510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K222379

B Applicant

Abbott Molecular Inc.

C Proprietary and Established Names

Alinity m STI Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QEP	Class II	21 CFR 866.3393 - Device To Detect Nucleic Acids From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections And Associated Resistance Marker(S)	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The Alinity m STI Assay was previously cleared (K202977). In this submission, performance data provided in support of adding the following claims to the Intended Use of the Alinity m STI Assay:

-Detection of *Chlamydia trachomatis* (CT) ribosomal RNA in female urine and in gynecological samples collected in PreservCyt solution; and
-Detection of *Neisseria gonorrhoeae* (NG) genomic DNA in female urine

No modifications were made to assay reagents, procedures, or devices used to collect samples or execute the assay.

B Measurand:

Chlamydia trachomatis (CT) -Ribosomal RNA
Neisseria gonorrhoeae (NG) -DNA
Trichomonas vaginalis (TV) – Ribosomal RNA
Mycoplasma genitalium (MG) – Ribosomal RNA

C Type of Test:

Qualitative, real time nucleic acid amplification test (NAAT)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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

• CT: vaginal swabs (clinician-collected and self-collected in a clinical setting), endocervical swabs, 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 and urine. If endocervical swab specimens or urine specimens test negative, testing with a vaginal swab may be indicated if M. genitalium infection is suspected.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For use with the Alinity m System

D Special Instrument Requirements:

Alinity m System needed to execute the Alinity m STI Assay

IV Device/System Characteristics:

A Device Description:

The Alinity m System is a fully integrated instrument that can process 300 samples per day from first sample aspiration to the last test result. The Alinity m System supports random access to assays as well as continuous loading of samples, reagents, and commodities. All the necessary reagents are pre-loaded onto the instrument prior to running samples.

All stages of the Alinity m STI Assay procedure are executed automatically by the Alinity m System. 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 steps of the Alinity m STI Assay consist of:

- Sample preparation and nucleic acid isolation from specimens
- RT-PCR assembly for relevant RNA targets (CT)
- PCR amplification and amplicon detection of specific targets
- Result calculation and reporting of quantitative or qualitative results.

The Alinity m STI Assay requires the following:

1. Alinity m STI AMP Kit (09N17-095) comprised of two separate reagent trays:
    - Alinity m STI AMP Tray 1 (4x96-well plates): contains lyophilized, unit-dose RT-PCR amplification and detection reagents
    - Alinity m STI ACT Tray 2 (4x96-well plates): contains liquid to rehydrate lyophilized reagents
2. Alinity m STI CTRL Kit 09N17-085 consists of single-use tubes containing liquid form:
    - Negative controls (12 tubes x 0.47mL)
    - Positive controls (12 tubes x 0.47mL)
3. Alinity m multi-Collect Specimen Collection Kit (List No. 09N19-015), with the following components:
    - One Transport Tube filled with 1.4 mL Alinity m Transport Buffer
    - One individually packaged Sterile Specimen Collection Swab
    - One disposable Transfer Pipette
4. Alinity m Sample Prep Kit 1 (List No. 09N18-001) is used to isolate nucleic acids from biological samples for analysis in PCR tests and consists of:
    - Alinity m Elution Buffer 1 which contains nuclease, protease free molecular grade water, and Tween 20 and preservatives
    - Alinity m Microparticles 1, which contains magnetic microparticles in 6.2 M Guanidine hydrochloride solution
5. Alinity m System Solutions (List No. 09N20) collectively encompass:

- 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)

6. Alinity m Tubes and Caps (List No. 09N49) collectively encompass:
    - Alinity m LRV Tube (List No. 09N49-001)
    - 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 Aliquot Tube (List No. 09N49-013)
7. Alinity m System (List No. 08N53-002)

Specimen Collection:

Endocervical, vaginal, oropharyngeal, and rectal swabs, female urine and male urine specimens must be collected using the Alinity m multi-Collect Specimen Collection Kit, according to the instructions for use. Gynecological specimens in PreservCyt Solution (Hologic Inc.) must be collected and handled according to the manufacturer's instructions. For PreservCyt specimens, only the aliquot taken from the PreservCyt vial prior to cytology processing must be transferred to an Alinity m Transfer Tube for processing on the Alinity m System.

B Principle of Operation:

Nucleic acids from specimens are extracted automatically on-board the Alinity m System using the Alinity m Sample Prep Kit 1, Alinity m Lysis Solution, Alinity m Diluent Solution, and Alinity m Ethanol. 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:

External assay controls are included in the Alinity m STI CTRL Kit. These controls are recommended to be tested at the minimum frequency of once 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.

Internal assay controls are used to demonstrate proper sample processing and assay validity.

- Endogenous cellular control (CC): Amplification and detection of human DNA sequence demonstrates proper sample processing and adequate sample input. The Alinity m STI amplification reagents include primers and probes that amplify and detect the CC.

- Exogenous internal control (IC): An exogenous, armored RNA sequence is included in the lyophilized Alinity m STI amplification reagents to confirm that no PCR inhibitors are present in the sample.

C Instrument Description Information:

1. Instrument Name:

   Alinity m System

2. Specimen Identification:

   The system includes a touchscreen where the operator directs the system to execute various tasks, and a barcode scanner for sample identification.

3. Specimen Sampling and Handling:

   The samples may be loaded on the system in any order. The system pipettor robot dispenses and aspirates liquids, as appropriate for each reaction. Sample handling and reagent transport is performed by a handler robot.

4. Calibration:

   No assay calibration is performed for the Alinity m STI panel.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Alinity m STI Assay

B Predicate 510(k) Number(s):
K202977

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222379	K202977
Device Trade Name	Alinity m STI	Alinity m STI
General Device Characteristic Similarities		
Assay Type	Same	Qualitative Nucleic Acid Amplification Test (NAAT)
Assay Targets	Same	CT ribosomal RNA NG genomic DNA TV ribosomal RNA

		MG ribosomal RNA
Sample Preparation Procedure	Same	Automated extraction and purification
Amplification Technology	Same	Real-time PCR
Assay Controls	Same	External and internal positive and negative controls
General Device Characteristic Differences		
Intended Use/Indications For Use	The Alinity m STI Assay is an *in vitro* polymerase chain reaction (PCR) assay for use with the automated Alinity m System for the direct, qualitative detection and differentiation of RNA from *Chlamydia trachomatis* (CT), *Trichomonas vaginalis* (TV), *Mycoplasma genitalium* (MG), and DNA from *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of urogenital disease(s) caused by infection from these organisms. The assay may be used to test the following specimens from symptomatic and asymptomatic individuals for the following analytes: CT: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, male urine, female urine, gynecological specimens in ThinPrep PreservCyt Solution, oropharyngeal swabs, and rectal swabs NG: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, male urine, female urine, oropharyngeal swabs, and rectal swabs TV: vaginal swabs (clinician-collected and self-collected in a	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), *Trichomonas vaginalis* (TV), *Mycoplasma genitalium* (MG), and DNA from *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of urogenital disease(s) caused by infection from these organisms. The assay may be used to test the following specimens from symptomatic and asymptomatic individuals for the following analytes: CT: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, male urine, oropharyngeal swabs, and rectal swabs NG: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, male urine, oropharyngeal swabs, and rectal swabs TV: vaginal swabs (clinician-collected and self-collected in a clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, female urine, and male urine

	clinical settings), endocervical swabs, gynecological specimens in ThinPrep PreservCyt Solution, female urine, and male urine MG: vaginal swabs (clinician collected and self-collected in a clinical settings), endocervical swabs, and male urine. A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher clinical sensitivity compared to endocervical swabs. If endocervical swab specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected.	MG: vaginal swabs (clinician collected and self-collected in a clinical settings), endocervical swabs, and male urine A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher clinical sensitivity compared to endocervical swabs. If endocervical swab specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected.
Specimen Types	Endocervical swabs (CT, NG, TV) Self-collected vaginal swabs (CT, NG, TV, MG) Clinician- collected vaginal swabs (CT, NG, TV, MG) Male urine (CT, NG, TV, MG) Female urine (CT, NG, TV) Gynecological specimens in PreservCyt Solution (CT, NG, TV) Oropharyngeal swabs (CT, NG) Rectal swabs (CT, NG)	Endocervical swabs (CT, NG, TV) 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)

VI Standards/Guidance Documents Referenced:

Class II Special Controls as per 21 CFR 866.3393

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Please refer to K202977 for the precision and reproducibility conducted in support of the Alinity m STI Assay. An updated precision information is provided below:

Updated CT Analyte Between-Day Precision Data from K202977

	Matrix			
	Urine		Swab	
Panel Description	**SD**	**% CV**	**SD**	**% CV**
CT High Pos (NG, TV & MG High Pos)	0.612	3.7	0.000	0.0

CT High Pos (NG, TV & MG at 2X LoD Claim)	0.404	2.4	0.040	0.2
CT at 2X LoD Claim (MG High Pos, NG & TV at 2X LoD Claim)	0.548	1.8	0.055	0.2
CT at 2X LoD Claim (TV High Pos, NG & MG at 2X LoD Claim)	0.281	0.9	0.062	0.2
CT at 2X LoD Claim (NG High Pos, TV & MG at 2X LoD Claim)	0.216	0.7	0.025	0.1
CT at 2X LoD Claim (NG, TV & MG at 2X LoD Claim)	0.298	1.0	0.044	0.1
CT at 2X LoD Claim (CT only)	0.151	0.5	0.023	0.1
CT at LoD Claim	0.352	1.1	0.038	0.1
CT at Sub-LoD (High Negative)	0.339	0.9	0.000	0.0
CT Negative	....	....	....	....

Updated NG Analyte Between-Day Precision Data from K202977

	Matrix					
	Urine		Swab		PreservCyt	
Panel Description	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
NG High Pos (CT, TV & MG High Pos)	0.227	1.0	0.076	0.4	0.000	0.0
NG High Pos (CT, TV & MG at 2X LoD Claim)	0.279	1.2	0.236	1.1	0.038	0.2
NG at 2X LoD Claim (MG High Pos, CT & TV at 2X LoD Claim)	0.262	0.8	0.127	0.4	0.000	0.0
NG at 2X LoD Claim (TV High Pos, CT & MG at 2X LoD Claim)	0.203	0.7	0.175	0.6	0.071	0.2
NG at 2X LoD Claim (CT, TV & MG at 2X LoD Claim)	0.245	0.8	0.091	0.3	0.084	0.3
NG at 2X LoD Claim (CT High Pos, TV & MG at 2X LoD Claim)	0.233	0.7	0.158	0.5	0.000	0.0
NG at 2X LoD Claim (NG only)	0.150	0.5	0.052	0.2	0.092	0.3
NG at LoD Claim	0.280	0.9	0.090	0.3	0.000	0.0
NG at Sub-LoD (High Negative)	0.000	0.0	0.000	0.0	0.000	0.0
NG Negative	....	....	....	....	....	....

Updated TV Analyte Between-Day Precision Data from K202977

	Matrix					
	Urine		Swab		PreservCyt	
Panel Description	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
TV High Pos (CT, NG & MG High Pos)	0.626	6.4	0.121	1.2	0.000	0.0
TV High Pos (CT, NG & MG at 2X LoD Claim)	0.638	6.5	0.139	1.4	0.000	0.0
TV at 2X LoD Claim (MG High Pos, CT & NG at 2X LoD Claim)	0.243	0.9	0.000	0.0	0.000	0.0
TV at 2X LoD Claim (NG High Pos, CT & MG at 2X LoD Claim)	0.305	1.1	0.157	0.5	0.054	0.2
TV at 2X LoD Claim (CT High Pos, NG & MG at 2X LoD Claim)	0.398	1.4	0.113	0.4	0.030	0.1
TV at 2X LoD Claim (CT, NG & MG at 2X LoD Claim)	0.302	1.1	0.141	0.5	0.000	0.0
TV at 2X LoD Claim (TV only)	0.289	1.1	0.063	0.2	0.118	0.4
TV at LoD Claim	0.329	1.1	0.096	0.3	0.115	0.4
TV at Sub-LoD (High Negative)	0.205	0.6	0.160	0.5	0.124	0.4
TV Negative	....	....	....	....	....	....

Updated MG Analyte Between-Day Precision Data from K202977

	Matrix			
	Urine		Swab	
Panel Description	**SD**	**% CV**	**SD**	**% CV**
MG High Pos (CT, NG & TV High Pos)	0.612	3.0	0.000	0.0
MG High Pos (CT, NG & TV at 2X LoD Claim)	0.257	1.2	0.000	0.0
MG at 2X LoD Claim (TV High Pos, CT & NG at 2X LoD Claim)	0.598	1.9	0.057	0.2
MG at 2X LoD Claim (NG High Pos, CT & TV at 2X LoD Claim)	0.317	1.0	0.082	0.3
MG at 2X LoD Claim (CT High Pos, NG & TV at 2X LoD Claim)	0.443	1.4	0.037	0.1
MG at 2X LoD Claim (CT, NG & TV at 2X LoD Claim)	0.352	1.1	0.048	0.2
MG at 2X LoD Claim (MG only)	0.257	0.8	0.023	0.1
MG at LoD Claim	0.479	1.5	0.011	0.0
MG at Sub-LoD (High Negative)	0.819	2.1	0.000	0.0
MG Negative	....	....	....	....

In support of the CT in PreservCyt Specimen claim, the following within-lab precision and reproducibility data was also provided.

Within Laboratory Precision Analysis of CT in PreservCyt					Within Run		Between Run		Between Day		Within Lab[c]		Between Instrument/Lot		Total[d]	
Panel Description	**N[a]**	**n[b]**	**% Agreement (n/N)**	**Mean CN**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
CT High Pos (NG, TV & MG High Pos)	144	144	100.0%	17.21	0.181	1.0	0.095	0.6	0.024	0.1	0.205	1.2	0.089	0.5	0.224	1.3
CT High Pos (NG, TV & MG at 2X LoD Claim)	144	144	100.0%	17.66	0.102	0.6	0.073	0.4	0.000	0.0	0.125	0.7	0.113	0.6	0.169	1.0
CT at 2X LoD Claim (MG High Pos, NG & TV at 2X LoD Claim)	144	144	100.0%	29.77	0.102	0.3	0.049	0.2	0.036	0.1	0.118	0.4	0.082	0.3	0.144	0.5
CT at 2X LoD Claim (TV High Pos, NG & MG at 2X LoD Claim)	144	144	100.0%	30.77	0.162	0.5	0.144	0.5	0.000	0.0	0.216	0.7	0.196	0.6	0.292	0.9
CT at 2X LoD Claim (NG High Pos, TV & MG at 2X LoD Claim)	144	144	100.0%	29.83	0.220	0.7	0.032	0.1	0.000	0.0	0.222	0.7	0.149	0.5	0.268	0.9
CT at 2X LoD Claim (NG, TV & MG at 2X LoD Claim)	144	144	100.0%	30.33	0.607	2.0	0.000	0.0	0.126	0.4	0.620	2.0	0.000	0.0	0.620	2.0
CT at 2X LoD Claim (CT only)	144	144	100.0%	31.09	0.402	1.3	0.141	0.5	0.000	0.0	0.426	1.4	0.180	0.6	0.462	1.5
CT at LoD Claim	144	144	100.0%	31.22	0.721	2.3	0.000	0.0	0.300	1.0	0.781	2.5	0.000	0.0	0.781	2.5
CT at Sub-LoD (High Negative)	144	40	27.8%	37.36	0.228	0.6	0.348	0.9	0.125	0.3	0.434	1.2	0.224	0.6	0.489	1.3
CT Negative[e]	576	576	100%	….	….	….	….	….	….	….	….	….	….	….	….	….

[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/Day, Between-Run/Day and Between-Day Components.

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

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

Reproducibility Analysis of CT in PreservCyt					Within Run		Between Run		Between Lot		Between Site		Total[c]	
Panel Description	**N[a]**	**n[b]**	**% Agreement (n/N)**	**Mean CN**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
CT High Pos (NG, TV & MG High Pos)	150	150	100.0%	17.40	0.212	1.2	0.105	0.6	0.081	0.5	0.080	0.5	0.263	1.5
CT High Pos (NG, TV & MG at 2X LoD Claim)	150	150	100.0%	17.64	0.333	1.9	0.175	1.0	0.197	1.1	0.000	0.0	0.424	2.4
CT at 2X LoD Claim (MG High Pos, NG & TV at 2X LoD Claim)	150	150	100.0%	30.07	0.216	0.7	0.141	0.5	0.162	0.5	0.000	0.0	0.305	1.0
CT at 2X LoD Claim (TV High Pos, NG & MG at 2X LoD Claim)	150	150	100.0%	29.92	0.153	0.5	0.097	0.3	0.071	0.2	0.047	0.2	0.200	0.7
CT at 2X LoD Claim (NG High Pos, TV & MG at 2X LoD Claim)	150	150	100.0%	31.14	0.223	0.7	0.152	0.5	0.095	0.3	0.124	0.4	0.312	1.0
CT at 2X LoD Claim (NG, TV & MG at 2X LoD Claim)	150	150	100.0%	30.57	0.650	2.1	0.321	1.1	0.000	0.0	0.137	0.4	0.738	2.4
CT at 2X LoD Claim (CT only)	150	150	100.0%	31.63	0.779	2.5	0.184	0.6	0.457	1.4	0.000	0.0	0.921	2.9
CT at LoD Claim	150	150	100.0%	31.73	0.935	2.9	0.163	0.5	0.000	0.0	0.158	0.5	0.962	3.0
CT at Sub-LoD (High Negative)	150	37	24.7%	37.33	0.646	1.7	0.215	0.6	0.740	2.0	0.000	0.0	1.005	2.7
CT Negative[d]	600	598	99.7%	….	….	….	….	….	….	….	….	….	….	….

[a] N: Total number of replicates

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

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

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

The provided reproducibility data supported the CT in PreservCyt claim.

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

   Please refer to K202977 for the Analytical specificity/interference studies conducted in support of the Alinity m STI Assay.

4. Assay Reportable Range:

   Not applicable

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

   Please refer to K202977 for the traceability, stability, and expected values studies conducted in support of the Alinity m STI Assay.

6. Detection Limit:

   Please refer to K202977 for the LoD studies conducted in support of the Alinity m STI Assay.

7. Assay Cut-Off:

   Please refer to K202977 for the Assay cut-off studies conducted in support of the Alinity m STI Assay.

8. Carry-Over:

   Please refer to K202977 for the Carry-over studies conducted in support of the Alinity m STI Assay.

B Comparison Studies:

See Clinical Studies section below.

1. Matrix Comparison:

   Please refer to K202977.

C Clinical Studies:

Data from two studies were provided to support the new claims in this submission. A prospective clinical study was initiated to acquire fresh female urine samples and assess the clinical performance of the Alinity m STI Assay in detection of CT and NG in female urine. Separately, archived, prospectively collected samples from the previous clinical study (in support of K202977) were used to assess the performance of the device in detecting CT in gynecological samples collected in PreservCyt.

The clinical performance of the Alinity m STI Assay was assessed using a composite comparator algorithm (CCA) to establish specimen-specific agreement with FDA cleared assays. The positive percent agreement (PPA) and negative percent agreement (NPA) was determined by the CCA using two NAATs (NAAT1 and NAAT2). If the two comparator assays did not agree or if one comparator result was missing or indeterminate, a third tiebreaker NAAT (NAAT3) was used. A specimen CCA was categorized as "Positive" when two of the three comparator results were positive, and "Negative" when two of the three comparator results were negative.

Specimen-specific Agreement Performance of Alinity m STI Assay for CT and NG in female urine:

Urine specimens were prospectively collected from female subjects 14 years of age or older at 14 geographically diverse sites. A total of 2798 asymptomatic and symptomatic subjects were enrolled. Each subject provided one urine specimen. Samples were aliquoted into the Alinity m multi-Collect Specimen Collection Kit and comparator collection devices and shipped to appropriate testing laboratories for Alinity m STI Assay and comparator testing.

Alinity m STI Assay testing was performed at external clinical testing sites representing the intended users of the Alinity m STI Assay and System. Comparator testing was performed at one external site. The total duration of Alinity m STI Assay testing was from November 23, 2021 to June 2, 2022.

Of 2798 specimens, 11 specimens were excluded due to sample handling errors, leaving 2787 specimens for testing. Two specimens generated invalid final results for CT and NG while one additional specimen had an indeterminate CCA result for NG, leaving a total of 2785 results for CT and 2784 results for NG used in calculating the performance.

Results of CT and NG in Female Urine CCA Study:

When comparing Alinity m STI Assay results against the CCA result, the following PPA and NPA values were reported for CT and NG detection in female urine (summarized in Table 1 and 2):

Table 1: Specimen-specific agreement for Alinity m STI Assay for CT in female urine using CCA analysis

Symptom Status	N	Alinity+ CCA+	Alinity- CCA+	Alinity- CCA-	Alinity+ CCA-	n/N	PPA (95% CI)	n/N	NPA (95% CI)
Symptomatic	714	47	2	664	1	47/49	95.9% (86.3, 98.9)	664/665	99.8% (99.2, 100.0)
Asymptomatic	2071	130	4	1934	3	130/134	97.0% (92.6, 98.8)	1934/1937	99.8% (99.5, 99.9)
Total	2785	177	6	2598	4	177/183	96.7% (93.0, 98.5)	2598/2602	99.8% (99.6, 99.9)

The overall PPA and NPA values, for symptomatic and asymptomatic subjects combined, are 96.7% and 99.8%. 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: Specimen-specific agreement for Alinity m STI Assay for NG in female urine using CCA analysis

Symptom Status	N	Alinity+ CCA+	Alinity- CCA+	Alinity- CCA-	Alinity+ CCA-	n/N	PPA (95% CI)	n/N	NPA (95% CI)
Symptomatic	714	15	0	699	0	15/15	100.0% (79.6, 100.0)	699/699	100.0% (99.5, 100.0)
Asymptomatic	2070	33	1	2034	2	33/34	97.1% (85.1, 99.5)	2034/2036	99.9% (99.6, 100.0)
Total	2784	48	1	2733	2	48/49	98.0% (89.3, 99.6)	2733/2735	99.9% (99.7, 100.0)

The overall PPA and NPA values, for symptomatic and asymptomatic subjects combined, are 98% and 99.9%. The NG clinical sensitivity based on the PIS was up to 9.8% lower in female urine than in vaginal swab specimens.

Specimen-specific Agreement Performance of Alinity m STI Assay for CT in PreservCyt:

Previously collected gynecological samples stored in ThinPrep (PreservCyt) were used for CCA testing. The samples were prospectively collected and tested with the Alinity m STI Assay in the clinical study used to support K202977.

PreservCyt gynecological samples were aliquoted into the respective comparator NAAT transfer kits, shipped to, and tested at CLIA certified sites (one site per comparator NAAT). The CCA result (2/3 rule determination) for these samples was compared to Alinity m STI Assay test results.

Results of CT in PreservCyt CCA Study:

When comparing Alinity m STI Assay results against the CCA result, the following PPA and NPA values were reported for CT in PreservCyt samples as summarized in Table 3:

Table 3: Specimen-specific agreement for Alinity m STI Assay for CT in PreservCyt using CCA analysis

Symptom Status	N	Alinity+ CCA+	Alinity- CCA+	Alinity- CCA-	Alinity+ CCA-	n/N	PPA (95% CI)	n/N	NPA (95% CI)
Symptomatic	714	66	1	885	1	66/67	98.5% (92.0, 99.7)	885/886	99.9% (99.4, 100.0)
Asymptomatic	2070	52	1	927	6	52/53	98.1% (90.1, 99.7)	927/933	99.4% (98.6, 99.7)
Total	2784	118	2	1812	7	118/120	98.3% (94.1, 99.5)	1812/1819	99.6% (99.2, 99.8)

The overall PPA and NPA values, for symptomatic and asymptomatic subjects combined, are 98.3% and 99.6%. The CT clinical sensitivity based on the PIS was up to 10.7% lower in PreservCyt than in vaginal swab specimens.

Positive and Negative Predictive Values for CT and NG Analytes in Tested Specimen Types

The positive and negative predictive values (PPV and NPV, respectively) for CT and NG in female urine and CT in gynecological samples stored in PreservCyt were calculated for hypothetical prevalence values ranging from 0.5% to 30% (see Tables 4 and 5).

Table 4. 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; PreservCyt = Gynecological samples stored in PreservCyt; FU= Female Urine; MU = Male Urine. Shaded cells (data supporting the new claims in this submission) are added to tables originally produced for the predicate device, K202977.

Table 5. 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; PreservCyt = Gynecological samples stored in PreservCyt; FU= Female Urine; MU = Male Urine. Shaded cells (data supporting the new claims in this submission) are added to tables originally produced for the predicate device, K202977.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Positivity of CT and NG in Female Urine at Collection Sites:

A summary of the positivity for CT and NG in female urine and CT in PreservCyt specimens, as determined by the Alinity m STI Assay for each specimen type, is presented by collection site and overall in Table 6 and 7.

Table 6: Positivity of Analytes in Female Urine samples as determined by Alinity m STI Assay by Collection Site

	% Positivity (No. Pos / No. Tested)	
Site	**CT**	**NG**
01	1.9 (2/105)	1.0 (1/105)
02	8.4 (33/394)	1.8 (7/394)
03	5.2 (5/96)	1.0 (1/96)
04	11.8 (70/594)	3.5 (21/594)
05	4.9 (23/466)	1.3 (6/466)
06	9.4 (8/85)	1.2 (1/85)
07	2.3 (7/305)	1.0 (3/305)
08	6.0 (23/383)	2.4 (9/382)
09	1.9 (2/104)	0.0 (0/104)
10	1.8 (2/109)	0.0 (0/109)
11	6.5 (2/31)	0.0 (0/31)
12	4.0 (3/75)	1.3 (1/75)
13	0.0 (0/20)	0.0 (0/20)
14	5.6 (1/18)	0.0 (0/18)
All	6.5 (181/2785)	1.8 (50/2784)

Positivity of CT in Gynecological Samples Collected at Clinical Study Sites:

Table 7: Positivity of CT in PreservCyt Specimens as Determined by Alinity m STI Assay by Collection Site

	% Positivity (#positive/# tested)
Site	**PreservCyt**
01	2.8 (1/36)
02	3.4 (9/268)
03	2.7 (6/224)
04	15.8 (3/19)
05	6.8 (18/263)

06	0.0 (0/4)
07	2.9 (9/310)
08	1.9 (2/105)
09	9.3 (10/108)
10	5.7 (6/106)
11	0.0 (0/18)
12	4.2 (2/48)
13	6.8 (3/44)
14	0.0 (0/39)
15	8.1 (3/37)
16	11.8 (2/17)
17	0.0 (0/41)
18	0.0 (0/5)
19	11.1 (1/9)
20	-
21	6.1 (8/132)
22	2.9 (1/34)
23	9.8 (12/122)
24	2.6 (1/38)
25	10.6 (5/47)
26	7.4 (2/27)
27	6.0 (5/83)
28	11.7 (27/230)
29	7.0 (6/86)
30	20.0 (13/65)
31	12.7 (9/71)
32	9.8 (5/51)
33	25.5 (12/47)
All	6.6 (181/2734)

PreservCyt = gynecological samples stored in PreservCyt

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The proposed labeling for the following new claims added in this submission are acceptable:

CT in female urine
NG in female urine
CT in gynecological samples stored in ThinPrep (PreservCyt)

IX Conclusion:

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