150	100.0%	31.78	0.285	0.9	0.180	0.6	0.117	0.4	0.108	0.3	0.373	1.2
	NG at LoD Claim	150	150	100.0%	32.49	0.336	1.0	0.185	0.6	0.053	0.2	0.116	0.4	0.405	1.2
	NG at Sub-LoD (High Negative)	150	80	53.3%	36.95	0.934	2.5	0.000	0.0	0.126	0.3	0.163	0.4	0.956	2.6
	NG Negative[d]	600	600	100.0%	....	....	....	....	....	....	....	....	....	....	....
PreservCyt	NG High Pos (CT, TV & MG High Pos)	150	150	100.0%	21.64	0.322	1.5	0.182	0.8	0.086	0.4	0.169	0.8	0.415	1.9
	NG High Pos (CT, TV & MG at 2X LoD Claim)	150	150	100.0%	25.30	0.239	0.9	0.198	0.8	0.055	0.2	0.097	0.4	0.329	1.3
	NG at 2X LoD Claim (MG High Pos, CT & TV at 2X LoD Claim)	150	150	100.0%	31.08	0.285	0.9	0.231	0.7	0.142	0.5	0.000	0.0	0.394	1.3
	NG at 2X LoD Claim (TV High Pos, CT & MG at 2X LoD Claim)	150	150	100.0%	31.16	0.271	0.9	0.176	0.6	0.000	0.0	0.085	0.3	0.334	1.1
	NG at 2X LoD Claim (CT High Pos, TV & MG at 2X LoD Claim)	150	150	100.0%	30.39	0.328	1.1	0.163	0.5	0.137	0.5	0.000	0.0	0.392	1.3
	NG at 2X LoD Claim (CT, TV & MG at 2X LoD Claim)	150	150	100.0%	32.06	0.376	1.2	0.309	1.0	0.225	0.7	0.000	0.0	0.536	1.7
	NG at 2X LoD Claim (NG only)	150	150	100.0%	30.48	0.318	1.0	0.245	0.8	0.240	0.8	0.128	0.4	0.485	1.6
	NG at LoD Claim	150	150	100.0%	33.10	0.413	1.2	0.166	0.5	0.193	0.6	0.000	0.0	0.486	1.5
	NG at Sub-LoD (High Negative)	150	63	42.0%	37.46	0.742	2.0	0.000	0.0	0.323	0.9	0.000	0.0	0.810	2.2
	NG Negative[d]	600	598	99.7%	....	....	....	....	....	....	....	....	....	....	....

[a] N: Total number of replicates

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

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

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

Table 12. 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
	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 13. Reproducibility Analysis: MG 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	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 in 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 negative panel members for MG.

CLINICAL PERFORMANCE

Clinical Study Results – Urogenital Specimens

Performance characteristics of the Alinity m STI Assay with urogenital specimens were established in multicenter clinical studies conducted in the United States.

Study 1

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 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 Assay testing was performed at 3 external clinical testing sites. Comparator assays were used to establish the Patient Infected Status (PIS) or Composite Comparator Algorithm (CCA) result as specified further below. The following comparator assays were used on the indicated analyte and specimen types. 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). In addition, up to 3 comparator NAATs were tested with PreservCyt specimens for CT. 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 tested with vaginal swab specimens for females and 3 NAATs tested with urine specimens for males.

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 **Tables 18**, **19**, **26** and **27** 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 3 swab comparator NAAT results were negative in cases where the 3rd NAAT was used as a tie-breaker. Refer to **Tables 32**, **33**, **36,** and **37** for the female PIS algorithm.

A male subject was categorized as infected for CT, NG, TV or MG if a minimum of 2 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 2 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 1 or more comparator NAATs were negative. Refer to **Tables 24, 25, 30, 31, 34, 35, 38,** and **39** 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, and 93 subjects for MG).

Alinity m STI Assay 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 PIS 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 14a**. NG sensitivity and specificity for female and male subjects by specimen type and by symptom status are presented in **Table 15a**. TV sensitivity and specificity for female and male subjects by specimen type and by symptom status are presented in **Table 16a**. MG sensitivity and specificity for female and male subjects by specimen type and by symptom status are presented in **Table 17**.

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 49, 49, 54 and 38, respectively, or approximately 0.3%.

For PreservCyt specimens, the Alinity m STI Assay performance for detection of CT was evaluated by comparison to a Composite Comparator Algorithm (CCA) to establish specimen-specific agreement with other FDA cleared assays for detection of CT. The PreservCyt specimen-specific status was determined using the results of up to 3 NAATs. Specimens were initially tested with 2 NAATs. If the NAATs did not agree or if 1 result was missing or indeterminate, a third tiebreaker NAAT was used. A PreservCyt specimen was considered positive for CT if at least 2 comparator NAATs were positive for the PreservCyt specimen. A PreservCyt specimen was considered negative if at least 2 comparator NAATs were negative. CT specimen-specific positive and negative agreement for PreservCyt by symptom status are presented in **Table 14b**. A total of 1,939 CT results were used in the CCA analysis. The CT clinical sensitivity based on the PIS was up to 10.7% lower in PreservCyt than in vaginal swab specimens.

For female urine, the TV result of the Alinity m STI Assay was compared against a specimen-specific TV status. The female urine specimen-specific status was determined using the results of 2 NAATs. 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 16b**. The TV clinical sensitivity based on the PIS was up to 6.6% lower in female urine than in vaginal swab specimens.

Study 2

The study was conducted to evaluate the performance of the Alinity m STI Assay for detection of CT and NG infections in female urine. Urine specimens were prospectively collected from female subjects 14 years of age or older at 14 geographically diverse sites. A total of 2,798 asymptomatic and symptomatic subjects were enrolled. Study subjects were classified as symptomatic if the subject reported STI related symptoms. Each subject provided 1 urine specimen.

Alinity m STI Assay test results for CT and NG in urine were compared to the CCA results to establish specimen-specific agreement with other FDA cleared assays. Alinity m STI Assay testing was performed at external clinical testing sites. Comparator assays for CT and NG included 3 commercially available nucleic acid amplification tests (NAAT) tested on the urine specimen. Specimens were initially tested with 2 NAATs. If the NAATs did not agree or if 1 result was missing or indeterminate, a third tiebreaker NAAT was used.

The CCA result was determined for each analyte (CT and NG) based on the combined urine results from the comparator assays. A specimen was categorized as "Positive" for CT or NG if at least 2 comparator assay results were positive and "Negative" for CT or NG if at least 2 comparator assay results were negative.

If a CCA could not be determined due to missing and/or indeterminate results from the comparator assays, the specimen was excluded from the analysis for that analyte. The specimen-specific NG status could not be determined for 1 subject. Out of 2,798 specimens, a total of 2,785 CT and 2,784 NG results were used in the analysis.

CT specimen-specific positive and negative agreement for female urine by symptom status are presented in **Table 14c**. The CT clinical sensitivity based on the PIS was up to 12.3% lower in female urine than in vaginal swab specimens. NG specimen-specific positive and negative agreement for female urine by symptom status are presented in **Table 15b**. The NG clinical sensitivity based on the PIS was up to 9.8% lower in female urine than in vaginal swab specimens.

CT Performance

Table 14a. CT Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens (Compared to PIS)

								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 14b. CT Specimen-Specific Positive and Negative Agreement for ThinPrep (PreservCyt) by Symptom Status (Compared to CCA)

								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
CT	PreservCyt	Symptomatic	953	66	1	885	1	98.5 (92.0, 99.7)	66/67	99.9 (99.4, 100.0)	885/886
		Asymptomatic	986	52	6	927	1	98.1 (90.1, 99.7)	52/53	99.4 (98.6, 99.7)	927/933
		All	1939	118	7	1812	2	98.3 (94.1, 99.5)	118/120	99.6 (99.2, 99.8)	1812/1819

CCA = Composite Comparator Algorithm

Table 14c. CT Specimen-Specific Positive and Negative Agreement for Female Urine by Symptom Status (Compared to CCA)

								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
CT	Female Urine	Symptomatic	714	47	1	664	2	95.9 (86.3, 98.9)	47/49	99.8 (99.2, 100.0)	664/665
		Asymptomatic	2071	130	3	1934	4	97.0 (92.6, 98.8)	130/134	99.8 (99.5, 99.9)	1934/1937
		All	2785	177	4	2598	6	96.7 (93.0, 98.5)	177/183	99.8 (99.6, 99.9)	2598/2602

CCA = Composite Comparator Algorithm

NG Performance

Table 15a. NG Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens (Compared to PIS)

								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 other swabs were collected. 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 15b. NG Specimen-Specific Positive and Negative Agreement for Female Urine by Symptom Status (Compared to CCA)

								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
NG	Female Urine	Symptomatic	714	15	0	669	0	100.0 (79.6, 100.0)	15/15	100.0 (99.5, 100.0)	669/699
		Asymptomatic	2070	33	2	2034	1	97.1 (85.1, 99.5)	33/34	99.9 (99.6, 100.0)	2034/2036
		All	2784	48	2	2733	1	98.0 (89.3, 99.6)	48/49	99.9 (99.7, 100.0)	2733/2735

CCA = Composite Comparator Algorithm

TV Performance

Table 16a. TV Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens (Compared to PIS)

								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

Table 16b. TV Specimen-Specific Positive and Negative Agreement for Female Urine by Symptom Status (Compared to CCA)

								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

CCA = Composite Comparator Algorithm

MG Performance

Table 17. MG Clinical Sensitivity and Specificity by Gender, Specimen Type and Symptom Status for Urogenital Specimens (Compared to PIS)

								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, CCA, individual comparator results and Alinity m STI Assay result are summarized. CT results for infected and non-infected female subjects are presented in **Tables 18, 19, 20** and **21,** for endocervical, self-collected vaginal, clinician-collected vaginal, and PreservCyt and **Tables 22** and **23** for female urine. CT results for infected and non-infected male subjects are presented in **Tables 24** and **25**. NG results for infected and non-infected female subjects are presented in **Tables 26** and **27**, for endocervical, self-collected vaginal, clinician-collected vaginal, and PreservCyt and in **Tables 28** and **29** for female urine. NG results for infected and non-infected male subjects are presented in **Tables 30** and **31**. TV results for infected and non-infected female subjects are presented in **Tables 32** and **33**, and for infected and non-infected male subjects in **Tables 34** and **35**. MG results for infected and non-infected female subjects are presented in **Tables 36** and **37**, and for infected and non-infected male subjects in **Tables 38** and **39**.

Table 18. CT Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				Number of Subjects		
E	FU	VS	FU	E	SCV	CCV	PreservCyt	Symptomatic	Asymptomatic	Total
+	+	+	+	+	+	+	+	84	57	141
+	+	+	+	N/A	+	+	+	1	1	2
+	+	+	+	+	N/A	+	+	0	1	1
+	+	+	+	+	+	+	N/A	7	6	13
+	+	+	+	N/A	N/A	+	+	0	1	1
+	+	+	+	N/A	+	+	N/A	1	1	2
+	+	+	+	N/A	+	N/A	N/A	1	0	1
+	+	+	+	+	+	-	+	0	1	1
+	+	+	+	+	+	+	-	4	2	6
+	+	+	+	-	+	+	-	1	1	2
N/A	+	+	+	+	+	+	+	2	0	2
N/A	+	+	+	N/A	+	+	+	1	0	1
N/A	+	+	+	N/A	N/A	N/A	+	1	0	1
N/A	+	+	+	+	+	+	-	0	1	1
+	+	N/A	+	+	+	+	+	1	0	1
+	+	+	N/A	+	+	+	+	2	2	4
+	N/A	+	N/A	+	+	+	+	1	0	1
-	+	+	+	+	+	+	+	1	0	1
-	+	+	+	N/A	+	N/A	N/A	1	0	1
-	+	+	+	+	+	+	-	2	1	3
-	+	+	+	-	+	+	N/A	0	1	1
-	+	+	+	-	+	+	-	0	2	2
-	+	+	+	-	+	-	-	0	1	1
+	-	+	+	+	+	+	+	1	1	2
+	-	+	+	+	+	+	-	1	0	1
+	-	+	+	+	-	+	N/A	1	0	1
+	+	+	-	+	+	+	+	2	1	3
+	+	+	-	N/A	+	N/A	N/A	1	0	1
+	+	+	-	-	+	+	-	1	1	2
-	+	N/A	+	-	-	-	-	1	0	1
+	N/A	+	-	+	+	+	+	0	1	1
-	+	+	-	+	+	+	+	1	0	1
-	+	+	-	+	+	+	-	1	0	1
-	+	+	-	-	+	-	-	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 19. CT Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				Number of Subjects		
E	FU	VS	FU	E	SCV	CCV	PreservCyt	Symptomatic	Asymptomatic	Total
-	-	-	-	-	-	-	-	1105	1179	2284
-	-	-	-	N/A	-	-	-	6	8	14
-	-	-	-	-	N/A	-	-	9	20	29
-	-	-	-	-	-	N/A	-	6	9	15
-	-	-	-	-	-	-	N/A	159	216	375
-	-	-	-	N/A	-	N/A	-	0	1	1
-	-	-	-	N/A	-	-	N/A	10	36	46
-	-	-	-	-	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	3	5	8
-	-	-	-	+	-	-	-	7	6	13
-	-	-	-	-	+	-	-	3	5	8
-	-	-	-	-	-	+	-	8	4	12
-	-	-	-	-	-	-	+	3	10	13
-	-	-	-	+	-	-	N/A	0	2	2
-	-	-	-	-	+	-	N/A	1	1	2
-	-	-	-	-	-	+	N/A	1	0	1
-	-	-	-	-	+	+	-	1	0	1
N/A	-	-	-	-	-	-	-	14	16	30
N/A	-	-	-	N/A	-	-	-	5	6	11
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	-	10	2	12
-	N/A	-	-	-	-	-	-	5	5	10
-	N/A	-	-	-	-	-	N/A	1	2	3
-	-	N/A	-	-	-	-	-	7	10	17
-	-	N/A	-	-	-	-	N/A	1	1	2
-	-	N/A	-	N/A	N/A	N/A	-	0	1	1
-	-	N/A	-	-	-	+	-	1	0	1
-	-	N/A	-	-	+	+	-	1	0	1
-	-	-	N/A	-	-	-	-	9	8	17
-	-	-	N/A	-	-	-	N/A	1	0	1
N/A	N/A	-	-	-	-	-	-	9	2	11
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
N/A	N/A	-	-	-	-	-	+	0	1	1
+	-	-	-	-	-	-	-	6	2	8
+	-	-	-	N/A	-	-	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
-	-	+	-	-	+	-	-	1	0	1
-	-	+	-	-	-	+	-	2	1	3
-	-	+	-	-	+	+	-	1	1	2
-	-	+	-	+	+	+	+	0	1	1
-	-	-	+	N/A	-	N/A	N/A	1	0	1
+	+	-	-	+	-	-	N/A	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 20. CT Analysis Per CCA- POSITIVE FEMALE PreservCyt Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
PreservCyt	PreservCyt	PreservCyt	PreservCyt	Symptomatic	Asymptomatic	Total
+	+	N/A	+	64	52	116
+	+	N/A	-	1	1	2
+	-	+	+	2	0	2

N/A = Not Available

Table 21. CT Analysis Per CCA- NEGATIVE FEMALE PreservCyt Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
PreservCyt	PreservCyt	PreservCyt	PreservCyt	Symptomatic	Asymptomatic	Total
-	-	N/A	-	881	923	1804
-	-	N/A	+	1	6	7
-	+	-	-	4	2	6
+	-	-	-	0	1	1
-	-	-	-	0	1	1

N/A = Not Available

Table 22. CT Analysis Per CCA- POSITIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
FU	FU	FU	FU	Symptomatic	Asymptomatic	Total
+	+	N/A	+	44	127	171
-	+	+	-	1	2	3
+	+	N/A	-	1	1	2
+	-	+	+	0	2	2
-	+	+	+	2	0	2
+	+	+	+	1	0	1
+	N/A	+	+	0	1	1
+	-	+	-	0	1	1

FU = Female Urine, N/A = Not Available

Table 23. CT Analysis Per CCA- NEGATIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
FU	FU	FU	FU	Symptomatic	Asymptomatic	Total
-	-	N/A	-	654	1907	2561
-	N/A	-	-	7	21	28
-	-	-	-	2	2	4
-	-	N/A	+	1	2	3
+	-	-	-	1	1	2
N/A	-	-	-	0	2	2
+	-	-	+	0	1	1
-	+	-	-	0	1	1

FU = Female Urine, N/A = Not Available

Table 24. 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 25. 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 26. NG Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				Number 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 27. NG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1		NAAT 2		Alinity m STI				Number 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

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

NAAT 1		NAAT 2		Alinity m STI				Number of Subjects		
E	FU	VS	FU	E	SCV	CCV	PreservCyt	Symptomatic	Asymptomatic	Total
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
-	-	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 28. NG Analysis Per CCA- POSITIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
FU	FU	FU	FU	Symptomatic	Asymptomatic	Total
+	+	N/A	+	14	31	45
-	+	+	+	0	2	2
+	+	+	+	1	0	1
+	+	N/A	-	0	1	1

FU = Female Urine, N/A = Not Available

Table 29. NG Analysis Per CCA- NEGATIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	Number of Subjects		
FU	FU	FU	FU	Symptomatic	Asymptomatic	Total
-	-	N/A	-	686	2003	2689
-	N/A	-	-	7	21	28
-	-	-	-	5	8	13
N/A	-	-	-	0	2	2
-	-	N/A	+	0	2	2
+	-	-	-	1	0	1

FU = Female Urine, N/A = Not Available

Table 30. 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 31. 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 32. 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
-	+	+	+	+	+	+	-	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 33. 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

Table 33 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	-	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
-	-	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, N/A = Not Available

Table 34. 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 35. 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 36. MG Analysis Per Patient Infected Status- INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI			Number 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, E = Endocervical Swab, CCV = Clinician-Collected Vaginal Swab, SCV = Self-Collected Vaginal Swab, N/A = Not Available

Table 37. MG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI			Number 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

Table 37 Continued. MG Analysis Per Patient Infected Status- NOT INFECTED FEMALE Subjects (Urogenital)

NAAT 1	NAAT 2	NAAT 3	Alinity m STI			Number of Subjects		
VS	VS	VS	E	SCV	CCV	Symptomatic	Asymptomatic	Total
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
+	-	-	+	-	+	2	0	2
+	-	-	-	+	+	6	2	8
+	-	-	+	+	+	1	1	2
-	+	-	-	-	-	0	3	3
-	-	-	-	-	-	3	0	3

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

Table 38. 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 39. 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 these studies were 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 40** through **Table 45**. **Tables 40**, **42**, **44** and **45** are from **Study 1**. **Tables 41** and **43** are from **Study 2**.

Table 40. 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	PreservCyt	MU
01	2.4 (1/41)	2.4 (1/41)	5.1 (2/39)	2.8 (1/36)	15.3 (9/59)
02	4.0 (22/552)	4.6 (26/568)	4.2 (24/567)	3.4 (9/268)	4.7 (42/889)
03	2.7 (6/225)	4.1 (9/222)	4.3 (10/232)	2.7 (6/224)	3.5 (9/260)
04	21.1 (4/19)	15.8 (3/19)	21.1 (4/19)	15.8 (3/19)	17.2 (20/116)
05	7.2 (17/237)	7.1 (18/254)	7.2 (18/251)	6.8 (18/263)	3.9 (9/233)
06	0.0 (0/4)	0.0 (0/3)	0.0 (0/4)	0.0 (0/4)	0.0 (0/24)
07	3.5 (14/395)	3.4 (15/438)	3.2 (14/433)	2.9 (9/310)	3.6 (22/606)
08	2.9 (3/103)	2.9 (3/105)	2.9 (3/104)	1.9 (2/105)	15.2 (12/79)
09	6.6 (7/106)	7.5 (8/107)	6.6 (7/106)	9.3 (10/108)	4.3 (2/47)
10	4.8 (5/105)	3.8 (4/105)	4.8 (5/104)	5.7 (6/106)	12.7 (14/110)
11	0.0 (0/18)	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)	4.2 (2/48)	5.6 (2/36)
13	7.7 (4/52)	9.8 (5/51)	7.7 (4/52)	6.8 (3/44)	18.8 (6/32)
14	0.0 (0/39)	2.6 (1/38)	0.0 (0/39)	0.0 (0/39)	8.0 (2/25)
15	8.1 (3/37)	10.8 (4/37)	8.1 (3/37)	8.1 (3/37)	14.7 (10/68)
16	11.8 (2/17)	12.5 (2/16)	12.5 (2/16)	11.8 (2/17)	16.7 (1/6)
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	11.1 (1/9)	11.1 (1/9)	12.5 (1/8)	11.1 (1/9)	7.7 (1/13)
20	-	-	-	-	0.0 (0/1)
21	7.5 (10/133)	9.9 (13/131)	9.8 (13/133)	6.1 (8/132)	14.3 (11/77)
22	5.9 (2/34)	5.7 (2/35)	8.6 (3/35)	2.9 (1/34)	19.2 (5/26)
23	7.6 (9/118)	9.2 (11/120)	10.7 (13/121)	9.8 (12/122)	4.4 (2/45)
24	5.3 (2/38)	5.4 (2/37)	8.1 (3/37)	2.6 (1/38)	8.2 (5/61)
25	12.0 (6/50)	12.0 (6/50)	15.7 (8/51)	10.6 (5/47)	4.1 (2/49)
26	10.3 (3/29)	6.9 (2/29)	10.3 (3/29)	7.4 (2/27)	18.2 (6/33)
27	6.0 (5/84)	4.7 (4/85)	4.7 (4/85)	6.0 (5/83)	7.3 (4/55)
28	12.9 (29/225)	13.4 (31/231)	13.4 (31/231)	11.7 (27/230)	14.7 (20/136)
29	9.2 (8/87)	9.2 (8/87)	8.1 (7/86)	7.0 (6/86)	16.8 (20/119)
30	20.0 (13/65)	25.0 (16/64)	21.9 (14/64)	20.0 (13/65)	25.4 (15/59)
31	14.1 (10/71)	12.9 (9/70)	12.5 (9/72)	12.7 (9/71)	18.6 (11/59)
32	9.8 (5/51)	10.0 (5/50)	10.0 (5/50)	9.8 (5/51)	19.6 (10/51)
33	27.7 (13/47)	29.8 (14/47)	29.8 (14/47)	25.5 (12/47)	26.4 (19/72)
All	6.7 (206/3087)	7.1 (225/3163)	7.1 (226/3166)	6.6 (181/2734)	8.4 (294/3487)

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

Table 41. Positivity of CT Female Urine as Determined by Alinity m STI Assay by Collection Site

% Positivity (Number Positive / Number Tested with Valid Results)	
Site	FU
01	1.9 (2/105)
02	8.4 (33/394)
03	5.2 (5/96)
04	11.8 (70/594)
05	4.9 (23/466)
06	9.4 (8/85)
07	2.3 (7/305)
08	6.0 (23/383)
09	1.9 (2/104)
10	1.8 (2/109)
11	6.5 (2/31)
12	4.0 (3/75)
13	0.0 (0/20)
14	5.6 (1/18)
All	6.5 (181/2785)

FU = Female Urine

Table 42. 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 43. Positivity of NG Female Urine as Determined by Alinity m STI Assay by Collection Site

	% Positivity (Number Positive / Number Tested with Valid Results)
Site	**FU**
01	1.0 (1/105)
02	1.8 (7/394)
03	1.0 (1/96)
04	3.5 (21/594)
05	1.3 (6/466)
06	1.2 (1/85)
07	1.0 (3/305)
08	2.4 (9/382)
09	0.0 (0/104)
10	0.0 (0/109)
11	0.0 (0/31)
12	1.3 (1/75)
13	0.0 (0/20)
14	0.0 (0/18)
All	1.8 (50/2784)

FU = Female Urine

Table 44. 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 45. 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 **Tables 46** through **49** for CT, NG, TV, and MG, respectively.

Table 46. 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
PreservCyt	PPV (%)	42.8	60.1	75.3	88.7	94.3	96.3	97.4	98.0	98.5
	NPV (%)	99.9	99.9	99.8	99.4	98.7	97.9	97.0	96.1	95.0
FU	PPV (%)	52.2	68.7	81.6	92.0	96.0	97.5	98.2	98.6	98.9
	NPV (%)	99.9	99.9	99.7	99.3	98.5	97.6	96.6	95.6	94.4
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, FU = Female Urine, MU = Male Urine

Table 47. 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
FU	PPV (%)	67.5	80.6	89.4	95.6	97.9	98.6	99.0	99.3	99.4
	NPV (%)	100.0	99.9	99.8	99.5	98.9	98.3	97.6	96.8	96.0
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, FU = Female Urine, MU = Male Urine

Table 48. 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 49. 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

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 **Tables 52**, **53**, **54**, and **55** 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 Assay 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 50**. Sensitivity and specificity for NG for oropharyngeal and rectal specimens are presented in **Table 51**.

Table 50. 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 51. 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 (89.3,97.9)	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 52**, and for infected and non-infected rectal specimens in **Table 53**. NG results for infected and non-infected oropharyngeal specimens are presented in **Table 54**, and for infected and non-infected rectal specimens in **Table 55**.

Table 52. 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 53. 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 54. 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 55. 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 56**.

Table 56. 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 (30/2316)	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 57** and **Table 58** for CT and NG, respectively.

Table 57. 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 58. 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

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Key to Symbols

REF	Reference Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
AMP TRAY	AMP TRAY
ACT TRAY	ACT TRAY
UNIT	Unit
Rx ONLY	For Prescription Use Only
	Systemic Health Effects
	Warning
	Caution
	Consult Instructions for Use
	Temperature Limitation
Σ	Contains Sufficient for<*n*> tests
	Use By
	Manufacturer

TECHNICAL ASSISTANCE

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