A. 510(k) Number:

K140354

B. Purpose for Submission:

The purpose of this submission is to report a change in swab material (due to a supplier change) for the Abbott multi-Collect Specimen Collection Kit that was cleared in conjunction with the Abbott RealTime CT/NG Assay (K092704). The supplier change will allow for the use of an alternative polyester fiber in the manufacture of the swab bud tip for the collection device. The current polyester fiber used for the swab bud tip, a trademark form of polyester known as DuPont Dacron (supplied by DuPont), will no longer be available for the manufacture of collection swab tips, after current inventory is exhausted. The alternative polyester fiber is Barnet P-2182 (supplied by William Barnett and Sons, LLC).

C. Measurand:

The Abbott RealTime CT/NG Assay is an in vitro diagnostic test used to detect the presence of Chlamydia trachomatis (CT) cryptic plasmid deoxyribonucleic acid (DNA) and Neisseria gonorrhoeae (NG) genomic DNA using polymerase chain reaction (PCR).

D. Type of Test:

Nucleic acid amplification and detection by polymerase chain reaction (PCR)

E. Applicant:

Abbott Molecular Inc.

F. Proprietary and Established Names:

Abbott RealTime CT/NG Assay

Abbott multi-Collect Specimen Collection Kit

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3120, Chlamydia serological reagents
21 CFR 866.3390, *Neisseria* spp. direct serological test reagents

21 CFR 866.2900, Microbiological specimen collection and transport device

2. **Classification:**

Class II

3. **Product code:**

LSL, MKZ, LIO

4. **Panel:**

Microbiology (83)

**H. Intended Use:**

1. **Intended use(s):**

The Abbott RealTime CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens.

The Abbott multi-Collect Specimen Collection Kit is intended for the collection and transportation of male and female swab and urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* per instructions provided. Refer to the specimen collection procedure in the package insert for the specimen collection instructions for specific sample types.

Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Abbott multi-Collect Specimen Collection Kit is not intended for home use.

2. **Indication(s) for use:**

Same as intended use.

3. **Special conditions for use statement(s):**

Prescription only.

4. **Special instrument requirements:**
The Abbott RealTime CT/NG Assay uses PCR technology with homogenous real-time fluorescence detection on the m2000 System. This system consists of the Abbott m2000sp Instrument for DNA extraction and Abbott m2000rt Instrument for DNA amplification and detection.

I. Device Description:

The Abbott multi-Collect Specimen Collection Kit is available in two configurations, one containing a Transport Tube with a solid cap (List No. 9K12-03) and the other containing a Transport Tube with a pierceable cap (List No. 9K12-04). Both configurations of the Abbott multi-Collect Specimen Collection Kit can be used to collect either a swab or a urine specimen. Each kit contains a specimen collection swab, a transfer pipette (for use with urine samples), and a transport tube with 1.2 mL specimen transport buffer (STB; used to stabilize DNA until sample preparation). After specimen collection, a swab is placed into the transport tube with STB until the time of testing.

The specimen collection swab provided with the Abbott multi-Collect Specimen Collection Kit is approximately 14 cm in length with a polyester fiber tip. The swab shaft has a polystyrene solid core that includes an orange colorant. The swab has a molded score completely around the shaft, between 7.86 cm and 7.89 cm from the swab tip, to provide a clean break-point. The polyester-fiber swab tip is approximately 1.3 cm in length and less than 3.28 mm in diameter. Each swab is individually packed into a heat sealed, printed pouch and then sterilized by gamma irradiation.

The Abbott multi-Collect Specimen Collection Kit is cleared for use in conjunction with the Abbott RealTime CT/NG Assay (K092704).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   
   Abbott RealTime CT/NG Assay
   Abbott multi-Collect Specimen Collection Kit

2. Predicate 510(k) number(s):

   K092704

3. Comparison with predicate:

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>The Abbott RealTime CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection</td>
<td>The Abbott RealTime CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection</td>
</tr>
</tbody>
</table>
of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens.

The Abbott multi-Collect Specimen Collection Kit is intended for the collection and transportation of male and female swab and urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* per instructions provided. Refer to the specimen collection procedure in the package insert for the specimen collection instructions for specific sample types.

Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated.

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device K140354</th>
<th>Predicate Device K092704</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection Swab Design</td>
<td>Same as predicate</td>
<td>Individually packaged sterile specimen collection swab</td>
</tr>
<tr>
<td>Swab Filter Tip Materials</td>
<td>Barnet P-2182</td>
<td>DuPont Dacron</td>
</tr>
<tr>
<td>Supplier for Swab Filter Tip Materials</td>
<td>William Barnett and Sons, LLC</td>
<td>DuPont</td>
</tr>
</tbody>
</table>
### Table

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>K140354</td>
<td>K092704</td>
</tr>
<tr>
<td>Swab Shaft</td>
<td>Same as predicate</td>
<td>Polystyrene solid core</td>
</tr>
<tr>
<td>Sample Types</td>
<td>Same as predicate</td>
<td>Endocervical swab specimens, self-collected vaginal swab specimens, clinician-collected vaginal swab specimens, male urethral swab specimens</td>
</tr>
<tr>
<td>Unused Swab Storage Conditions</td>
<td>Same as predicate</td>
<td>Stored at room temperature</td>
</tr>
<tr>
<td>Specimen Transport</td>
<td>Same as predicate</td>
<td>Stored at 2 to 30°C for up to 14 days after collection</td>
</tr>
<tr>
<td>Long-term Specimen Storage</td>
<td>Same as predicate</td>
<td>Store at -10°C or below for up to 90 days after collection</td>
</tr>
<tr>
<td>Swab shelf life</td>
<td>Same as predicate</td>
<td>18 months</td>
</tr>
</tbody>
</table>

### K. Standard/Guidance Document Referenced (if applicable):

5. 510(k) Memorandum #K97-1: 1997, Deciding When to Submit a 510(k) for a Change to an Existing Device.

### L. Test Principle:

The Abbott RealTime CT/NG Assay is a nucleic acid based test using polymerase chain reaction (PCR). The specimen collection swab provided with the Abbott multi-Collect Specimen Collection Kit is used to collect a sample that is placed into a transport tube with STB until the time of testing. Infection is detected through the use of PCR to amplify and detect bacterial DNA. The presence of amplified CT cryptic plasmid DNA and NG genomic DNA can be detected through a sequence-specific labeled probe that hybridizes with the target sequence. Cleavage of the probe during PCR releases a fluorescent reporter dye from the quencher dye and results in a signal that is used to detect the target-specific product.
M. Performance Characteristics (if/when applicable):

1. **Analytical performance:**

   All studies described below (except the biocompatibility and sterility testing) were conducted using plasmid targets. The CT plasmid contained highly conserved target sequences derived from the cryptic plasmid found in all serovars including A through K and L1 through L3. The NG plasmid contained Opa gene target sequences which are highly conserved among all strains of NG.

   a. **Precision/Reproducibility:**

   **Precision**

   An in-house precision study was performed with a four-member panel consisting of a high CT/NG positive sample (45,000 copies and 22,000 copies per 400 µl respectively), a high CT/low NG positive sample (45,000 copies and 640 copies per 400 µl), a low CT/high NG positive sample (640 copies and 22,000 copies per 400 µl), and a CT/NG negative sample. Positive panel members were prepared by diluting stocks of CT or NG plasmid into an Abbott multi-Collect Specimen Collection Kit Transport Tube with STB followed by a Specimen Collection Swab to simulate a swab sample.

   Three runs were performed per day for three days on three Abbott m2000sp/m2000rt Systems with each run testing seven replicates of the four panel members using three lots of swabs (3 runs per day x 3 days x 3 instruments x 4 panel members x 7 replicates per panel member x 3 swab lots = 756 measurements per analyte). One replicate was excluded from the analysis due to an “unrecoverable instrument error,” so the final number of measurements considered was 755 measurements per analyte. Three technicians participated in the reproducibility study, with each operator running a single run each day. For the Abbott RealTime CT/NG Amplification Reagents, the Internal Control (IC), and the Abbott mSample Preparation SystemDNA reagents, one lot of each were included in this study. Results of the precision study are summarized in the table below.
Table 1: Overall Precision (Instrument and Swab Lots Combined)

<table>
<thead>
<tr>
<th>Assay</th>
<th>Panel Member</th>
<th>No. Tested</th>
<th>No. Positive</th>
<th>No. Negative</th>
<th>Positive Rate (%)</th>
<th>95% CI</th>
<th>Negative Rate (%)</th>
<th>Lower Bound One-Sided 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>1 High CT / High NG</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>100</td>
<td>98</td>
<td>0</td>
<td>N/A^1</td>
</tr>
<tr>
<td></td>
<td>2 High CT / Low NG</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>100</td>
<td>98</td>
<td>0</td>
<td>N/A^1</td>
</tr>
<tr>
<td></td>
<td>3 Low CT / High NG</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>100</td>
<td>98</td>
<td>0</td>
<td>N/A^1</td>
</tr>
<tr>
<td></td>
<td>4 Negative CT / Negative NG</td>
<td>188</td>
<td>1</td>
<td>187</td>
<td>1</td>
<td>N/A^1</td>
<td>99</td>
<td>98</td>
</tr>
<tr>
<td>NG</td>
<td>1 High CT / High NG</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>100</td>
<td>98</td>
<td>0</td>
<td>N/A^1</td>
</tr>
<tr>
<td></td>
<td>2 High CT / Low NG</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>100</td>
<td>98</td>
<td>0</td>
<td>N/A^1</td>
</tr>
<tr>
<td></td>
<td>3 Low CT / High NG</td>
<td>189</td>
<td>189</td>
<td>0</td>
<td>100</td>
<td>98</td>
<td>0</td>
<td>N/A^1</td>
</tr>
<tr>
<td></td>
<td>4 Negative CT / Negative NG</td>
<td>188</td>
<td>0</td>
<td>188</td>
<td>0</td>
<td>N/A^1</td>
<td>100</td>
<td>98</td>
</tr>
</tbody>
</table>

^1 Not applicable

The data presented in Table 1 demonstrates 100% detection of various concentrations of CT and NG DNA in the three positive panel members. Although a false positive occurred for CT in one of the replicates for the negative panel members (1/188 = 1% false positive rate), the percent negative rate for the negative panel met the pre-determined acceptance criteria of ≥ 95% for each analyte, indicating that precision of the new swab fiber for the detection of CT and NG DNA with the Abbott RealTime CT/NG Assay, is acceptable.

b. **Linearity/assay reportable range:**

N/A

c. **Traceability, Stability, Expected values (controls, calibrators, or methods):**

**Freeze/Thaw Stability**

The freeze/thaw stability study was conducted to confirm that the Specimen Collection Swabs manufactured with the new swab material meet the specimen storage claim previously cleared in K092704: Specimens should not undergo more than four freeze/thaw cycles.

Three lots of swabs (30 replicates per lot) were placed in low positive CT and NG spiked samples prepared in STB and stored in the Abbott multi-Collect Specimen Collection Kit Transport Tubes. Samples contained a target concentration of 640 copies of CT and 640 copies of NG in 400 µL (approximately 2X the assay LoD). Samples underwent 5 freeze/thaw cycles (freeze at -15 to 25°C for ≥ 90 minutes and thaw at 2-30°C for ≥ 60 minutes) prior to testing with the Abbott RealTime CT/NG Assay. For the Abbott RealTime CT/NG Amplification Reagents, one lot of each, the Internal Control (IC), and the Abbott mSample Preparation SystemDNA reagents were included in this study. One m2000sp/m2000rt instrument was included. Results of the freeze/thaw study are summarized in the table below.
Table 2: Percent of positive samples after 5 freeze/thaw cycles

<table>
<thead>
<tr>
<th>Assay</th>
<th>Swab Lot</th>
<th>No. of Replicates Tested</th>
<th>No. of Positive Replicates</th>
<th>Percent Positive Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>All</td>
<td>90</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>30</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>30</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>30</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td>NG</td>
<td>All</td>
<td>90</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>30</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>30</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>30</td>
<td>30</td>
<td>100</td>
</tr>
</tbody>
</table>

The data indicates that, following five freeze/thaw cycles, the percent positive rate for CT and NG samples at a concentration 2X the LoD was 100%. This supports the claim previously cleared in K092704 (no more than 4 freeze/thaw cycles).

**90 Day Specimen Stability**

The 90 day specimen stability study was conducted to confirm that the Specimen Collection Swabs manufactured with the new swab material meet the following specimen storage claim previously cleared in K092704: 14 days at 2 to 30°C and 90 days at -10°C or colder.

For the duration of the 90 day stability study, three lots of swabs were placed in high and low CT and NG positive samples prepared in STB and stored in the Abbott multi-Collect Specimen Collection Kit Transport Tubes. Low positive samples contained a target concentration of 640 copies of CT and 640 copies of NG in 400 µL (approximately 2X the assay LoD). High positive samples contained a target concentration of 2,000,000 copies of CT and 2,000,000 copies of NG in 400 µL (approximately 6250X the assay LoD). For the Abbott RealTime CT/NG Amplification Reagents, the Internal Control (IC), and the Abbott mSample Preparation SystemDNA reagents, one lot of each were included in this study. One m2000sp/m2000rt instrument was included.

Samples were tested at baseline, day 14, day 56, and day 105. Six replicates were tested at each time point for each of the three lots (6 x 3 = 18 measurements per time point) under the following conditions:
<table>
<thead>
<tr>
<th>Temperature Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Storage Condition</td>
</tr>
<tr>
<td>14 days at 2 to 8°C or</td>
</tr>
<tr>
<td>14 days at 30°C</td>
</tr>
<tr>
<td>Intermediate Frozen Condition</td>
</tr>
<tr>
<td>56 days at -10°C or colder</td>
</tr>
<tr>
<td>Final Frozen Condition</td>
</tr>
<tr>
<td>105 days at -10°C or colder</td>
</tr>
</tbody>
</table>

Mean cycle number was compared for all storage conditions and time points tested for CT and NG high and low positive samples. The results showed that incubation under all conditions described above resulted in a cycle number change ≤ 1, indicating that the new swab material does not affect the stability of CT and NG DNA collected with the swab and stored at either 2-30°C for up to 14 days or at -10°C or colder for up to 90 days.

**Real Time Specimen Stability**

The real time specimen stability study was conducted to confirm that the Specimen Collection Swabs manufactured with the new swab material meet the shelf life claims previously cleared in K092704: Sample storage at 2-30°C for up to 14 days, sample storage at -10°C or colder for up to 90 days, and swab shelf life of 18 months.

To confirm that the new swab material meets the shelf life claim of 18 months expiration dating, swabs were tested at baseline (3 runs) and then again at various time points (7, 13, 18, and 19 months; 2 runs at each) after storage at one of two different conditions:

i. **Ambient temperature (AT):** Three lots of swabs were stored at ambient temperature (15 to 30°C).

ii. **Transport temperature extremes (TTE):** One lot of swabs were stored at the following temperatures and times to simulate potential shipping conditions: 15 to 30°C for ≥ 120 hours, followed by 30 ± 2°C for ≥ 64 hours, followed by 40 ± 2°C for ≥ 88 hours, followed by 3 cycles of 12 hours at -20 ± 5°C and 12 hours at 5 ± 3°C, then storage at 15 to 30°C until testing.

To confirm that the new swab material meets the sample stability claims for patient specimens (both at the beginning and end of their 18 month expiration dating), one lot of swabs stored at either AT or TTE were tested at the following time points:

i. **Storage at 2-30°C for 14 days** with testing at baseline and on day 14 (1 run per time point) followed by

ii. **Storage at -10°C for 90 days** with testing at day 45 and day 90 (1 run per time point).
Swabs were placed in high and low CT and NG positive samples prepared in STB and stored in the Abbott multi-Collect Specimen Collection Kit Transport Tube. Low positive samples contained a target concentration of 640 copies of CT and 640 copies of NG in 400 µL (approximately 2X the assay LoD). High positive samples contained a target concentration of 2,000,000 copies of CT and 2,000,000 copies of NG in 400 µL (approximately 6,250X the assay LoD). For each run, 5 low positives, 5 high positives, and 15 negative (STB only) were included per lot. For the Abbott RealTime CT/NG Amplification Reagents, the Internal Control (IC), and the Abbott mSample Preparation SystemDNA reagents, one lot of each were included in this study. One m2000sp/m2000rt instrument was included.

Several indicators (e.g., fractional cycle number, decision cycle, maximum ratio) were assessed for changes to determine if a loss in sample stability had occurred. Regression plots were generated for each stability indicator vs. time in days to determine the mean with 95% confidence interval and action limits around the regression line (note that the action limits used are the same action limits cleared for use in K092704).

For all time points tested for each storage condition and swab lot, the results were within the action limits indicating that, at baseline, the new swab material does not affect the stability of CT and NG DNA collected with the swab stored at either 2-30°C for up to 14 days or at -10°C or colder for up to 90 days. This study is on-going and will be completed in December 2015; therefore, an accelerated stressed sample stability study was conducted to obtain the data to support the 18 month shelf life for the new swab material.

**Accelerated Stressed Swab Stability**

The accelerated stressed swab stability study was conducted to confirm that the Specimen Collection Swabs manufactured with the new swab material meet the claims for shelf life previously cleared in K092704: swab shelf life of 18 months.

Swabs were stored at one of two conditions prior to testing:

i. **Accelerated Stressed Swabs**: Incubated for 16.3 weeks at 55°C (± 4°C) with a relative humidity of 50 ± 20%. These parameters were used to simulate 2.5 years of storage on the shelf.

ii. **Non-stressed swabs**: Stored at ambient temperature (25 °C).

After storage at the conditions described above, swabs were placed in low positive CT and NG spiked samples prepared in STB and stored in the Abbott multi-Collect Specimen Collection Kit Transport Tubes. Samples contained a target concentration of 320 copies of CT and 320 copies of NG in 400 µL (approximately 1X the assay LoD). Swabs were tested at 14 days at -10°C, 7 days at 4°C, 4 days at 23°C, or 1 day at 40°C time points. For each storage condition (stressed and non-stressed), three lots (with 28 samples each) were tested for each time point.

For the Abbott RealTime CT/NG Amplification Reagents, the Internal Control (IC), and the Abbott mSample Preparation SystemDNA reagents, one lot of each were included in
this study. Two m2000sp/m2000rt instruments were included.

For all time points tested for each storage condition and swab lot, the detection rate was ≥ 98%. This is comparable to the values that were cleared in K092704, therefore, this indicates that, when the new swab material is stored at accelerated aging conditions designed to mimic an 18 month shelf life; it does not affect the ability of the swab to collect CT and NG DNA for detection with the Abbott RealTime CT/NG Assay.

**Biocompatibility**

Because the swab is a surface device that contacts the skin and mucosal membranes for a limited duration (< 24 hours), in accordance with ISO 10993-1:2009, the following biocompatibility studies were conducted:

- Cytotoxicity – MEM Elution (ISO 10993-5: 2009)
- Sensitization – Guinea Pig Maximization (ISO 10993-10: 2010)
- Irritation – Intracutaneous Reactivity (ISO 10993-10:2010)
- Irritation – Vaginal Mucosal Irritation (ISO 10993-10:2010)

These studies were conducted according to the protocols outlined by the International Organization for Standardization document cited above. The results were acceptable to demonstrate that the new swab material is non-cytotoxic, non-sensitizing, and non-irritating.

**Sterilization**

Swabs are sterilized by radiation. Studies were conducted according to the following document: ANSI/AAMI/ISO 11137-2:2006 (Corrected 21 April 2009). The results were acceptable to demonstrate that the new swab material is sterile.

d. **Detection limit:**

**Limit of Detection (LoD) Confirmation**

For the LoD confirmation study, a stock solution was prepared containing 32,800 copies per mL of CT and 32,800 copies per mL of NG plasmid diluted in Abbott RealTime CT/NG Negative Control diluent. Dry swabs were placed in this stock solution where they absorbed approximately 30 µL, resulting in a concentration of 948 copies of CT and/or NG plasmid per swab. Next, the CT/NG positive swabs were inserted into an Abbott multi-Collect Specimen Collection Kit Transport Tube containing 1.2 mL of STB. The swab shaft was broken at the scored line and the collection tube was recapped and vortexed for 10 to 30 seconds. From this sample, 400 µl of STB (containing 320 copies of plasmid DNA) was removed from the transport tube for DNA extraction on the m2000sp instrument. Based on the data provided by Abbott, it is estimated that 50% of the DNA is recovered after extraction; therefore, the resulting 100 µl of sample contained 160 copies of plasmid. From this sample, 25 µl (containing 40 copies of plasmid
DNA/reaction) was removed for DNA amplification on the m2000rt instrument.

Three swab lots were used to prepare the samples co-spiked with CT and NG at a concentration that is 1X the assay LoD. Each swab lot was tested with 26 replicates per run over three runs (3 lots x 26 replicates x 3 runs = 234 samples). Each run included two replicates of the Abbott RealTime CT/NG cutoff control and one replicate of a CT/NG negative control. For the Abbott RealTime CT/NG Amplification Reagents, the Internal Control (IC), and the Abbott mSample Preparation System DNA reagents, one lot of each were included in this study. One m2000sp/m2000rt instrument was included. Results of the LoD confirmation study are summarized in the table below.

Table 3: Detection Rate Analysis for Swab LoD Study

<table>
<thead>
<tr>
<th>Assay</th>
<th>No. of Swabs Tested</th>
<th>No. of Swabs Tested Positive</th>
<th>Detection Rate (%)</th>
<th>Lower Bound One-sided 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>234</td>
<td>234</td>
<td>100</td>
<td>99</td>
</tr>
<tr>
<td>NG</td>
<td>234</td>
<td>229</td>
<td>98</td>
<td>96</td>
</tr>
</tbody>
</table>

The data shows that samples were positive at a detection rate ≥ 98%, indicating that the new swab material does not reduce the ability of the Abbott RealTime CT/NG Assay to detect CT and NG DNA at the LoD concentration previously cleared in K092704.

e. Analytical specificity:

N/A

f. Assay cut-off:

The assay cutoff previously cleared for the Abbott RealTime CT/NG Assay in K092704 (7.4 cycles and 4.4 cycles beyond the mean cutoff control cycle number for CT and NG, respectively) has not been changed; therefore, no additional testing was required.

2. Comparison studies:

a. Method comparison with predicate device:

Based on the results of the analytical testing, the changes to the swab material do not affect the performance of the Abbott RealTime CT/NG Assay; therefore, additional clinical testing (beyond what was provided in K092704) is not required.

b. Matrix comparison:

N/A

3. Clinical studies:
a. Clinical Sensitivity and Specificity

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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