April 22, 2025

BD Integrated Diagnostic Solutions/Becton, Dickinson & Company
Teresa Jennifer Sugumar
Staff Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K243343
Trade/Device Name: BD CTGCTV2
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: October 25, 2024
Received: October 25, 2024

Dear Teresa Jennifer Sugumar:

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
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)*
K243343

Device Name
BD CTGCTV2

Indications for Use *(Describe)*
The BD CTGCTV2 assay incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from:
Chlamydia trachomatis (CT)
Neisseria gonorrhoeae (GC)
Trichomonas vaginalis (TV)

The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting) and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in ThinPrep® PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep® Pap test. The assay may also be used for the detection of CT and GC DNA in clinician-collected rectal and oropharyngeal swab specimens.

The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial, gonococcal, and/or trichomoniasis urogenital disease and chlamydial and gonococcal extragenital infection.

The BD CTGCTV2 assay is available for use with the BD MAX™ System (urogenital specimens) or the BD COR™ System (urogenital and extragenital specimens), as described above.

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.

510(k) Summary
BD CTGCTV2

Summary Preparation Date:

10/25/2024

Submitted by:

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Teresa Jennifer Sugumar, MS
Staff Regulatory Affairs Specialist
Tel: (862) 376-7814

Email: teresa.jennifer.sugumar@bd.com

Device

Trade Name/Device Name: BD CTGCTV2

Proprietary Names

For the instrument:

BD COR™ System

For the assay:

BD CTGCTV2

Common Names

For the instrument:

High-throughput molecular system

For the assay:

CT, GC and TV assay

Regulatory Information

Regulation section:

21 CFR §866.3393, Nucleic Acid Detection System For Non-Viral Microorganism(S) Causing Sexually Transmitted Infections

Classification:

Class II

Panel:

Microbiology

Product Code(s):

QEP - Nucleic Acid Detection System For Non-Viral Microorganism(S) Causing Sexually Transmitted Infections

LSL - DNA-Reagents, Neisseria

MKZ - DNA Probe, Nucleic Acid Amplification, Chlamydia

OUY - Trichomonas Vaginalis Nucleic Acid Amplification Test System

OOI - Real time nucleic acid amplification system

Predicate Device:

Trade Name/Device Name: BD CTGCTV2

510(k) Number: (K210585)

Device Establishment:

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Registration Number: 1119779

Performance Standards:

- ISO 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14971 Third Edition 2019-12 – Medical devices – Application of risk management to medical devices

- ISO 14155 Third edition 2020-07 – Clinical investigation of medical devices for human subjects – Good clinical practice
- ISO 20417 First edition 2021-04 Corrected version 2021 – Medical devices –Information to be supplied by the manufacturer
- ISO 15223-1 Fourth edition 32021-07 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1 General requirements
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION – Medical device software – Software life cycle processes
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION – Medical devices – Part 1: Application of usability engineering to medical devices
- CLSI MM03-ED3:2015 Molecular Diagnostic Methods for Infectious Diseases, Third Edition
- CLSI MM13-ED2:2020 Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, Second Edition
- CLSI EP05-A3:2019 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition
- CLSI EP25-A:2009 Evaluation of Stability of In Vitro Diagnostic Reagents, First Edition

FDA Guidance:

21 CFR §866.3393, Nucleic Acid Detection System For Non-Viral Microorganism(S) Causing Sexually Transmitted Infections

Intended Use:

The BD CTGCTV2 assay incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (GC)
- *Trichomonas vaginalis* (TV)

The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting) and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in ThinPrep® PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep® Pap test. The assay may also be used for the detection of CT and GC DNA in clinician-collected rectal and oropharyngeal swab specimens.

The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial, gonococcal, and/or trichomoniasis urogenital disease and chlamydial and gonococcal extragenital infection.

The BD CTGCTV2 assay is available for use with the BD MAX™ System (urogenital specimens) or the BD COR™ System (urogenital and extragenital specimens), as described above.

Special Conditions for Use Statement:

For Prescription Use Only
For *in vitro* diagnostic use only

Special Instrument Requirements:

BD CTGCTV2 is performed on the BD COR™ System.

Principles of the Procedure

The BD CTGCTV2 assay, performed on the BD COR™ System (hereafter referred to as BD CTGCTV2), is designed for use with the applicable BD Molecular specimen collection and transport devices for male and female urine, rectal swabs, oropharyngeal swabs, vaginal swabs, endocervical swabs, and LBC specimens (PreservCyt®). Specimens are collected and transported to the testing laboratory using their respective transport devices under conditions of time and temperature that have been determined to maintain the integrity of the target nucleic acids.

The BD COR™ MX Instrument, when combined with the BD COR™ PX Instrument, is to be used for automated sample preparation, extraction, and purification of nucleic acids from multiple specimen types, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based real-time PCR for simultaneous and differential detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.

The BD CTGCTV2 assay extraction reagents are dried in 96-well microtiter plates that contain binding magnetic affinity beads and Sample Processing Control (SPC). Each tube is capable of binding and eluting sample nucleic acids. The SPC monitors the integrity of the reagents and the process steps involved in DNA extraction, amplification and detection, as well as for the presence of potential assay inhibitors.

The BD CTGCTV2 assay liquid reagent plate includes Wash, Elution and Neutralization buffers. The beads (described above), together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH. When performed on BD COR™ System, there is an additional buffer to rehydrate the dried extraction mix. Eluted DNA is neutralized and transferred to the Amplification reagent (described below) to rehydrate the PCR reagents. After reconstitution, the BD COR™ System dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the BD PCR Cartridge. Microvalves in the BD

PCR Cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture and thus prevent evaporation and contamination.

The BD CTGCTV2 assay is comprised of two targets for *Chlamydia trachomatis* (detected on the same optical channel), two targets for *Neisseria gonorrhoeae* (detected on two different optical channels) and one target for *Trichomonas vaginalis* (detected on one optical channel). Only one *Chlamydia trachomatis* target is required to be positive in order to report a positive result. Both *Neisseria gonorrhoeae* targets are required to be positive in order to report a positive result.

The amplified DNA targets are detected using hydrolysis (TaqMan®) probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end, with a quencher moiety. Probes labeled with different fluorophores are used to detect the target analytes in different optical channels of the BD COR™ System. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'-3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The BD COR™ System monitors these signals at each cycle of the PCR and interprets the data at the end of the reaction to provide qualitative test results for each analyte (i.e., positive or negative).

Substantial Equivalence[1]:

Table 1 provides the similarities and differences between the BD CTGCTV2, respectively, in comparison to the predicate device, BD CTGCTV2.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1. Comparison of the Subject Device to the Predicate Device

Device and Predicate Device	Subject Device	Predicate Device
Device Trade Name	BD CTGCTV2	BD CTGCTV2
Device 510(k) Number	-	K210585
Regulation	21 CFR 866.3393	21 CFR 866.3393
Product Code	QEP, OUY, LSL, MKZ, OOI	QEP, OUY, LSL, MKZ
Device Class	II	II
Intended Use	The BD CTGCTV2 assay incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from: • *Chlamydia trachomatis* (CT) • *Neisseria gonorrhoeae* (GC) • *Trichomonas vaginalis* (TV) The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting) and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in ThinPrep® PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep® Pap test. The assay may also be used for the detection of CT and GC DNA in clinician-collected rectal and oropharyngeal swab specimens. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial, gonococcal, and/or trichomoniasis urogenital disease and chlamydial and gonococcal extragenital infection. The BD CTGCTV2 assay is available for use with the BD MAX™ System (urogenital specimens) or the BD	The BD CTGCTV2 incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from: • *Chlamydia trachomatis* (CT) • *Neisseria gonorrhoeae* (GC) • *Trichomonas vaginalis* (TV) The assay may be used for detection of CT, GC and/or TV DNA in patient- or clinician-collected vaginal swab specimens (in a clinical setting), and male and female urine specimens. The assay may also be used for the detection of CT and GC DNA in endocervical swab and Liquid-Based Cytology (LBC) specimens in ThinPrep® PreservCyt® Solution using an aliquot that is removed prior to processing for the ThinPrep® Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial urogenital disease, gonococcal urogenital disease and/or trichomoniasis. The BD CTGCTV2 assay is available for use with the BD MAX™ System or the BD COR™ System.

<table>
<tr><th>Device and Predicate Device</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td></td><td>COR™ System (urogenital and extragenital specimens), as described above.</td><td></td></tr>
<tr><td>Indications for Use</td><td>Same</td><td>Asymptomatic and Symptomatic Patients</td></tr>
<tr><td>Specimen Type</td><td>Clinician-collected vaginal swab, patient collected vaginal swab, endocervical swab, PreservCyt LBC, female and male urine, rectal and oropharyngeal swab</td><td>Clinician-collected vaginal swab, patient collected vaginal swab, endocervical swab, PreservCyt LBC, female and male urine</td></tr>
<tr><td>On-Board Lysis (OBL)</td><td>30’ OBL for urogenital samples
10’ OBL for LBC samples
10’ OBL for extragenital samples</td><td>30’ OBL for urogenital samples
10’ OBL for LBC samples</td></tr>
<tr><td>Technology</td><td>Same</td><td>PCR</td></tr>
<tr><td>Organisms Detected</td><td>Same</td><td>CT, GC, and TV</td></tr>
<tr><td>Sample Prep/BD COR™ of Results</td><td>Same</td><td>Automated by BD COR ™ System</td></tr>
<tr><td>Assay Controls</td><td>Same</td><td>Sample Processing Control</td></tr>
<tr><td>Target Detection</td><td>Same</td><td><table><tr><th>Target</th><th>Dye</th><th>Channel</th></tr><tr><td>CT</td><td>FAM</td><td>FAM</td></tr><tr><td>CT</td><td>FAM</td><td>FAM</td></tr><tr><td>GC (GC1)</td><td>CFO</td><td>VIC</td></tr><tr><td>GC (GC2)</td><td>Q705</td><td>CY5.5</td></tr><tr><td>TV</td><td>Q670</td><td>CY5</td></tr></table></td></tr>
<tr><td>Collection/ Transport Device</td><td>Same

Note: Rectal and oropharyngeal samples will utilize existing Swab Sample Buffer Tube (2.0 mL)</td><td>Swab Sample Buffer Tube (2.0 mL)
Urine Sample Buffer Tube (0.5 mL)
LBC Sample Buffer Tube (1.5 mL)</td></tr>
<tr><td>Sample Prep</td><td>Same

Note: Rectal and oropharyngeal samples will utilize existing prep of 1 swab added to Swab Sample Buffer Tube</td><td>1 swab added to Swab Sample Buffer Tube
2.0 mL urine added to Urine Sample Buffer Tube
0.5 mL LBC added to LBC Sample Buffer Tube</td></tr>
</table>

Analytical Performance Evaluation

The focus of this submission is the addition of extragenital specimen claims (rectal and oropharyngeal) for testing *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC); TV was not assessed for extragenital specimens.

Limit of Detection (LoD)

The analytical sensitivity/Limit of Detection (LoD) of the BD CTGCTV2 assay in rectal and oropharyngeal matrix was determined as follows: A microbial suspension was prepared from each of two (2) representative strains of the target organisms detected by the BD CTGCTV2 assay. Each target organism was quantified prior to testing. Positive specimens were prepared by inoculating pooled rectal and oropharyngeal swabs in sample buffer with multiple concentrations of each representative serovar/strain. Each matrix suspension was tested with at least 20 replicates per concentration using at least 2 BD COR™ Systems and 2 reagent lots of the BD CTGCTV2 assay. Analytical sensitivity (LoD), defined as the lowest concentration at which at least 95% of all replicates tested positive, ranged from 1.25 to 25 units/mL. The Limit of Detection results are presented in Table 2.

Table 2. Limit of Detection of the BD CTGCTV2 Assay for Extragenital Sample Types

Organism	Strain	Specimen	LoD Concentration (units/mL)[a]
Chlamydia trachomatis	Serovar H	Rectal	2.5
		Oropharyngeal	1.875
	Serovar D	Rectal	2.5
		Oropharyngeal	1.25
Neisseria gonorrhoeae	ATCC® 19424	Rectal	25
		Oropharyngeal	20
	ATCC® 49226	Rectal	20
		Oropharyngeal	10

[a] Units/mL LoD concentration represented in Elementary Bodies (EB)/mL for *Chlamydia trachomatis* and CFU/mL for *Neisseria gonorrhoeae*.

Inclusivity

The analytical reactivity of the BD CTGCTV2 assay was evaluated on the BD COR™ System. The study evaluated the ability of the BD CTGCTV2 assay to detect clinically relevant and geographically diverse serovars and/or strains of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* when tested in rectal and oropharyngeal matrices. The study included thirteen (13) additional *Chlamydia trachomatis* serovars (A, B, C, E, F, G, I, J, K, LGV1, LGV2, LGV3, and vE) and thirty (30) *Neisseria gonorrhoeae* strains. These 43 serovars/strains, which represented public collections and well-characterized clinical isolates, were spiked into rectal and oropharyngeal pools prepared in sample buffer at 2x LoD for each organism. Each serovar/strain was tested in 3 replicates. Of the 43 organisms tested, four (4) which did not confirm at 2x LoD, upon initial testing and required titration. The results for *Chlamydia trachomatis* and *Neisseria*

gonorrhoeae are presented in Table 3 and Table 4 and show the LoD level which were detected at 100%.

Table 3. Inclusivity Results (Performed on BD COR™ System) – *Chlamydia trachomatis*

Organism	Serovar	Rectal	Oropharyngeal
		EBs/mL	EBs/mL
Chlamydia trachomatis	A	5	3.75
	B	5	3.75
	C	5	3.75
	E	5	3.75
	F	5	3.75
	G	5	3.75
	I	10	7.50
	J	5	3.75
	K	5	3.75
	LGV1[a]	37	63
	LGV2[a]	32	40
	LGV3[a]	40	79
	vE	5	3.75

[a] LGV1, LGV2, and LGV3 were assessed as genomic DNA in copies/mL but were diluted to a level that was comparable to 2x LoD.

Table 4. Inclusivity Results (Performed on BD COR™ System) – *Neisseria gonorrhoeae*

Organism	Strain	Rectal	Oropharyngeal
		CFU/mL	CFU/mL
Neisseria gonorrhoeae	27	50	40
	3	75	60

Cross-Reactivity

The analytical specificity/cross-reactivity of the BD CTGCTV2 assay for extragenital specimens was evaluated on the BD COR™ System. The BD CTGCTV2 assay was performed on samples containing phylogenetically related microorganisms likely to be found in extragenital specimens. The bacterial cells, yeasts and parasites were tested in the Sample Buffer Tube at $1x10^6$ cells/mL, genomic DNA cp/mL, cysts/mL or EB/mL. Viruses were tested at $1x10^5$ viral particles (PFU), $TCID_{50}$ or genomic equivalents/mL. Five (5) microorganisms *Entamoeba histolytica,* Enterovirus, *Giardia lamblia,* Human metapneumovirus, and Rhinovirus were tested at lower concentrations which are listed below in Table 5. BD CTGCTV2 assay performed on the BD COR™ System has been shown to be equivalent on the BD MAX™ System under K210585 and some microorganisms were leveraged from previous analytical studies. All bacterial strains, yeast, parasites and viruses assessed produced negative results with the BD CTGCTV2 assay. Organisms for rectal and oropharyngeal specimen types that were tested are represented in Table 5.

Table 5. BD CTGCTV2 Assay Specificity Organisms (Bacteria, Yeasts, Parasites and Viruses) Specific to Extragenital Specimen Types

Organism	Organism	Organism
Acinetobacter baumannii	*Giardia lamblia*[c]	*Proteus mirabilis*
Adenovirus	*Helicobacter pylori*	*Providencia stuartii*
Aggregatibacter actinomycetemcomitans	Herpes simplex virus 1	*Pseudomonas aeruginosa*
Anaerococcus tetradius	Human influenza virus A	Respiratory syncytial virus
Arcanobacterium haemolyticum	Human influenza virus B	Rhinovirus[e]
Bifidobacterium adolescentis	Human metapneumovirus[d]	*Saccharomyces cerevisiae*
Bordetella pertussis	*Klebsiella pneumoniae*	*Salmonella enterica* serovar Minnesota
Campylobacter rectus	*Lactobacillus acidophilus*	*Shigella sonnei*
Candida albicans	*Listeria monocytogenes*	*Staphylococcus aureus*
Clostridium difficile	*Moraxella catarrhalis*	*Streptococcus agalactiae*
Coronavirus	*Morganella morganii*	*Streptococcus anginosus*
Corynebacterium diphtheriae	*Mycoplasma pneumoniae*	*Streptococcus dysgalactiae*
Entamoeba histolytica[a]	Norovirus	*Tannerella forsythus (Bacteroides forsythus)*
Enterobacter cloacae	*Parvimonas micra* (*Peptostreptococcus micros*)	*Treponema denticola*
Enterococcus faecalis	*Porphyromonas gingivalis*	*Veillonella parvula*
Enterovirus[b]	*Prevotella bivia*	*Vibrio cholerae*
Fusobacterium necrophorum	*Prevotella oralis (Bacteroides oralis)*	*Yersinia enterocolitica*

[a]*Entamoeba histolytica* tested at $5x10^3$ cells/mL.
[b]Enterovirus tested at $1x10^4$ $TCID_{50}$/mL.
[c]*Giardia lamblia* tested at $1x10^5$ cysts/mL.
[d]Human metapneumovirus tested at $5x10^3$ cp/mL.
[e]Rhinovirus tested at $3x10^3$ $TCID_{50}$/mL.

Microbial Interference

Microbial Interference of the BD CTGCTV2 assay for extragenital specimens was evaluated on the BD COR™ System. A total of twenty-five (25) organisms for Rectal and thirty-one (31) organisms for Oropharyngeal were evaluated for potential interference with the BD CTGCTV2 assay. Bacterial cells, yeasts and parasites were tested in the Sample Buffer Tube at $1x10^6$cells/mL, genomic DNA cp/mL, cysts/mL or EB/mL. Viruses were tested at $1x10^5$ viral particles (PFU), $TCID_{50}$ or genomic equivalents/mL. Five (5) microorganisms *Entamoeba histolytica,* Enterovirus, *Giardia lamblia,* Human metapneumovirus, and Rhinovirus were tested at lower concentrations which are listed below in Table 6 and Table 7. *Chlamydia trachomatis* and *Neisseria gonorrhoeae* was co-spiked with all organisms at a 3x level. Organism assessed where *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were detected at 100% in rectal and oropharyngeal specimens are represented in Table 6 and Table 7.

Table 6. BD CTGCTV2 Assay Microbial Interference Specific to Rectal Specimen

Organism	Organism	Organism
Acinetobacter baumannii	*Helicobacter pylori*	*Salmonella enterica* serovar Minnesota
Anaerococcus tetradius	*Lactobacillus acidophilus*	*Shigella sonnei*
Bifidobacterium adolescentis	*Listeria monocytogenes*	*Staphylococcus aureus*
Clostridium difficile	*Morganella morganii*	*Streptococcus agalactiae*
Entamoeba histolytica[a]	Norovirus	*Streptococcus dysgalactiae*
Enterobacter cloacae	*Prevotella bivia*	*Vibrio cholerae*
Enterococcus faecalis	*Proteus mirabilis*	*Yersinia enterocolitica*
Enterovirus[b]	*Providencia stuartii*	
Giardia lamblia[c]	*Pseudomonas aeruginosa*	

[a]*Entamoeba histolytica* tested at $5x10^3$ cells/mL.
[b]Enterovirus tested at $1x10^4$ $TCID_{50}$/mL.
[c]*Giardia lamblia* tested at $1x10^5$ cysts/mL.

Table 7. BD CTGCTV2 Assay Microbial Interference Specific to Oropharyngeal Specimen

Organism	Organism	Organism
Adenovirus	Human influenza virus B	Respiratory syncytial virus
Aggregatibacter actinomycetemcomitans	Human metapneumovirus[a]	Rhinovirus[b]
Arcanobacterium haemolyticum	*Klebsiella pneumoniae*	*Saccharomyces cerevisiae*
Bordetella pertussis	*Lactobacillus acidophilus*	*Staphylococcus aureus*
Campylobacter rectus	*Moraxella catarrhalis*	*Streptococcus anginosus*
Candida albicans	*Mycoplasma pneumoniae*	*Streptococcus dysgalactiae*
Coronavirus	*Parvimonas micra* (*Peptostreptococcus micros*)	*Tannerella forsythus (Bacteroides forsythus)*
Corynebacterium diphtheriae	*Porphyromonas gingivalis*	*Treponema denticola*
Fusobacterium necrophorum	*Prevotella bivia*	*Veillonella parvula*
Herpes simplex virus 1	*Prevotella oralis (Bacteroides oralis)*	
Human influenza virus A	*Pseudomonas aeruginosa*	

[a]Human metapneumovirus tested at $5x10^3$ cp/mL.
[b]Rhinovirus tested at $3x10^3$ $TCID_{50}$/mL.

Interfering Substances

The interfering substances study of the BD CTGCTV2 assay was performed on the BD COR™ System for extragenital specimens. Thirty-nine (39) biological and chemical substances that may be present in extragenital specimens were evaluated for potential interference with the BD CTGCTV2 assay. Included in this study were antibiotic, over the counter medications, astringents, antiseptics, lubricants, contraceptives, and biological substances that were tested at a

concentration that may be found in extragenital specimens. Negative rectal and oropharyngeal pooled specimens and a target mix of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* positive at 3x LoD were tested with the highest amount of each compound likely to be found in the specimens. Potentially interfering substances in rectal specimens include zinc oxide, feces, fecal fat (stearic acid) and whole blood. Potentially interfering substances in oropharyngeal specimens include Beconase AQ, Prilosec, toothpaste, and whole blood. The following substances shown in Table 8 and Table 9 did not cause interference with the BD CTGCTV2 assay at the concentrations shown below.

Table 8. Exogenous and Endogenous Substances Tested for Interference in Rectal Swab Specimens

Substance	Concentration
Vaseline (Petroleum Jelly)	5%
Miconazole Nitrate Cream	2% w/v
Zinc Oxide	10% w/w paste[a]
Hemorrhoid Gel (Phenylephrine HCL)	2% w/v
Hemorrhoid Gel (Witch Hazel)	3.75%
Bactroban (Mupirocin)	3.75%
Mineral Oil	2% v/v
Imodium (Leperamide HCL)	0.00667 mg/mL
Condoms (Nonoxynol-9)	7% v/v
Ex-Lax (Sennosides)	0.1 mg/mL
Moist Towelettes (Benzalkonium Chloride)	0.12% w/v
Gaviscon (Aluminum Hydroxide/Magnesium Carbonate)	0.1 mg/mL
Feces	1.75%[a]
Fecal Fat (Palmitic acid)	2 mg/mL
Fecal Fat (Stearic Acid)	1 mg/mL[a]
Whole Blood	5 µL/mL[a]
KY Lubricating Jelly	137.5 mg/mL
Mucous (Bovine Cervical)	5.0% v/v

[a] May interfere with the BD CTGCTV2 assay when at concentrations higher than shown.

Table 9. Exogenous and Endogenous Substances Tested for Interference in Oropharyngeal Swab Specimens

Substance	Concentration
Neo-synephrine	3.75%
Afrin Nasal Spray (Oxymetazoline HCL)	7.5 mg/mL
Zicam Nasal Gel (Zinc Acetate)	20%
Saline Nasal Spray	15%
Relenza (Zanamivir)	45% v/v (1 mg)
Tobrex 0.3% (Tobramycin)	9% v/v (0.27 mg)
Rebetol (Ribavrin)	5 ng/mL
TamiFlu (Oseltamivir)	7.5 mg/mL

Substance	Concentration
Beconase AQ (Beclomethasone dipropionate)	1.75%[a]
Tums (Calcium Carbonate)	0.5 mg/mL
Pepto Bismol (Bismuth Subsalicylate)	0.87 mg/mL
Tagamet	0.5 mg/mL
Prilosec (delayed release) (Omeparazole Magnesium)	0.25 mg/mLa
Vancomycin HCL	12.5 mg/mL
Sucrets lozenges (Menthol Dyclonine)	10 mg/mL
Barium Sulfate	5 mg/mL
Chloraseptic Spray (Menthol/Benzocaine/Dextromethorphan Hydrobromide)	10 mg/mL
Toothpaste (Sodium Monoflurophosphate)	10 mg/mL[a]
Mouthwash (Cetylpyridinium Chloride/ Domiphen Dromide /Denatured Alcohol)	25% v/v
Lip Balm (Camphor/Menthol/ Petolatum/Phenol)	5 mg/mL
Cold Sore medication (Docosanol)	10 mg/mL
Whole Blood	10 µL/mL[a]
Mucous (Bovine Cervical)	5.0% v/v

[a] May interfere with the BD CTGCTV2 assay when at concentrations higher than shown.

Mixed Infection/Competitive Interference

The mixed infection/competitive interference study of the BD CTGCTV2 assay was performed on the BD COR™ System for Extragenital specimen. The mixed infection/competitive interference study was designed to evaluate the ability of the BD CTGCTV2 assay to detect low concentrations of the target organisms in the presence of high concentration of the other two target organisms. Three test samples were prepared in pooled clinical matrix (rectal and oropharyngeal) each containing one of the target organisms (*Chlamydia trachomatis* and *Neisseria gonorrhoeae*) at 1.5x their respective LoD. A high target mix comprised of organisms representative of the other two BD CTGCTV2 assay analytes at a concentration ≥1 x 10^6 EB, CFU or TV/mL were spiked into each sample to simulate mixed infections. The samples were tested in 20 replicates. All two low target organisms were successfully detected at ≥95% by the BD CTGCTV2 assay in the presence of the other two organisms at high concentrations in rectal and oropharyngeal specimens.

Specimen Stability

Extragenital Swab specimens must be transferred to a BD Molecular Swab Sample Buffer Tube immediately after collection. Once in the BD Molecular Sample Buffer Tube, the swab specimens can be stored for a total of 21 days at 2–30 °C. A Sample Buffer Tube with a pierced cap can be stored upright for up to 4 days (included in the 21 days total storage duration) at 2–30 °C (Table 10).

Table 10. Swab Specimen Storage and Transport

Specimen Stability	Transport and/or Storage Time/Temperature
In BD Molecular Swab Sample Buffer Tube	Up to 21 days at 2–30 °C
Upon puncture of BD Pierceable Caps	Up to 4 days punctured within 21 days at 2–30 °C

Expected Values

Positivity for Extragenital Specimens

The positivity rate of the BD CTGCTV2 assay on the BD COR™ System with extragenital specimens, as observed during the multi-center clinical study, is shown by specimen type in Table 11 below.

Table 11. Positivity Rate with BD COR™ System by Symptomatic Status, Target, and Specimen Type

Symptomatic Status	Specimen Type	Positivity Rate	
		CT	GC
Asymptomatic	Oropharyngeal	1.4% 21/1,553	3.3% 52/1,553
	Rectal	5.7% 88/1,537	3.3% 51/1,537
Symptomatic	Oropharyngeal	1.2% 9/735	6.9% 51/735
	Rectal	7.5% 54/723	6.1% 44/723
Unknown	Oropharyngeal	0.0% 0/17	0.0% 0/17
	Rectal	0.0% 0/17	5.9% 1/17
Total	Oropharyngeal	1.3% 30/2,305	4.5% 103/2,305
	Rectal	6.2% 142/2,277	4.2% 96/2,277

Hypothetical Predictive Values for Extragenital Specimens

Table 12 provides positive and negative predictive values based on hypothetical prevalence rates.

Table 12. Positive and Negative Predictive Values Based on Hypothetical Prevalence

Specimen Type	Hypothetical Prevalence	Estimate (95% CI)			
		CT		GC	
		PPV	NPV	PPV	NPV
Oropharyngeal	1%	82.1% (66.3, 93.4)	100% (99.9, 100)	63.3% (50.1, 76.2)	99.9% (99.9, 100)
	2%	90.3% (79.9, 96.6)	100% (99.7, 100)	77.7% (67.0, 86.6)	99.9% (99.7, 99.9)
	5%	96.0% (91.1, 98.7)	100% (99.3, 100)	90.0% (83.9, 94.4)	99.6% (99.3, 99.8)
	10%	98.1% (95.6, 99.4)	100% (98.4, 100)	95.0% (91.7, 97.2)	99.2% (98.4, 99.7)
	15%	98.8% (97.2, 99.6)	100% (97.5, 100)	96.8% (94.6, 98.2)	98.7% (97.5, 99.5)
	20%	99.1% (98.0, 99.7)	100% (96.6, 100)	97.7% (96.1, 98.8)	98.2% (96.5, 99.3)
	25%	99.3% (98.5, 99.8)	100% (95.5, 100)	98.3% (97.1, 99.1)	97.6% (95.4, 99.0)
Rectal	1%	63.8% (50.6, 76.8)	100% (99.9, 100)	84.1% (67.9, 94.8)	100% (99.9, 100)
	2%	78.1% (67.4, 87.0)	100% (99.9, 100)	91.4% (81.1, 97.4)	99.9% (99.8, 100)
	5%	90.2% (84.2, 94.5)	99.9% (99.7, 100)	96.5% (91.7, 99.0)	99.8% (99.5, 99.9)
	10%	95.1% (91.9, 97.3)	99.7% (99.3, 99.9)	98.3% (95.9, 99.5)	99.5% (98.9, 99.9)
	15%	96.9% (94.7, 98.3)	99.6% (98.9, 99.9)	98.9% (97.4, 99.7)	99.3% (98.2, 99.8)
	20%	97.8% (96.2, 98.8)	99.4% (98.4, 99.9)	99.2% (98.1, 99.8)	99.0% (97.5, 99.7)
	25%	98.3% (97.1, 99.1)	99.2% (97.9, 99.8)	99.4% (98.6, 99.8)	98.6% (96.6, 99.6)

Clinical Performance Study for Extragenital Specimens

The performance of the BD CTGCTV2 assay on the BD COR™ System using oropharyngeal and rectal swabs was established by comparing the assay results obtained on the BD COR™ System to a composite comparator algorithm (CCA) comprised of three commercially available NAATs. Specimens were collected from subjects enrolled at eight geographically diverse sites including STD, family planning, HIV, and research clinics. The performance (sensitivity and specificity) of the BD CTGCTV2 assay on the BD COR™ System versus the CCA was evaluated. A positive or negative CCA result was defined by the concurrence of at least 2 out of 3 commercially available NAAT assay results.

A total of 2,439 subjects were consented to participate in the collection. Of those, 2,375 were found eligible based on pre-determined inclusion/exclusion criteria. A total of 4,652 specimens (oropharyngeal and rectal swabs) were considered eligible for randomization into the study, of

which 4,579 were considered eligible for testing (2,303 oropharyngeal swabs and 2,276 rectal swabs). The sensitivity for the CT target was 97.7% (129/132) for rectal samples and 100% (24/24) for oropharyngeal samples. The sensitivity for the GC target was 95.8% (91/95) for rectal samples and 92.8% (90/97) for oropharyngeal samples. The specificity for the CT target was 99.4% (2,130/2,142) for rectal samples and 99.8% (2,269/2,274) for oropharyngeal samples. The specificity of the GC target was 99.8% (2,177/2,181) for rectal samples and 99.5% (2,194/2,206) for oropharyngeal samples (Table 13).

Table 13. Clinical Performance of BD CTGCTV2 Assay on BD COR™ System for Extragenital Specimens Compared to CCA, by Symptomatic Status, Target, and Specimen Type

Symptomatic Status	Specimen Type	CT		GC	
		PPA (%) (95% CI)	NPA (%) (95% CI)	PPA (%) (95% CI)	NPA (%) (95% CI)
Asymptomatic	Oropharyngeal	100 17/17 (81.6–100)	99.8 1,526/1,529 (99.4–99.9)	93.5 43/46 (82.5–97.8)	99.4 1,498/1,507 (98.9–99.7)
	Rectal	97.6 81/83 (91.6–99.3)	99.5 1,446/1,453 (99.0–99.8)	100 50/50 (92.9–100)	99.9 1,486/1,487 (99.6–100)
Symptomatic	Oropharyngeal	100 7/7 (64.6–100)	99.7 726/728 (99.0–99.9)	92.2 47/51 (81.5–96.9)	99.6 679/682 (98.7–99.9)
	Rectal	98.0 48/49 (89.3–99.6)	99.3 667/672 (98.3–99.7)	90.9 40/44 (78.8–96.4)	99.6 675/678 (98.7–99.8)
Unknown	Oropharyngeal	NA	100 17/17 (81.6–100)	NA	100 17/17 (81.6–100)
	Rectal	NA	100 17/17 (81.6–100)	100 1/1 (20.7–100)	100 16/16 (80.6–100)
Total	Oropharyngeal	100 24/24 (86.2–100)	99.8 2,269/2,274 (99.5–99.9)	92.8 90/97 (85.8–96.5)	99.5 2,194/2,206 (99.1–99.7)
	Rectal	97.7 129/132 (93.5–99.2)	99.4 2,130/2,142 (99.0–99.7)	95.8 91/95 (89.7–98.4)	99.8 2,177/2,181 (99.5–99.9)

NA =Not Available. There were 17 subjects with unknown symptomatic status. Among these subjects, there were no oropharyngeal or rectal samples positive for CT and no oropharyngeal samples positive for GC.

Non-Reportable Results for BD COR™ System for Extragenital Specimens

Non-reportable results were defined as results obtained while assessing the CT/GC targets with the BD CTGCTV2 assay on BD COR™ System which resulted in a sample processing control or system failure. A failure may also occur when the External Control produces an unexpected result such as an External Positive Control that produces a negative result or an External Negative Control that produces a positive result.

The non-reportable rate calculations were obtained using the specimen tested during the clinical performance study, detailed above. The subject/specimen and the BD CTGCTV2 assay must be compliant to qualify the data included in the calculation for the denominator of the UNR/IND/INC rate. To be considered compliant for non-reportable rate calculations, the specimen must have been collected from a compliant subject, have a compliant reference result per the CCA, been handled within known stability, and had sufficient volume to be run on the BD CTGCTV2 assay. A UNR is counted in the numerator only if it is subject/specimen compliant, BD CTGCTV2 assay compliant, and External Controls yield expected results. External Controls are not considered for IND/INC numerator calculations.

Table 14 through Table 16 provide the unresolved, indeterminate, incomplete, and total rate per target (CT/GC/Combined), stratified by specimen type. The combined rate on initial test across all sample types and combined targets was 0.6%. There were no INC results in any initial test or repeated test in this study.

Table 14. Unresolved/Indeterminate/Incomplete Rate by CT Target and Specimen Type

CT	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total Rate	
Specimen Type	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)
Oropharyngeal[b]	0.4% 9/2,307 (0.2, 0.7)	0.0% 1/2,306 (0.0, 0.2)	0.3% 7/2,307 (0.1, 0.6)	0.0% 0/2,306 (0.0, 0.2)	0.0% 0/2,307 (0.0, 0.2)	0.0% 0/2,306 (0.0, 0.2)	0.7% 16/2,307 (0.4, 1.1)	0.0% 1/2,306 (0.0, 0.2)
Rectal[c]	0.2% 5/2,279 (0.1, 0.5)	0.0% 1/2,278 (0.0, 0.2)	0.3% 6/2,279 (0.1, 0.6)	0.0% 0/2,278 (0.0, 0.2)	0.0% 0/2,279 (0.0, 0.2)	0.0% 0/2,278 (0.0, 0.2)	0.5% 11/2,279 (0.3, 0.9)	0.0% 1/2,278 (0.0, 0.2)
Total	0.3% 14/4,586 (0.2, 0.5)	0.0% 2/4,584 (0.0, 0.2)	0.3% 13/4,586 (0.2, 0.5)	0.0% 0/4,584 (0.0, 0.1)	0.0% 0/4,586 (0.0, 0.1)	0.0% 0/4,584 (0.0, 0.1)	0.6% 27/4,586 (0.4, 0.9)	0.0% 2/4,584 (0.0, 0.2)

[a] The final rate is calculated with the number of remaining non-reportable events after repeat testing.

b The denominator in the final non-reportable rate for the oropharyngeal specimen type (and ultimately Total rate) is decreased by one due to a missing BD COR™ System result upon repeat.

[C] The denominator in the final non-reportable rate for the rectal specimen type (and ultimately Total rate) is decreased by one due to a missing BD COR™ System result upon repeat.

Unresolved= invalid SPC due to presence of inhibitory substances or reagent failure

Indeterminate= BD COR™ System failure (with Warning or Error Codes)

Incomplete= aborted run or BD COR™ System failure that halts robot operations (with Warning or Error Codes)

Table 15. Unresolved/Indeterminate/Incomplete Rate by GC Target and Specimen Type

GC	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total Rate	
Specimen Type	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)
Oropharyngeal[b]	0.4% 9/2,307 (0.2, 0.7)	0.0% 1/2,306 (0.0, 0.2)	0.3% 7/2,307 (0.1, 0.6)	0.0% 0/2,306 (0.0, 0.2)	0.0% 0/2,307 (0.0, 0.2)	0.0% 0/2,306 (0.0, 0.2)	0.7% 16/2,307 (0.4, 1.1)	0.0% 1/2,306 (0.0, 0.2)
Rectal[c]	0.1% 3/2,279 (0.0, 0.4)	0.0% 1/2,278 (0.0, 0.2)	0.3% 6/2,279 (0.1, 0.6)	0.0% 0/2,278 (0.0, 0.2)	0.0% 0/2,279 (0.0, 0.2)	0.0% 0/2,278 (0.0, 0.2)	0.4% 9/2,279 (0.2, 0.7)	0.0% 1/2,278 (0.0, 0.2)
Total	0.3% 12/4,586 (0.1, 0.5)	0.0% 2/4,584 (0.0, 0.2)	0.3% 13/4,586 (0.2, 0.5)	0.0% 0/4,584 (0.0, 0.1)	0.0% 0/4,586 (0.0, 0.1)	0.0% 0/4,584 (0.0, 0.1)	0.5% 25/4,586 (0.4, 0.8)	0.0% 2/4,584 (0.0, 0.2)

[a] The final rate is calculated with the number of remaining non-reportable events after repeat testing.

b The denominator in the final non-reportable rate for the oropharyngeal specimen type (and ultimately Total rate) is decreased by one due to a missing BD COR™ System result upon repeat.

[C] The denominator in the final non-reportable rate for the rectal specimen type (and ultimately Total rate) is decreased by one due to a missing BD COR™ System result upon repeat.

Unresolved= invalid SPC due to presence of inhibitory substances or reagent failure

Indeterminate= BD COR™ System failure (with Warning or Error Codes)

Incomplete= aborted run or BD COR™ System failure that halts robot operations (with Warning or Error Codes)

Table 16. Unresolved/Indeterminate/Incomplete Rate for CT and GC by Specimen Type

Combined Target	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total Rate	
Specimen Type	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)	Initial (95% CI)	Valid Repeat[a] (95% CI)
Oropharyngeal[b]	0.4% 9/2,307 (0.2, 0.7)	0.0% 1/2,306 (0.0, 0.2)	0.3% 7/2,307 (0.1, 0.6)	0.0% 0/2,306 (0.0, 0.2)	0.0% 0/2,307 (0.0, 0.2)	0.0% 0/2,306 (0.0, 0.2)	0.7% 16/2,307 (0.4, 1.1)	0.0% 1/2,306 (0.0, 0.2)
Rectal[c]	0.2% 5/2,279 (0.1, 0.5)	0.0% 1/2,278 (0.0, 0.2)	0.3% 6/2,279 (0.1, 0.6)	0.0% 0/2,278 (0.0, 0.2)	0.0% 0/2,279 (0.0, 0.2)	0.0% 0/2,278 (0.0, 0.2)	0.5% 11/2,279 (0.3, 0.9)	0.0% 1/2,278 (0.0, 0.2)
Total	0.3% 14/4,586 (0.2, 0.5)	0.0% 2/4,584 (0.0, 0.2)	0.3% 13/4,586 (0.2, 0.5)	0.0% 0/4,584 (0.0, 0.1)	0.0% 0/4,586 (0.0, 0.1)	0.0% 0/4,584 (0.0, 0.1)	0.6% 27/4,586 (0.4, 0.9)	0.0% 2/4,584 (0.0, 0.2)

[a] The final rate is calculated with the number of remaining non-reportable events after repeat testing.

b The denominator in the final non-reportable rate for the oropharyngeal specimen type (and ultimately Total rate) is decreased by one due to a missing BD COR™ System result upon repeat.

[C] The denominator in the final non-reportable rate for the rectal specimen type (and ultimately Total rate) is decreased by one due to a missing BD COR™ System result upon repeat.

Unresolved= invalid SPC due to presence of inhibitory substances or reagent failure

Indeterminate= BD COR™ System failure (with Warning or Error Codes)

Incomplete= aborted run or BD COR™ System failure that halts robot operations (with Warning or Error Codes)