simpli-COLLECT™ STI Test

REF 09N93-001
09R02-001

53-608395/R1

Created March 2025

Rx ONLY

IVD

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Abbott

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CUSTOMER ASSISTANCE

For Laboratorians

Customer Service: 1-800-553-7042

Customer Service International: Call your Abbott Representative

For Patients

Contact your healthcare provider with questions regarding test results/ diagnosis or assistance with obtaining a new kit. Contact your testing laboratory or healthcare provider with questions regarding return shipping.

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

NAME

simpli-COLLECT™ STI Test

INTENDED USE

The simpli-COLLECT STI Test is a test system intended for in vitro detection and identification of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) in home-collected specimens. The specimens are shipped to a clinical laboratory for testing using the Alinity m STI Assay with the automated Alinity m System for the direct, qualitative detection and differentiation of ribosomal RNA from CT, DNA from NG, ribosomal RNA from TV, and ribosomal RNA from MG, to aid in the diagnosis of disease(s) caused by infection from these organisms. The assay may be used to test the following self-collected specimens from symptomatic and asymptomatic individuals for the following analytes:

- CT: vaginal swabs, female urine, and male urine
- NG: vaginal swabs, female urine, and male urine
- TV: vaginal swabs, female urine, and male urine
- MG: vaginal swabs and male urine

The simpli-COLLECT STI Test contains all the necessary components for the self-collection and transport of urine from male and female patients (simpli-COLLECT Urine Collection Kit) or vaginal swabs from female patients (simpli-COLLECT Swab Collection Kit) in their home, or in similar environments. The simpli-COLLECT Collection Kits may also be used to self-collect specimens in a clinic.

SUMMARY AND EXPLANATION OF THE TEST

The simpli-COLLECT STI Test is a test system for detection and identification of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) in self-collected specimens using the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit.

The kit is prescribed, and given or sent to the patient. The patient follows the instructions provided in the kit to collect the urine or swab specimen and transport it to the laboratory. Samples collected at home with the simpli-COLLECT collection kits are tested in a clinical laboratory with the Alinity m STI Assay. The Alinity m STI Assay uses PCR technology to detect sexually transmitted pathogens: CT, NG, TV, and MG.

simpli-COLLECT Urine Collection Kit

The simpli-COLLECT Urine Collection Kit allows patients to self-collect urine specimens at home or other setting outside of a clinical setting. The kit is prescribed, and given or sent to the patient. The patient collects and transfers the urine specimen to the Alinity m Sample Tube, which contains 1.35 mL of transport buffer, before returning it to the laboratory for analysis.

Each kit is labeled with a unique kit identifier which may be used for traceability purposes. The unique kit identifier is a coded 2D datamatrix barcode which consists of 11 numeric characters. It is located on the side of each kit box. This unique kit identifier matches the barcode on the sample tube and the biohazard bag labels, which are placed on the sample tube and the biohazard bag by the patient.

simpli-COLLECT Swab Collection Kit

The simpli-COLLECT Swab Collection Kit allows patients to self-collect vaginal swab specimens at home or other setting outside of a clinical setting. The kit is prescribed, and then given or sent to the patient. The patient collects and transfers the specimen to the Alinity m Sample Tube, which contains 1.35 mL of transport buffer, before returning it to the laboratory for analysis.

Each kit is labeled with a unique kit identifier which may be used for traceability purposes. The unique kit identifier is a coded 2D datamatrix barcode which consists of 11 numeric characters. It is located on the side of each kit box. This unique kit identifier matches the barcode on the sample tube and the biohazard bag labels, which are placed on the sample tube and the biohazard bag by the patient.

Alinity m STI Assay

The Alinity m STI Assay uses PCR technology with homogenous real-time fluorescence detection. The assay detects ribosomal RNA from CT, DNA from NG, ribosomal RNA from TV, and ribosomal RNA from 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]

REAGENTS

simpli-COLLECT Urine Collection Kit

Case Contents

Σ 24 simpli-COLLECT Urine Collection Kits

26 mailing pouches (2 extra)

Each non-reusable simpli-COLLECT Urine Collection Kit includes the following:

- 1 Urine Cup
- 1 Abbott Sample Collection containing:
  - 1 Alinity m Sample Tube with Liquid Buffer, containing 1.35 mL of Liquid Buffer
  - 1 Dropper
- 1 Tube and Cap Holder
- 1 Tube and Bag Label sheet
- 1 Biohazard Bag
- 1 Patient Instructions for Use
  NOTE: The patient will use the kit box as the return box.

simpli-COLLECT Swab Collection Kit

Case Contents

Σ 24 simpli-COLLECT Swab Collection Kits

26 mailing pouches (2 extra)

Each non-reusable simpli-COLLECT Swab Collection Kit includes the following:

- 1 Abbott Swab Collection containing:
  - 1 Alinity m Sample Tube with Liquid Buffer, containing 1.35 mL of Liquid Buffer
  - 1 Specimen Collection Swab
- 1 Tube and Cap Holder
- 1 Tube and Bag Label sheet
- 1 Biohazard Bag
- 1 Patient Instructions for Use
  NOTE: The patient will use the kit box as the return box.

WARNINGS AND PRECAUTIONS

General

- **For In Vitro Diagnostic Use**

Laboratory Warnings and Precautions

- Follow all instructions in this package insert.
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.[24,25]
- Do not send the simpli-COLLECT Collection Kit to the patient if the kit is damaged, the kit box is open, or the kit is leaking. Discard unused, damaged, or leaking kits in accordance with local, state, and federal regulations.[24,25]
- Do not send the simpli-COLLECT Collection Kit to the patient if the kit is beyond its expiration date.
- Do not open the kit prior to sending to patient.
- Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.
- Avoid touching the blue top of the Alinity m Pierceable Cap to prevent potential contamination.

Warnings and precautions for the Alinity m STI Assay are provided in the Alinity m STI AMP Kit package insert.

Patient Warnings and Precautions

- Follow all instructions in the Instructions for Use. If you do not follow the instructions, your result could be incorrect.
- Keep out of reach of children under 14 years old.
- Do not use the simpli-COLLECT Urine Collection Kit or simpli-COLLECT Swab Collection Kit if the kit is damaged, the kit box is open, or if the kit is leaking. Discard unused, damaged, or leaking kits in accordance with local, state, and federal regulations.
- Do not use the simpli-COLLECT Urine Collection Kit or simpli-COLLECT Swab Collection Kit if the kit is beyond its expiration date. Use of expired kits can lead to incorrect results.
- Pregnant women should not use the simpli-COLLECT Swab Collection Kit without first discussing with their healthcare provider.
- The sample tube with liquid buffer contains detergent. The liquid in the tube may cause skin or eye irritation. If the liquid comes in contact with your skin or eyes, rinse with water for several minutes. Remove contact lenses, if present and easy to do, and continue rinsing. If irritation continues, seek medical advice.
- Protective eyewear is recommended while using this kit.
- Wash hands thoroughly after handling.
- Do not ingest.
- Avoid contact with skin and eyes.
- Only use the swab provided with the simpli-COLLECT Swab Collection Kit.
- A negative test result does not preclude the possibility of infection with other pathogens.
- The test system is not a substitute for visits to a healthcare provider. The information provided by the product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.
- Anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to the CDC website at www.cdc.gov/std/).
- Contact a healthcare provider prior to collecting the sample if the user has a condition that makes it difficult to use the test (eg, problems with vision, handling the test components, or understanding test instructions or results).
- Accurate results are dependent on adequate product storage and adherence to the specimen collection and testing procedures.
- Failure to follow test procedures can lead to incorrect results.

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled with appropriate biosafety practices.[24,25]

The following warnings and precautions apply to: Transport Buffer	
WARNING	
H320	Causes eye irritation.
Prevention	
P264	Wash hands thoroughly after handling.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice / attention.

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.

Kit Storage

	Storage Temperature	Maximum Storage Time
Unopened	15°C to 30°C	Until expiration date

Kit storage is the same for both the simpli-COLLECT Urine and simpli-COLLECT Swab Collection Kits. simpli-COLLECT Collection Kits may be shipped at ambient temperature.

LABORATORY PROCEDURE

Materials Provided

- simpli-COLLECT Urine Collection Kits
- simpli-COLLECT Swab Collection Kits

Kit Materials Required But Not Provided

- Pre-paid mailing label for return. Contact information for the laboratory must be printed on the mailing label in order to meet shipping regulations.
  NOTE: A fast, reliable shipping service is recommended to ensure the collected sample is received by laboratory within 6 days of sample collection.

Assay Materials Required But Not Provided

- 09N17-095 Alinity m STI AMP Kit
- 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
- 09N49-012 Alinity m Pierceable Caps
- 09N17-03B (v2.00) or higher Alinity m STI Application Specification File
- Vortex mixer
- Calibrated pipettes capable of delivering 100 µL to 1000 µL
- Aerosol barrier pipette tips for 100 µL 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 Alinity m System, 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.

Preparing simpli-COLLECT Collection Kit for Patient Receipt

Inspect simpli-COLLECT Collection Kit for damage or leaking. Do not send to patient if kit is damaged, leaking, or if the kit box has been opened. Do not open kit box prior to sending to patient.

Assemble mailing pouch for patient receipt.

Include the following in the mailing pouch:

- simpli-COLLECT Collection Kit
- Pre-paid return mailing label
  NOTE: Contact information for the laboratory must be printed on mailing label.

Mail to patient's provided address.

Please note, each kit is labeled with a unique kit identifier which may be used for traceability purposes. It is located on the side of each kit box (same box the patient will use as the return box); the patient will place labels displaying the unique kit code on the sample tube and biohazard bag.

Upon Receipt of Specimen From Patient

Patients return the specimen to the laboratory in the return box (the same kit box sent to the patient). The return box includes a unique kit identifier (2D datamatrix barcode), which can be used for traceability purposes. Sample tubes containing the specimen arrive enclosed in the biohazard bag. Do not use specimens if the sample tube is damaged or if specimen has leaked from the tube.

The sample tube should arrive labeled with the patient's first and last name, date of birth, date of specimen collection, and the unique kit identifier. The name and date of birth are used to confirm patient identity. If the sample tube does not contain a label, it should be rejected.

The date of specimen collection on the sample tube should be checked upon receipt. Specimens must be received by the laboratory within 6 days of the specimen collection date. Specimens received greater than 6 days from the specimen collection date should be rejected, and a new specimen should be requested. Specimens may be received at any time of day within the 6 days, up to midnight on the sixth day.

If the sample tube label contains illegible content, the label on the biohazard bag may be referenced to confirm patient identity or date of collection.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Collection by the Patient

Vaginal swab specimens must be collected using the simpli-COLLECT Swab Collection Kit (List No. 09R02-001). Urine specimens must be collected using the simpli-COLLECT Urine Collection Kit (List No. 09N93-001). The samples are collected and mailed to the laboratory by the patients within 24 hours of collection using the instructions provided in the collection kit.

Specimen Preparation for Analysis by the Laboratory

simpli-COLLECT Swab Collection Kit and simpli-COLLECT Urine Collection Kit sample tubes should be labeled with the patient's name, date of birth, date of specimen collection, and a unique kit identifier (2D datamatrix barcode), which can be used for traceability purposes. If the sample tube does not contain a label, it should be rejected. The date of collection on the sample tube should be checked prior to testing. Specimen storage time is based on the date of collection.

Once received by the laboratory, simpli-COLLECT specimens may be stored per the instructions in the **Specimen Storage** section. Specimens must not exceed the maximum storage time listed in the **Specimen Storage** section prior to testing. Specimens may be tested at any time of day within the specimen stability claim, up to midnight on the maximum storage day.

simpli-COLLECT specimens are sent to the laboratory in a labeled biohazard bag. If the sample tube label contains illegible content, the label on the biohazard bag may be referenced to confirm patient identity and/or date of collection.

For swab specimens self-collected with the simpli-COLLECT Swab Collection Kit, only the orange-shaft swab provided in the kit should be used. A sample tube containing no swab, a different type of swab, or other foreign objects should not be used with the Alinity m STI Assay.

A sample tube received with the white tip not submerged in the buffer should not be used with the Alinity m STI Assay.

For urine specimens self-collected with the simpli-COLLECT Urine Collection Kit, ensure that the urine level falls within the indicated fill window of the Transport Tube. It may be necessary to partially remove the sample label to see the fill window if the patient obscured it. A sample tube containing an incorrect volume of urine or containing foreign objects should not be used with the Alinity m STI Assay.

Do not use specimens collected with the simpli-COLLECT Collection Kits if the sample tube is damaged or if specimen has leaked from the tube.

Specimen Type

simpli-COLLECT kits can be used to collect the specimen types listed below for testing on Alinity m STI Assay. Performance with other collection devices or specimen types has not been evaluated.

Collection Device	Specimen Type
simpli-COLLECT Swab Collection Kit	Vaginal Swab
simpli-COLLECT Urine Collection Kit	Female Urine
	Male Urine

NOTE: The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to use the correct specimen types for the assay.

Specimen Storage

Specimen	Temperature	Maximum Storage Time[a]
simpli-COLLECT Specimens	2°C to 30°C	14 days
	−25°C to −15°C	60 days[b]

[a] Maximum Storage Time is from date of specimen collection.
[b] Avoid more than 4 freeze thaw cycles

Specimen Shipping

simpli-COLLECT specimens should be shipped at ambient temperature.

simpli-COLLECT specimens must be received by the laboratory within 6 days of the specimen collection date. Specimens received greater than 6 days from the specimen collection date should be rejected, and a new specimen should be requested. Specimens may be received at any time of day within the 6 days, up to midnight on the sixth day.

Specimens must not exceed the maximum storage time listed in the **Specimen Storage** section prior to testing. simpli-COLLECT specimens may be tested at any time of day within the specimen stability claim, including up to midnight on the maximum storage day.

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 simpli-COLLECT specimens, do not touch the top of the pierceable caps to avoid contamination.

For vaginal specimens, do not remove the swab from the transport tube. The swab does not interfere with the instrument's ability to aspirate the sample.

If precipitate is observed in urine specimens in simpli-COLLECT Urine Collection sample tubes, heat the specimens at 37°C for 10 minutes and mix thoroughly to ensure uniformity.

Frozen Specimens

If urine or vaginal swab specimens collected in simpli-COLLECT Sample Tubes are stored frozen, they 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.

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 simpli-COLLECT Collection Kits 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.
- 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 **Alinity m STI 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 **Alinity m STI 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.
- 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.
- Clean the retention bar after each use.
- 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 control reagents are contained in single-use tubes with solid caps. Remove caps from the tube prior to use. Discard tubes after use.
- Refer to the Alinity m STI AMP Kit (09N17-095) package insert for additional procedural precautions before processing samples.

ALINITY M STI ASSAY PROCEDURE

For detailed instructions on assay procedure, refer to the Alinity m STI AMP Kit (09N17-095) package insert. 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 the control status. If control testing is required, refer to the **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 vaginal swab and male urine, any combination of the four assays can be selected for a given specimen.
- For female urine, only CT, NG and/or TV should be selected.

One PCR reaction can detect one or more pathogens with the Alinity m 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.

simpli-COLLECT 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 for specimen tubes allowable on the Alinity m System are summarized in the following table.

Tube Type	List No.	Minimum Volume Required
simpli-COLLECT Swab Collection Kit Sample Tube	09R02-001	0.35 mL
simpli-COLLECT Urine Collection Kit Sample Tube	09N93-001	0.35 mL

It is recommended that specimen tubes containing a swab are capped when tested. Urine specimens 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

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.

For information on Negative and Positive Controls, refer to the Alinity m STI AMP Kit package insert and the Alinity m STI CTRL Kit package insert.

For information on detection of assay inhibition and/or cell inadequacy, refer to the Alinity m STI AMP Kit package insert.

RESULTS

For Patients

Talk to your healthcare provider about your test results.

For Laboratorians

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.

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, Results 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

- Optimal performance of this kit requires appropriate specimen collection, handling, preparation, and storage. Refer to the **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** for additional information.
- The simpli-COLLECT Urine Collection Kit should only be used to collect urine samples. The simpli-COLLECT Swab Collection Kit should only be used to collect vaginal swab samples. Refer to the **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** for additional information.
- Pregnant women should not use the simpli-COLLECT Swab Collection Kit without first discussing with their healthcare provider.
- Vaginal swab sampling is not designed to replace cervical exams for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the self-collected vaginal swab specimen as a replacement for a pelvic exam.
- Vaginal swab samples are the preferred sample type for sexually transmitted infection testing in women. A urine sample is acceptable for women but may detect fewer infections when compared to vaginal swab samples.
- Assay interference may be observed in the presence of gel-based hand sanitizers at concentrations greater than 0.1% in simpli-COLLECT urine specimens and simpli-COLLECT vaginal swab specimens. Assay interference may also be observed in the presence of Vaseline® Intensive Care™ Deep Restore Lotion at concentrations greater than 0.5% in simpli-COLLECT urine specimens.

Refer to the Alinity m STI AMP Kit package insert for assay limitations.

SPECIFIC PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The limit of detection (LoD) for vaginal and urine specimens was determined by testing dilutions of CT, NG, TV, and MG organisms in pooled negative vaginal swab 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[26,27]). 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 vaginal and urine 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

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 and urine matrices.
- NG: 28 additional isolates at 7.5 CFU/mL. All isolates were detected at ≥95.0% across swab and urine matrices.
- TV: Strains Z070, Z158, and Z159 at 0.1 TV/mL. All strains were detected at ≥95.0% across swab and urine 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

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 (Campylobacter ureolyticus)	*Mycoplasma pneumoniae*
	*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	
Cryptococcus neoformans	*Neisseria meningitidis* Serogroup Y*
Dientamoeba fragilis[a]	*Neisseria perflava**
Entercoccus faecalis	*Neisseria polysaccharea**
Enterobacter aerogenes	*Neisseria sicca**
Enterobacter cloacae	*Neisseria subflava**
Escherichia coli	*Pentatrichomonas hominis*
Fusobacterium nucleatum	*Peptostreptococcus anaerobius*
Gardnerella vaginalis	*Prevotella bivia*
Haemophilus ducreyi[a]	*Propionibacterium acnes*
Herpes simplex virus I	*Proteus mirabilis*
Herpes simplex virus II	*Pseudomonas aeruginosa*
Human Immunodeficiency virus 1	*Staphylococcus aureus*
	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.

Evaluation of Potential Interfering Substances

The potential for interference in the Alinity m STI Assay was assessed with 35 substances that may be found in urine and vaginal swab samples (**Table 2**). Substances were diluted into pooled vaginal swab 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 2** for all positive and negative samples. Cycle number delays were observed for seminal fluid, γ-globulin, and glucose in urine, which could result in interference at lower target levels.

Table 2. Potentially Interfering Substances in Urogenital Specimens

Substance	Matrix[a]	Test Level
Blood	U, S	5.0% v/v
Norforms Deodorant Suppositories	U, S	0.25% w/v
Progesterone	U, S	20 ng/mL
Beta Estradiol	U, S	1.2 ng/mL
Leukocytes	U, S	10^6 cells/mL
Mucus	U	0.2 % v/v
	S	0.8 % v/v
Seminal Fluid	U[b], S	5.0% 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	3×10^4 CFU/mL
Staphylococcus saprophyticus (Urinary tract infection organism)	U	3×10^4 CFU/mL
Escherichia coli (Urinary tract infection organism)	U	3×10^4 CFU/mL
Ibuprofen	U	495.1 µg/mL
Phenazopyridine Hydrochloride	U	80 µg/mL
Clotrimazole Vaginal Cream	S	0.25% w/v
KY Jelly Personal Lubricant	S	0.25% w/v
Metronidazole	S	40.1 µg/mL
Miconazole-3	S	0.25% w/v
Monistat-1	S	0.25% w/v
Terconazole Vaginal Cream	S	0.25% w/v
Preparation H Hemorrhoidal Cream	S	0.25% w/v
Vagisil Anti-Itch Cream	S	0.25% w/v
Vagisil Moisturizing Gel	S	0.25% w/v
Povidone-Iodine Medicated Douche	S	0.25% w/v
Yeast Gard Douche	S	0.25% w/v
Vaginal Contraceptive Foam	S	0.25% w/v

[a] U = Urine, S = Swab

[b] Cycle number delays were observed for seminal fluid, γ-globulin, and glucose in urine, which could result in interference at lower target levels.

An additional study was conducted to assess the potential for interference in the Alinity m STI Assay with 11 substances that may be present on the hands of patients who use the simpli-COLLECT Swab Collection Kit or simpli-COLLECT Urine Collection Kit in a non-clinical setting (**Table 3**). Substances were diluted into pooled vaginal swab or pooled urine matrices. For each substance and matrix, both CT, NG, TV, and MG positive and negative samples were tested. The positive samples contained CT, NG, TV, and MG organisms. No interference was observed in the presence of any of the substances at the concentrations shown in **Table 4** for all positive and negative samples. Assay interference was observed in the presence of Purell Advanced Hand Sanitizer Sanitizing Gel and Germ-X Advanced Moisturizing Hand Sanitizer with Aloe at concentrations greater than 0.1% in both swab and urine samples. Assay interference was also observed in the presence of Vaseline Intensive Care Deep Restore Lotion at concentrations greater than 0.5% in urine samples.

Table 3. Potentially Interfering Hand Contaminants Evaluated in Swab and Urine matrices

Hand Contaminants	Matrix[a]	Test Level
Purell Advanced Hand Sanitizer Sanitizing Gel	S, U	0.1% v/v
Germ-X Advanced Moisturizing Hand Sanitizer with Aloe	S, U	0.1% v/v
Tap Water	S, U	1.0% v/v
Touchland Glow Mist	S, U	1.0% v/v
Honest Hand Sanitizer Spray	S, U	1.0% v/v
Meyer's Clean Day Hand Sanitizer	S, U	1.0% v/v
Vaseline Intensive Care Deep Restore Lotion	S	1.0% v/v
	U	0.5% v/v
CeraVe Daily Moisturizing Lotion	S, U	1.0% v/v
Aveeno Daily Moisturizing Body Lotion	S, U	1.0% v/v
Palmolive Fresh & Clean Dish Liquid	S, U	1.0% v/v
Softsoap, Aquarium	S, U	1.0% v/v

[a] U = Urine, S = Swab

Competitive Interference

A competitive interference study was conducted to challenge the performance of the Alinity m STI Assay with swab 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 3.0×10^5 EB/mL for CT, 1.6×10^4 CFU/mL for NG, 6.0×10^4 TV/mL for TV, and 1.1×10^6 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 urine and swab 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 4**). 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 5, 6, 7,** and **8**, respectively.

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

Table 5. Within Laboratory Precision: CT 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	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 2 X 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%	....	....	....	....	....	....	....	....	....	....	....	....	....

[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 6. 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%	....	....	....	....	....	....	....	....	....	....	....	....	....

[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 7. 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%	....	....	....	....	....	....	....	....	....	....	....	....	....

[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 8. Within Laboratory Precision: MG 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	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 6.2×10^5 EB/mL CT, 1.6×10^4 CFU/mL NG, 6.0×10^4 TV/mL TV and 1.1×10^6 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 6.2×10^5 EB/mL CT, 1.6×10^4 CFU/mL NG, 6.0×10^4 TV/mL TV and 1.1×10^6 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 analytes were 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%).

simpli-COLLECT Specimen Shipping Stability

simpli-COLLECT specimen shipping stability was evaluated by subjecting vaginal swab and urine samples to simulated summer and winter shipping profiles. The shipping profiles included extreme temperature conditions that may be experienced during shipment at ambient conditions. For each matrix and shipping profile, CT, NG, TV, and MG negative samples and CT, NG, TV, and MG positive samples were tested. The study demonstrated that simpli-COLLECT vaginal swab and urine specimens are stable after extreme shipping conditions.

Reproducibility

Reproducibility performance of the Alinity m STI Assay was evaluated by testing panel members in urine and swab 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 9, 10, 11, and 12,** respectively.

Table 9. Reproducibility Analysis: CT Results

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

[a] N: Total number of replicates

[b] n: Number of replicates with detectable analyte for positive panel and non-detected for negative panel; the number of replicates were used 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 10. 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%	....	....	....	....	....	....	....	....	....	....	....

[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 11. 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%	....	....	....	....	....	....	....	....	....	....	....

[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 12. 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

Performance characteristics of the Alinity m STI Assay with vaginal and urine specimens were established in multicenter clinical studies conducted in the United States. For details on the study designs, refer to the Alinity m STI Assay package insert.

Alinity m STI Assay results from vaginal swab and male urine specimens were compared to a patient infected status (PIS) for determination of clinical sensitivity and specificity. Alinity m STI Assay results from female urine were compared to a urine composite comparator algorithm (CCA) for determination of positive agreement and negative agreement. Refer to the Alinity m STI Assay package insert for details.

Tables 13a, 14a, 15a, and 16 show the clinical sensitivity and specificity of the Alinity m STI Assay for detection of CT, NG, TV, and MG, respectively, for self-collected vaginal swabs and male urine. **Tables 13b, 14b, and 15b** show the positive agreement and negative agreement for detection of CT, NG, and TV for female urine.

Clinical Summary

With vaginal swab specimens, the Alinity m STI Assay demonstrated 98.5% sensitivity (the test's ability to correctly identify an individual with a disease) and 99.3% specificity (the test's ability to correctly identify an individual who does not have a disease) for detection of *Chlamydia trachomatis* (CT), 100.0% sensitivity and 99.7% specificity for detection of *Neisseria gonorrhoeae* (NG), 99.4% sensitivity and 97.8% specificity for detection of *Trichomonas vaginalis* (TV), and 95.4% sensitivity and 98.6% specificity for detection of *Mycoplasma genitalium* (MG).

With male urine, the Alinity m STI Assay demonstrated 97.2% sensitivity and 99.5% specificity for detection of CT, 100.0% sensitivity and 99.9% specificity for detection of NG, 98.7% sensitivity and 99.2% specificity for detection of TV, and 98.1% sensitivity and 97.5% specificity for detection of MG.

With female urine, the Alinity m STI Assay demonstrated 96.7% positive agreement (the test's ability to correctly identify a urine sample with an infection) and 99.8% negative agreement (the test's ability to correctly identify a urine sample that does not have an infection) for detection of CT, 98.0% positive agreement and 99.9% negative agreement for detection of NG, and 97.7% positive agreement and 99.1% negative agreement for detection of TV.

CT Performance

Table 13a. 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	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
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

TP = true positive, FP = false positive, TN = true negative, FN = false negative

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 13b. 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 14a. 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	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
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

TP = true positive, FP = false positive, TN = true negative, FN = false negative

Table 14b. 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 15a. 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	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
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

TP = true positive, FP = false positive, TN = true negative, FN = false negative

Table 15b. 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 16. 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	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
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

TP = true positive, FP = false positive, TN = true negative, FN = false negative

Refer to the Alinity m STI Assay AMP Kit package insert for details on the numbers of specimens in all combinations of PIS, CCA, individual comparator results, and Alinity m STI Assay results.

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KEY TO SYMBOLS

REF	Reference Number
simpli-COLLECT SWAB COLLECTION KIT	simpli-COLLECT Swab Collection Kit
simpli-COLLECT URINE COLLECTION KIT	simpli-COLLECT Urine Collection Kit
MAILING POUCH	Mailing Pouch
	Do Not Re-use
LOT	Lot Number
INFORMATION FOR USA ONLY	Information for USA Only
IVD	In Vitro Diagnostic Medical Device
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
Rx ONLY	For Prescription Use Only
	Sufficient For <n> Tests
	Temperature Limit
	Consult Instructions For Use or Consult Electronic Instructions For Use
	Expiration Date
UNIQUE KIT ID	Unique Kit Identifier
	Do Not Use If Package Is Damaged and Consult Instructions for Use
	Recyclable
	Biological Risks
MAX	Minimum / Maximum Urine Fill Volume
MIN	
STORE AT	Store At
	Peel Here
AMP TRAY	AMP TRAY
ACT TRAY	ACT TRAY
UNIT	Unit

	Health Hazard
	Exclamation Mark
	Caution
	Manufacturer

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