January 30th, 2025

Abbott Molecular
Stacy Ferguson
Director Regulatory Affairs
1300 E Touhy Ave
Des Plaines, Illinois 60018

Re: K243410
Trade/Device Name: simpli-COLLECT STI Test
Regulation Number: 21 CFR 866.3385
Regulation Name: System For Detection Of Nucleic Acid From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections Using Home-Collected Specimens
Regulatory Class: Class II
Product Code: QYA
Dated: October 31, 2024
Received: November 1, 2024

Dear Stacy Ferguson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243410

Device Name

simpli-COLLECT STI Test

Indications for Use *(Describe)*

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.

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.

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510(k) Summary

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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:	Stacy Ferguson Director Regulatory Affairs Abbott Molecular, Inc. 1300 E. Touhy Avenue Des Plaines, IL 60018 Phone: 224-361-7449 Fax: 224-361-7269
Date Prepared:	January 29, 2025

1.2 Device Information

Trade Name	Regulation Name	Product Code	Regulation Number	Class
simpli-COLLECT STI Test	System for detection of nucleic acid from non-viral microorganism(s) causing STIs using specimens collected at home	QYA	866.3385	II

1.3 Predicate Devices

Predicate Device Name	510(k)	Date Cleared
Simple Test 2	DEN200070	11/15/2023

1.4 Device Description

1.4.1 simpli-COLLECT STI Test

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 (simpli-COLLECT Urine Collection Kit [09N93001] and the simpli-COLLECT Swab Collection Kit [09R02-001]).

This test system uses the Alinity m STI Assay (cleared under K202977 and K222379) for real time RT-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 vaginal swab specimens or male and female urine specimens.

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

- Alinity m STI AMP Kit (09N17-095), which 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 (09N17-085), which 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 −15°C to −25°C.

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.

Nucleic acids from specimens are extracted automatically on-board the Alinity m System using the Alinity m Sample Prep Kit 1, Alinity m Lysis Solution, Alinity m Ethanol Solution 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 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 0.47 mL of both the Alinity m STI Negative CTRL and Alinity m STI 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 AMP kit configuration includes 4 trays (96 tests per tray) of both an AMP TRAY 1 and ACT TRAY 2. The AMP Kit provides sufficient reagents for 384 tests.

1.4.2 simpli-COLLECT Collection Kits

The simpli-COLLECT Urine Collection Kit is used to collect, stabilize, and transport male urine specimens for the detection of *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis*, and *Mycoplasma genitalium*, and female urine

specimens for the detection of *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Each kit can be used to collect 1 urine specimen. The collected specimens are intended for testing with the Alinity m STI assay. The simpli-COLLECT Urine Collection Kit contains the following components: 1 Abbott Sample Collection pack, which contains 1 Alinity m Sample Tube with Liquid Buffer and 1 Transfer Pipette, 1 Tube and Bag Label Sheet, 1 Urine Cup/Urine Collection Cup, 1 simpli-COLLECT Urine Collection Kit Patient Instructions For Use, 1 Biohazard Bag with Absorbent Pad, 1 Tube and Cap Holder, and 1 simpli-COLLECT Urine Collection Kit Box.

The simpli-COLLECT Swab Collection Kit is used to collect, stabilize, and transport vaginal swab specimens for the detection *of Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis*, and *Mycoplasma genitalium*. Each kit can be used to collect 1 vaginal swab specimen. The collected specimens are intended for testing with the Alinity m STI assay. The simpli-COLLECT Swab Collection Kit contains the following components: 1 Abbott Swab Collection pack, which contains 1 Alinity m Sample Tube with Liquid Buffer and 1 Specimen Collection Swab, 1 Tube and Bag Label Sheet, 1 Biohazard Bag with Absorbent Pad, 1 Tube and Cap Holder, 1 simpli-COLLECT Swab Collection Kit Patient Instructions For Use, and 1 simpli-COLLECT Swab Collection Kit Box.

1.5 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.

1.6 Similarities and Differences to Predicate Device

1.6.1 Alinity m STI Assay

There are no technological differences between the simpli-COLLECT STI Test and the predicate device. The similarities and differences between the simpli-COLLECT STI Test and the predicate device are shown in **Table 1**; The differences are shown in *underlined italics.*

Table 1. Similarities and *Differences* Between Alinity m STI and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
	simpli-COLLECT STI Test	**Simple 2 Test (DEN00070)**
Conditions for use	*For prescription use only*	OTC-Over the Counter
Assay Type	Same	Qualitative
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.	The Simple 2 Test is intended for in vitro detection and identification of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC) in home-collected specimens which are shipped to a clinical laboratory for testing using the Aptima Combo 2 assay on the Panther System. This product is available over-the-counter (OTC) to consumers 18 years of age and older. The Simple 2 Test contains all the necessary components to collect urine from male patients (Simple 2 Urine Home Collection Kit [Penile]) or vaginal swabs from female patients (Simple 2 Swab Home Collection Kit [Vaginal]) in their home, or in similar environments, without supervision from a healthcare provider. The Simple 2 Test Collection Kits may also be used to self-collect specimens in a clinic. The testing is performed, as determined to be appropriate, based on the results of LetsGetChecked Suitability Questionnaire. This test system is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

Table 1. Similarities and *Differences* Between Alinity m STI and Predicate Device		
Feature	**Current Submission**	**Predicate Device**
	simpli-COLLECT STI Test	**Simple 2 Test (DEN00070)**
Specimen Collection and Trasport	**simpli-COLLECT Urine Collection Kit** **Simpli-COLLECT Swab Collection Kit**	**Simple Test 2 (Simple 2 Urine Home Collection Kit (Penile))** **Simple 2 Test Simple 2 Swab Home Collection Kit (Vaginal)**
Minimum Age of Users	*14 years*	18 years
Assay Targets	CT ribosomal RNA NG genomic DNA *TV ribosomal RNA* *MG ribosomal RNA*	CT ribosomal RNA NG genomic DNA
Technology/Dectection	*Real-Time Reverse Transcription-Polymerate Chain Reaction (RT-PCR)*	Target Capture (TC), Transcription-mediated Amplifcation (TMA), Dual Kinectic Assay (DKA)
Instrument System	*Alinity m System*	Panther System
Assay Controls	Internal Control (IC) Negative Control Positive Control	CT Positive/NG Negative Control CT Negative/NG Positive Control
Results Reporting	Positive, negative, and invalid. Initial invalid require retest.	Positive, negative, equivocal, and invalid. Initial equivocal and invalid require retest.

1.7 Performance Data

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

1.7.1 Specific Performance Characteristics

1.7.1.1 Precision (Repeatability/Reproducibility)

Precision studies were conducted previously to support the clearance of K202977. There are no changes to Alinity m STI reagents, sample processing, assay procedure, and data reduction; therefore, further precision studies were not necessary.

1.7.1.2 Analytical Sensitivity/Detection Limit

Analytical Sensitivity/Detection Limit studies were conducted previously to support the clearance of K202977. There are no changes to Alinity m STI reagents, sample processing, assay procedure, and data reduction; therefore, further Analytical Sensitivity/Detection Limit studies were not necessary.

1.7.1.3 Analytical Specificity/Interference

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

An additional study evaluating the potential for interference by hand contaminants was conducted for this submission. Please refer to **Section 1.7.1.3.1.**

1.7.1.3.1 Potentially Interfering Hand Contaminants

The potential for interference in the Alinity m STI assay was assessed with 11 potential hand contaminants (see **Table 2**). Hand contaminants were diluted into swab and urine matrices that were negative or positive for CT, NG, TV, and MG.

No interference was observed in the presence of the substances and concentrations listed in **Table 2**. Assay interference may be observed in the presence of Purell Advanced Hand Sanitizer at concentrations greater than 0.1% v/v in urine and swab matrix, Germ X

Advanced Moisturizing Hand Sanitizer with Aloe at concentrations greater than 0.1% v/v in urine and swab matrix, and Vasoline Intensive Care Deep Restore Lotion at concentrations greater than 0.5% v/v in urine matrix.

Limitations for assay use with Purell Advanced Hand Sanitizer Sanitizing Gel, Germ X advanced Moisturizing Hand Sanitizer with Aloe in swab and urine samples, and Vaseline Intensive Care Deep Restore Lotion in urine samples are reflected in assay labeling.

Table 2. Potentially Interfering Hand Contaminants Evaluated in Swab and Urine matrices.

Hand contaminants	Matrix	Highest concentration Tested with No Interference
Purell Advanced Hand Sanitizer Sanitizing Gel	Swab, Urine	0.1% v/v
Germ·X Advanced Moisturizing Hand Sanitizer with Aloe	Swab, Urine	0.1% v/v
Tap Water	Swab, Urine	1.0% v/v
Touchland Glow Mist	Swab, Urine	1.0% v/v
Honest Hand Sanitizer Spray	Swab, Urine	1.0% v/v
Meyer's Clean Day Hand Sanitizer	Swab, Urine	1.0% v/v
Vaseline Intensive Care Deep Restore Lotion	Swab	1.0% v/v
	Urine	0.5% v/v
CeraVe Daily Moisturizing Lotion	Swab, Urine	1.0% v/v
Aveeno Daily moisturizing body lotion	Swab, Urine	1.0% v/v
Palmolive Fresh & Clean Dish Liquid	Swab, Urine	1.0% v/v
Softsoap, Aquarium	Swab, Urine	1.0% v/v

1.7.1.4 Assay Cut-Off

Assay cut-off studies were conducted previously to support the clearance of K202977. There are no changes to Alinity m STI reagents, sample processing, assay procedure, and data reduction; therefore, further assay cut-off studies were not necessary.

1.7.2 Clinical Performance

1.7.2.1 Clinical Study Results - Urogenital Specimens

Performance characteristics of the Alinity m STI assay with swab and urine specimens were established in a multicenter clinical study conducted in the United States to support the clearance of K202977 and K222379.

1.7.2.2 Human Factors Studies

A human factors summative usability study, to evaluate patient interaction with the simpli-COLLECT Urine Collection Kit and simpli-COLLECT Swab Collection Kit in a simulated home environment, was conducted. Kit usability and user label comprehension were evaluated through simulated use, knowledge-based questions, and subjective feedback in individual, in-person sessions. The study enrolled 223 participants from across six user groups: males and females ages 14 – 17, ages 18 – 64, and ages ≥65. Approximately half of the participants in each user group had access only to the paper Instructions For Use (IFU) that comes in the kit. The other half of the participants had access to both the paper IFU and an instructional video. No training was provided to any of the participants since end users are expected to use the collection kits without formalized training. Participants were observed while collecting and packaging a sample and difficulties were noted. The packaged samples were then evaluated for errors according to the laboratory accessioning criteria. At the end of the study, a questionnaire, aimed at evaluating users' ability to locate and understand key communication messages found in the labeling, was issued to all study participants.

The results of the usability study demonstrated that lay users are able to collect and ship a urine specimen using the simpli-Collect Urine Collection Kit (List No. 09N93-001) and a vaginal specimen using the simpli-COLLECT Swab Collection Kit (List No. 09R02-001) with minimal error. The results of the user label comprehension (i.e., the questionnaire) demonstrated that the labeling for both kits is easy to understand by lay users.

1.8 Conclusion Drawn from the Studies

The studies conducted for this submission demonstrate that the simpli-COLLECT Urine Collection Kit and simpli-COLLECT Swab Collection Kit devices, used with the Alinity m STI assay on the Alinity m System, perform comparably to the predicate device in the collection and transport of clinical specimens for nucleic acid testing and support a substantial equivalence decision. The studies demonstrated that lay users can self-collect and prepare specimens for transport without additional risks of erroneous results.