March 3, 2023

Abbott Molecular Inc.
Paul Matushek
Associate Director Regulatory Affairs
1300 E Touhy Ave
Des Plaines, Illinois 60018

Re: K222379
Trade/Device Name: Alinity m STI Assay
Regulation Number: 21 CFR 866.3393
Regulation Name: Device To Detect Nucleic Acids From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections And Associated Resistance Marker(S)
Regulatory Class: Class II
Product Code: QEP, OUY, LSL, MKZ
Dated: August 4, 2022
Received: August 5, 2022

Dear Paul Matushek:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

Himani Bisht -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222379

Device Name
Alinity m STI Assay

Indications for Use *(Describe)*
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 the 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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Section 5: 510(k) Summary

Table of Contents

1.0 510(k) Summary

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

1.1 Submitter

Applicants Name and Address:	Abbott Molecular Inc. 1300 E. Touhy Ave Des Plaines, IL 60018
Contact Person:	Paul Matushek Associate Director Regulatory Affairs Abbott Molecular, Inc. 1300 E. Touhy Avenue Des Plaines, IL 60018 Phone: 224-361-7331 Fax: 224-361-7269
Date Prepared:	March 1, 2023

1.2 Device Information

Trade Name	Regulation Name	Classification Product Code	Regulation Number	Class
Alinity m STI Assay	Nucleic Acid Detection System For Non-Viral Microorganism(s) Causing Sexually Transmitted Infections	QEP	866.3393	II

1.3 Predicate Device

Device Name	Predicate Device	510(k)	Cleared
Alinity m STI Assay	Alinity m STI Assay	K202977	04/29/2022

1.4 Device Description

1.4.1 Alinity m STI Assay

The Alinity m STI Assay utilizes real time PCR to amplify and detect *Chlamydia trachomatis* (CT) ribosomal RNA sequences, *Neisseria gonorrhoeae* (NG) genomic DNA sequences, *Trichomonas vaginalis* (TV) ribosomal RNA sequences, *Mycoplasma genitalium* (MG) ribosomal RNA sequences, and human genomic DNA sequences that have been extracted from endocervical swab specimens, vaginal swab specimens, oropharyngeal swab specimens, rectal swab specimens, male and female urine specimens, and gynecological specimens preserved in PreservCyt Solution. Endocervical swab, vaginal swab, oropharyngeal swab, rectal swab, and urine specimens are collected with the Alinity m multi-Collect Specimen Transport Kit. PreservCyt specimens are transferred to a transport tube for processing on the Alinity m System.

This device is similar to the predicate device originally cleared (K202977). It does not introduce any changes to the Alinity m STI Assay reagents, sample processing, assay procedure, and data reduction. This device is updating the previous FDA-cleared Intended Use (K202977) to include claims for the following specimens for the following analytes:

- CT: Gynecological specimens in ThinPrep PreservCyt Solution, female urine
- NG: Female urine

Two studies were initiated to support these claims (refer to **Section 1.7.2.)** This supplemental data was used with data previously obtained from the Alinity m STI Assay clinical testing studies submitted in K202977.

The steps of the Alinity m STI Assay consist of sample preparation, RT-PCR assembly, amplification/detection, and result calculation and reporting. All stages of the Alinity m STI Assay procedure are executed automatically by the Alinity m System. No intermediate processing or transfer steps are performed by the user. The Alinity m System is designed to be a random-access analyzer that can perform the Alinity m STI Assay in parallel with other Alinity m assays on the same instrument.

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

- Alinity m STI AMP Kit (List No. 09N17-095) consists of multi-well amplification plates containing lyophilized, unit-dose RT-PCR amplification/detection reagents and multi-well activator plates containing liquid, unit-dose activation reagents (MgCl2, TMAC, and KCl). The intended storage condition for the Alinity m STI AMP Kit is 2°C to 8°C.
- Alinity m STI CTRL Kit (List No. 09N17-085) consists of negative controls and positive controls, each supplied as liquid in single-use tubes. The intended storage condition for the Alinity m STI Control Kit is -25°C to -15°C.

Nucleic acids from specimens are extracted automatically onboard the Alinity m System 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 Ethanol supplied by customers, and Alinity m Diluent Solution. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash and elution. The resulting purified nucleic acids are then combined with the liquid unit-dose activator reagent, lyophilized unit-dose Alinity m STI amplification reagents, and Alinity m Vapor Barrier Solution, and transferred by the instrument to an amplification/detection module for reverse transcription, PCR amplification, and real-time fluorescence detection.

Assay controls are tested at or above an established minimum frequency of every 24 hours to help ensure that instrument and reagent performance remain satisfactory. During each control event, a negative control and a positive control are processed through sample preparation and RT-PCR procedures that are identical to those used for specimens. Assay controls are used to demonstrate proper sample processing and assay validity. The CTRL kit configuration includes 12 vials at 0.47mL of both the Alinity m STI Negative and Positive CTRL.

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

inhibitors are present in the sample. The β-globin control and internal control are both used to demonstrate assay validity.

The Alinity m STI Assay also utilizes the following accessories:

- Alinity m STI Assay Application Specification File, List No. 09N17-03A
- Alinity m System and System Software, List No. 08N53-002
- Alinity m Sample Prep Kit 1, List No. 09N18-001
- Alinity m multi-Collect Specimen Collection Kit, List No. 09N19-015
- Alinity m Tubes and Caps, List No. 09N49:
  - Alinity m Transport Tube Pierceable Capped, List No. 09N49-010
  - Alinity m Transport Tube, List No. 09N49-011
  - Alinity m Pierceable Cap, List No. 09N49-012
- Alinity m System Solutions, List No. 09N20:
  - Alinity m Lysis Solution, List No. 09N20-001
  - Alinity m Ethanol Solution, List No. 09N20-002
  - Alinity m Diluent Solution, List No. 09N20-003
  - Alinity m Vapor Barrier Solution, List No. 09N20-004

1.5 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 the 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.

1.6 Similarities and Differences to Predicate Devices

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

The Alinity m STI Assay has the same general intended uses as the predicate device. There are no technological differences between the Alinity m STI Assay (expanded claim discussed in this submission) and the predicate device (K202977); therefore, no new types of safety or effectiveness questions are raised.

These devices are similar in that there are no changes to the Alinity m STI Assay reagents, sample processing, assay procedure, and data reduction. This device is updating the previous FDA-cleared Intended Use (K202977) to include claims for the following specimens for the following analytes:

- CT: Gynecological specimens in ThinPrep PreservCyt Solution, female urine
- NG: Female urine

The primary similarities and differences between the Alinity m STI Assay and the predicate device are shown in **Table 1.**

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Device		
Description	**Subject Device**	**Predicate Device**
	Alinity m STI Assay	**Alinity m STI Assay (K202977)**
General Device Characteristics--Similarities		
Assay Type	Same	Qualitative Nucleic acid amplification
Assay Targets	Same	CT ribosomal RNA NG genomic DNA TV ribosomal RNA MG ribosomal RNA
Sample Preparation Procedure	Same	Automated
Amplification Technology	Same	Real-Time PCR
Assay Controls	Same	Negative Control Positive Control Internal Control (IC) Cellular Control (CC)

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Device		
Description	**Subject Device**	**Predicate Device**
	Alinity m STI Assay	**Alinity m STI Assay (K202977)**
General Device Characteristics--*Differences*		
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 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 the higher clinical sensitivity compared to endocervical swabs. If endocervical swab	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 RNA from *Chlamydia trachomatis* (CT), DNA from *Neisseria gonorrhoeae* (NG), ribosomal RNA from *Trichomonas vaginalis* (TV), and ribosomal RNA from *Mycoplasma genitalium* (MG), to aid in the diagnosis of disease(s) caused by infection from these organisms. The assay may be used to test the following specimens from symptomatic and asymptomatic individuals for the following analytes: CT: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, male urine, oropharyngeal swabs, and rectal swabs NG: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, male urine, oropharyngeal swabs, and rectal swabs TV: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, female urine, and male urine MG: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, and male urine A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to the higher clinical sensitivity compared to endocervical swabs. If endocervical swab

Table 1. Similarities and *Differences* Between Alinity m STI Assay and Nucleic Acid Amplification Tests-Predicate Device		
Description	**Subject Device**	**Predicate Device**
	Alinity m STI Assay	**Alinity m STI Assay (K202977)**
	specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected.	specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected.
Specimen Types	All listed under predicate and additionally: *Female urine (CT, NG)* *Gynecological specimens in PreservCyt Solution (CT)*	Endocervical swabs (CT, NG, TV, MG) Self-collected vaginal swabs (CT, NG, TV, MG) Clinician- collected vaginal swabs (CT, NG, TV, MG) Male urine (CT, NG, TV, MG) Female urine (TV) Gynecological specimens in PreservCyt Solution (NG, TV) Oropharyngeal swabs (CT, NG) Rectal swabs (CT, NG)

1.7 Performance Data

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

1.7.1 Specific Performance Characteristics

Verification studies were conducted previously to support the clearance of K202977. There is no change to Alinity m STI reagents manufacturing process or specifications, reagents, sample processing, assay procedure, and data reduction. Therefore, there is no need for additional verification studies for the Alinity m STI Assay. Urine specimens and PreservCyt specimens were previously assessed to support the clearance of K202977.

1.7.1.1 Analytical Sensitivity

Analytical Sensitivity was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.1.2 Inclusivity

Inclusivity was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.1.3 Evaluation of Potential Cross Reacting Microorganisms

Evaluation of Potential Cross Reacting Microorganisms was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.1.4 Evaluation of Potential Interfering Substances

Evaluation of Potential Interfering Substances was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.1.5 Competitive Interference Study

Competitive Interference study was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.1.6 Within-Laboratory Precision

Within-Laboratory Precision was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.1.7 Sample Carryover

Sample Carryover was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.2 Clinical Performance

1.7.2.1 Reproducibility

Reproducibility was conducted previously to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.2.2 Clinical Study Results - Urogenital Specimens

Performance characteristics of the Alinity m STI Assay with urogenital specimens were established in a multicenter clinical study conducted in the United States to support the clearance of K202977 (refer to Decision Summary for K202977). Claims for CT, NG, TV, and MG in vaginal swabs, endocervical swabs and male urine, for TV in female urine, and for NG and TV in gynecological specimens in ThinPrep PreservCyt solution were cleared. Additional data to obtain claims for CT and NG in female urine, and for CT in gynecological specimens in ThinPrep PreservCyt solution have been submitted in this 510(k). Please see supporting studies for these specimen types discussed in **Section 1.7.2.4,** and **Section 1.7.2.5.**

1.7.2.3 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 to support the clearance of K202977. Please refer to decision summary of K202977.

1.7.2.4 Alinity m STI Clinical Testing Study of Female Urine for CT and NG

Urine specimens were 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.

Specimen testing methods included the Alinity m STI Assay and comparator assays for CT and NG. Alinity m STI Assay testing was performed at 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.

For each subject, a Composite Comparator Algorithm (CCA) was determined for each analyte (CT and NG) based on the combined urine results from the comparator assays. A female subject 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 subject was excluded from the analysis for that analyte. Out of 2798 subjects, a total of 2785 CT and 2784 NG results were used in the analysis.

CT specimen-specific positive and negative agreement for female urine by symptom status are presented in **Table 2**. The CT clinical sensitivity based on the Patient Infect Status (PIS) was up to 12.3% lower in female urine than in vaginal swab specimens.

Table 2. CT Specimen-Specific Positive and Negative Agreement for Female Urine by Symptom Status

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

The specimen-specific NG status could not be determined for 1 subject. NG specimen-specific positive and negative agreement for female urine by symptom status are presented in **Table 3**. The NG clinical sensitivity based on the PIS was up to 9.8% lower in female urine than in vaginal swab specimens.

Table 3. NG Specimen-Specific Positive and Negative Agreement for Female Urine by Symptom Status

								PPA		NPA	
Analyte	**Specimen Type**	**Symptom Status**	**N**	**Alinity+ CCA+**	**Alinity+ CCA-**	**Alinity- CCA-**	**Alinity- CCA+**	**Estimate (95% CI)**	**n / N**	**Estimate (95% CI)**	**n / N**
NG	Female Urine	Symptomatic	714	15	0	699	0	100.0 (79.6,100.0)	15/15	100.0 (99.5,100.0)	699/699
		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

The numbers of specimens in all combinations of PIS, CCA, individual comparator results and the Alinity m STI Assay result are summarized. CT results for infected and non-infected female urine specimens are presented in **Table 4** and **Table 5**. NG results for infected and non-infected female urine specimens are presented in **Table 6** and **Table 7**.

Table 4. CT Analysis Per CCA POSITIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	No. 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 5. CT Analysis Per CCA NEGATIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	No. 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 6. NG Analysis Per CCA POSITIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	No. 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 7. NG Analysis Per CCA NEGATIVE FEMALE Urine Specimens

NAAT 1	NAAT 2	NAAT 3	Alinity m STI	No. 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

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 for CT, as determined by the Alinity m STI Assay for female urine specimen type, is presented by collection site and overall in **Table 8**. A summary of the positivity for NG, as determined by the Alinity m STI Assay for female urine specimen type, is presented by collection site and overall in **Table 9**.

Table 8. Positivity of CT Female Urine as Determined by Alinity m STI Assay by Collection Site

Site	% Positivity (Number Positive / Number Tested with Valid Results)
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 9. Positivity of NG Female Urine as Determined by Alinity m STI Assay by Collection Site

Site	% Positivity (Number Positive / Number Tested with Valid Results)
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

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 previously reported in K202977. Estimates of the PPV and NPV for the Alinity m STI Assay for urogenital specimens are presented in **Table 10** for CT and **Table 11** for NG. The predictive values for endocervical swab, self-collected vaginal swab, clinician-collected vaginal swab, and male urine in this table were previously reported in K202977. The shaded rows refer to data relevant to the new claims that have been added to the table.

Table 10. 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
CCV	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
SCV	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
E	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
PreservCyt	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
FU	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
MU	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 11. 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
CCV	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
SCV	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
E	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
PreservCyt	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
FU	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
MU	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

1.7.2.5 Comparator Testing of ThinPrep (PreservCyt) for CT

Performance characteristics of the Alinity m STI Assay with urogenital specimens were established in a multicenter clinical study conducted in the United States (refer to K202977). Each female subject in the study provided a gynecological specimen collected in PreservCyt Solution, which was tested with both the Alinity m STI Assay and up to 3 comparator NAATs. A total of 1939 specimens from the multicenter clinical study were included in the analysis.

The CT result of the Alinity m STI Assay was compared against a specimen-specific CT CCA status. The PreservCyt CCA 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 12**. The CT clinical sensitivity based on the PIS was up to 10.7% lower in PreservCyt than in vaginal swab specimens.

Table 12. CT Specimen-Specific Positive and Negative Agreement for ThinPrep (PreservCyt) by Symptom Status

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

The number of specimens in all combinations of CCA, individual comparator results and the Alinity m STI Assay result are summarized. CT results for infected and non-infected female subjects are presented in **Table 13** and **Table 14**.

Table 13. 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 14. 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

Expected Values

The prevalence of CT in this study was dependent on several factors including age, gender, clinic type, presence of symptoms, and the method of testing. A summary of the positivity for CT, as determined by the Alinity m STI Assay for each specimen type, is presented by collection site and overall in **Table 15**. The expected values for endocervical swab, self-collected vaginal swab, clinician-collected vaginal swab, and male urine in this table were previously reported in K202977.

Table 15. Positivity of CT as Determined by the Alinity m STI Assay by Specimen Type and Clinical Site for Urogenital Specimens

	% Positivity (# positive/# tested with valid results)				
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)

Table 15. Positivity of CT as Determined by the Alinity m STI Assay by Specimen Type and Clinical Site for Urogenital Specimens

	% Positivity (# positive/# tested with valid results)				
Site	**E**	**SCV**	**CCV**	**PreservCyt**	**MU**
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

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 previously reported in K202977. Estimates of the PPV and NPV for the Alinity m STI Assay for urogenital specimens are presented in **Table 16**. The predictive values for endocervical swab, self-collected vaginal swab, clinician-collected vaginal swab, and male urine in this table were previously reported in K202977. The shaded rows refer to data relevant to the new claims that have been added to the table.

Table 16. 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
CCV	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
SCV	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
E	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
PreservCyt	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
FU	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
MU	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

1.8 Conclusions Drawn from the Studies

The fundamental scientific technology of the Alinity m STI Assay is the same as the FDA cleared Alinity m STI Assay. The additional studies included in this submission support the inclusion of claims for the following specimens for the following analytes:

- CT: Gynecological specimens in ThinPrep PreservCyt Solution, female urine
- NG: Female urine

The Alinity m STI Assay is substantially equivalent to the predicate device.