May 10, 2022

Becton Dickinson and Company
Jessica Dewyer
Senior Manager, Regulatory Affairs
7 Loveton Circle
Sparks, Maryland 21152

Re: K210585
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, OUY, LSL, MKZ
Dated: February 25, 2021
Received: February 26, 2021

Dear Jessica Dewyer:

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
Assistant Director
Viral Respiratory and HPV Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2023 *See PRA Statement below.*

510(k) Number *(if known)*
K210585

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 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 on the BD MAX System or the BD COR System.

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

BD CTGCTV2 on BD COR System
K210585

Summary Preparation Date:

4/27/2022

Submitted by:

BD Integrated Diagnostic Solutions
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Jessica Dewyer, Senior Manager, Regulatory Affairs
Becton Dickinson and Company
7 Loveton Circle, Sparks, MD 21152 USA
(520) 486-8516
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Proprietary Names:
For the instrument:
BD COR PX/MX 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 (83)

Product Code(s):
QEP
MKZ
LSL
OUY

Predicate Device

BD CTGCTV2 on BD MAX System (K182692)

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 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.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: BD COR PX/MX System

Device Description

As with the existing BD CTGCTV2 for BD MAX System, K182692, the BD COR PX/MX (BD COR) high throughput system conducts sample extraction steps to isolate and concentrate DNA which is then amplified to detect specific sequences for diagnostic purposes.

The BD COR System is designed to allow the user to place clinical specimens directly into designated transport racks to be loaded into the System. Once the specimens are loaded, the System will perform the necessary pre-analytical steps such as vortexing, aliquoting into a molecular tube with the correct diluent, sorting/grouping of the secondary samples for testing by assay, pre-warming and

cooling of the sample (where required), and transport of the sample into a molecular analyzer, where extraction, amplification and detection will take place.

Additionally, the steps of ordering tests on the instrument for specific samples will be managed directly by the user interaction with the Laboratory Information System (LIS), which communicates with the instrument.

Once the clinical specimens are received in the laboratory and loaded into the transport racks, the user will not be required to directly handle the specimen again prior to result reporting and removal from the system.

Test Principle

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, 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 MX, 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 PX/MX 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 PX/MX 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 PX/MX 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 assay and the predicate device.

[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 to the Predicate Device

Items	***BD CTGCTV2***	***BD CTGCTV2 for BD MAX System***
510(k)#	K210585	K182692
Regulation	866.3393, 866.3120, 866.3390, 866.3860	866.3120, 866.3390, 866.3860
Product Code	QEP, MKZ, LSL, OUY	MKZ, LSL, OUY
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 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.	The BD CTGCTV2 for BD MAX™ System, performed on the BD MAX™ System, 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.
Indications for Use	Same	Asymptomatic and Symptomatic Patients
Specimen Type	Same	Clinician-collected vaginal swab, patient collected vaginal swab, endocervical swab, PreservCyt LBC, female and male urine
Technology	Same	PCR
Organisms Detected	Same	CT, GC, and TV
DNA extraction, amplification and detection	Automated by BD COR System	Automated by BD MAX System
Assay Controls	Same	Sample Processing Control

Analytical Performance

Analytical performance of the BD CTGCTV2 assay was evaluated on the BD MAX System and the results may be found under K182692. As the formulation of the BD CTGCTV2 assay reagents for use on the BD COR System has not changed from those used with the BD MAX System, certain analytical studies performed and documented in the package insert on BD MAX can be leveraged for and are applicable to the BD COR System (specimen stability, analytical sensitivity, inclusivity, cross-reactivity,

and interfering substances). The following sections describe the analytical studies that were performed to demonstrate that the assay performance, when used on BD COR, is unchanged from the performance demonstrated on the BD MAX System. The new analytical studies included: within-laboratory precision and multi-site reproducibility, confirmation of the analytical sensitivity and a cross-contamination study, all performed on the BD COR System.

Precision for BD COR System

Within-laboratory precision was evaluated for the BD CTGCTV2 assay on the BD COR System at one site with one reagent lot. Testing was performed over 12 days, with 3 runs per day (2 technologists, 6 days per technologist), for a total of 36 runs. Test samples were contrived in female urine, and in PreservCyt LBC specimen matrix and included *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* (urine only) panel members. Each panel member was tested in two replicates. The following target concentrations were used for spiking levels of the target organisms contained in each panel member:

- Moderate Positive (MP): 3x LoD
- Low Positive (LP): 1.5x LoD
- High Negative (HN): <1x LoD (expected negative 5% to 95% of the time)
- True negative (TN): no target

Precision study results for the BD CTGCTV2 assay on the BD COR System are described in **Table 2** and **Table 3,** while the variance component analyses are described in **Table 4** and **Table 5**.

Table 2: Percent Agreement with Expected Results for Within-lab Precision on BD COR with PreservCyt Samples

			BD COR System (PreservCyt)			
Target	***Level***	***N***	***N Correct***	***% Correct***	***95% CI***	
					Lower Bound	*Upper Bound*
CT	MP	72	72	100%	94.9%	100%
	LP	72	71	98.6%	92.5%	99.8%
	HN[b]	72	28	38.9%	28.5%	50.4%
	TN[a]	72	72	100%	94.9%	100%
GC	MP	72	69	95.8%	88.5%	98.6%
	LP	72	67	93.1%	84.8%	97.0%
	HN[b]	72	31	43.1%	32.3%	54.6%
	TN[a]	72	72	100%	94.9%	100%

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

Table 3: Percent Agreement with Expected Results for Within-lab Precision on BD COR with Urine Samples

Target	*Level*	*N*	*BD COR System (Urine)*			
			N Correct	*% Correct*	*95% CI*	
					Lower Bound	*Upper Bound*
CT	MP	72	72	100%	94.9%	100%
	LP	72	72	100%	94.9%	100%
	HN[b]	72	39	54.2%	42.7%	65.2%
	TN[a]	72	72	100%	94.9%	100%
GC	MP	72	71	98.6%	92.5%	99.8%
	LP	72	72	100%	94.9%	100%
	HN[b]	72	32	44.4%	33.5%	55.9%
	TN[a]	72	72	100%	94.9%	100%
TV	MP	72	72	100%	94.9%	100%
	LP	72	72	100%	94.9%	100%
	HN[b]	72	27	37.5%	27.2%	49.0%
	TN[a]	72	72	100%	94.9%	100%

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

Table 4: Variance component analysis results, BD COR PreservCyt

				Within Run		**Between Run**		**Between Day**		**Total**	
Target	**Level**	**N**	**Mean**	**SD**	**CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**CV**
CT	MP	72	32.86	0.55	1.67	0.26	0.78	0.00	0.00	0.61	1.85
	LP	71	34.06	1.25	3.68	0.31	0.90	0.00	0.00	1.29	3.79
GC1	MP	69	31.89	0.68	2.14	0.00	0.00	0.00	0.00	0.68	2.14
	LP	67	33.78	1.52	4.50	0.00	0.00	0.00	0.00	1.52	4.50
GC2	MP	72	30.24	0.36	1.18	0.07	0.23	0.07	0.23	0.37	1.23
	LP	70	31.63	0.66	2.10	0.00	0.00	0.00	0.00	0.66	2.10

Table 5: Variance component analysis results, BD COR Urine

				Within Run		**Between Run**		**Between Day**		**Total**	
Target	**Level**	**N**	**Mean**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
CT	MP	72	1.71	0.50	1.57	0.00	0.00	0.2	0.62	0.54	1.69
	LP	72	32.93	0.95	2.87	0.65	1.99	0.00	0.00	1.15	3.49
CG1	MP	71	31.52	1.03	3.28	0.33	1.04	0.00	0.00	1.08	3.44
	LP	72	32.47	0.80	2.45	0.38	1.18	0.00	0.00	0.88	2.72
GC2	MP	71	29.57	0.66	2.25	0.16	0.55	0.14	0.49	0.70	2.36
	LP	72	30.54	0.51	1.66	0.00	0.00	0.14	0.44	0.53	1.72
TV	MP	72	32.00	0.86	2.70	0.08	0.26	0.00	0.00	0.87	2.71
	LP	72	33.2	1.18	3.56	0.00	0.00	0.00	0.00	1.18	3.56

Reproducibility for BD COR System

For the Site-to-Site reproducibility study, three (3) sites (2 external and one internal) were provided the same panels as described for the Precision study, above. Each site performed testing on 6 distinct days (consecutive or not), wherein three (3) panels were tested by each of two (2) technologists (3 days per technologist) with one lot of reagents.

The overall PreservCyt site-to-site reproducibility percent agreement was 100% for TN and ranged from 38.9% to 48.1% for HN, 91.7% to 98.1% for LP and 98.1% to 100% MP categories (see **Table 6**).

The overall (across sites) Urine site-to-site reproducibility percent agreement was 100% for TN, LP and MP and ranged from 37.0% to 58.3% for HN categories (see **Table 7**).

Analysis of variance of the Ct.Score results from valid tests performed on PreservCyt positive panel members (see **Table 8**) yielded overall CV (%) ranged from 1.75% to 4.15%.

Analysis of variance of the Ct.Score results from valid tests performed on Urine positive panel members (see **Table 9**) yielded overall CV (%) ranged from 1.74% to 4.18%.

Table 6: Percent Agreement with Expected Results for Site to Site with PreservCyt for BD COR System

				BD COR System (PreservCyt)			
Target	***Level***	***Site***	***N Total***	***N Correct***	***% Correct***	***95% CI***	
						Lower Bound	*Upper Bound*
CT	*MP*	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	LP	1	36	35	97.2%	85.8%	99.5%
		2	36	36	100%	90.4%	100%
		3	36	35	97.2%	85.8%	99.5%
		Overall	108	106	98.1%	93.5%	99.5%
	HN[b]	1	36	16	44.4%	29.5%	60.4%
		2	36	21	58.3%	42.2%	72.9%
		3	36	15	41.7%	27.1%	57.8%
		Overall	108	52	48.1%	39.0%	57.5%
	TN[a]	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
GC	*MP*	1	36	34	94.4%	81.9%	98.5%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	106	98.1%	93.5%	99.5%
	LP	1	36	32	88.9%	74.7%	95.6%
		2	36	33	91.7%	78.2%	97.1%
		3	36	34	94.4%	81.9%	98.5%
		Overall	108	99	91.7%	84.9%	95.6%
	HN[b]	1	36	12	33.3%	20.2%	49.7%
		2	36	12	33.3%	20.2%	49.7%
		3	36	18	50.0%	34.5%	65.5%
		Overall	108	42	38.9%	30.2%	48.3%
	TN[a]	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

Table 7: Percent Agreement with Expected Results for Site to Site with Urine for BD COR System

				BD COR System (Urine)			
						95% CI	
Target	*Level*	*Site*	*N Total*	*N Correct*	*% Correct*	*Lower Bound*	*Upper Bound*
CT	*MP*	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	LP	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	HN[b]	1	36	23	63.9%	47.6%	77.5%
		2	36	21	58.3%	42.2%	72.9%
		3	36	19	52.8%	37.0%	68.0%
		Overall	108	63	58.3%	48.9%	67.2%
	TN[a]	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
GC	*MP*	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	LP	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	HN[b]	1	36	17	47.2%	32.0%	63.0%
		2	36	18	50.0%	34.5%	65.5%
		3	36	10	27.8%	15.8%	44.0%
		Overall	108	45	41.7%	32.8%	51.1%
	TN[a]	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
TV	*MP*	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	LP	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%
		Overall	108	108	100%	96.6%	100%
	HN[b]	1	36	11	30.6%	18.0%	46.9%
		2	36	17	47.2%	32.0%	63.0%
		3	36	12	33.3%	20.2%	49.7%
		Overall	108	40	37.0%	28.5%	46.4%
	TN[a]	1	36	36	100%	90.4%	100%
		2	36	36	100%	90.4%	100%
		3	36	36	100%	90.4%	100%

		Overall	108	108	100%	96.6%	100%

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.
[b] For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

Table 8: Variance Component Analysis Results for Site to Site with PreservCyt on BD COR

				Within Run (Residual)		Between Run		Between Day		Between Site		Total	
Target	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
CT	MP	108	33.05	0.65	1.96	0.19	0.58	0.00	0.00	0.26	0.78	0.72	2.18
	LP	106	33.98	0.78	2.28	0.00	0.00	0.29	0.87	0.00	0.00	0.83	2.44
GC1	MP	106	32.07	0.94	2.93	0.00	0.00	0.27	0.86	0.33	1.02	1.03	3.22
	LP	99	33.73	1.40	4.15	0.00	0.00	0.00	0.00	0.00	0.00	1.40	4.15
GC2	MP	108	30.43	0.50	1.66	0.00	0.00	0.00	0.00	0.18	0.58	0.53	1.75
	LP	105	31.79	0.74	2.33	0.00	0.00	0.00	0.00	0.26	0.83	0.79	2.47

Table 9: Variance Component Analysis Results for Site to Site with Urine on BD COR

				Within Run (Residual)		Between Run		Between Day		Between Site		Total	
Target	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
CT	MP	108	31.76	0.52	1.65	0.00	0.00	0.18	0.56	0.00	0.00	0.55	1.74
	LP	108	33.03	0.99	2.98	0.28	0.84	0.00	0.00	0.00	0.00	1.02	3.10
GC1	MP	108	31.39	0.89	2.84	0.37	1.18	0.10	0.30	0.00	0.00	0.97	3.09
	LP	108	32.36	0.89	2.74	0.18	0.54	0.00	0.00	0.33	1.03	0.96	2.98
GC2	MP	108	29.75	0.50	1.68	0.03	0.09	0.14	0.49	0.15	0.50	0.54	1.82
	LP	108	30.69	0.53	1.71	0.18	0.58	0.00	0.00	0.19	0.63	0.59	1.92
TV	MP	108	32.29	0.72	2.23	0.12	0.37	0.12	0.36	0.23	0.71	0.77	2.40
	LP	108	33.49	1.37	4.09	0.17	0.52	0.00	0.00	0.22	0.65	1.40	4.18

Quality Controls

External Control materials are not provided by BD; however, Quality Control procedures are included in the package insert. Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program:

- Commercially available positive control materials
- *Chlamydia trachomatis* serovar H (ATCC VR-879)
- *Neisseria gonorrhoeae* (ATCC 19424)
- *Trichomonas vaginalis* (ATCC 30001)
- External negative control
- Use a non-inoculated BD Molecular Swab Sample Buffer Tube

The assay includes a Specimen Processing Control (SPC) that is present in the Extraction Tube. The SPC monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances.

Analytical Sensitivity Confirmation Study for BD COR System

The analytical sensitivity/Limit of Detection (LoD) of the BD CTGCTV2 assay in urine, vaginal swab and PreservCyt LBC specimen matrix on the BD COR System was confirmed to be equivalent to that of the BD MAX System. Four panel members (**Table 10**) were created using the LoD previously determined on the BD MAX System at the following target levels in pooled female urine, pooled vaginal swab and pooled PreservCyt LBC matrix: Low Positive (1.5x LoD) and Moderate Positive (3x LoD). The

panel members were prepared with microbial suspensions from each of two (2) representative strains of the target organisms detected by the BD CTGCTV2 assay. Each target organism was quantified prior to spiking into negative clinical matrix. Urine and Swab panel members were tested on the BD COR and BD MAX Systems. Each panel member in PreservCyt had pre-analytical sample dilution performed by BD COR System. Additionally, pre-analytical samples were manually pipetted for testing on the BD COR System and the BD MAX System.

Results from this study demonstrate that the analytical sensitivity (LoD, **Table 11**) of the BD CTGCTV2 assay in vaginal, urine and PreservCyt LBC samples on BD COR is equivalent to the analytical sensitivity (LoD) demonstrated on the BD MAX as shown in **Tables 12-15**.

Table 10: Analytical Sensitivity Confirmation Panel Members

Panel Member	CT	GC	TV	Target Level
A	Serovar D	49226	30001	1.5x LoD
B	Serovar H	19424	50143	
C	Serovar D	49226	30001	3x LoD
D	Serovar H	19424	50143	

Table 11: Limit of Detection of the BD CTGCTV2 Assay (performed on BD MAX)

Organism	Strain	Specimen	LoD Concentration (units/mL)[a]
Chlamydia trachomatis	Serovar H	Urine	2.5
		Swab	2.5
		PreservCyt	5
	Serovar D	Urine	1.25
		Swab	5
		PreservCyt	5
Neisseria gonorrhoeae[b]	ATCC 19424	Urine	30
		Swab	40
		PreservCyt	30
	ATCC 49226	Urine	20
		Swab	30
		PreservCyt	40
Trichomonas vaginalis	ATCC 30001	Urine	5
		Swab	7.5
	ATCC 50143	Urine	2.5
		Swab	1.88

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

[b] The presented LoDs for *Neisseria gonorrhoeae* in the three specimen types were re-established in CFU/mL on the BD MAX and were shown to be equivalent to the assay LoDs previously established on the BD MAX instrument in cells/mL.

Table 12: Analytical Sensitivity Confirmation in Vaginal Swabs on BD COR System

BD MAX vs BD COR Vaginal Swab				
Panel	**Assay Target**	**BD MAX Mean Ct.Score**	**BD COR Mean Ct.Score**	**Difference in Mean Ct.Score (BD COR – BD MAX) with 95% CI**
A	CT	31.66	31.14	-0.52 (-0.857, -0.178)
	GC1	31.16	31.08	-0.08 (-0.347, 0.183)
	GC2	29.98	29.34	-0.64 (-0.876, -0.407)
	TV	33.17	33.29	0.12 (-0.283, 0.527)
B	CT	33.56	33.1	-0.46 (-0.793, -0.122)
	GC1	30.53	30.49	-0.04 (-0.276, 0.204)
	GC2	29.41	28.74	-0.67 (-0.857, -0.494)
	TV	33.17	33.6	0.43 (-0.155, 1.010)
C	CT	30.41	30.2	-0.21 (-0.377, -0.033)
	GC1	29.89	30.08	0.19 (0.006, 0.383)
	GC2	28.74	28.36	-0.38 (-0.575, -0.193)
	TV	32.03	32.47	0.44 (0.163, 0.722)
D	CT	32.51	31.95	-0.56 (-0.842, -0.271)
	GC1	29.34	29.47	0.13 (-0.027, -0.290)
	GC2	28.44	27.79	-0.65 (-0.841, -0.458)
	TV	31.94	32.07	0.13 (-0.139, 0.404)

Table 13: Analytical Sensitivity Confirmation in Urine on BD COR System

BD MAX vs BD COR Urine				
Panel	**Assay Target**	**BD MAX Mean Ct.Score**	**BD COR Mean Ct.Score**	**Difference in Mean Ct.Score (BD COR – BD MAX) with 95% CI**
A	CT	32.95	32.54	-0.41 (-0.802, -0.013)
	GC1	31.21	31.54	0.33 (0.054, 0.603)
	GC2	30.59	29.49	-1.10 (-1.375, -0.842)
	TV	32.95	32.99	0.04 (-0.244, 0.339)
B	CT	32.46	32.12	-0.34 (-0.629, -0.061)
	GC1	29.96	30.3	0.34 (0.197, 0.486)
	GC2	29.34	28.52	-0.82 (-0.989, -0.662)
	TV	31.29	31.66	0.37 (0.208, 0.518)
C	CT	31.78	31.64	-0.14 (-0.378, 0.111)
	GC1	30.08	30.7	0.62 (0.442, 0.792)
	GC2	29.37	28.68	-0.69 (-0.888, -0.494)
	TV	31.86	32.15	0.29 (0.077, 0.500)
D	CT	31.3	31.24	-0.06 (-0.267, 0.134)
	GC1	28.83	29.26	0.43 (0.283, 0.564)
	GC2	28.28	27.52	-0.76 (-0.893, -0.621)
	TV	30.32	30.57	0.25 (0.103. 0.414)

Table 14: Analytical Sensitivity Confirmation in Manually Converted[a] LBC on BD COR System

BD MAX vs BD COR Manually Converted LBC				
Panel	**Assay Target**	**BD MAX Mean Ct.Score**	**BD COR Mean Ct.Score**	**Difference in Mean Ct.Score (BD COR – BD MAX) with 95% CI**
A	CT	32.54	32.45	-0.09 (-0.281, 0.105)
	GC1	32.4	32.63	0.23 (-0.261, 0.723)
	GC2	30.56	30.69	0.13 (-0.027. 0.300)
B	CT	33.65	33.77	0.12 (-0.225, 0.450)
	GC1	32.61	33.04	0.43 (0.066, 0.794)
	GC2	30.99	31.06	0.07 (-0.118, 0.262)
C	CT	31.72	31.49	-0.23 (-0.419, -0.022)
	GC1	31	31.58	0.58 (0.341, 0.804)
	GC2	29.57	29.74	0.17 (0.040, 0.296)
D	CT	32.74	32.57	-0.17 (-0.396, 0.056)
	GC1	31.42	32.06	0.64 (0.348, 0.927)
	GC2	29.86	30.05	0.19 (0.043, 0.332)

[a.] Sample transfer from PreservCyt vial to BD Molecular LBC SBT manually performed prior to loading onto the COR System. This represents one of the possible workflows for LBC samples on BD COR

Table 15: Analytical Sensitivity Confirmation in LBC Converted[a] on BD COR System

MAX vs COR PX Converted LBC				
Panel	**Assay Target**	**MAX Mean Ct.Score**	**BD COR Mean Ct.Score**	**Difference in Mean Ct.Score (COR - MAX) with 95% CI**
A	CT	32.54	32.83	0.29 (0.076, 0.516)
	GC1	32.4	32.64	0.24 (-0.243, 0.734)
	GC2	30.56	31.02	0.46 (0.279, 0.650)
B	CT	33.65	33.85	0.20 (-0.130, 0.523)
	GC1	32.61	33.32	0.71 (0.316, 1.100)
	GC2	30.99	31.34	0.35 (0.160, 0.551)
C	CT	31.72	31.72	0 (-0.179, 0.185)
	GC1	31	31.64	0.64 (0.419, 0.861)
	GC2	29.57	30.03	0.46 (0.332, 0.587)
D	CT	32.74	32.81	0.07 (-0.157, 0.297)
	GC1	31.42	32.26	0.54 (0.544, 1.144)
	GC2	29.86	30.26	0.40 (0.250, 0.537)

[a] Sample transfer from PreservCyt vial to BD Molecular LBC SBT performed automatically by BD COR System

Cross-Contamination for BD COR System

A study was conducted to investigate cross-contamination while processing samples with high microbial load of *Chlamydia trachomatis* in the BD CTGCTV2 assay. High positive samples contained *Chlamydia trachomatis* (VR-885, Serovar D) spiked into pooled PreservCyt LBC matrix at a concentration of ≥1 x 10^6 EB/mL. The negative samples consisted of PreservCyt media vials without any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were alternated in the BD COR™ T-Rack and tested across 45 runs, using three BD COR Systems for a total of 540 positive and 540 negative samples tested. Of the 540 negative samples tested, two false positive results were obtained (0.37%, 95% CI: 0.10–1.34%).

Clinical Agreement Study between BD MAX and BD COR Systems

The clinical performance of the BD CTGCTV2 assay was established based on the data from BD MAX. For the purpose of demonstrating that use of the assay with the BD COR doesn't compromise the safety and effectiveness of the assay, clinical comparison studies were performed on both the BD MAX and BD COR Systems. The performance of the BD CTGCTV2 assay on the BD COR was evaluated in a clinical agreement study by comparing the assay results obtained on the BD COR System to the results obtained on the BD MAX System. BD MAX results served as reference in the clinical agreement study.

Remnant urine specimens from the previous clinical trial for BD CTGCTV2 on BD MAX as well as urine specimens obtained from both internal and external collections were used for the comparison study. Clinical panels were created either with individual specimens, or negative clinical specimens spiked with a positive clinical specimen. No more than two negative specimens were combined as background negative matrix, and no more than one clinical positive was used per panel. The clinical agreement study included 433 independent panel members. The panels were prepared so that a majority of the positive specimens for CT, GC or TV were at analyte levels of Low Positive and Moderate Positive. Six aliquots were prepared from each panel member. Among them, three aliquots were tested on the BD COR System with two aliquots each being tested at an external site and the third aliquot being tested at an internal site. The other three aliquots were all tested internally with each aliquot being tested on a separate BD MAX™ System.

To demonstrate that the performance of the BD CTGCTV2 assay on the BD COR System is equivalent to the performance of BD MAX, both positive/negative percent agreement analysis and Deming regression analysis of the Ct.Score values were performed. Positive Percent Agreement (PPA) and Negative percent Agreement (NPA) between the BD MAX and BD COR Systems were calculated separately for each target. For each target, the PPA and NPA were calculated for each of the three sites where BD COR testing occurred, against composite comparator results where the positive or negative status of a panel member is defined by ≥2 out of 3 evaluable results obtained on the BD MAX. Out of 214 panel members assessed for CT, 106 were positive by BD MAX and 108 were negative by BD MAX. Out of 218 panel members assessed for GC, 111 were positive by BD MAX and 107 were negative by BD MAX. Out of the 215 panel members assessed for TV, 105 were positive by BD MAX and 110 were negative by BD MAX. Two panel members, each with a valid BD MAX result and a non-evaluable BD COR result (one non-evaluable BD COR result due to a non-readable label and the other non-evaluable BD COR result due to a non-compliant event), were not included in the calculation of the PPA or NPA.

PPA and NPA estimates were also averaged across the three BD COR testing sites. The PPA and NPA results as well as the corresponding 95% confidence interval at each BD COR testing site and the average across all BD COR testing sites are summarized in **Table 16-Table 18**, for each target. The denominator for PPA and NPA calculations includes panel members with equivocal comparator results from BD MAX, as indicated at the bottom of the tables. Equivocal BD MAX comparator result is defined as one positive, one negative and one non-evaluable result from the BD MAX.

The systematic differences in numeric value between Ct.Score results from BD COR and BD MAX were evaluated by the Weighted Deming regression analysis based on the average Ct.Score of BD COR results and the average Ct.Score of BD MAX results of a given panel member across all corresponding testing sites. The results from the Deming regression analysis are provided in **Figures 1** through **4** for CT, GC1, GC2 and TV, respectively. The point estimate of intercept and slope, as well as the corresponding 95% confidence interval of each Deming regression line are provided in **Table 19**. Additionally, the Weighted Deming regression bias estimate along with 95% confidence interval at different analyte levels are presented in **Table 20**. The "Ct.Score for BD MAX" in the table were calculated as the average Ct.Score from all samples at the corresponding analyte level.

Table 16: Percent Agreement of BD COR versus BD MAX Result by Test Site for CT

BD COR Test Site			BD MAX Result	
			BD MAX Positive Result	BD MAX Negative Result
1	BD COR Result	Positive	105	0
		Negative	0	108
		Total	105	108
	PPA: 100.0% (105/105), 95%CI: (96.5%, 100.0%)[b] NPA: 100.0% (108/108), 95%CI: (96.6%, 100.0%)			
2			**BD MAX Result**	
			BD MAX Positive Result	BD MAX Negative Result
	BD COR Result	Positive	106	0
		Negative	0	108
		Total	106	108
	PPA: 100.0% (106/106), 95%CI: (96.5%, 100.0%) NPA: 100.0% (108/108), 95%CI: (96.6%, 100.0%)			
3			**BD MAX Result**	
			BD MAX Positive Result	BD MAX Negative Result
	BD COR Result	Positive	106	0
		Negative	0	108
		Total	106	108
	PPA: 100.0% (106/106), 95%CI: (96.5%, 100.0%) NPA: 100.0% (108/108), 95%CI: (96.6%, 100.0%)			
Average PPA: 100%, 95% CI: N/A[a] Average NPA: 100%, 95% CI: N/A[a] Number of BD MAX equivocal results: 0				

[a] Confidence intervals calculated by the bootstrap method for point estimates close to 100% have not been included, as suggested by FDA guidance for assay migration studies.

[b] Confidence intervals for point estimates at each site were calculated by a score method and confidence intervals for point estimates averaged over 3 sites were calculated by a bootstrap method.

Table 17: Percent Agreement of BD COR versus BD MAX Result by Test Site for GC

BD COR Test Site			BD MAX Result	
			BD MAX Positive	BD MAX Negative
1	BD COR Result	Positive	110	0
		Negative	1	107
		Total	111	107
	PPA: 99.1% (110/111), 95%CI: (95.1%, 99.8%)[b] NPA: 100.0% (107/107), 95%CI: (96.5%, 100.0%)			
			BD MAX Result	
			BD MAX Positive	BD MAX Negative
2	BD COR Result	Positive	108	0
		Negative	2	107
		Total	110	107
	PPA: 98.2% (108/110), 95%CI: (93.6%, 99.5%) NPA: 100.0% (107/107), 95%CI: (96.5%, 100.0%)			
			BD MAX Result	
			BD MAX Positive	BD MAX Negative
3	BD COR Result	Positive	106	0
		Negative	5	107
		Total	111	107
	PPA: 95.5% (106/111), 95%CI: (89.9%, 98.1%) NPA: 100.0% (107/107), 95%CI: (96.5%, 100.0%)			
Average PPA: 97.6%, 95% CI: (95.6%, 99.1%) Average NPA: 100%, 95% CI: N/A[a] Number of BD MAX equivocal results: 0				

[a] Confidence intervals calculated by the bootstrap method for point estimates close to 100% have not been included, as suggested by FDA guidance for assay migration studies.

[b] Confidence intervals for point estimates at each site were calculated by a score method and confidence intervals for point estimates averaged over 3 sites were calculated by a bootstrap method.

Table 18: Percent Agreement of BD COR™ versus BD MAX™ Result by Test Site for TV

BD COR Test Site			BD MAX Result	
			BD MAX Positive Result	BD MAX Negative Result
1	**BD COR Result**	Positive	105	1
		Negative	0	109
		Total	105	110
	PPA: 100.0% (105/105), 95%CI: (96.5%, 100.0%)[a] NPA: 99.1% (109/110), 95%CI: (95.0%, 99.8%)			
2			**BD MAX Result**	
			BD MAX Positive Result	BD MAX Negative Result
	BD COR Results	Positive	105	3
		Negative	0	107
		Total	105	110
	PPA: 100.0% (105/105), 95%CI: (96.5%, 100.0%) NPA: 97.3% (107/110), 95%CI: (92.3%, 99.1%)			
3			**BD MAX Result**	
			BD MAX Positive Result	BD MAX Negative Result
	BD COR Results	Positive	104	1
		Negative	1	109
		Total	105	110
	PPA: 99.0% (104/105), 95%CI: (94.8%, 99.8%) NPA: 99.1% (109/110), 95%CI: (95.0%, 99.8%)			
Average PPA: 99.7%, 95% CI: (99%, 100%) Average NPA: 98.5%, 95% CI (96.3%, 100%) Number of BD MAX equivocal results: 0				

[a] Confidence intervals for point estimates at each site were calculated by a score method and confidence intervals for point estimates averaged over 3 sites were calculated by a bootstrap method.

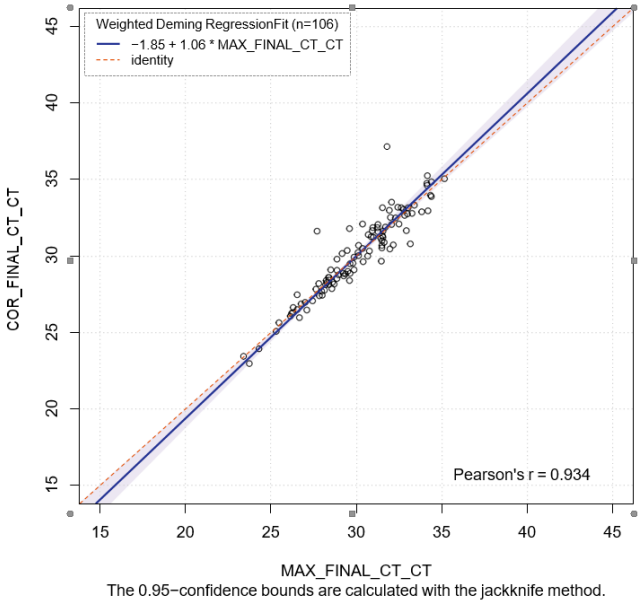
Table 19: Weighted Deming Regression Coefficients for Ct.Score for BD COR versus BD MAX

Target	Site	Parameter	Estimate	95% CI
CT	Overall	Intercept	-1.85	(-3.88, 0.18)
CT	Overall	Slope	1.06	(0.99, 1.13)
GC1	Overall	Intercept	-0.06	(-0.99, 0.87)
GC1	Overall	Slope	1.02	(0.99, 1.06)
GC2	Overall	Intercept	-0.72	(-1.76, 0.33)
GC2	Overall	Slope	1.03	(0.99, 1.07)
TV	Overall	Intercept	-2.25	(-5.30, 0.80)
TV	Overall	Slope	1.09	(0.98, 1.19)

Table 20: Weighted Deming Regression Bias Estimate for BD COR versus BD MAX

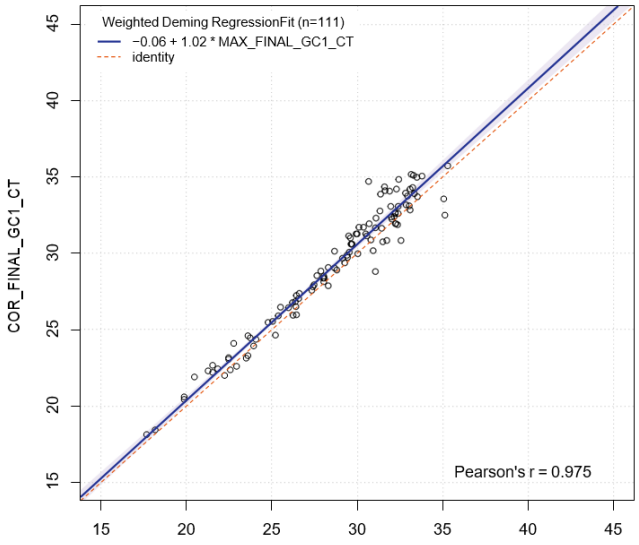
Target	Site	Actual Level	Ct. Score of BD MAX	Bias Estimate at Ct. Score	95% CI
CT	Overall	High Positive	26.36	-0.22	-0.42, -0.02
CT	Overall	Moderate Positive	29.49	-0.03	-0.20, 0.13
CT	Overall	Low Positive	32.79	0.17	-0.18, 0.52
CT	Overall	Negative	45.00	0.93	-0.27, 2.13
GC1	Overall	High Positive	24.15	0.47	0.32, 0.61
GC1	Overall	Moderate Positive	29.54	0.58	0.38, 0.78
GC1	Overall	Low Positive	32.67	0.65	0.36, 0.94
GC1	Overall	Negative	45.00	0.92	0.21, 1.63
GC2	Overall	High Positive	22.96	0.01	-0.16, 0.17
GC2	Overall	Moderate Positive	28.21	0.17	-0.03, 0.37
GC2	Overall	Low Positive	30.74	0.25	-0.03, 0.53
GC2	Overall	Negative	45.00	0.70	-0.15, 1.54
TV	Overall	High Positive	26.08	0.03	-0.33, 0.38
TV	Overall	Moderate Positive	29.49	0.32	0.16, 0.48
TV	Overall	Low Positive	32.82	0.61	0.20, 1.03
TV	Overall	Negative	45.00	1.68	0.01, 3.34

Figure 1: Deming Regression for the BD CTGCTV2 assay on the BD COR System versus the BD MAX System – CT



The 0.95−confidence bounds are calculated with the jackknife method.

Figure 2: Deming Regression for the BD CTGCTV2 on the BD COR System versus the BD MAX System - GC1



The 0.95−confidence bounds are calculated with the jackknife method.

Figure 3: Deming Regression for the BD CTGCTV2 assay on the BD COR System versus the BD MAX System - GC2

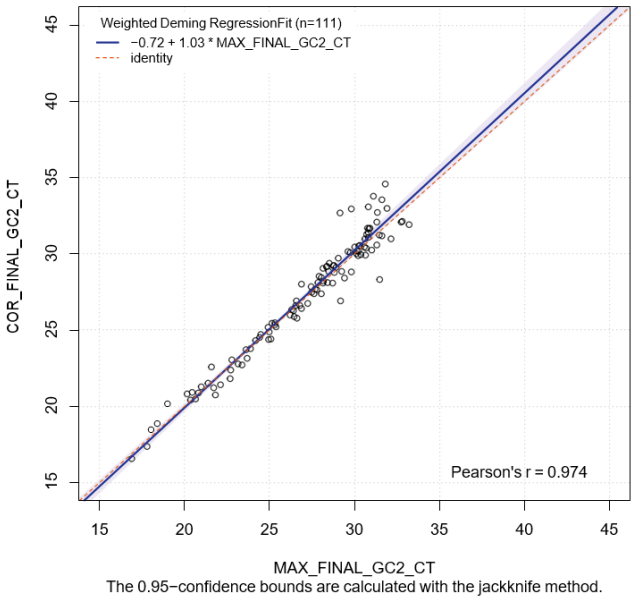
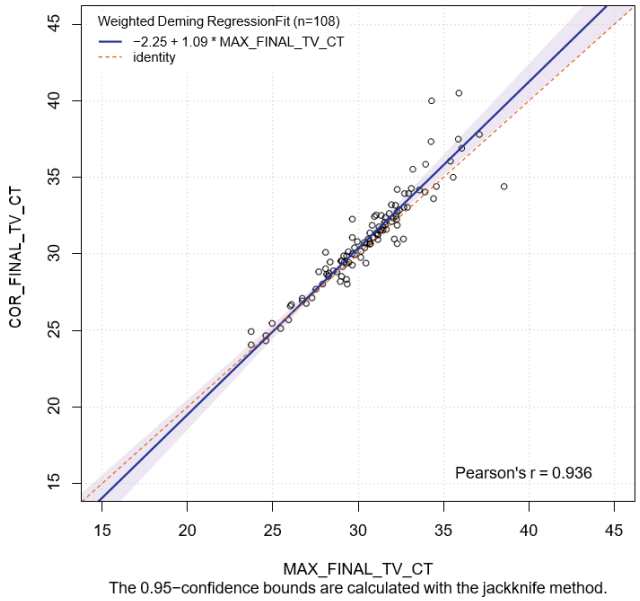


Figure 4: Deming Regression for the BD CTGCTV2 assay on the BD COR System versus the BD MAX System - TV



BD CTGCTV2 for BD COR System Non-Reportable Results

Non-reportable results on the BD COR are reported in the same manner as on the BD MAX and the definitions of all possible Non-reportable events are summarized in **Table 21**. Error results on the BD COR System were marked noncompliant if they were due to an operator error

and were not included in the Non-reportable rate calculation. Non-reportable rates on BD COR System are shown in **Table 22**.

Table 21: Definition of Non-reportable events on the BD COR system

BD COR Non-reportable Result	Non-reportable Result Definition
UNR - Unresolved	Invalid SPC due to presence of inhibitory substances or reagent failure
IND – Indeterminate	BD COR System failure (with Warning or Error Codes)
INC - Incomplete	Aborted run or BD COR System failure that halts robot operations (with Warning or Error Codes)

Table 22: Summary of BD COR Total Non-Reportable Rate for Combined Target by BD COR Test Site

Site	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total Rate	
	Initial (95% CI)	Final[a,b] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)
1	0.0% (0/433) (0.0%,0.9%)	0.0% (0/432) (0.0%,0.9%)	0.2% (1/433) (0.0%,1.3%)	0.0% (0/432) (0.0%,0.9%)	0.0% (0/433) (0.0%,0.9%)	0.0% (0/432) (0.0%,0.9%)	0.2% (1/433) (0.0%, 1.3%)	0.0% (0/432) (0.0%,0.9%)
2	0.0% (0/432) (0.0%,0.9%)	0.0% (0/432) (0.0%,0.9%)	6.0% (26[c]/432) (4.1%,8.7%)	0.0% (0/432) (0.0%,0.9%)	0.0% (0/432) (0.0%,0.9%)	0.0% (0/432) (0.0%,0.9%)	6.0% (26/432) (4.1%, 8.7%)	0.0% (0/432) (0.0%,0.9%)
3	0.2% (1/433) (0.0%,1.3%)	0.0% (0/433) (0.0%,0.9%)	0.7% (3/433) (0.2%,2.0%)	0.0% (0/433) (0.0%,0.9%)	0.0% (0/433) (0.0%,0.9%)	0.0% (0/433) (0.0%,0.9%)	0.9% (4/433) (0.4%,2.4%)	0.0% (0/433) (0.0%,0.9%)
Total	0.1% (1/1298) (0.0%,0.4%)	0.0% (0/1297) (0.0%,0.3%)	2.3% (30/1298) (1.6%,3.3%)	0.0% (0/1297) (0.0%,0.3%)	0.0% (0/1298) (0.0%,0.3%)	0.0% (0/1297) (0.0%,0.3%)	2.4% (31/1298) (1.7%,3.4%)	0.0% (0/1297) (0.0%,0.3%)

[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 BD site (and ultimately Total rate) is decreased by one due to a missing BD COR™ result.

[c] The 26 initial indeterminate results occurred on two runs, 12 and 14 for each run. Each occurrence was due to a consumable positioning issue. Reteaching of the robot was completed, and all samples were retested and generated reportable results.