October 01, 2025

Visby Medical, Inc.
Jennifer Albrecht
Director of Regulatory Affairs
3010 North 1st Street
San Jose, California 95134

Re: K251501
Trade/Device Name: Visby Medical Men's Sexual Health Test
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
Dated: May 9, 2025
Received: May 15, 2025

Dear Jennifer Albrecht:

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)*
K251501

Device Name
Visby Medical Men's Sexual Health Test

Indications for Use *(Describe)*
The Visby Medical Men's Sexual Health Test is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test for the rapid detection and differentiation of DNA from Chlamydia trachomatis and Neisseria gonorrhoeae in male urine specimens. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with Chlamydia trachomatis and Neisseria gonorrhoeae in males.

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

A. Submitter

Name:	Visby Medical, Inc.
Address:	3010 N. First Street San Jose, CA 95134
Phone:	1-833-468-4729
Contact:	Jennifer Albrecht
Date Prepared:	May 15, 2025

B. Device

Name of Device:	Visby Medical Men's Sexual Health Test
Common Name:	Visby Men's Sexual Health Test
Classification Name:	Nucleic Acid Detection System for Non-Viral Microorganism(s) Causing Sexually Transmitted Infections
Regulatory Classification:	Class II
Regulation:	21 CFR 866.3393
Primary Product Code:	QEP

C. Predicate Device

Visby Medical Sexual Health Test (K220407)

D. Device Description

The Visby Medical Men's Sexual Health Test is a single-use (disposable), fully automated, rapid, compact device that contains PCR assays for qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) DNA in male urine samples from symptomatic or asymptomatic individuals. The device automatically performs all steps required to complete lysis, PCR amplification, and detection.

The Visby Medical Men's Sexual Health Test is designed to be simple to use. When combined with a user-provided urine collection cup and a Visby power adapter accessory, the test contains all the materials required to perform the test. The patient collects a first catch urine sample in a standard urine collection cup (not provided). The operator starts the test by using a provided fixed-volume disposable transfer pipette to transfer ~ 450 µL of urine from the collection cup into a dropper tube containing ~900 µL of Visby Medical Men's Sexual Health Buffer. The operator transfers the entire volume (~1.35 mL) of the sample (urine in buffer) into the sample port of the device by squeezing the dropper tube to release all of the sample into the device sample port. The operator then slides a purple switch on the front of the device to both close the sample port and initiate the fully automated testing process. At this point, blinking white lights on

the front of the device indicate the test is in progress. Test results are available in just under 30 minutes at which time a green "READY" status light will appear at the bottom of the device, and a purple color will appear in the "RESULTS VALID" spot, indicating a valid test. A purple spot adjacent to "CHLAMYDIA" and/or "GONORRHEA" signifies the presence of amplified CT and/or NG DNA in the sample.

E. Intended Use

The Visby Medical Men's Sexual Health Test is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test for the rapid detection and differentiation of DNA from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in male urine specimens. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in males.

F. Substantial Equivalence

The Visby Medical Men's Sexual Health Test is substantially equivalent to the Visby Medical Sexual Health Test, K220407.

The following table compares the Visby Medical Men's Sexual Health Test to the Visby Medical Sexual Health Test and outlines the similarities and differences between the two tests.

Characteristic	**Predicate Device:** **Visby Medical** **Sexual Health Test**	**Subject Device:** **Visby Medical** **Men's Sexual Health Test**
510(k) Number	K220407	N/A
Regulation	21 CFR 866.3393	Same
Product Code	QEP	Same
Device Class	Class II	Same
Technology/ Detection	Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections	Same

Characteristic	Predicate Device: **Visby Medical** **Sexual Health Test**	Subject Device: **Visby Medical** **Men's Sexual Health Test**
Intended Use	The Visby Medical Sexual Health Test is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test intended for use in point-of-care or clinical laboratory settings for the rapid detection and differentiation of DNA from *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* in self-collected female vaginal swab specimens using the Visby Medical Sexual Health Vaginal Specimen Collection Kit in a health care setting. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.	The Visby Medical Men's Sexual Health Test is a single-use (disposable), fully integrated, automated Polymerase Chain Reaction (PCR) in vitro diagnostic test intended for the rapid detection and differentiation of DNA from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in male urine specimens. The test results are to aid in the diagnosis of symptomatic or asymptomatic infections with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in males.
Indication for Use	Symptomatic and asymptomatic patients; Rx - For Prescription Use Only	Same
Sample to answer system	Automated	Same
Specimen Types	Patient-collected vaginal swab in Visby Collection Media	Patient-collected male urine
Organisms Detected	*Chlamydia trachomatis* (CT) *Neisseria gonorrhoeae* (NG) *Trichomonas vaginalis* (TV)	*Chlamydia trachomatis* (CT) *Neisseria gonorrhoeae* (NG)
Collection Kit	Swab collection kit	Urine cup (not provided)
Sample Extraction	Self-contained and automated after vaginal swab elution into collection media	Self-contained and automated after urine sample dilution into buffer
Assay Results	Qualitative	Same
Instrument System	N/A, self-contained assay and instrument system	Same
Assay Controls	Internal processing control (IPC), External controls available.	Same
Turn-around Time	Approximately 30 minutes to results.	Same

G. Summary of Performance Data

Clinical Evaluation

Performance characteristics of the Visby Medical Men's Sexual Health Test were established in a clinical study that included testing of prospectively collected fresh specimens. The objective of the study was to establish the clinical performance of the Visby Medical Men's Sexual Health Test for the detection and differentiation of chlamydia (*Chlamydia trachomatis* [CT]) and gonorrhea (*Neisseria gonorrhoeae* [NG]) in patient collected urine samples tested by untrained users in point of care settings. This study was conducted at seven POC sites in CLIA Waived testing settings in the US. All study specimens were tested with the Visby Medical Men's Sexual Health Test by typical CLIA Waived operators according to the Quick Reference Guide (QRG) and Instructions for Use (IFU). Specimens were collected and tested between October 2024 and March 2025.

Prospective Sample Testing

Male subjects ≥14 years of age who were symptomatic or asymptomatic for sexually transmitted infections (STIs) were prospectively enrolled at seven clinical study site representative of CLIA waived testing facilities in the US. The collected urine samples were provided to participating study operators who tested them on-site with the Visby device. The remaining urine sample was sent to two reference laboratories for comparator testing with three FDA cleared nucleic acid amplification tests (NAATs) detecting CT and NG.

A total of 1289 subjects were enrolled in the study. Seventeen (17) study specimens were excluded from the performance evaluation due to procedural errors by site study staff or incomplete study procedures (n=8), withdrawal of consent (n=4), lack of a valid Visby test result (n=3), or for the subject not meeting inclusion criteria (n=2). A total of 1272 males (310 symptomatic and 962 asymptomatic) were included in the performance evaluation. Among the 1276 tests performed on the Visby Test, 55 had an invalid result on the first test (4.3%). After a single retest was performed on these 55 specimens, 52 provided a valid result, for a final invalid rate of 0.2% (3/1276).

The sensitivity and specificity of CT and NG are shown in Table 1 below.

Table 1. Prospective Fresh Male Urine Specimen Performance – Enrollment from October 2024 to March 2025 (Visby vs. Comparator Assays)

Target	N	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)
CT	1272	145	8	1112	7	95.4% (90.8%-97.8%)	99.3% (98.6%-99.6%)
NG	1272	55	8	1209	0	100.0% (93.5%-100.0%)	99.3% (98.7%-99.7%)

Reproducibility

A study was performed to evaluate the reproducibility of the Visby Medical Men's Sexual Health Test when used by untrained users in CLIA Waived settings. The operators performing the testing were non-laboratorians representing healthcare professionals that may be encountered at such sites. The study evaluated five (5) panel members that were prepared using cultured organisms in pooled urine (previously determined to be negative for CT and NG). The study was performed with negative (unspiked), low positive (1x LoD), and moderate positive (3-5x LoD) samples.

A total of six (6) study operators (2 operators at each site) tested the panel three (3) times each testing day, over six (6) non-consecutive days. Three device lots were used in the study. A summary of the results (count correct / total count) and % agreement with expected results for each panel member by site and overall is presented in the table below. The Visby Test demonstrated that untrained users perform testing accurately and reproducibly.

Table 2. Summary of Reproducibility Results with the Visby Medical Men's Sexual Health Test

Panel Member	Site 1	Site 2	Site 3	Overall Agreement	
	% Agreement (count)	% Agreement (count)	% Agreement (count)	% Agreement (count)	95% CI
Moderate Positive CT	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
Low Positive CT	97.2% (35/36)	97.2% (35/36)	100.0% (36/36)	98.1% (106/108)	93.5%-99.5%
Moderate Positive NG	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
Low Positive NG	100.0% (36/36)[a]	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%
Negative	100.0% (36/36)	100.0% (36/36)	100.0% (36/36)	100.0% (108/108)	96.6%-100.0%

[a] One test was unexpectedly positive for CT.

Analytical Evaluation

Limit of Detection

The limit of detection (LoD) is the lowest concentration of pathogen that is reliably detected by the Visby Medical Men's Sexual Health Test. The LoD of the Visby Men's Sexual Health Test was determined for CT in elementary bodies per mL (EB/mL) and NG in colony forming units per mL (cfu/mL), from two distinct strains or serovars, spiked into negative urine in single-positive samples. LoD is defined as the lowest concentration per sample that can be detected 95% of the time. The LoD values for each strain were estimated by probit analysis of the results from a range-finding study of five different concentrations in replicates of 10 per concentration. The calculated LoDs were

confirmed by testing 20 replicates and demonstrating that at least 19 out of 20 replicates were positive. The LoD of the Visby Medical Men's Sexual Health Test for each organism are summarized in Table 3 below.

Table 3. Limit of Detection (LoD) for the Visby Medical Men's Sexual Health Test

Organism	LoD
CT Serovar H (ATCC VR-879)	14.0 EB/mL
CT Serovar D (ATCC VR-885)	32.5 EB/mL
NG (ATCC 19424)	32.0 cfu/mL
NG (ATCC 49226)	2.5 cfu/mL

Inclusivity

The ability of the Visby Medical Men's Sexual Health Test to detect bacterial strains that represent the clinical and genetic diversity of the target organisms was evaluated by testing 14 serovars of CT and 30 strains of NG near the LoD. Each organism was individually spiked into negative urine at 3x LoD and tested in 3 replicates. If any strain did not result in 3/3 positive results, then the next lower dilution was tested until it was detected in 3/3 replicates. All 14 CT serovars and 30 NG strains were successfully detected at the following concentrations:

Table 4. Analytical Reactivity (Inclusivity) of the Visby Medical Men's Sexual Health Test for CT

ATCC Number	Serovar	CT Concentration Tested
VR-571B	A	97.5 EB/mL
VR-573	B	97.5 EB/mL
VR-347	Ba	97.5 EB/mL
VR-1500	C	97.5 EB/mL
VR-348B	E	97.5 EB/mL
nvCT, Swedish variant	E	97.5 EB/mL
VR-346	F	97.5 EB/mL
VR-878	G	97.5 EB/mL
VR-880	I	97.5 EB/mL
VR-886	J	97.5 EB/mL
VR-887	K	97.5 EB/mL
VR-901B	LGV I	97.5 EB/mL
VR-902B	LGV II	195.0 EB/mL
VR-903	LGV III	97.5 EB/mL

Table 5. Analytical Reactivity (Inclusivity) of the Visby Medical Men's Sexual Health Test for NG

ATCC Number	NG Concentration Tested	ATCC Number	NG Concentration Tested
BAA-1833	96.0 cfu/mL	27632	96.0 cfu/mL
BAA-1839	96.0 cfu/mL	27633	96.0 cfu/mL
BAA-1847	96.0 cfu/mL	31148	96.0 cfu/mL
9826	96.0 cfu/mL	31149	96.0 cfu/mL
9827	96.0 cfu/mL	31151	96.0 cfu/mL
9830	96.0 cfu/mL	31356	96.0 cfu/mL
10874	96.0 cfu/mL	31397	96.0 cfu/mL
11688	96.0 cfu/mL	31398	96.0 cfu/mL
11689	96.0 cfu/mL	31401	96.0 cfu/mL
19088	96.0 cfu/mL	31402	96.0 cfu/mL
23050	96.0 cfu/mL	31403	96.0 cfu/mL
23051	96.0 cfu/mL	31406	96.0 cfu/mL
27628	96.0 cfu/mL	35541	96.0 cfu/mL
27629	96.0 cfu/mL	43069	96.0 cfu/mL
27631	96.0 cfu/mL	49981	96.0 cfu/mL

Cross-Reactivity and Microbial Interference

The potential for cross reactivity from microorganisms that may be found in urine other than the target pathogens (CT and NG) on the performance of the Visby Medical Men's Sexual Health Test was evaluated. Eighty-three (83) microorganisms were tested in triplicate at high concentrations (≥10^5 units/mL for viruses and ≥10^6 units/mL for bacteria, protozoa, and yeast) in negative samples (urine). A single false positive CT result (out of 3 replicates) was observed with inactivated HIV-1 (ZeptoMetrix NATHIV1-LIN) material; negative results were returned in 10/10 tests with live HIV-1 culture fluid.

Additionally, three organisms could not be obtained for direct testing (Bacterial Vaginosis Associated Bacteria 2 (BVAB-2), *Megasphaera* type 1, and *Dientamoeba fragilis*). The sequences of these organisms were analyzed against the Visby Men's Sexual Health Test primer and amplicon sequences using basic local alignment search tool (BLAST). No match was found for any of the 3 organisms.

Microbial Interference was evaluated on the Visby Men's Sexual Health Test by testing 11 microorganisms chosen based on the likelihood of their presence in a urine sample or genetic similarities to the target organisms in the presence of low concentrations of the target organisms (3x LoD for CT and NG). No microbial interference was observed with any of the organisms tested. The 11 microorganisms chosen are denoted in the following table by an asterisk.

Table 6. Microorganisms Evaluated for Cross-Reactivity and Microbial Interference (denoted by *) on Visby Medical Men's Sexual Health Test

Microorganism (ATCC Number)
Acinetobacter lwoffii (15309)
Actinomyces israelii (12102)
Atopobium vaginae (BAA-55)
Bacteroides fragilis (25285)
Bacteroides ureolyticus (33387)
Bifidobacterium adolescentis (15703)
Bifidobacterium longum (15697)
BV associated bacteria[1] (BVAB-2, N/A)
Campylobacter jejuni (33291)
*Candida albicans** (801504, ZeptoMetrix)
Candida glabrata (90030)
Candida parapsilosis (22019)
Candida tropicalis (750)
*Chlamydia pneumoniae** (53592)
*Chlamydophila psittaci** (MBC013-R, Vircell)
Clostridium difficile (9689)
Clostridium perfringens (13124)
Corynebacterium genitalium (33034)
Corynebacterium xerosis (373)
Cryptococcus neoformans (66031)
Cutibacterium acnes (6919)
Dientamoeba fragilis[1] (N/A)
Enterobacter cloacae (13047)
*Enterococcus faecalis** (29212)
*Escherichia coli** (25922)
Fusobacterium nucleatum (25586)
Gardnerella vaginalis (14018)
Haemophilus ducreyi (33940)
Herpes simplex virus I* (VR-539)
Herpes simplex virus II (VR-540)
HIV-1* (0801032CF, ZeptoMetrix)
Human papilloma virus 16 E6/E7 (Transformed cells) (CRL-2616)
Kingella dentrificans (33394)
Klebsiella aerogenes (13048)
Klebsiella oxytoca (49131)
Klebsiella pneumoniae (13883)
Lactobacillus acidophilus (4356)
Lactobacillus brevis (14869)
Lactobacillus jensenii (25258)
Lactobacillus vaginalis (49540)
Lactococcus lactis (19435)
Listeria monocytogenes (19115)
Megashaera type 1[1] (N/A)

Microorganism (ATCC Number)
Mobiluncus curtisii (35241)
Mobiluncus mulieris (35243)
*Mycoplasma genitalium** (49123)
Mycoplasma hominis (23114)
Neisseria cinerea (14685)
Neisseria elongata (25295, 29315, 49378)
Neisseria flava (14221)
Neisseria flavescens (13116, 13120)
Neisseria lactamica (23970, 23971, 23972, 49142)
Neisseria meningitidis serogroup a* (13077)
Neisseria meningitidis serogroup b (13090)
Neisseria meningitidis serogroup c (13102)
Neisseria meningitidis serogroup D (13113)
Neisseria meningitidis serogroup w-135 (35559)
Neisseria meningitidis serogroup y (35561)
Neisseria mucosa (19695, 25998, 49233)
Neisseria perflava (14799)
Neisseria polysaccharea (43768)
Neisseria sicca (9913, 29193, 29256)
Neisseria subflava (4788)
Pentatrichomonas hominis (30000)
Peptostreptococcus anaerobius (27337)
Prevotella bivia (29303)
Proteus mirabilis (7002)
Pseudomonas aeruginosa (0801519, ZeptoMetrix)
Staphylococcus aureus (12600)
Staphylococcus epidermidis (14990)
Streptococcus agalactiae (13813)
Streptococcus pyogenes (19615)
*Trichomonas tenax** (30207)
*Trichomonas vaginalis** (30001)
Ureaplasma parvum (27815)
Ureaplasma urealyticum (27618)

[1] These organisms were not available for direct testing and were evaluated using in-silico analysis

* These organisms were also tested in microbial interference

Competitive Interference

The Visby Medical Men's Sexual Health Test was evaluated for performance in the case of a mixed infection (presence of multiple target organisms), where the potential for high concentrations of one target organism to interfere with detection of low concentrations of another target organism was evaluated. Each of the target organisms (CT and NG) were spiked into negative urine at varying concentrations and then tested in triplicate. Low concentrations were prepared at 3x LoD for the respective organisms and high concentrations were prepared at 1 x 10^6 units/mL. No competitive interference was observed at the levels tested for the two target organisms.

Table 7. Competitive Interference Evaluated on the Visby Medical Men's Sexual Health Test

Organism and Concentration		CT (# Positive / # Tested)	NG (# Positive / # Tested)
CT	NG		
Low	High	3/3	3/3
Low	Low	3/3	3/3
Low	Neg	3/3	0/3
High	High	3/3	3/3
High	Low	3/3	3/3
High	Neg	3/3	0/3
Neg	High	0/3	3/3
Neg	Low	0/3	3/3
Neg	Neg	0/3	0/3

Endogenous/Exogenous Interfering Substances

Potentially interfering substances that may be found in a urine sample were evaluated to determine if they interfere with the accuracy of test results. The potentially interfering substances were diluted in the negative urine and tested in the presence of low concentrations (3x LoD) of CT and NG organisms. The testing was also performed with negative urine samples. All samples were tested in triplicate. As shown in Table 8 below, all the negative and positive samples returned expected results. None of the tested substances were found to interfere with test results.

Table 8. Potentially Interfering Substances Evaluated on the Visby Medical Men's Sexual Health Test

Substance	Concentration Tested	Negative Sample (# Expected Results / # Tests)	Positive Sample (# Expected Results / # Tests)
Endogenous Substances: Test substances produced by the body			
Acidic Urine	pH 4	3/3	3/3
Alkaline Urine	pH 9	3/3	3/3
Albumin (BSA)	500 µg/mL	3/3	3/3
Beta Estradiol	0.07 mg/mL	3/3	3/3
Bilirubin	100 µg/mL	3/3	3/3
Glucose	1 mg/mL	3/3	3/3
Leukocytes	$1x10^6$ cells/mL	3/3	3/3
Mucin (Bovine)	0.80% w/v	3/3	3/3
Progesterone	0.07 mg/mL	3/3	3/3
Seminal Fluid	5% v/v	3/3	3/3
Whole Blood	1% v/v	3/3	3/3
Exogenous Substances: Common prescription and over-the-counter drugs			
Acetaminophen	2200 µg/mL	3/3	3/3
Amoxicillin Trihydrate	6900 µg/mL	3/3	3/3
Aspirin	1200 µg/mL	3/3	3/3
Azithromycin	2900 µg/mL	3/3	3/3
Biotin	10 µg/mL	3/3	3/3
Ceftriaxone	1200 µg/mL	3/3	3/3
Doxycycline	500 µg/mL	3/3	3/3
Erythromycin	900 µg/mL	3/3	3/3
Ibuprofen	1200 µg/mL	3/3	3/3
Metronidazole	1500 µg/mL	3/3	3/3
Naproxen	1200 µg/mL	3/3	3/3
Phenazopyridine Hydrochloride	500 µg/mL	3/3	3/3
Tetracycline Hydrochloride	1700 µg/mL	3/3	3/3
Trimethoprim	250 µg/mL	3/3	3/3
Sulfamethoxazole	1800 µg/mL	3/3	3/3
External Substances: Can be introduced during collection			
Abreva Cold Sore Cream	0.25% w/v	3/3	3/3
KY Jelly Personal Lubricant	0.25% w/v	3/3	3/3
Preparation H Hemorrhoidal Ointment	0.25% w/v	3/3	3/3
Talcum Powder	0.25% w/v	3/3	3/3

Specimen Stability

The stability of urine specimens was determined when stored at room temperature (30°C) or refrigerated (2 - 8°C) conditions. CT and NG were spiked into negative urine at 2x LoD and tested at baseline and at each storage time-point with 20 replicates. All low positive devices returned the expected double positive results at all time-points tested. Based on the results, the following specimen stability in Visby Men's Sexual Health Buffer is claimed:

- Room temperature (15 – 30°C) storage up to 180 minutes (3 hours)
- Refrigerated (2 – 8°C) storage up to 24 hours

H. Conclusion

The analytical and clinical studies have demonstrated that the Visby Medical Men's Sexual Health Test is substantially equivalent to the predicate device (K220407).