



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

**I Background Information:**

**A 510(k) Number**

K243410

**B Applicant**

Abbott Molecular

**C Proprietary and Established Names**

simpli-COLLECT STI Test

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
QYA	Class II	21 CFR 866.3385 - System For Detection Of Nucleic Acid From Non-Viral Microorganism(S) Causing Sexually Transmitted Infections Using Home-Collected Specimens	MI - Microbiology

**II Submission/Device Overview:**

**A Purpose for Submission:**

To obtain market clearance for the simpli-COLLECT STI Test.

**B Measurand:**

*Chlamydia trachomatis* (CT) ribosomal RNA  
*Neisseria gonorrhoeae* (NG) genomic DNA  
*Trichomonas vaginalis* (TV) ribosomal RNA  
*Mycoplasma genitalium* (MG) ribosomal RNA

## **C Type of Test:**

Qualitative, real time nucleic acid amplification test (NAAT) system for detection of nucleic acid using home-collected specimens.

## **III Intended Use/Indications for Use:**

### **A Intended Use(s):**

See Indications for Use below.

### **B Indication(s) for 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.

### **C Special Conditions for Use Statement(s):**

Rx - For Prescription Use Only

IVD – For in vitro diagnostic use

### **D Special Instrument Requirements:**

Alinity m System

## **IV Device/System Characteristics:**

### **A Device Description:**

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 urine and vaginal swab specimens self-collected in a home setting using the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit. This test system uses the Alinity m STI Assay (cleared under K202977 and K222379) for real time RT-PCR amplification and detection of CT ribosomal RNA sequences, NG genomic DNA sequences, TV ribosomal RNA sequences, MG ribosomal RNA sequences, and human genomic DNA sequences that have been extracted from the vaginal swab specimens, or male and female urine specimens.

The simpli-COLLECT collection kits are available as a case which includes 24 sealed collection kits, 26 mailing pouches, and instructions on mailing the sealed collection kits to the patients. When the test is prescribed to a patient by the healthcare provider (HCP), individual collection kit is either given or sent to the patient in the mailing pouch along with a pre-paid return mailing label supplied by the testing laboratory. Each kit is labeled with a unique kit identifier located on the side of the kit box which may be used for traceability purposes. The patient will also place labels displaying the unique kit code on the Sample Tube and Biohazard Bag. The patient collects the sample using the supplied collection kit, packages it and ships it to the laboratory for testing with the Alinity m STI Assay. Results are reported to the healthcare provider (HCP) per the laboratory's standard procedures. Patients receive the results through the prescribing HCP.

#### simpli-COLLECT Urine Collection Kit

The simpli-COLLECT Urine Collection Kit is used to collect, stabilize, and transport male urine specimens for the detection of CT, NG, TV, and MG, and female urine specimens for the detection of CT, NG and TV. Each kit can be used to collect one urine specimen.

The simpli-COLLECT Urine Collection Kit contains the following components:

- One Sample Tube with Liquid Buffer,
- One Dropper,
- One Tube and Bag Label Sheet,
- One Urine Collection Cup,
- One simpli-COLLECT Urine Collection Kit Patient Instructions for Use,
- One Biohazard Bag,
- One Tube and Cap Holder, and
- One Return Box (same as simpli-COLLECT Urine Collection Kit Box).

The user receives a simpli-COLLECT Urine Collection Kit along with a return mailing label to mail the sample back to the testing laboratory. Upon receiving the kit, user unpacks it; then urinates directly into the provided urine collection cup to collect the first 20 mL to 30 mL of urine; uses the transfer pipette to transfer urine to the sample tube with liquid transport buffer (between the MIN and MAX lines in the fill window of the tube); labels both the sample tube and the biohazard bag (with name and date of collection); places the tube in the biohazard bag followed by placing it in the simpli-COLLECT Urine Collection Kit box; applies the mailing return label to the box; mails the sample to the testing laboratory within 24 hours of collection.

#### simpli-COLLECT Swab Collection Kit

The simpli-COLLECT Swab Collection Kit is used to collect, stabilize, and transport vaginal swab specimens for the detection of CT, NG, TV, and MG. Each kit can be used to collect one vaginal swab specimen.

The simpli-COLLECT Swab Collection Kit contains the following components:

- One Sample Tube with Liquid Buffer,
- One Specimen Collection Swab,
- One Tube and Bag Label Sheet,
- One simpli-COLLECT Swab Collection Kit Patient Instructions for Use,
- One Biohazard Bag,
- One Tube and Cap Holder, and
- One Return Box (same as simpli-COLLECT Swab Collection Kit Box).

The user receives a simpli-COLLECT Swab Collection Kit along with a return mailing label to mail the sample back to the testing laboratory. Upon receiving the kit, user unpacks it; then self-collects a vaginal sample using the specimen collection swab; places the swab in the sample tube with liquid transport buffer and snaps the swab handle at the scored line; fills out and labels both the sample tube and the biohazard bag (with name and date of collection); places the sample tube in the biohazard bag followed by placing it in the simpli-COLLECT Swab Collection Kit box; applies the mailing return label to the box; mails the sample to the testing laboratory within 24 hours of collection.

#### Alinity m STI Assay

The Alinity m STI assay, cleared under K202977 and K222379, remains unchanged in all regards, i.e., in sample processing in the laboratory, assay procedure, or data analysis. Please refer to the decision summaries of K202977 and K222379 for more information.

### **B Principle of Operation:**

The simpli-COLLECT STI Test is comprised of the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit and the Alinity mSTI assay. The Alinity m STI assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) assay for amplification and detection of *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. 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, and result calculation and reporting of quantitative or qualitative results. All stages of the Alinity m STI assay procedure are executed automatically by the Alinity m System. Additional details regarding the principle of operation for the Alinity m STI assay may be found under K202977 and K222379.

### **C Instrument Description Information:**

#### 1. Instrument Name:

Alinity m System

#### 2. Specimen Identification:

The specimen ID is entered into the LIS system which gets encrypted into the barcode on the label. Alinity m system includes 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:

Not applicable

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

Simple 2 Test

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

DEN200070

**C Comparison with Predicate(s):**

Device & Predicate Device(s):	<u>K243410</u>	<u>DEN200070</u>
Device Trade Name	simpli-COLLECT STI Test	Simple 2 Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	The simpli-COLLECT STI Test is a test system intended for in vitro detection and identification of <i>Chlamydia trachomatis</i> (CT), <i>Neisseria gonorrhoeae</i> (NG), <i>Trichomonas vaginalis</i> (TV), and <i>Mycoplasma genitalium</i> (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	The Simple 2 Test is intended for in vitro detection and identification of <i>Chlamydia trachomatis</i> (CT) and/or <i>Neisseria gonorrhoeae</i> (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

	<p>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:</p> <ul style="list-style-type: none"> <li>•CT: vaginal swabs, female urine, and male urine</li> <li>•NG: vaginal swabs, female urine, and male urine</li> <li>•TV: vaginal swabs, female urine, and male urine</li> <li>•MG: vaginal swabs and male urine</li> </ul> <p>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</p>	<p>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.</p> <p>The testing is performed, as determined to be appropriate, based on the results of LetsGetChecked Suitability Questionnaire.</p> <p>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.</p> <p>Testing is limited to the manufacturer, Priva Path Laboratories (d.b.a. LetsGetChecked, Inc.).</p>
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Assay Type	Same	Qualitative
Assay Targets	CT ribosomal RNA NG genomic DNA TV ribosomal RNA MG ribosomal RNA	CT ribosomal RNA NG genomic DNA
Results Reporting	Positive, negative, and invalid. Initial invalid require retest.	Positive, negative, equivocal, and invalid. Initial equivocal and invalid require retest.
Specimen Collection and Transport	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)
Assay Controls	Internal Control (IC) Negative Control Positive Control	CT Positive/NG Negative Control CT Negative/NG Positive Control
<b>General Device Characteristic Differences</b>		
Conditions for use	For prescription use only	OTC-Over the Counter
Minimum Age of Users	14 years	18 years
Technology/Detection	Real-Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)	Target Capture (TC), Transcription-mediated Amplification (TMA), Dual Kinetic Assay (DKA)
Instrument System	Alinity m System	Panther System

## VI Standards/Guidance Documents Referenced:

Class II Special Controls as per 21 CFR 866.3385

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

#### 1. Precision/Reproducibility:

Reproducibility and within laboratory precision studies were previously reviewed and described in K202977.

2. Linearity:

Not applicable; this is a qualitative assay.

3. Analytical Specificity/Interference:

Analytical Specificity/Interference studies were previously reviewed and described in K202977. Additional studies performed to evaluate the effect of interference due to common hand contaminants are described below.

4. Assay Reportable Range:

Not applicable; this is a qualitative assay.

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

Traceability, Stability, Expected Values (Controls, Calibrators, or Methods) were previously reviewed and described in K202977.

Stability of the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit was evaluated in the studies described below.

***a. Unopened simpli-COLLECT Swab Collection Kit and simpli-COLLECT Urine Collection Kit Stability***

A multi-lot stability study was conducted to establish the shelf-life of simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kits. Three different lots were tested at month 0, 1, 2, 5, 8, 10, 14, 20, 24 and 25 (10 total timepoints) with a minimum of five replicates at each time point. At each timepoint, CT, NG, TV, and MG organisms spiked into either pooled negative urine or pooled negative vaginal swab matrix at 2x Limit of Detection (LoD), were added to the transport buffer in the Sample Tubes before testing with Alinity m STI assay. All samples produced the expected results through 25 months of the study. The study results demonstrated the stability of the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit for up to 24 months when stored at ambient temperature (15°C to 30°C).

***b. Shipping Stability for simpli-COLLECT Swab Collection Kit and simpli-COLLECT Urine Collection Kit***

Shipping stability studies were performed to evaluate the stability of the simpli-COLLECT Urine Collection Kits and the simpli-COLLECT Swab Collection Kits under extreme temperature conditions that may be experienced during shipping. One lot of the collection kit was subjected to storage under the summer and winter shipping temperature cycles. Pooled urine or pooled vaginal swab matrix was co-spiked with CT, NG, TV, and MG organisms at the Low Positive and Moderate Positive concentrations as shown below:



- Low Positive samples in pooled urine: 0.07 Elementary Bodies (EB)/mL for CT, 0.06 Colony Forming Units (CFU)/mL for NG, 0.006 TV/mL for TV and 10.24 Genome Equivalents (GE)/mL for MG.
- Moderate Positive samples in pooled urine: 0.35 EB/mL for CT, 0.3 CFU/mL for NG, 0.0295 TV/mL for TV and 50.12 GE/mL for MG.
- Low Positive samples in pooled vaginal swab matrix: 0.205 EB/mL for CT, 0.04 CFU/mL for NG, 0.01056 TV/mL for TV and 16.64 GE/mL for MG.
- Moderate Positive samples in pooled vaginal swab matrix: 1.025 EB/mL for CT, 0.2 CFU/mL for NG, 0.0528 TV/mL for TV and 80.32 GE/mL for MG.

Thirty (30) Low Positive, ten (10) Moderate Positive and ten (10) Negative samples were evaluated at baseline (T0) and after storage through the summer and winter shipping temperature cycles. Expected results were generated for both urine and vaginal swab samples tested after collection kit storage through the summer and winter shipping temperature cycles. The study result demonstrate that the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit are stable even when exposed to extremes of temperature during shipping.

***c. Effect on Physical Properties of the Transport Buffer Upon Storage at Extreme Temperatures***

The study evaluated the effect on the pH, color, and turbidity of the transport buffer in the Sample Tube upon storage at extreme temperatures. One lot of the transport buffer was subjected to storage under the summer and winter shipping temperature cycles for a total cycle time of 375 hours followed by incubation at 31°C for 16 days to mimic storage of specimen. The transport buffer was evaluated for pH, color, and turbidity at baseline (T0) and after storage through the summer and winter shipping temperature cycles. The study result demonstrated that there was no impact on the pH of the transport buffer under extreme storage conditions. In addition, visual inspection of the transport buffer indicated there was no color change, cloudiness, or presence of particulate after storage under extreme conditions. Turbidity of the transport buffer was also evaluated by measuring absorbance using a Spectrophotometer. The study results indicated that there was no change in the turbidity of the transport buffer after exposure to extreme shipping temperature profiles.

**6. Detection Limit:**

The Detection Limit was previously reviewed and described in K202977.

**7. Assay Cut-Off:**

Assay cut-off was previously reviewed and described in K202977.

**8. Carry-Over:**

Carry-Over study was previously reviewed and described in K202977.

## **B Comparison Studies:**

### 1. Method Comparison with Predicate Device:

Refer to the clinical study section (VII.C) below.

### 2. Matrix Comparison:

Please refer to K202977.

## **C Clinical Studies:**

### 1. Clinical Sensitivity:

Clinical Sensitivity of the assay for detection of the target analytes in self-collected swabs and urine was previously reviewed and described in K202977 and K222379.

### 2. Clinical Specificity:

Clinical Specificity of the assay for detection of the target analytes in self-collected swabs and urine was previously reviewed and described in K202977 and K222379.

## **D Clinical Cut-Off:**

Not applicable

## **E Expected Values/Reference Range:**

Expected Values/Reference Range were previously reviewed and described in K202977 and K222379.

## **F Other Supportive Performance Characteristics Data:**

Analytical studies including interference with hand contaminants, urine and swab specimen stability and flex studies were conducted as described below. For these studies, samples were prepared by co-spiking CT, NG, TV and MG organisms in negative urine or negative vaginal swab matrix at the concentrations shown below:

- Low Positive samples in urine: 0.07 Elementary Bodies (EB)/mL for CT, 0.06 Colony Forming Units (CFU)/mL for NG, 0.006 TV/mL for TV and 10.24 Genome Equivalents (GE)/mL for MG.
- Moderate Positive samples in urine: 0.35 EB/mL for CT, 0.3 CFU/mL for NG, 0.0295 TV/mL for TV and 50.12 GE/mL for MG.
- Low Positive samples in vaginal swab matrix: 0.205 EB/mL for CT, 0.04 CFU/mL for NG, 0.01056 TV/mL for TV and 16.64 GE/mL for MG.
- Moderate Positive samples in vaginal swab matrix: 1.025 EB/mL for CT, 0.2 CFU/mL for NG, 0.0528 TV/mL for TV and 80.32 GE/mL for MG.

## 1. Interference with Hand Contaminants

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

Interference studies were performed to evaluate the effect of inadvertent introduction of common hand contaminants to swab and urine samples collected with simpli-COLLECT Swab Collection Kit or simpli-COLLECT Urine Collection Kit when used in home environment. Pooled urine or vaginal swab matrix containing common hand contaminants (water, soap, hand sanitizer and lotion) were co-spiked with CT, NG, TV, and MG organisms at Low Positive concentrations as noted above, to determine if accidental introduction of exogenous substances that may be introduced during specimen collection present a risk for false results. Each potentially interfering substance was tested at 1% v/v. A minimum of five positive and five negative replicates were tested for each substance.

Assay interference was observed in the presence of Purell Advanced Hand Sanitizer Sanitizing Gel and Germ X Advanced Moisturizing Hand Sanitizer with Aloe in both swab and urine samples. Assay interference was also observed in the presence of Vaseline Intensive Care Deep Restore Lotion in urine samples. Additional testing at lower test substance concentrations were performed to determine the concentration where interference is no longer observed. No interference was observed in the presence of any of the substances at the concentrations shown in the table below for all positive and negative samples. Additional limitations have been included in the labeling to caution the user about the interference from the above-mentioned substances. Additionally, the instructions direct the user to wash their hands with soap and water and dry thoroughly which serves to lower the risk of sample contamination.

**Table 1. Potentially Interfering Hand Contaminants Evaluated in Swab and Urine Matrices**

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

<sup>a</sup>U = Urine, S = Swab

<sup>b</sup>Interference was observed at concentrations higher than these concentrations.

## 2. Urine and Vaginal Swab Specimen Stability

Specimen stability studies including the shipping stability were performed to evaluate the stability of samples under extreme shipping conditions that samples may encounter when shipped via commercial carriers and during the storage at a testing laboratory. Pooled urine or pooled vaginal swab matrix was co-spiked with CT, NG, TV, and MG organisms at the Low Positive and Moderate Positive concentrations as noted above. Thirty (30) Low Positive, ten (10) Moderate Positive and ten (10) Negative samples were evaluated at baseline (T0) and through the summer and winter shipping temperature cycles for approximately 180 hours, followed by storage at 2 to 8°C and 30°C for 15 or 17 days and a minimum of four hours on-board the Alinity m System.

The expected results were generated for all samples at tested conditions in both urine and vaginal swab matrix tested under both summer and winter shipping temperature cycles supporting 6 days of shipping stability followed by storage at 2 to 30°C for up to 14 days and on-board stability claim for up to 4 hrs.

## 3. Flex Studies

Flex studies were conducted to evaluate the performance of the test system under conditions of stress. Contrived low positive samples used for flex studies were prepared in pooled urine or pooled vaginal swab matrix co-spiked with CT, NG, TV, and MG organisms at Low Positive concentrations as noted above.

Except where indicated below, for each condition being evaluated in the flex studies, each Low Positive sample was tested in six replicates. Samples were tested according to the instructions for use protocol, except for the noted deviations dictated by the flex parameter under evaluation.

### *a. Low Transport Buffer Volume in the simpli-COLLECT Swab Collection Kit Sample Tube*

simpli-COLLECT Swab Collection Kit Sample Tubes are prepared with a fixed volume of the transport buffer (1.4 mL). Users of the simpli-COLLECT Swab Collection Kit are instructed not to remove any liquid from the Sample Tube during specimen collection. To determine if spilling or removing of the transport buffer from the Sample Tube could lead to erroneous results, the Sample Tubes were filled with different volumes of transport buffer: 1.4 mL (control), 0.7 mL and 0.3 mL. simpli-COLLECT swabs co-spiked with CT, NG, TV, and MG organisms at Low Positive concentrations were added to these tubes, followed by testing with Alinity m STI assay. Six replicates were tested for each volume of the transport buffer. All samples generated expected results demonstrating that the risks of erroneous results due to low transport buffer in the simpli-COLLECT Swab Collection Kit Sample Tubes are minimal.

### *b. Incorrect Volume of Urine Transferred to the simpli-COLLECT Urine Collection Kit Sample Tube*

The instructions for the simpli-COLLECT Urine Collection Kit indicates to add urine so that the final sample volume is within the black fill lines indicated on the urine Sample Tube. This results in a urine to transport buffer ratio of 3:2. Users of the collection kit are instructed not to remove any liquid from the Sample Tube during specimen collection

either prior or after addition of the urine to the tube. In both cases, the ratio of the urine to transport buffer would increase from the intended ratio. Alternatively, a user may erroneously add urine below the fill window, which would decrease the ratio of urine to transport buffer from the intended ratio. The study was performed to assess the impact of various ratios of urine to transport buffer on the performance of the Alinity m STI assay. Sample Tubes were prepared at urine-to-transport buffer ratio of 6:7 (underfilled tubes where the sample level reaches only the “MIN” on the Sample Tube) and 5:1 (overfilled tubes where the sample level reaches to the cap of the Sample Tube). CT, NG, TV, and MG organisms were co-spiked at Low Positive concentration into these tubes, followed by testing with Alinity m STI assay on the day of preparation (Day 0) and after storage at 31°C for 17 days (Day 17), which is beyond the specimen stability claim for simpli-COLLECT urine specimens. Five replicates of each sample were tested. All samples generated expected results when tested on Day 0 and Day 17, demonstrating that the risks of erroneous results due to incorrect volume of urine transferred to the simpli-COLLECT Urine Collection Kit Sample Tubes are minimal. The risk is further mitigated by the clear directions in the labeling to add the urine so that the liquid level is between the two lines on the Sample Tube.

**c. *Delay of Urine Transfer to the simpli-COLLECT Urine Collection Kit Sample Tube***

The instructions for the simpli-COLLECT Urine Collection Kit directs the user to transfer the urine from the collection cup into the Sample Tube after collection. The study was performed to determine the effect of delay of urine transfer from the collection cup to the Sample Tubes. In this study, negative pooled urine was co-spiked with CT, NG, TV, and MG organisms at Low Positive concentration and stored at 31°C for 0, 24 and 48 hrs. At each time point, an aliquot was transferred into the Sample Tube with the transport buffer and tested for the presence of the analytes using the Alinity m STI assay. Five replicates were tested at each time point. All samples generated expected results demonstrating that the risks of erroneous results due to delay in urine transfer to the simpli-COLLECT Urine Collection Kit Sample Tubes are minimal.

#### **4. Usability and Label Comprehension Studies**

To demonstrate that the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit can be used by the lay user in a home setting with minimal error, usability and label comprehension studies were conducted. These studies enrolled a total of 223 participants from six user groups as described in the table below. Each of the user groups was split between using just the paper instructions (IFU only) or a combination of the paper and the video instructions (IFU and video). Study enrollment covered a range of education across the participants with less than high school, high school graduate, some college, college graduate, and post-graduate.

**Table 2. Human Factors Study Enrollment User Groups**

User Group	Sample Type	Instructions Available	Number Enrolled
Male, age 14 - 17	Urine	IFU only	14
		IFU and video	13
Male, age 18 - 64	Urine	IFU only	13
		IFU and video	14
Male, age 65+	Urine	IFU only	14

		IFU and video	13
Female, age 14 - 17	Urine	IFU only	14
		IFU and video	13
	Swab	IFU only	10
		IFU and video	10
Female, age 18 - 64	Urine	IFU only	13
		IFU and video	14
	Swab	IFU only	10
		IFU and video	10
Female, age 65+	Urine	IFU only	13
		IFU and video	14
	Swab	IFU only	11
		IFU and video	10
<b>Total</b>	223		

Usability of the simpli-COLLECT Urine Collection Kit (162 participants) and of the simpli-COLLECT Swab Collection Kit (61 participants) was evaluated in a simulated home environment. The study participants were asked to follow the home collection instructions provided with the kit (see table above) to complete tasks required for use of the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit, including opening the kit box, sample preparation and sample packaging. Kit usability and user label comprehension were evaluated through simulated use, knowledge-based questions, and subjective feedback in individual, in-person sessions. 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 223 samples packaged by the study participants were shipped to an external site and evaluated for critical errors that could lead to sample rejection upon receipt in the laboratory. The results of these studies demonstrated that the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit are easy to use by the lay users in the home environment.

After packaging of the sample, user label comprehension was evaluated for the simpli-COLLECT Urine Collection Kit (162 participants) and for the simpli-COLLECT Swab Collection Kit (61 participants). The study participants were interviewed by the study staff to evaluate participant's ability to locate and understand the key communication messages found in the labeling, i.e., limitations and warnings, actions that can lead to erroneous results and what to do if they occur). The results of user label comprehension studies demonstrated that the labeling of the simpli-COLLECT Urine Collection Kit and the simpli-COLLECT Swab Collection Kit is easy to understand by lay users.

## **VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

## **IX Conclusion:**

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