



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**I Background Information:**

**A 510(k) Number**

K210585

**B Applicant**

Becton Dickinson and Company

**C Proprietary and Established Names**

BD CTGCTV2

**D Regulatory Information**

| <b>Product Code(s)</b> | <b>Classification</b> | <b>Regulation Section</b>  | <b>Panel</b>      |
|------------------------|-----------------------|--|-------------------|
| QEP                    | Class II              | 21 CFR 866.3393 - Device To Detect Nucleic Acids From Non-Viral Microorganism(s) Causing Sexually Transmitted Infections And Associated Resistance Marker(s) | MI - Microbiology |
| OUY                    | Class II              | 21 CFR 866.3860 - Trichomonas vaginalis nucleic acid assay   | MI - Microbiology |
| LSL                    | Class II              | 21 CFR 866.3390 - Neisseria spp. direct serological test reagents  | MI - Microbiology |
| MKZ                    | Class I, reserved     | 21 CFR 866.3120 - Chlamydia serological reagents   | MI - Microbiology |

## **II Submission/Device Overview:**

### **A Purpose for Submission:**

To demonstrate that the performance of the BD CTGCTV2 assay on the BD COR (New System) is equivalent to the performance of the above assay on the BD MAX (Old System) based on the Assay Migration Study approach.

### **B Measurand:**

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

### **C Type of Test:**

Qualitative real-time PCR

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

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

See Indications for Use below.

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

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

Rx - For Prescription Use Only

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

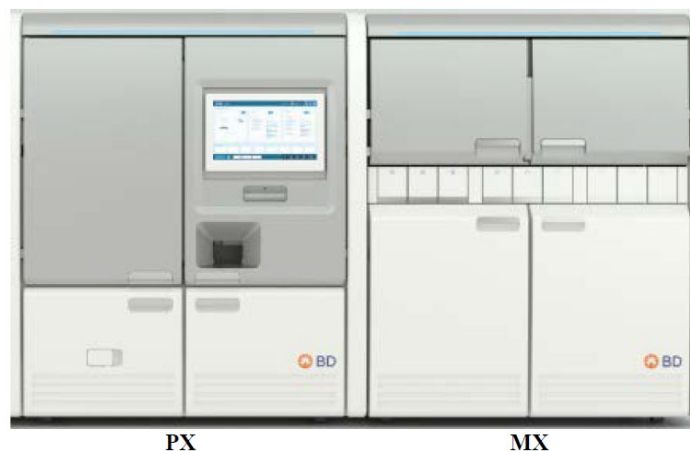
BD COR System

## IV Device/System Characteristics:

### A Device Description:

The New System, BD COR instrument, was developed as a high volume molecular testing device to support the need of diagnostic laboratories for automated processing of large volumes of clinical samples with a concurrent reduction of manual user intervention to obtain test results. When performed on the BD COR system, the CTGCTV2 Assay has no changes to the PCR primer and probe sequences, reagent formulations, detection method, or result analysis algorithms as it compares when performed on the Old System, BD MAX instrument. For an overview of BD CTGCTV2 assay, please refer to K182692. To support the high-throughput capacity on the BD COR, the Unitized Reagent Strips for use on the BD MAX were updated to reagent plates that are sufficient for up to 96 samples. The plastics and the lidding material used for these reagent plates are similar to those used for the BD MAX consumable. Additionally, the PCR cartridge remains unchanged between the BD MAX and the BD COR. The Sample Processing Control, the recommended External Controls as well as the Result Interpretation also remain unchanged between the two instruments.

The BD COR is comprised of a single PX pre-analytical system attached to an MX analyzer, as shown below.

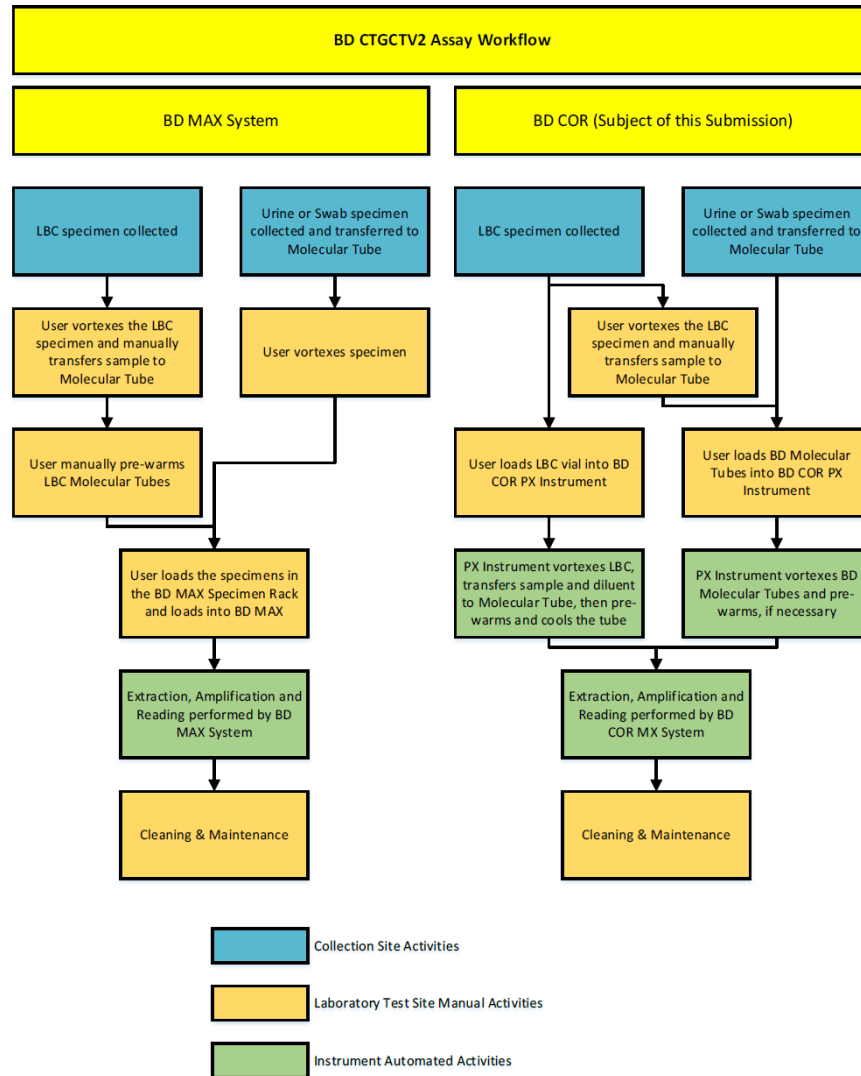


**BD COR Instrument**

The PX performs the pre-analytical steps required for the assay, specimen loading and unloading, and contains the primary user interface. The PX is specifically designed to automatically perform a number of steps that are performed manually when testing samples using the BD MAX. As such, the sample vortexing, aliquoting clinical specimens into a molecular vial with the correct diluent, sorting/grouping of the samples, pre-warming and cooling of the samples, and transport of the samples to the MX analyzer are all performed by the PX. The MX is a high-throughput molecular analyzer and performs all the BD CTGCTV2 Assay workflow steps that are carried out on the BD MAX (as described in K182692). The MX was specifically designed to utilize the same fundamental operating principles and methodologies as the BD MAX System and contains instrumentation and reagents for extraction, amplification and

detection of target DNA. 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. Additionally, there are no changes to the sample collection kits and associated sample collection procedures.

The comparison of the workflow between BD MAX and BD COR is illustrated below.



### BD CTGCTV2 Assay Workflow Comparison between BD MAX and BD COR

The BD COR System incorporates current consumable contamination prevention features of the BD MAX to manage sample contamination in the instruments. These practices include the restriction of pipette travel while containing sample, the use of air transport gaps, and single use consumables to minimize sample contamination during the extraction process. Users will be provided instructions on required regular contamination management cleaning.

## **B Principle of Operation:**

The BD CTGCTV2 Assay has not been changed for the migration to the BD COR, but steps of the procedure that were manually performed by users are automated when using the PX/MX. Users may still manually aliquot PreservCyt (LBC) specimen into the BD Molecular LBC Sample Buffer Tube (SBT) prior to testing on the BD COR. However, the BD COR has the capability to perform all steps of the BD CTGCTV2 Assay to include specimen aliquoting from PreservCyt LBC vial into an SBT filled from bulk buffer bottles. Once specimens are loaded into the PX, the PX performs all pre-analytical steps, including sample transfer into SBTs (when required), pre-warming (when required) to homogenize matrix and lyse cells, vortexing, and cooling. Following the pre-processing steps, the PX loads samples into shuttles that transfer samples to the MX. After arriving at the MX, samples undergo extraction, amplification, and real-time detection of target DNA, which are the same as those performed by the BD MAX.

## **C Instrument Description Information:**

1. Instrument Name:

The BD COR System

2. Specimen Identification:

The BD COR System is designed to allow the users to place clinical specimens directly into designated transport racks to be loaded onto the PX. Once loaded onto the system, sample login will be performed automatically by the PX and assay menu selection will be automatically made based on Laboratory Information System (LIS) order.

3. Specimen Sampling and Handling:

Automatically performed by the PX Instrument of the BD COR.

4. Calibration:

BD COR does not require user calibration. Annual preventative maintenance is required to be performed by BD authorized service personnel.

5. Quality Control:

The Quality Control for the BD CTGCTV2 Assay remains the same for both BD MAX and BD COR.

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

Similar to the BD MAX, External Control materials are not provided by BD for the BD COR. External positive and negative controls are not used by the BD COR system software for the purpose of test result interpretation. External controls are treated as patient samples. The external positive control is intended to monitor for substantial reagent failure. The external negative control is intended to detect reagent or environmental contamination (or carry-over) by target nucleic acids. It is recommended that one external positive control and one external negative control be run at least daily until adequate process validation is achieved on the BD COR in each laboratory setting. Reduced frequency of control testing should be in accordance with applicable regulations as suggested in the package insert.

**V Substantial Equivalence Information:**

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

BD CTGCTV2 for BD MAX System

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

K182692

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

| <b>Device &amp; Predicate Device(s):</b>          | <u>K210585</u>   | <u>K182692</u>   |
|---|--|--|
| Device Trade Name                                 | BD CTGCTV2<br>(for Use with the BD COR System)   | BD CTGCTV2 for BD MAX System   |
| <b>General Device Characteristic Similarities</b> |  |  |
| Intended Use/Indications For Use                  | The BD CTGCTV2 assay incorporates automated DNA extraction and real-time polymerase chain reaction (PCR) for the direct, qualitative detection of DNA from: <ul style="list-style-type: none"> <li>• <i>Chlamydia trachomatis</i> (CT)</li> <li>• <i>Neisseria gonorrhoeae</i> (GC)</li> </ul> | The BD CTGCTV2 for BD MAX System, performed on the BD MAX System, incorporates automated DNA extraction and real-time polymerase |

|                             |  |   |
|-----------------------------|--|---|
|                             | <ul style="list-style-type: none"> <li>• <i>Trichomonas vaginalis</i> (TV)</li> </ul> <p>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.</p> <p>The BD CTGCTV2 assay is available for use with the BD MAX System or the BD COR System.</p> | <p>chain reaction (PCR) for the direct, qualitative detection of DNA from:</p> <ul style="list-style-type: none"> <li>• <i>Chlamydia trachomatis</i> (CT)</li> <li>• <i>Neisseria gonorrhoeae</i> (GC)</li> <li>• <i>Trichomonas vaginalis</i> (TV)</li> </ul> <p>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.</p> <p>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.</p> |
| Collection/Transport Device | Same   | Swab Sample Buffer Tube (2.0 mL)<br>Urine Sample Buffer Tube (0.5 mL)<br>LBC Sample Buffer Tube (1.5 mL)  |
| Sample Preparation          | Same   | 1 swab added to Swab Sample Buffer Tube<br><br>2.0 mL urine added to Urine Sample Buffer Tube<br>0.5 mL LBC added to LBC Sample Buffer Tube   |
| Assay Results               | Same   | Qualitative   |
| Organisms Detected          | Same   | CT, GC, and TV  |
| Instrument                  | BD COR   | BD MAX  |

| Technology                                       | Same                           | Real-time PCR  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
|--|--------------------------------|--|--------|-----|---------|----|-----|-----|----|-----|-----|----------|-----|-----|----------|------|-------|----|------|-----|
| Specimens  | Same                           | <p>For CT and GC:</p> <ul style="list-style-type: none"> <li>• Clinician-collected vaginal swab</li> <li>• Patient-collected vaginal swab</li> <li>• Endocervical swab</li> <li>• PreservCyt LBC</li> <li>• Urine (female and male)</li> </ul> <p>For TV:</p> <ul style="list-style-type: none"> <li>• Clinician-collected vaginal swab,</li> <li>• Patient-collected vaginal swab</li> <li>• Urine (female and male)</li> </ul> |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| Assay Controls                                   | Same                           | Sample Processing Control  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| Extraction                                       | Same Same                      | Magnetic affinity beads with affinity beads with p   |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| On-board Lysis                                   | Same                           | On-board lysis of all specimens  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| Target Detection                                 | Same                           | <table border="1"> <thead> <tr> <th>Target</th> <th>Dye</th> <th>Channel</th> </tr> </thead> <tbody> <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> </tbody> </table>                                      | Target | Dye | Channel | CT | FAM | FAM | CT | FAM | FAM | GC (GC1) | CFO | VIC | GC (GC2) | Q705 | CY5.5 | TV | Q670 | CY5 |
| Target   | Dye                            | Channel  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| CT   | FAM                            | FAM  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| CT   | FAM                            | FAM  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| GC (GC1)   | CFO                            | VIC  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| GC (GC2)   | Q705                           | CY5.5  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| TV   | Q670                           | CY5  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| <b>General Device Characteristic Differences</b> |                                |  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| LBC Sample Transfer from PreservCyt Vial to SBT  | Automatic (on board) or manual | Manual   |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| LBC Sample Pre-warm                              | Automatic (on board)           | by BD Pre-Warm Heater  |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |
| Maximum Output of Results per Run                | 72 samples                     | 24 samples   |        |     |         |    |     |     |    |     |     |          |     |     |          |      |       |    |      |     |

## VI Standards/Guidance Documents Referenced:

1. CDRH Draft Guidance for Industry and Food and Drug Administration Staff: Assay Migration Studies for In Vitro Diagnostic Devices. April 25, 2013



2. CDRH Draft Guidance for Industry and Food and Drug Administration Staff: Establishing the Performance Characteristics of In Vitro Diagnostics Devices for *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*: Screening and Diagnostic Testing May 11, 2011

3. CDRH Guidance for Industry and Food and Drug Administration Staff: Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*. August 4, 2015.

## VII Performance Characteristics:

### A Analytical Performance:

#### 1. Precision/Reproducibility:

##### a. Within-laboratory Precision

Within-laboratory precision was evaluated for the BD CTGCTV2 assay on the BD COR System and the BD MAX System concurrently at an internal site with one reagent lot. For each instrument, testing was performed over 12 days (two operators, six days per operator) with three runs per day, for a total of 36 runs. Each sample was tested in duplicate for each run. Testing panel members were prepared by spiking different levels of target in pooled negative female urine or pooled negative PreservCyt LBC specimen matrix. The strains/serovars tested include Serovar D for CT, Strain 49226 for GC and Strain 30001 for TV (TV target was evaluated in urine matrix only, consistent with the Intended Use). The target concentrations (based on the LoD determined on the BD MAX System) used for spiking and a list of panel members tested are shown below:

- Moderate Positive (MP): 3x LoD
- Low Positive (LP): 1.5x LoD
- High Negative (HN): <1x LoD
- True Negative (TN): no target

#### Panel Members Tested for Precision and Reproducibility Studies, PreservCyt

| Panel Member | CT | GC |
|--------------|----|----|
| 1            | MP | TN |
| 2            | LP | TN |
| 3            | HN | TN |
| 4            | TN | MP |
| 5            | TN | LP |
| 6            | TN | HN |
| 7            | TN | TN |

**Panel Members Tested for Precision and Reproducibility Studies, Urine**

| Panel Member | CT | GC | TV |
|--------------|----|----|----|
| 1            | MP | TN | TN |
| 2            | LP | TN | TN |
| 3            | HN | TN | TN |
| 4            | TN | MP | TN |
| 5            | TN | LP | TN |
| 6            | TN | HN | TN |
| 7            | TN | TN | MP |
| 8            | TN | TN | LP |
| 9            | TN | TN | HN |
| 10           | TN | TN | TN |

The Percent Agreement with expected results for each panel member in the Precision study on each instrument is summarized below.

**Percent Agreement for the BD COR and the BD MAX, PreservCyt**

| Target | Level           | N  | BD COR System (PreservCyt) |                     | BD MAX System (PreservCyt) |                     |
|--------|-----------------|----|----------------------------|---------------------|----------------------------|---------------------|
|        |                 |    | N Correct                  | % Correct (95% CI)  | N Correct                  | % Correct (95% CI)  |
| CT     | MP              | 72 | 72                         | 100% (94.9%-100%)   | 72                         | 100% (94.9%-100%)   |
|        | LP              | 72 | 71                         | 98.6% (92.5%-99.8%) | 72                         | 100% (94.9%-100%)   |
|        | HN <sup>a</sup> | 72 | 28                         | 38.9% (28.5%-50.4%) | 38                         | 52.8% (41.4%-63.9%) |
|        | TN <sup>b</sup> | 72 | 72                         | 100% (94.9%-100%)   | 71                         | 98.6% (92.5%-99.8%) |
| GC     | MP              | 72 | 69                         | 95.8% (88.5%-98.6%) | 70                         | 97.2% (90.4%-99.2%) |
|        | LP              | 72 | 67                         | 93.1% (84.8%-97.0%) | 71                         | 98.6% (92.5%-99.8%) |
|        | HN <sup>a</sup> | 72 | 31                         | 43.1% (32.3%-54.6%) | 45                         | 62.5% (51.0%-72.8%) |
|        | TN <sup>b</sup> | 72 | 72                         | 100% (94.9%-100%)   | 72                         | 100% (94.9%-100%)   |

<sup>a</sup>For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

<sup>b</sup>For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

**Percent Agreement for the BD COR and the BD MAX, Urine**

| Target | Level           | N  | BD COR System (Urine) |                     | BD MAX System (Urine) |                     |
|--------|-----------------|----|-----------------------|---------------------|-----------------------|---------------------|
|        |                 |    | N Correct             | % Correct (95% CI)  | N Correct             | % Correct (95% CI)  |
| CT     | MP              | 72 | 72                    | 100% (94.9%-100%)   | 72                    | 100% (94.9%-100%)   |
|        | LP              | 72 | 72                    | 100% (94.9%-100%)   | 71                    | 98.6% (92.5%-99.8%) |
|        | HN <sup>a</sup> | 72 | 39                    | 54.2% (42.7%-65.2%) | 37                    | 51.4% (40.1%-62.6%) |
|        | TN <sup>b</sup> | 72 | 72                    | 100% (94.9%-100%)   | 72                    | 100% (94.9%-100%)   |
| GC     | MP              | 72 | 71                    | 98.6% (92.5%-99.8%) | 71                    | 98.6% (92.5%-99.8%) |
|        | LP              | 72 | 72                    | 100% (94.9%-100%)   | 67                    | 93.1% (84.8%-97.0%) |
|        | HN <sup>a</sup> | 72 | 32                    | 44.4% (33.5%-55.9%) | 21                    | 29.2% (19.9%-40.5%) |
|        | TN <sup>b</sup> | 72 | 72                    | 100% (94.9%-100%)   | 72                    | 100% (94.9%-100%)   |
| TV     | MP              | 72 | 72                    | 100% (94.9%-100%)   | 71                    | 98.6% (92.5%-99.8%) |
|        | LP              | 72 | 72                    | 100% (94.9%-100%)   | 72                    | 100% (94.9%-100%)   |
|        | HN <sup>a</sup> | 72 | 27                    | 37.5% (27.2%-49.0%) | 27                    | 37.5% (27.2%-49.0%) |
|        | TN <sup>b</sup> | 72 | 72                    | 100% (94.9%-100%)   | 72                    | 100% (94.9%-100%)   |

<sup>a</sup>For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

<sup>b</sup>For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

The Variance Component Analysis results for the within-laboratory Precision study on the BD COR and the BD MAX Systems are summarized below. The mean values and the associated variance components (SD and %CV) are based on the Ct.score.

**Variance Component Analysis for the BD COR, PreservCyt**

| Target | Level | N  | Mean  | Within Run |      | Between Run |      | Between Day |      | Total |      |
|--------|-------|----|-------|------------|------|-------------|------|-------------|------|-------|------|
|        |       |    |       | 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 |

### Variance Component Analysis for the BD MAX, PreservCyt

| Target | Level | N  | Mean  | Within Run |      | Between Run |      | Between Day |      | Total |      |
|--------|-------|----|-------|------------|------|-------------|------|-------------|------|-------|------|
|        |       |    |       | SD         | %CV  | SD          | %CV  | SD          | %CV  | SD    | %CV  |
| CT     | MP    | 72 | 32.18 | 0.46       | 1.42 | 0.22        | 0.68 | 0.00        | 0.00 | 0.51  | 1.57 |
|        | LP    | 72 | 33.58 | 0.87       | 2.59 | 0.00        | 0.00 | 0.38        | 1.13 | 0.95  | 2.82 |
| GC1    | MP    | 70 | 31.39 | 0.61       | 1.94 | 0.00        | 0.00 | 0.16        | 0.49 | 0.63  | 2.00 |
|        | LP    | 71 | 32.45 | 0.75       | 2.31 | 0.00        | 0.00 | 0.19        | 0.58 | 0.77  | 2.39 |
| GC2    | MP    | 71 | 29.91 | 0.42       | 1.40 | 0.06        | 0.20 | 0.26        | 0.86 | 0.50  | 1.66 |
|        | LP    | 71 | 30.97 | 0.54       | 1.74 | 0.16        | 0.52 | 0.14        | 0.44 | 0.58  | 1.87 |

### Variance Component Analysis for the BD COR, Urine

| Target | Level | N  | Mean  | Within Run |      | Between Run |      | Between Day |      | Total |      |
|--------|-------|----|-------|------------|------|-------------|------|-------------|------|-------|------|
|        |       |    |       | SD         | %CV  | SD          | %CV  | SD          | %CV  | SD    | %CV  |
| CT     | MP    | 72 | 31.71 | 0.50       | 1.57 | 0.00        | 0.00 | 0.20        | 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 |
| GC1    | 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 | 33.20 | 1.18       | 3.56 | 0.00        | 0.00 | 0.00        | 0.00 | 1.18  | 3.56 |

### Variance Component Analysis for the BD MAX, Urine

| Target | Level | N  | Mean  | Within Run |      | Between Run |      | Between Day |      | Total |      |
|--------|-------|----|-------|------------|------|-------------|------|-------------|------|-------|------|
|        |       |    |       | SD         | %CV  | SD          | %CV  | SD          | %CV  | SD    | %CV  |
| CT     | MP    | 72 | 32.35 | 0.97       | 3.00 | 0.00        | 0.00 | 0.00        | 0.00 | 0.97  | 3.00 |
|        | LP    | 71 | 33.63 | 1.58       | 4.70 | 0.00        | 0.00 | 0.00        | 0.00 | 1.58  | 4.70 |
| GC1    | MP    | 72 | 31.24 | 1.10       | 3.53 | 0.00        | 0.00 | 0.00        | 0.00 | 1.10  | 3.53 |
|        | LP    | 67 | 32.49 | 1.32       | 4.07 | 0.00        | 0.00 | 0.00        | 0.00 | 1.32  | 4.07 |
| GC2    | MP    | 71 | 30.19 | 1.02       | 3.39 | 0.38        | 1.27 | 0.30        | 1.00 | 1.13  | 3.76 |
|        | LP    | 68 | 32.00 | 1.70       | 5.30 | 0.00        | 0.00 | 0.00        | 0.00 | 1.70  | 5.30 |
| TV     | MP    | 71 | 32.11 | 1.81       | 5.63 | 0.00        | 0.00 | 0.00        | 0.00 | 1.81  | 5.63 |
|        | LP    | 72 | 33.40 | 1.29       | 3.87 | 0.82        | 2.46 | 0.00        | 0.00 | 1.53  | 4.59 |

Additionally, the ratio of the standard deviations (Total) of the BD COR and the BD MAX Systems (from the above variance component tables) along with the 95% confidence interval for this ratio are shown below.

**Ratio of Total Standard Deviations (BD COR: BD MAX), PreservCyt**

| Target | Level | Mean<br>BD<br>COR | Mean<br>BD<br>MAX | BD COR          |      | BD MAX |      | Ratio<br>of SD | 95% CI <sup>b</sup> |      |
|--------|-------|-------------------|-------------------|-----------------|------|--------|------|----------------|---------------------|------|
|        |       |                   |                   | DF <sup>a</sup> | SD   | DF     | SD   |                |                     |      |
| CT     | MP    | 32.86             | 32.18             | 71              | 0.61 | 71     | 0.51 | 1.20           | 0.95                | 1.52 |
|        | LP    | 34.06             | 33.58             | 70              | 1.29 | 71     | 0.95 | 1.36           | 1.08                | 1.72 |
| GC1    | MP    | 31.89             | 31.39             | 68              | 0.68 | 69     | 0.63 | 1.09           | 0.85                | 1.38 |
|        | LP    | 33.78             | 32.45             | 66              | 1.52 | 70     | 0.77 | 1.96           | 1.54                | 2.49 |
| GC2    | MP    | 30.24             | 29.91             | 71              | 0.37 | 70     | 0.50 | 0.75           | 0.59                | 0.95 |
|        | LP    | 31.63             | 30.97             | 69              | 0.66 | 70     | 0.58 | 1.15           | 0.91                | 1.46 |

<sup>a</sup> DF, degree of freedom

<sup>b</sup> 95% CI for the ratio of SD is calculated based on the F-statistic for a ratio of variances

**Ratio of Total Standard Deviations (BD COR: BD MAX), Urine**

| Target | Level | Mean<br>BD<br>COR | Mean<br>BD<br>MAX | BD COR          |      | BD MAX |      | Ratio<br>of SD | 95% CI <sup>b</sup> |      |
|--------|-------|-------------------|-------------------|-----------------|------|--------|------|----------------|---------------------|------|
|        |       |                   |                   | DF <sup>a</sup> | SD   | DF     | SD   |                |                     |      |
| CT     | MP    | 31.71             | 32.35             | 71              | 0.54 | 71     | 0.97 | 0.55           | 0.44                | 0.70 |
|        | LP    | 32.93             | 33.63             | 71              | 1.15 | 70     | 1.58 | 0.73           | 0.57                | 0.92 |
| GC1    | MP    | 31.52             | 31.24             | 70              | 1.08 | 71     | 1.10 | 0.98           | 0.78                | 1.24 |
|        | LP    | 32.47             | 32.49             | 71              | 0.88 | 66     | 1.32 | 0.67           | 0.53                | 0.85 |
| GC2    | MP    | 29.57             | 30.19             | 70              | 0.70 | 70     | 1.13 | 0.62           | 0.49                | 0.78 |
|        | LP    | 30.54             | 32.00             | 71              | 0.53 | 67     | 1.70 | 0.31           | 0.24                | 0.39 |
| TV     | MP    | 32.00             | 32.11             | 71              | 0.87 | 70     | 1.81 | 0.48           | 0.38                | 0.61 |
|        | LP    | 33.20             | 33.40             | 71              | 1.18 | 71     | 1.53 | 0.77           | 0.61                | 0.98 |

<sup>a</sup> DF, degree of freedom

<sup>b</sup> 95% CI for the ratio of SD is calculated based on the F-statistic for a ratio of variances

**b. Site-to-Site Reproducibility**

For the Site-to-Site Reproducibility study for the BD CTGCTV2 assay performed concurrently on the BD COR and the BD MAX, three sites (two external and one internal) were provided the

same panels as described for the Precision study and the tests were performed on one BD COR and one BD MAX at each site. Each site performed testing on each instrument on six distinct days with two operators each performing the test on three days with one lot of reagents. Each operator performed three runs per day. Site-by-Site and Overall Percent Agreement on the BD COR and the BD MAX are shown below.

**Site-by-Site and Overall Percent Agreement for the BD COR and the BD MAX,  
PreservCyt**

| Target | Level           | Site | BD COR System (PreservCyt) |           |                     | BD MAX System (PreservCyt) |                     |
|--------|-----------------|------|----------------------------|-----------|---------------------|----------------------------|---------------------|
|        |                 |      | N Total                    | N Correct | % Correct (95% CI)  | N Correct                  | % Correct (95% CI)  |
| CT     | MP              | 1    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | 2    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | 3    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | All  | 108                        | 108       | 100% (96.6%-100%)   | 108                        | 100% (96.6%-100%)   |
|        | LP              | 1    | 36                         | 35        | 97.2% (85.8%-99.5%) | 36                         | 100% (90.4%-100%)   |
|        |                 | 2    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | 3    | 36                         | 35        | 97.2% (85.8%-99.5%) | 36                         | 100% (90.4%-100%)   |
|        |                 | All  | 108                        | 106       | 98.1% (93.5%-99.5%) | 108                        | 100% (96.6%-100%)   |
|        | HN <sup>a</sup> | 1    | 36                         | 16        | 44.4% (29.5%-60.4%) | 17                         | 47.2% (32.0%-63.0%) |
|        |                 | 2    | 36                         | 21        | 58.3% (42.2%-72.9%) | 18                         | 50.0% (34.5%-65.5%) |
|        |                 | 3    | 36                         | 15        | 41.7% (27.1%-57.8%) | 20                         | 55.6% (39.6%-70.5%) |
|        |                 | All  | 108                        | 52        | 48.1% (39.0%-57.5%) | 55                         | 50.9% (41.6%-60.2%) |
|        | TN <sup>b</sup> | 1    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | 2    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | 3    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | All  | 108                        | 108       | 100% (96.6%-100%)   | 108                        | 100% (96.6%-100%)   |
| GC     | MP              | 1    | 36                         | 34        | 94.4% (81.9%-98.5%) | 36                         | 100% (90.4%-100%)   |
|        |                 | 2    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | 3    | 36                         | 36        | 100% (90.4%-100%)   | 36                         | 100% (90.4%-100%)   |
|        |                 | All  | 108                        | 106       | 98.1% (93.5%-99.5%) | 108                        | 100% (96.6%-100%)   |
|        | LP              | 1    | 36                         | 32        | 88.9% (74.7%-95.6%) | 35                         | 97.2% (85.8%-99.5%) |
|        |                 | 2    | 36                         | 33        | 91.7% (78.2%-97.1%) | 36                         | 100% (90.4%-100%)   |
|        |                 | 3    | 36                         | 34        | 94.4% (81.9%-98.5%) | 35                         | 97.2% (85.8%-99.5%) |
|        |                 | All  | 108                        | 99        | 91.7% (84.9%-95.6%) | 106                        | 98.1% (93.5%-99.5%) |

|  |                 |     |     |     |                     |     |                     |
|--|-----------------|-----|-----|-----|---------------------|-----|---------------------|
|  | HN <sup>a</sup> | 1   | 36  | 12  | 33.3% (20.2%-49.7%) | 20  | 55.6% (39.6%-70.5%) |
|  |                 | 2   | 36  | 12  | 33.3% (20.2%-49.7%) | 13  | 36.1% (22.5%-52.4%) |
|  |                 | 3   | 36  | 18  | 50.0% (34.5%-65.5%) | 24  | 66.7% (50.3%-79.8%) |
|  |                 | All | 108 | 42  | 38.9% (30.2%-48.3%) | 57  | 52.8% (43.4%-61.9%) |
|  | TN <sup>b</sup> | 1   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|  |                 | 2   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|  |                 | 3   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|  |                 | All | 108 | 108 | 100% (96.6%-100%)   | 108 | 100% (96.6%-100%)   |

<sup>a</sup>. For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

<sup>b</sup>. For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

### Site-by-Site and Overall Percent Agreement for the BD COR and the BD MAX, Urine

| Target | Level           | Site | BD COR System (Urine) |           |                     | BD MAX System (Urine) |                     |
|--------|-----------------|------|-----------------------|-----------|---------------------|-----------------------|---------------------|
|        |                 |      | N Total               | N Correct | % Correct (95% CI)  | N Correct             | % Correct (95% CI)  |
| CT     | MP              | 1    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 2    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 3    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | All  | 108                   | 108       | 100% (96.6%-100%)   | 108                   | 100% (96.6%-100%)   |
|        | LP              | 1    | 36                    | 36        | 100% (90.4%-100%)   | 35                    | 97.2% (85.8%-99.5%) |
|        |                 | 2    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 3    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | All  | 108                   | 108       | 100% (96.6%-100%)   | 107                   | 99.1% (94.9%-99.8%) |
|        | HN <sup>a</sup> | 1    | 36                    | 23        | 63.9% (47.6%-77.5%) | 19                    | 52.8% (37.0%-68.0%) |
|        |                 | 2    | 36                    | 21        | 58.3% (42.2%-72.9%) | 18                    | 50.0% (34.5%-65.5%) |
|        |                 | 3    | 36                    | 19        | 52.8% (37.0%-68.0%) | 14                    | 38.9% (24.8%-55.1%) |
|        |                 | All  | 108                   | 63        | 58.3% (48.9%-67.2%) | 51                    | 47.2% (38.1%-56.6%) |
|        | TN <sup>b</sup> | 1    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 2    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 3    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | All  | 108                   | 108       | 100% (96.6%-100%)   | 108                   | 100% (96.6%-100%)   |
| GC     | MP              | 1    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 2    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |
|        |                 | 3    | 36                    | 36        | 100% (90.4%-100%)   | 36                    | 100% (90.4%-100%)   |

|    |                 |     |     |     |                     |     |                     |
|----|-----------------|-----|-----|-----|---------------------|-----|---------------------|
|    |                 | All | 108 | 108 | 100% (96.6%-100%)   | 108 | 100% (96.6%-100%)   |
|    | LP              | 1   | 36  | 36  | 100% (90.4%-100%)   | 34  | 94.4% (81.9%-98.5%) |
|    |                 | 2   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 3   | 36  | 36  | 100% (90.4%-100%)   | 33  | 91.7% (78.2%-97.1%) |
|    |                 | All | 108 | 108 | 100% (96.6%-100%)   | 103 | 95.4% (89.6%-98.0%) |
|    | HN <sup>a</sup> | 1   | 36  | 17  | 47.2% (32.0%-63.0%) | 12  | 33.3% (20.2%-49.7%) |
|    |                 | 2   | 36  | 18  | 50.0% (34.5%-65.5%) | 8   | 22.2% (11.7%-38.1%) |
|    |                 | 3   | 36  | 10  | 27.8% (15.8%-44.0%) | 11  | 30.6% (18.0%-46.9%) |
|    |                 | All | 108 | 45  | 41.7% (32.8%-51.1%) | 31  | 28.7% (21.0%-37.9%) |
|    | TN <sup>b</sup> | 1   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 2   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 3   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | All | 108 | 108 | 100% (96.6%-100%)   | 108 | 100% (96.6%-100%)   |
| TV | MP              | 1   | 36  | 36  | 100% (90.4%-100%)   | 35  | 97.2% (85.8%-99.5%) |
|    |                 | 2   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 3   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | All | 108 | 108 | 100% (96.6%-100%)   | 107 | 99.1% (94.9%-99.8%) |
|    | LP              | 1   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 2   | 36  | 36  | 100% (90.4%-100%)   | 35  | 97.2% (85.8%-99.5%) |
|    |                 | 3   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | All | 108 | 108 | 100% (96.6%-100%)   | 107 | 99.1% (94.9%-99.8%) |
|    | HN <sup>a</sup> | 1   | 36  | 11  | 30.6% (18.0%-46.9%) | 14  | 38.9% (24.8%-55.1%) |
|    |                 | 2   | 36  | 17  | 47.2% (32.0%-63.0%) | 16  | 44.4% (29.5%-60.4%) |
|    |                 | 3   | 36  | 12  | 33.3% (20.2%-49.7%) | 11  | 30.6% (18.0%-46.9%) |
|    |                 | All | 108 | 40  | 37.0% (28.5%-46.4%) | 41  | 38.0% (29.4%-47.4%) |
|    | TN <sup>b</sup> | 1   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 2   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | 3   | 36  | 36  | 100% (90.4%-100%)   | 36  | 100% (90.4%-100%)   |
|    |                 | All | 108 | 108 | 100% (96.6%-100%)   | 108 | 100% (96.6%-100%)   |

<sup>a</sup>. For the High Negative (HN) category, the reported agreement indicates the percent of positive results.

<sup>b</sup>. For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

The Variance Component Analysis results for the Site-to-Site Reproducibility study for the BD COR and the BD MAX Systems are shown below. The mean values and the associated variance components (SD and %CV) are based on the Ct.score.



**Site-to-Site Variance Component Analysis for BD COR, PreservCyt**

| Target | Level | N   | Mean  | Within Run |      | Between Run |      | Between Day |      | Between Site |      | Total |      |
|--------|-------|-----|-------|------------|------|-------------|------|-------------|------|--------------|------|-------|------|
|        |       |     |       | 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 |

**Site-to-Site Variance Component Analysis for BD MAX, PreservCyt**

| Target | Level | N   | Mean  | Within Run |      | Between Run |      | Between Day |      | Between Site |      | Total |      |
|--------|-------|-----|-------|------------|------|-------------|------|-------------|------|--------------|------|-------|------|
|        |       |     |       | SD         | %CV  | SD          | %CV  | SD          | %CV  | SD           | %CV  | SD    | %CV  |
| CT     | MP    | 108 | 31.90 | 0.46       | 1.44 | 0.07        | 0.23 | 0.00        | 0.00 | 0.23         | 0.73 | 0.52  | 1.63 |
|        | LP    | 108 | 33.04 | 0.70       | 2.11 | 0.00        | 0.00 | 0.30        | 0.92 | 0.22         | 0.65 | 0.79  | 2.39 |
| GC1    | MP    | 108 | 31.38 | 0.59       | 1.87 | 0.10        | 0.31 | 0.00        | 0.00 | 0.15         | 0.47 | 0.61  | 1.95 |
|        | LP    | 106 | 32.58 | 0.84       | 2.56 | 0.00        | 0.00 | 0.07        | 0.21 | 0.10         | 0.32 | 0.84  | 2.59 |
| GC2    | MP    | 108 | 29.96 | 0.37       | 1.24 | 0.00        | 0.00 | 0.08        | 0.28 | 0.18         | 0.60 | 0.42  | 1.40 |
|        | LP    | 107 | 31.03 | 0.46       | 1.48 | 0.00        | 0.00 | 0.00        | 0.00 | 0.22         | 0.72 | 0.51  | 1.64 |

**Site-to-Site Variance Component Analysis for BD COR, Urine**

| Target | Level | N   | Mean  | Within Run |      | Between Run |      | Between Day |      | Between Site |      | Total |      |
|--------|-------|-----|-------|------------|------|-------------|------|-------------|------|--------------|------|-------|------|
|        |       |     |       | 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 |

### Site-to-Site Variance Component Analysis for BD MAX, Urine

| Target | Level | N   | Mean  | Within Run |      | Between Run |      | Between Day |      | Between Site |      | Total |      |
|--------|-------|-----|-------|------------|------|-------------|------|-------------|------|--------------|------|-------|------|
|        |       |     |       | SD         | %CV  | SD          | %CV  | SD          | %CV  | SD           | %CV  | SD    | %CV  |
| CT     | MP    | 108 | 31.98 | 0.76       | 2.37 | 0.00        | 0.00 | 0.24        | 0.74 | 0.39         | 1.23 | 0.89  | 2.77 |
|        | LP    | 107 | 33.12 | 1.25       | 3.76 | 0.20        | 0.59 | 0.00        | 0.00 | 0.35         | 1.06 | 1.31  | 3.95 |
| GC1    | MP    | 108 | 31.26 | 1.34       | 4.29 | 0.00        | 0.00 | 0.32        | 1.02 | 0.33         | 1.06 | 1.42  | 4.54 |
|        | LP    | 103 | 32.24 | 1.02       | 3.17 | 0.09        | 0.29 | 0.00        | 0.00 | 0.00         | 0.00 | 1.03  | 3.18 |
| GC2    | MP    | 108 | 30.34 | 1.01       | 3.32 | 0.00        | 0.00 | 0.24        | 0.78 | 0.29         | 0.94 | 1.07  | 3.53 |
|        | LP    | 105 | 31.60 | 1.11       | 3.52 | 0.00        | 0.00 | 0.00        | 0.00 | 0.11         | 0.33 | 1.12  | 3.54 |
| TV     | MP    | 107 | 31.91 | 0.98       | 3.06 | 0.19        | 0.61 | 0.15        | 0.46 | 0.00         | 0.00 | 1.01  | 3.15 |
|        | LP    | 107 | 33.22 | 1.23       | 3.70 | 0.23        | 0.69 | 0.00        | 0.00 | 0.00         | 0.00 | 1.25  | 3.76 |

Additionally, the ratio of standard deviations of the BD COR to that of the BD MAX System (from the above variance component tables) along with 95% confidence intervals are shown below.

### Ratio of Standard Deviations (BD COR: BD MAX), Site-to-Site, PreservCyt

| Target | Level | Mean BD COR | Mean BD MAX | Repeatability (Within Run) |      |        |      |             |                     | Reproducibility (Total) |     |        |     |             |        |      |      |
|--------|-------|-------------|-------------|----------------------------|------|--------|------|-------------|---------------------|-------------------------|-----|--------|-----|-------------|--------|------|------|
|        |       |             |             | BD COR                     |      | BD MAX |      | Ratio of SD | 95% CI <sup>b</sup> | BD COR                  |     | BD MAX |     | Ratio of SD | 95% CI |      |      |
|        |       |             |             | DF <sup>a</sup>            | SD   | DF     | SD   |             |                     | DF                      | SD  | DF     | SD  |             |        |      |      |
| CT     | MP    | 33.05       | 31.90       | 53                         | 0.65 | 53     | 0.46 | 1.41        | 1.07                | 1.85                    | 107 | 0.72   | 107 | 0.52        | 1.39   | 1.15 | 1.68 |
|        | LP    | 33.98       | 33.04       | 52                         | 0.78 | 53     | 0.70 | 1.11        | 0.85                | 1.46                    | 105 | 0.83   | 107 | 0.79        | 1.05   | 0.87 | 1.27 |
| GC1    | MP    | 32.07       | 31.38       | 52                         | 0.94 | 53     | 0.59 | 1.60        | 1.22                | 2.10                    | 105 | 1.03   | 107 | 0.61        | 1.68   | 1.39 | 2.04 |
|        | LP    | 33.73       | 32.58       | 49                         | 1.40 | 52     | 0.84 | 1.67        | 1.27                | 2.21                    | 98  | 1.40   | 105 | 0.84        | 1.66   | 1.36 | 2.01 |
| GC2    | MP    | 30.43       | 29.96       | 53                         | 0.50 | 53     | 0.37 | 1.36        | 1.03                | 1.78                    | 107 | 0.53   | 107 | 0.42        | 1.27   | 1.05 | 1.54 |
|        | LP    | 31.79       | 31.03       | 52                         | 0.74 | 53     | 0.46 | 1.62        | 1.23                | 2.12                    | 104 | 0.79   | 106 | 0.51        | 1.54   | 1.27 | 1.87 |

<sup>a</sup> DF, degree of freedom

<sup>b</sup> 95% CI for the ratio of SD is calculated based on the F-statistic for a ratio of variances

### Ratio of Standard Deviations (BD COR: BD MAX), Site-to-Site, Urine

| Target | Level | Mean BD COR | Mean BD MAX | Repeatability (Within Run) |      |        |      |             |                     | Reproducibility (Total) |     |        |     |             |        |      |      |
|--------|-------|-------------|-------------|----------------------------|------|--------|------|-------------|---------------------|-------------------------|-----|--------|-----|-------------|--------|------|------|
|        |       |             |             | BD COR                     |      | BD MAX |      | Ratio of SD | 95% CI <sup>b</sup> | BD COR                  |     | BD MAX |     | Ratio of SD | 95% CI |      |      |
|        |       |             |             | DF <sup>a</sup>            | SD   | DF     | SD   |             |                     | DF                      | SD  | DF     | SD  |             |        |      |      |
| CT     | MP    | 31.76       | 31.98       | 53                         | 0.52 | 53     | 0.76 | 0.69        | 0.53                | 0.91                    | 107 | 0.55   | 107 | 0.89        | 0.62   | 0.52 | 0.76 |
|        | LP    | 33.03       | 33.12       | 53                         | 0.99 | 53     | 1.25 | 0.79        | 0.60                | 1.04                    | 107 | 1.02   | 106 | 1.31        | 0.78   | 0.65 | 0.95 |
| GC1    | MP    | 31.39       | 31.26       | 53                         | 0.89 | 53     | 1.34 | 0.66        | 0.51                | 0.87                    | 107 | 0.97   | 107 | 1.42        | 0.68   | 0.57 | 0.83 |

|        |    |       |       |    |      |    |      |      |      |      |     |      |     |      |      |      |      |
|--------|----|-------|-------|----|------|----|------|------|------|------|-----|------|-----|------|------|------|------|
|        | LP | 32.36 | 32.24 | 53 | 0.89 | 51 | 1.02 | 0.87 | 0.66 | 1.14 | 107 | 0.96 | 102 | 1.03 | 0.94 | 0.77 | 1.14 |
| GC2    | MP | 29.75 | 30.34 | 53 | 0.50 | 53 | 1.01 | 0.50 | 0.38 | 0.65 | 107 | 0.54 | 107 | 1.07 | 0.50 | 0.42 | 0.61 |
|        | LP | 30.69 | 31.60 | 53 | 0.53 | 52 | 1.11 | 0.47 | 0.36 | 0.62 | 107 | 0.59 | 104 | 1.12 | 0.53 | 0.43 | 0.64 |
| T<br>V | MP | 32.29 | 31.91 | 53 | 0.72 | 53 | 0.98 | 0.74 | 0.56 | 0.97 | 107 | 0.77 | 106 | 1.01 | 0.77 | 0.64 | 0.93 |
|        | LP | 33.49 | 33.22 | 53 | 1.37 | 53 | 1.23 | 1.12 | 0.85 | 1.47 | 107 | 1.40 | 106 | 1.25 | 1.12 | 0.93 | 1.36 |

<sup>a</sup>: DF, degree of freedom

<sup>b</sup>: 95% CI for the ratio of SD is calculated based on the F-statistic for a ratio of variances

## 2. Linearity:

Not applicable.

## 3. Analytical Specificity/Interference:

### a. Cross-reactivity

Please refer to K182692. The cross-reactivity study of the BD CTGCTV2 assay was performed on the BD MAX as demonstrated in K182692 and the data is applicable to the BD COR.

### b. Competitive Interference

Please refer to K182692. The Competitive Interference study of the BD CTGCTV2 assay was performed on the BD MAX as demonstrated in K182692 and the data is applicable to the BD COR.

### c. Interfering Substances

Please refer to K182692. The Interfering Substances study of the BD CTGCTV2 assay was performed on the BD MAX as demonstrated in K182692 and the data is applicable to the BD COR.

## 4. Assay Reportable Range:

Not applicable.

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

### a. Controls

Both the Specimen Processing Control (SPC) and External Control remain the same when performing the BD CTGCTV2 assay on the BD COR. The SPC is present in each Extraction

Tube. It monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances.

External Control materials are not provided by BD. Commercially available control material or a previously characterized clinical sample known to be positive may be used as a positive control. The BD Molecular Swab Sample Buffer Tube without the addition of organism or a previously characterized sample known to be negative is recommended for use as an external negative control.

**b. On-deck Specimen Stability**

To demonstrate the stability of urine, vaginal and PreservCyt specimens in Sample Buffer Tubes (SBTs) that are punctured, positive and negative samples were prepared in pooled negative urine, vaginal or PreservCyt matrix. Samples were then held at either 2-8°C or 33°C in SBTs for 17 days and then punctured and held at either 2-8°C or 33°C for additional seven days. The CTGCTV2 assay was performed at different time points including base line, upon puncture on the 17<sup>th</sup> day of the 21-day storage period (as representative of the specimen being punctured anytime prior to the 17<sup>th</sup> day), four days post puncture, as well as seven days post puncture. For PreservCyt LBC samples, the PreservCyt pool with spiked target were held at either 2-8°C or 30°C for 14 days. Then each PreservCyt pool was added to SBTs containing CTGCTV2 LBC sample buffer where half were pre-warmed prior to storage while the other half were pre-warmed after storage, just prior to puncture and testing. These samples were then held at 2-8°C or 33°C and tested in the same fashion as urine or vaginal samples. Data generated from the study support on-deck specimen stability at the following storage conditions.

**Swab and Urine Specimen Stability**

|  |  |
|--|--|
| In BD Molecular Swab or Urine SBT <sup>a</sup> | Up to 21 days at 2–30 °C   |
| Upon puncture of BD Pierceable Caps            | Up to 4 days <sup>b</sup> , punctured within 21 days and stored at 2-30 °C |

<sup>a</sup>. Swab and Urine specimens must be transferred to the corresponding BD Molecular SBT immediately after collection.

<sup>b</sup>. The “4 days” is included in the 21 days total storage duration at 2–30 °C.

**PreservCyt LBC Specimen Stability**

|  |  |
|--|--|
| Prior to transfer to BD Molecular LBC SBT or Molecular Aliquot Tube <sup>a</sup> | Up to 14 days at 2–30 °C   |
| In BD Molecular LBC SBT or Molecular Aliquot Tube (prior to or after pre-warm)   | Up to 21 days at 2–30 °C   |
| Upon puncture of BD Pierceable Caps  | Up to 4 days <sup>b</sup> , punctured within 21 days and stored at 2-30 °C |

<sup>a</sup>. PreservCyt specimens must be aliquoted into a BD Molecular LBC SBT or the Molecular Aliquot Tube prior to processing for the ThinPrep Pap test.

<sup>b</sup>. The “4 days” is included in the 21 days total storage duration at 2–30 °C.

## 6. Detection Limit:

### a. Limit of Detection (LoD)

To determine if the LoD of the BD CTGCTV2 assay when performed on the BD COR System is equivalent to the LoD of the assay when performed on the BD MAX, panel members spiked at Low Positive (1.5x LoD) and Moderate Positive (3x LoD) in pooled negative female urine, pooled negative vaginal swab and pooled negative PreservCyt LBC matrix were tested on the BD COR and the BD MAX in parallel. The four panel members (see table below) were created using the LoD previously determined on the BD MAX System. Each panel member in PreservCyt had pre-analytical sample dilution performed automatically by BD COR System. Additionally, pre-analytical samples were manually pipetted for testing on both the BD COR and the BD MAX Systems.

**Analytical Sensitivity Confirmation Panel Members**

| <b>Panel Member</b> | <b>CT</b> | <b>GC</b> | <b>TV</b> | <b>Target Level</b> |
|---------------------|-----------|-----------|-----------|---------------------|
| 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     |                     |

The Positive Percent Agreement analysis and the comparison of mean Ct.Score between the BD COR and the BD MAX were performed. The results for the comparison of mean Ct.Score are shown in the following tables. Results from this study demonstrate that the analytical sensitivity of the BD CTGCTV2 assay in vaginal swabs, urine and PreservCyt LBC samples on the BD COR is equivalent to the analytical sensitivity demonstrated on the BD MAX.

**Mean Ct.Score Comparison, BD COR vs. BD MAX, Vaginal Swab**

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

**Mean Ct.Score Comparison, BD COR vs. BD MAX, Urine**

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

**Mean Ct.Score Comparison, BD COR vs. BD MAX, LBC Converted<sup>a</sup> by BD COR**

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

<sup>a</sup>. Sample transfer from PreservCyt vial to BD Molecular LBC SBT performed automatically by BD COR System.



**Mean Ct.Score Comparison, BD COR vs. BD MAX, Manually Converted LBC<sup>a</sup> for BD COR**

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

<sup>a</sup>. 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 the BD COR.

**b. Inclusivity**

Please refer to K182692. The Inclusivity study of the BD CTGCTV2 assay was performed on the BD MAX as demonstrated in K182692 and the data is applicable to the BD COR.

**7. Assay Cut-Off:**

Please refer to K182692. The Cut-off values of the BD CTGCTV2 Assay as performed on the BD COR are the same as the Cut-off values when performed on the BD MAX.

## 8. Carry-Over:

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

## **B Comparison Studies:**

### 1. Method Comparison with Predicate Device:

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 the 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 sample. 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 the majority of the positive specimens for CT, GC or TV were at analyte levels of Low Positive and Moderate Positive. All panel members were randomized and masked. Six aliquots were prepared for each panel member. Among them, three aliquots were tested on separate BD COR Systems 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 on the BD MAX, both positive and negative percent agreement analysis as well as Deming regression analysis of the Ct.Score values were performed. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) between the results from the BD MAX and the BD COR Systems were calculated separately for each target. For each target, the comparator result was a composite of results obtained on the three BD MAX instruments where the positive or negative status of each panel member was determined by at least two out of three evaluable results (a “majority rule”). Based on the majority rule, 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 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.

The PPA and NPA for each target were calculated for each of the three sites where BD COR testing was performed. Additionally, 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 three BD COR testing sites are summarized in the following tables for each target. The denominator for PPA and NPA calculation includes panel members with equivocal comparator results from the 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.

**Percent Agreement BD COR vs. BD MAX, by Individual Site and Combined, CT**

| BD COR Test Site |   |               | BD MAX Result          |                        |                             |                        |                        |                             |
|------------------|---|---------------|------------------------|------------------------|-----------------------------|------------------------|------------------------|-----------------------------|
|                  |   |               | BD MAX Positive Result |                        |                             | BD MAX Negative Result |                        |                             |
|                  |   |               | 3 Positive             | 2 Positive, 1 Negative | 2 Positive, 1 Non-evaluable | 3 Negative             | 1 Positive, 2 Negative | 2 Negative, 1 Non-evaluable |
| 1                | BD COR Result   | Positive      | 102                    | 3                      | 0                           | 0                      | 0                      | 0                           |
|                  |   | Negative      | 0                      | 0                      | 0                           | 107                    | 1                      | 0                           |
|                  |   | Total         | 102                    | 3                      | 0                           | 107                    | 1                      | 0                           |
|                  |   | Positive Rate | 100%                   | 100%                   | NA                          | 0.0%                   | 0.0%                   | NA                          |
|                  | PPA: 100% (105/105), 95% CI: (96.5%, 100%) <sup>b</sup><br>NPA: 100% (108/108), 95% CI: (96.6%, 100%) |               |                        |                        |                             |                        |                        |                             |
| 2                |   |               | BD MAX Result          |                        |                             |                        |                        |                             |
|                  |   |               | BD MAX Positive Result |                        |                             | BD MAX Negative Result |                        |                             |
|                  |   |               | 3 Positive             | 2 Positive, 1 Negative | 2 Positive, 1 Non-evaluable | 3 Negative             | 1 Positive, 2 Negative | 2 Negative, 1 Non-evaluable |
|                  | BD COR Result   | Positive      | 102                    | 3                      | 1                           | 0                      | 0                      | 0                           |
|                  |   | Negative      | 0                      | 0                      | 0                           | 107                    | 1                      | 0                           |
| Total            |   | 102           | 3                      | 1                      | 107                         | 1                      | 0                      |                             |

|   |   |               |                        |                        |                             |                        |                        |                             |
|---|---|---------------|------------------------|------------------------|-----------------------------|------------------------|------------------------|-----------------------------|
|   |   | Positive Rate | 100%                   | 100%                   | 100%                        | 0.0%                   | 0.0%                   | NA                          |
|   | PPA: 100% (106/106), 95% CI: (96.5%, 100%)<br>NPA: 100% (108/108), 95% CI: (96.6%, 100%)  |               |                        |                        |                             |                        |                        |                             |
| 3 |   |               | <b>BD MAX Result</b>   |                        |                             |                        |                        |                             |
|   |   |               | BD MAX Positive Result |                        |                             | BD MAX Negative Result |                        |                             |
|   |   |               | 3 Positive             | 2 Positive, 1 Negative | 2 Positive, 1 Non-evaluable | 3 Negative             | 1 Positive, 2 Negative | 2 Negative, 1 Non-evaluable |
|   | <b>BD COR Result</b>  | Positive      | 102                    | 3                      | 1                           | 0                      | 0                      | 0                           |
|   |   | Negative      | 0                      | 0                      | 0                           | 107                    | 1                      | 0                           |
|   |   | Total         | 102                    | 3                      | 1                           | 107                    | 1                      | 0                           |
|   |   | Positive Rate | 100%                   | 100%                   | 100%                        | 0.0%                   | 0.0%                   | NA                          |
|   | PPA: 100% (106/106), 95% CI: (96.5%, 100%)<br>NPA: 100% (108/108), 95% CI: (96.6%, 100%)  |               |                        |                        |                             |                        |                        |                             |
|   | Average PPA: 100%, 95% CI: N/A <sup>a</sup><br>Average NPA: 100%, 95% CI: N/A <sup>a</sup><br>Number of BD MAX equivocal results: 0 |               |                        |                        |                             |                        |                        |                             |

<sup>a</sup>. Confidence intervals for point estimates close to 100% have not been included, as suggested by FDA guidance for assay migration studies.

<sup>b</sup>. Confidence intervals for point estimates at each site were calculated by a score method and confidence intervals for point estimates averaged over three sites were calculated by a bootstrap method.

**Percent Agreement BD COR vs. BD MAX, by Individual Site and Combined, GC**

| BD COR Test Site  | BD MAX Result   |                        |                             |                 |                        |                             |    |    |
|---|---|------------------------|-----------------------------|-----------------|------------------------|-----------------------------|----|----|
|   | BD MAX Positive   |                        |                             | BD MAX Negative |                        |                             |    |    |
|   | 3 Positive  | 2 Positive, 1 Negative | 2 Positive, 1 Non-evaluable | 3 Negative      | 1 Positive, 2 Negative | 2 Negative, 1 Non-evaluable |    |    |
| 1   | BD COR Result   | Positive               | 104                         | 5               | 1                      | 0                           | 0  | 0  |
|   |   | Negative               | 1                           | 0               | 0                      | 107                         | 0  | 0  |
|   |   | Total                  | 105                         | 5               | 1                      | 107                         | 0  | 0  |
|   |   | Positive Rate          | 99.0%                       | 100%            | 100%                   | 0.0%                        | NA | NA |
|   | PPA: 99.1% (110/111), 95% CI: (95.1%, 99.8%) <sup>b</sup><br>NPA: 100% (107/107), 95% CI: (96.5%, 100%) |                        |                             |                 |                        |                             |    |    |
| 2   | BD COR Result   | Positive               | 103                         | 5               | 0                      | 0                           | 0  | 0  |
|   |   | Negative               | 2                           | 0               | 0                      | 107                         | 0  | 0  |
|   |   | Total                  | 105                         | 5               | 0                      | 107                         | 0  | 0  |
|   |   | Positive Rate          | 98.1%                       | 100%            | NA                     | 0.0%                        | NA | NA |
|   | PPA: 98.2% (108/110), 95% CI: (93.6%, 99.5%)<br>NPA: 100% (107/107), 95% CI: (96.5%, 100%)              |                        |                             |                 |                        |                             |    |    |
| 3   | BD COR Result   | Positive               | 101                         | 4               | 1                      | 0                           | 0  | 0  |
|   |   | Negative               | 4                           | 1               | 0                      | 107                         | 0  | 0  |
|   |   | Total                  | 105                         | 5               | 1                      | 107                         | 0  | 0  |
|   |   | Positive Rate          | 96.2%                       | 80.0%           | 100%                   | 0.0%                        | NA | NA |
|   | PPA: 95.5% (106/111), 95% CI: (89.9%, 98.1%)<br>NPA: 100% (107/107), 95% CI: (96.5%, 100%)              |                        |                             |                 |                        |                             |    |    |
| Average PPA: 97.6%, 95% CI: (95.6%, 99.1%)<br>Average NPA: 100%, 95% CI: N/A <sup>a</sup> |   |                        |                             |                 |                        |                             |    |    |

Number of BD MAX equivocal results: 0

<sup>a</sup> Confidence intervals for point estimates close to 100% have not been included, as suggested by FDA guidance for assay migration studies.

<sup>b</sup> Confidence intervals for point estimates at each site were calculated by a score method and confidence intervals for point estimates averaged over three sites were calculated by a bootstrap method.

**Percent Agreement BD COR vs. BD MAX, by Individual Site and Combined, TV**

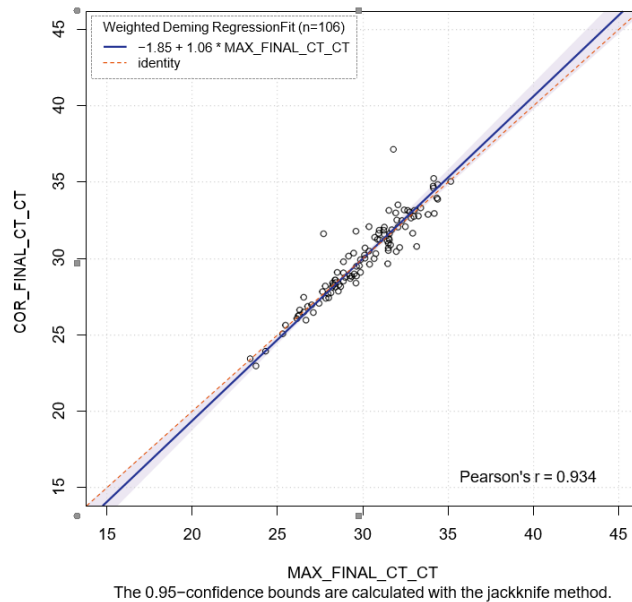
| BD COR Test Site |   |               | BD MAX Result          |                        |                             |                        |                        |                             |
|------------------|---|---------------|------------------------|------------------------|-----------------------------|------------------------|------------------------|-----------------------------|
|                  |   |               | BD MAX Positive Result |                        |                             | BD MAX Negative Result |                        |                             |
|                  |   |               | 3 Positive             | 2 Positive, 1 Negative | 2 Positive, 1 Non-evaluable | 3 Negative             | 1 Positive, 2 Negative | 2 Negative, 1 Non-evaluable |
| 1                | BD COR Result   | Positive      | 103                    | 2                      | 0                           | 0                      | 1                      | 0                           |
|                  |   | Negative      | 0                      | 0                      | 0                           | 106                    | 3                      | 0                           |
|                  |   | Total         | 103                    | 2                      | 0                           | 106                    | 4                      | 0                           |
|                  |   | Positive Rate | 100%                   | 100%                   | NA                          | 0.0%                   | 25.0%                  | NA                          |
|                  | PPA: 100% (105/105), 95% CI: (96.5%, 100%) <sup>a</sup><br>NPA: 99.1% (109/110), 95% CI: (95.0%, 99.8%) |               |                        |                        |                             |                        |                        |                             |
| 2                | BD COR Result   | Positive      | 103                    | 2                      | 0                           | 0                      | 3                      | 0                           |
|                  |   | Negative      | 0                      | 0                      | 0                           | 106                    | 1                      | 0                           |
|                  |   | Total         | 103                    | 2                      | 0                           | 106                    | 4                      | 0                           |
|                  |   | Positive Rate | 100%                   | 100%                   | NA                          | 0.0%                   | 75.0%                  | NA                          |
|                  | PPA: 100% (105/105), 95% CI: (96.5%, 100%)<br>NPA: 97.3% (107/110), 95% CI: (92.3%, 99.1%)              |               |                        |                        |                             |                        |                        |                             |
| 3                | BD COR Result   | Positive      | 102                    | 2                      | 0                           | 0                      | 1                      | 0                           |
|                  |   | Negative      | 1                      | 0                      | 0                           | 106                    | 3                      | 0                           |
|                  |   | Total         | 103                    | 2                      | 0                           | 106                    | 4                      | 0                           |
|                  |   | Positive Rate | 100%                   | 100%                   | NA                          | 0.0%                   | 75.0%                  | NA                          |

|   |               |       |      |    |      |       |    |
|---|---------------|-------|------|----|------|-------|----|
| <b>BD COR Result</b>  | Total         | 103   | 2    | 0  | 106  | 4     | 0  |
|   | Positive Rate | 99.0% | 100% | NA | 0.0% | 25.0% | NA |
| PPA: 99.0% (104/105), 95% CI: (94.8%, 99.8%)<br>NPA: 99.1% (109/110), 95% CI: (95.0%, 99.8%)                                  |               |       |      |    |      |       |    |
| Average PPA: 99.7%, 95% CI: (99%, 100%)<br>Average NPA: 98.5%, 95% CI: (96.3%, 100%)<br>Number of BD MAX equivocal results: 0 |               |       |      |    |      |       |    |

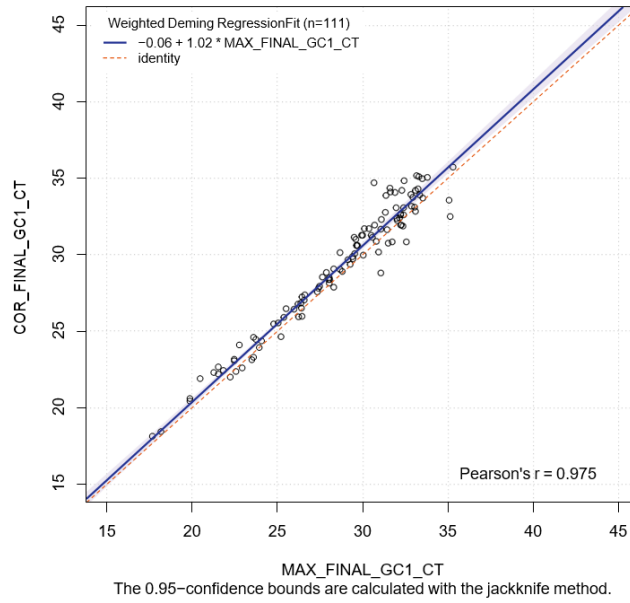
<sup>a</sup> Confidence intervals for point estimates at each site were calculated by a score method and confidence intervals for point estimates averaged over three sites were calculated by a bootstrap method.

The systematic differences in numeric value between Ct.Score results from the BD COR and the 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 three instruments. The results from the Deming regression analysis are provided for CT, GC1, GC2 and TV, respectively, as shown below.

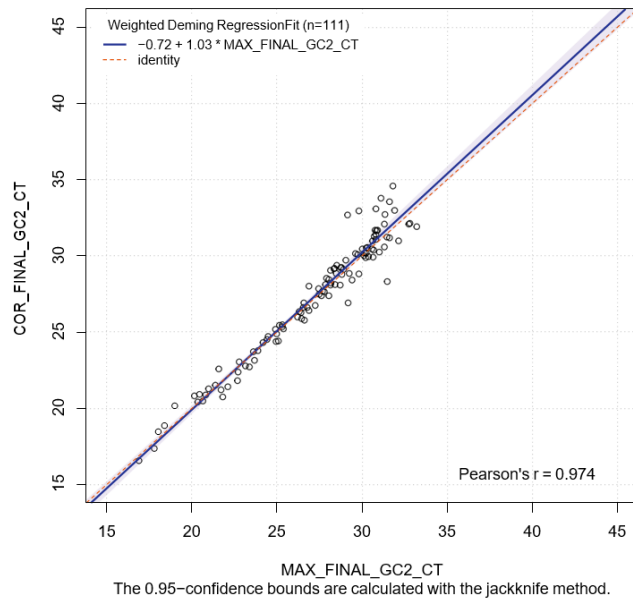
### Deming Regression BD COR vs. BD MAX, CT



### Deming Regression BD COR vs. BD MAX, GC1

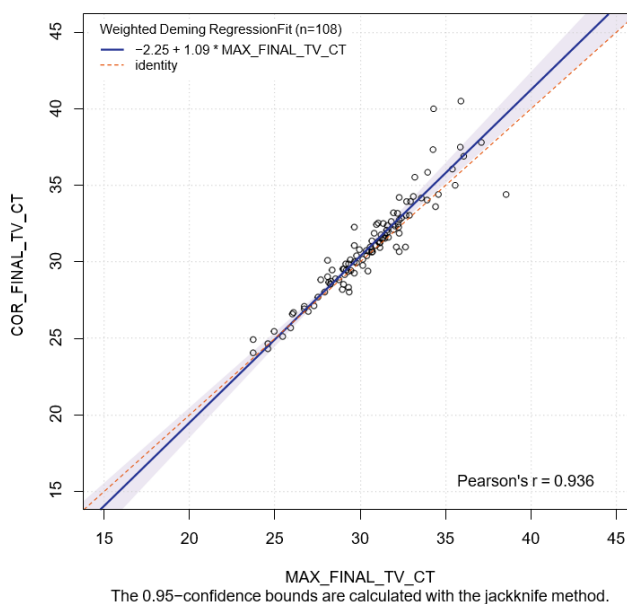


### Deming Regression BD COR vs. BD MAX, GC2





### Deming Regression BD COR vs. BD MAX, TV



The point estimates of intercept and slope, as well as the corresponding 95% confidence interval of each Deming regression line (based on the combined data from all three instruments for the BD MAX or the BD COR) are provided in table below. Additionally, the Weighted Deming regression bias estimate along with 95% confidence interval at different analyte levels are presented below.

#### Weighted Deming Regression Coefficients for Ct.Score

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

### Weighted Deming Regression Bias Estimate

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

<sup>a</sup>. The “Ct. Score for BD MAX” was calculated as the average Ct. Scores from all samples at the corresponding analyte level.

#### BD CTGCTV2 Assay Non-Reportable Results for BD COR System

Non-reportable results on the BD COR are reported in the same manner as on the BD MAX and the definition of all possible Non-reportable events are summarized in the table below.

| BD COR Non-reportable Result | Non-reportable Result Definition   |
|------------------------------|--|
| UNR - Unresolved             | Invalid SPC due to presence of inhibitory substances, 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) |

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 the BD COR System are shown below.

**BD COR Non-Reportable Rate for Combined Targets by Test Site**

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

<sup>a</sup> The final rate is calculated with the number of remaining Non-reportable events after repeat testing.

<sup>b</sup> 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.

<sup>c</sup> 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.

**2. Matrix Comparison:**

Not applicable.

**C. Clinical Studies:**

For the complete clinical data set in support of the CTGCTV2 Assay as performed on the BD MAX, refer to K182692.

**D. Clinical Cut-Off:**

Not applicable.

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

Refer to K182692.

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

### On-board Reagent Stability Studies

To demonstrate the stability of the BD COR reagents (BD COR CTGCTV2 Master Mix plates, BD COR CTGCTV2 Extraction plates, BD COR CTGCTV2 Liquid Extraction plates and BD COR CTGCTV2 LBC Diluent Bottle) after opening package or when stored on-board, the following evaluation was performed.

Testing of 48 positive and 24 negative samples was performed with reagents:

- a) Stored at  $5\pm 3^{\circ}\text{C}$  or  $27\pm 2^{\circ}\text{C}$  for 0 day, 6 or 8 months, representing storage temperatures prior to in-use or on-board storage.
- b) A portion of above reagents were moved to and stored at  $18\pm 2^{\circ}\text{C}$  or  $33\pm 2^{\circ}\text{C}$  (representing the in-use or on-board temperatures). These reagent plates were used for testing at 2, 5 and 6 days of storage; LBC Diluent was used for testing at 22, 45, and 46 days of storage.

Percent agreement as well as Ct.Score were evaluated at each time point as compared with the results at baseline. The data demonstrated that:

- The BD COR CTGCTV2 Master Mix plates, BD COR CTGCTV2 Extraction plates, and BD COR CTGCTV2 Liquid Extraction plates are stable for up to 5 days after opening or on-board the BD COR System (on-board temperature ranges from  $18\pm 2^{\circ}\text{C}$  to  $32\pm 2^{\circ}\text{C}$ ).
- The BD COR CTGCTV2 LBC Diluent Bottles are stable for up to 45 days after opening or on-board the BD COR System (on-board temperature ranges from  $18\pm 2^{\circ}\text{C}$  to  $32\pm 2^{\circ}\text{C}$ ).

## **VIII Proposed Labeling:**

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

## **IX Conclusion:**

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