# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number
K260184

### B Applicant
Becton, Dickinson and Company

### C Proprietary and Established Names
Onclarity Self-Collection Kit

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| SEP | Class II | 866.2920 - Device for home collection and transportation of clinical specimens by lay users for infectious disease testing | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:
To obtain clearance of standalone Onclarity Self-Collection Kit

### B Measurand:
Not applicable

### C Type of Test:
Vaginal swab collection for HPV molecular testing. Performance of this device has only been validated with the BD Onclarity HPV Assay.

## III Intended Use/Indications for Use:

### A Intended Use(s):
See Indications for Use below.

**B Indication(s) for Use:**

The Onclarity Self-Collection Kit is intended for the self-collection and transport of vaginal specimens for use with an FDA-approved HPV molecular assay with which the collection device has been validated. The Onclarity Self-Collection Kit contains all of the necessary components for the self-collection of a vaginal specimen in a home or private setting. Specimens can be collected and shipped dry.

**C Special Conditions for Use Statement(s):**
Rx Only

Performance of this device has only been validated with the BD Onclarity HPV Assay (P160037/S017 and P160037/S024).

**D Special Instrument Requirements:**
Not applicable

## IV Device/System Characteristics:

**A Device Description:**

The Onclarity Self-Collection Kit (including two configurations: Onclarity Self-Collection Kit-Viper LT and Onclarity Self-Collection Kit-COR) is a prescription device that is used to collect self-collected vaginal specimens at home or private settings. It contains all of the necessary components for the vaginal self-collection and for transport of the specimen to a clinical testing laboratory that includes a swab, instructions for use, a biohazard bag, and return shipping instructions. The Onclarity Self-Collection Kit-COR also includes an empty tube. The self-collected vaginal specimen is then shipped dry to a laboratory for testing with the BD Onclarity HPV assay on the BD Viper LT System or BD COR System as per the assay's instructions.

**B Principle of Operation:**

The swab head of the swab, contained in the Onclarity Self-Collection Kit, is composed of brush like nylon fibers to dislodge and collect cells. The collected swab is transported dry (no medium) to the testing laboratory.

When using Onclarity Self-Collection Kit-Viper LT, patients follow the provided Instructions for Use to collect vaginal specimen and place the collected swab back into the plastic sheath provided with the swab. The re-sheathed swab is then transported dry to the testing laboratory.

When using Onclarity Self-Collection Kit-COR, patients follow the provided Instructions for Use to collect vaginal specimen and the collected swab (packaged in a peel-patch) is placed and broken into an empty (no medium) BD Onclarity HPV Self-Collection Tube by the patient. The lid of the tube is secured, and specimen is then transported dry to the testing laboratory.

## V Substantial Equivalence Information:

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

Teal Wand

**B Predicate 510(k) Number(s):**
DEN240045

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

| **Device & Predicate Device(s):** | DEN240045 | K260184 |
|---|---|---|
| Device Trade Name | Teal Wand | Onclarity Self-Collection Kit |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The Teal Wand is a device for the self-collection of vaginal specimens for the purpose of collecting and transporting specimens for use in an FDA approved HPV molecular assay with which the collection device has been validated.<br><br>The Teal Wand can be used at-home or in any private setting. Specimens can be collected, stored, and shipped dry in an empty vial. | The Onclarity Self-Collection Kit is intended for the self-collection and transport of vaginal specimens for use with an FDA-approved HPV molecular assay with which the collection device has been validated. The Onclarity Self-Collection Kit contains all of the necessary components for the self-collection of a vaginal specimen in a home or private setting. Specimens can be collected and shipped dry. |
| Specimen Type | Vaginal Specimen | Vaginal Specimen |
| **General Device Characteristic Differences** | DEN240045 | K260184 |
| Structure and Material of Swab | Teal Wand with sponge head | Swab with brush like nylon fiber |

## VI Standards/Guidance Documents Referenced:

21 CFR 866.2920 Special controls

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:
   Not applicable.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

*Interfering Substances*

A study was performed to evaluate whether substances commonly used by lay users in home settings may interfere with the detection of HPV using Onclarity Self-Collection Kit collected samples. Both positive and negative contrived samples were tested with and without the potential interfering substances. The positive samples were prepared by co-spiking SiHa (HPV16), HeLa (HPV18), and MS751 (HPV45) cell lines at 3xLoD. A subset of interfering substances study data was leveraged from P160037-S017. Substances tested are described in the table below. The indicated concentrations represent the tested concentration of a substance, when assessed with the BD Onclarity HPV Assay, that did not result in interference.

| Potential Interfering Substance | Concentration without Interference |
|---|---|
| KY Jelly Personal Lubricant | 8% (w/v) [a] |
| VCF Vaginal Contraceptive Film | 3% (w/v) |
| Nonoxynol-9 Contraceptive Gel, 4% | 1% (w/v) [a] |
| Monistat 3 | 1.8% (w/v) |
| Clotrimazole 7 | 10% (w/v) |
| Tioconazole Ointment, 6.5% | 1% (w/v) |
| Clindamycin Vaginal Cream | 9% (w/v) |
| Summer's Eve Douche | 10% (v/v) |
| Zovirax (Acyclovir) Cream | 10% (w/v) |
| Vandazole Gel (Metronidazole Vaginal Gel, 0.75%) | 10% (w/v) |
| Summer's Eve Deodorant | 1% (w/v) [a] |
| Replens Moisturizer | 2.8% (w/v) [a] |
| Bovine Mucin | 7.8% (w/v) [a] |
| Progesterone | 20 ng/mL |
| Estradiol | 1.2 ng/mL |
| Whole Blood | 1% (v/v) [a] |
| Leukocytes | $1x10^6$ cells/mL |
| Semen | 10% (v/v) |
| Estrace, 0.01% | 7% (w/v) [a] |
| Crinone, 4% | 2% (w/v) [a] |
| Preparation H | 6% (w/v) [a] |
| Hand Soap (Softsoap) | 0.1% (w/v) [a] |
| Hand Sanitizer (Purell) | 7.1% (w/v) |
| Lotion (Gold Bond) | 1% (w/v) [a] |
| Sunscreen (Wegmans Sport) | 1% (w/v) [a] |
| Water | 5% (w/v) |

[a] May interfere with the detection of HPV when present at higher concentration than what is indicated in the table.

4. Detection Limit and Assay Reportable Range:

The LoD at the clinical cutoff for vaginal specimens are presented in the table below. HPV positive samples were prepared by using SiHa (HPV16), HeLa (HPV18), and MS751 (HPV45) cell lines and plasmids for the remaining 11 genotypes. Studies were performed on both BD Viper LT and BD COR Systems and results are the same between the two systems.

| Target | LOD (Cells or Copies/mL)[a] | 95% Confidence Interval | |
|---|---|---|---|
| | | Lower | Upper |
| SiHa (HPV16) | 9.7 | 7.7 | 13.4 |
| HeLa (HPV18) | 51 | 46 | 56 |
| MS751 (HPV45) | 305 | 284 | 343 |
| HPV31 | 692 | 650 | 817 |
| HPV33 | 1,376 | 1,272 | 1,451 |
| HPV35 | 1,552 | 1,317 | 1,780 |
| HPV39 | 1,531 | 1,419 | 1,685 |
| HPV51 | 1,229 | 1,155 | 1,353 |
| HPV52 | 833 | 744 | 934 |
| HPV56 | 836 | 737 | 911 |
| HPV58 | 2,990 | 2,656 | 7,818 |
| HPV59 | 772 | 722 | 899 |
| HPV66 | 701 | 646 | 767 |
| HPV68 | 2,079 | 1,995 | 2,125 |

a. Concentrations are provided in cells/mL (for HPV 16, 18, and 45) or copies/mL (for 11 other HR HPV genotypes) in the 3.0 mL sample input tube for BD Onclarity HPV Self Collection Diluent.

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

*Specimen Shipping Stability*

A specimen shipping stability study was conducted for a duration of 37.8 days to evaluate the stability of dry swab specimens for an anticipated 30-day dry storage period. The tested 37.8-day period included 10.1 days' exposure to conditions representing extreme cold and hot temperatures from collection to the point of receipt at the laboratory, and 27.7 days' dry storage at the laboratory after receipt. Additionally, following the above dry storage, samples were subjected to storage at different in-process steps (please refer to the last three rows under "Specimen Configuration" in the table below for these steps) to simulate possible wait time during testing. Positive swab samples were prepared by co-spiking SiHa (HPV 16) and Hela (HPV 18) cells at low positive concentrations (3xLoD) in the negative clinical vaginal matrix and then spiked directly onto swabs. Negative swab samples were prepared by spiking the negative clinical matrix directly onto swabs. Replicates of positive and negative samples were tested at baseline as well as at various storage stages. The study results support the following specimen shipping stability.

| Specimen Configuration | Temperature | Time |
|---|---|---|
| Dry swab in plastic sheath or empty BD Onclarity HPV Self Collection Tube, *in transit* [a] | Ambient | 7 days |
| Dry swab in plastic sheath or empty BD Onclarity HPV Self Collection Tube[a] | 2-30 °C | 30 days |
| | -20°C | 30 days |
| In BD Onclarity HPV Self Collection Diluent Tube or BD Onclarity HPV Self Collection Tube filled with diluent (after specimen transfer and prior to pre-warm) | Ambient | 3 days |
| In BD Onclarity HPV Self Collection Diluent Tube or BD Onclarity HPV Self Collection Tube filled with diluent, capped post pre-warm (after specimen transfer and sample pre-warm) | 2-30 °C | 3 days |
| | -20°C | 3 days |
| In BD Onclarity HPV Self Collection Diluent Tube or BD Onclarity HPV Self Collection Tube filled with diluent, punctured cap post pre-warm (after specimen transfer and sample pre-warm with punctured cap)[b] | 2-30°C | 3 days |

[a] The date of specimen collection on the biohazard bag should be checked upon receipt. Specimens must be received by the laboratory within 7 days of the specimen collection date. Specimens received greater than 7 days from the specimen collection date should be rejected, and a new specimen should be requested. Specimens may be received at any time of day within the 7 days. Specimens received within the aforementioned transit duration may be tested up to 30 days from the date of collection.

[b]Punctured caps do not need to be replaced prior to retesting.

*Onclarity Self-Collection Kit Swab Sterility and Shelf-life Stability*

The flocked swab contained in the Onclarity Self-Collection Kit is sterilized using Ethylene Oxide (EO). Sterility Assurance Level and EO residues level of the tested devices meet required specifications. Real time aging and shelf-life stability tests, including visual inspection, seal strength, dye penetration, microbial barrier, and sterility, were performed and support a shelf-life stability of 36 months.

6. Assay Cut-Off:
   Not applicable.

## B Comparison Studies:

1. Method Comparison with Predicate Device:
   Not applicable.

2. Matrix Comparison:
   Not applicable.

## C Clinical Studies:

*Study #1*

A prospective clinical study (LMI-001-A-S01) was conducted to provide data supporting the performance of the Onclarity Self-Collection Kit for use with the BD Onclarity HPV Assay. Vaginal swabs were self-collected in a simulated home environment. This study was conducted under the NCI-sponsored Cervical Cancer "Last Mile" Initiative "Self- collection for HPV testing to Improve Cervical Cancer Prevention" (SHIP) trial. A total of 554 subjects, from 13 colposcopy clinics across the continental United States and Puerto Rico, were enrolled in the study from September 2024 through February 2025. The study enrolled women referred for colposcopy or direct cervical excisional procedures (without intermediate colposcopy) based on abnormal cervical cancer screening conducted within 12 months preceding the referral visit. Women who were attending clinic for excisional procedures due to prior abnormal biopsy/colposcopy were excluded. Out of the 554 enrolled, 495 subjects were eligible for the study. The population of study subjects and their disease outcomes are listed in the following table.

| | | Clinician-collected Cervical (CC) HR-HPV | Self-collected Vaginal (SV) HR-HPV | Disease Outcomes | | |
|---|---|---|---|---|---|---|
| **Age category (years)** | **Subjects N (%)** | **Positive N (%)** | **Positive N (%)** | **≤CIN1 N (%)** | **≥CIN2 N (%)** | **≥CIN3 N (%)** |
| **Total** | 495 (100.0%) | 311 (100.0%) | 348 (100.0%) | 388 (100.0%) | 95 (100.0%) | 72 (100.0%) |
| **24-29** | 76 (15.4%) | 49 (15.8%) | 55 (15.8%) | 58 (14.9%) | 17 (17.9%) | 10 (13.9%) |
| **30-39** | 182 (36.8%) | 111 (35.7%) | 125 (35.9%) | 139 (35.8%) | 41 (43.2%) | 32 (44.4%) |
| **40-49** | 105 (21.2%) | 65 (20.9%) | 77 (22.1%) | 82 (21.1%) | 18 (18.9%) | 14 (19.4%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| **50-59** | 75 (15.2%) | 51 (16.4%) | 57 (16.4%) | 61 (15.7%) | 11 (11.6%) | 10 (13.9%) |
| **60+** | 57 (11.5%) | 35 (11.3%) | 34 (9.8%) | 48 (12.4%) | 8 (8.4%) | 6 (8.3%) |
| **Colposcopy Clinic Locations** | **Subjects N (%)** | **Positive N (%)** | **Positive N (%)** | **≤CIN1 N (%)** | **≥CIN2 N (%)** | **≥CIN3 N (%)** |
| **Total** | 495 (100.0%) | 311 (100.0%) | 348 (100.0%) | 388 (100.0%) | 95 (100.0%) | 72 (100.0%) |
| **Atlanta, GA** | 73 (14.7%) | 33 (10.6%) | 35 (10.1%) | 59 (15.2%) | 13 (13.7%) | 9 (12.5%) |
| **Chapel Hill, NC** | 67 (13.5%) | 46 (14.8%) | 48 (13.8%) | 50 (12.9%) | 16 (16.8%) | 15 (20.8%) |
| **Pittsburgh, PA** | 59 (11.9%) | 32 (10.3%) | 40 (11.5%) | 47 (12.1%) | 9 (9.5%) | 2 (2.8%) |
| **Cincinnati, OH** | 52 (10.5%) | 35 (11.3%) | 46 (13.2%) | 46 (11.9%) | 4 (4.2%) | 4 (5.6%) |
| **Birmingham, AL** | 38 (7.7%) | 30 (9.6%) | 27 (7.8%) | 31 (8.0%) | 7 (7.4%) | 5 (6.9%) |
| **Bronx, NY** | 50 (10.1%) | 25 (8.0%) | 34 (9.8%) | 44 (11.3%) | 6 (6.3%) | 4 (5.6%) |
| **Oklahoma City, OK** | 50 (10.1%) | 39 (12.5%) | 40 (11.5%) | 36 (9.3%) | 14 (14.7%) | 13 (18.1%) |
| **New Orleans, LA** | 26 (5.3%) | 16 (5.1%) | 20 (5.7%) | 19 (4.9%) | 6 (6.3%) | 6 (8.3%) |
| **Baltimore, MD** | 27 (5.5%) | 17 (5.5%) | 19 (5.5%) | 23 (5.9%) | 4 (4.2%) | 3 (4.2%) |
| **Richmond, VA** | 27 (5.5%) | 17 (5.5%) | 19 (5.5%) | 20 (5.2%) | 7 (7.4%) | 4 (5.6%) |
| **Houston, TX** | 18 (3.6%) | 14 (4.5%) | 14 (4.0%) | 8 (2.1%) | 7 (7.4%) | 5 (6.9%) |
| **San Juan, PR** | 6 (1.2%) | 5 (1.6%) | 4 (1.1%) | 3 (0.8%) | 2 (2.1%) | 2 (2.8%) |
| **Miami, FL** | 2 (0.4%) | 2 (0.6%) | 2 (0.6%) | 2 (0.5%) | 0 (0.0%) | 0 (0.0%) |

Once informed consent was obtained, each subject provided a self-collected vaginal (SV) swab specimen followed by a clinician-collected cervical specimen (CC). For the SV specimen, participants were provided packaged self-collection kits with an instruction sheet on how to collect the vaginal specimens. No instruction was provided by the study staff. After collecting the vaginal swab, the subject broke the swab off into the empty BD Onclarity HPV Self Collection Tube. The clinician collected the cervical specimen using a cervical cytobrush/spatula or broom device and transferred the collected specimen into 20 mL of PreservCyt liquid-based-cytology (LBC) medium (Hologic, Inc., Bedford, MA, USA). The vaginal specimens were transported dry at ambient temperature to the laboratory where they were resuspended in 3 mL of BD Onclarity HPV Assay diluent and tested on the BD COR System. The CC specimens in PreservCyt solution were shipped to one testing laboratory for testing with BD Onclarity HPV Assay. The linkage between CC and SV specimens were blinded. Cervical disease status was based on standard of care (SOC) colposcopy and/or histopathology outcomes as reported by study sites.

The clinical sensitivity, clinical specificity, and false positive rate in detecting precancer/cancer as well as the corresponding ratio between vaginal and cervical specimens were calculated. In addition, the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of the BD Onclarity HPV Assay results between the two specimen types were calculated. The above study endpoints were calculated along with two-sided 95% confidence intervals (95% CI).

Of the 495 eligible subjects, 33 were excluded due to the following reasons:

1) 21 subjects were not tested for HPV due to various reasons (CC not collected, specimen collection errors and specimen contamination issues).
2) 12 subjects (eight with SV and four with CC specimens) had invalid HPV test results.

Therefore, the PPA and NPA between CC and SV specimen was evaluated based on results from 462 subjects. For an additional 12 subjects, colposcopy was not possible due to clinical reasons or patient factors. Therefore, these 12 subjects were excluded from the analyses of clinical sensitivity, clinical specificity, and clinical false positive rate as well as the corresponding ratio between vaginal and cervical specimens.

The study results are presented in the following tables.

| ≥CIN3 | | | CC | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | HPV16 and/or HPV18 | 12 Other HR HPV | HR HPV Negative | | Invalid | Total |
| | | | | | HPV DNA Detected | HPV DNA Undetected | | |
| SV | HPV16 and/or HPV18 | | 19 | 0 | 0 | 0 | 0 | 19 |
| | 12 Other HR HPV | | 0 | 37 | 2 | 0 | 0 | 39 |
| | HR HPV Negative | HPV DNA Detected | 0 | 5 | 0 | 0 | 0 | 7 |
| | | HPV DNA Undetected | 1 | 1 | 0 | 0 | 0 | |
| | Invalid | | 0 | 3 | 0 | 0 | 0 | 3 |
| | Total | | 20 | 46 | 2 | | 0 | 68 |

Sensitivity (SV): HR HPV = 89.2% (58/65) (95% CI: 79.4%-94.7%)
Sensitivity (CC): HR HPV = 96.9% (63/65) (95% CI: 89.5%-99.2%)
Ratio of Sensitivity (SV:CC): HR HPV = 0.921 (89.2%/96.9%); (95% CI: 0.814-1.018)

| ≥CIN2 | | | CC | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | HPV16 and/or HPV18 | 12 Other HR HPV | HR HPV Negative | | Invalid | Total |
| | | | | | HPV DNA Detected | HPV DNA Undetected | | |
| SV | HPV16 and/or HPV18 | | 20 | 0 | 0 | 0 | 0 | 20 |
| | 12 Other HR HPV | | 1 | 49 | 2 | 0 | 0 | 52 |
| | HR HPV Negative | HPV DNA Detected | 0 | 6 | 1 | 2 | 0 | 14 |
| | | HPV DNA Undetected | 1 | 1 | 0 | 3 | 0 | |
| | Invalid | | 0 | 3 | 0 | 0 | 0 | 3 |
| | Total | | 22 | 59 | 8 | | 0 | 89 |

Sensitivity (SV): HR HPV = 83.7% (72/86) (95%CI: 74.5%-90.0%)
Sensitivity (CC): HR HPV = 90.7% (78/86) (95%CI: 82.7%-95.2%)
Ratio of Sensitivity (SV:CC): HR HPV = 0.923 (83.7%/90.7%); (95%CI: 0.832-1.003)

| ≤CIN1 | | CC | | | | |
|---|---|---|---|---|---|---|
| | | HPV16 and/or HPV18 | 12 Other HR HPV | HR HPV Negative | Invalid | Total |
| SV | HPV16 and/or HPV18 | 33 | 6 | 12 | 0 | 51 |
| | 12 Other HR HPV | 2 | 162 | 33 | 3 | 200 |
| | HR HPV Negative | 3 | 12 | 101 | 1 | 117 |
| | Invalid | 0 | 3 | 2 | 0 | 5 |
| | Total | 38 | 183 | 148 | 4 | 373 |

Specificity (SV): HR HPV = 31.9% (116/364) (95%CI: 27.3%-36.8%)
Specificity (CC): HR HPV = 40.1% (146/364) (95%CI: 35.2%-45.2%)
Ratio of Specificity (SV:CC): HR HPV = 0.795 (31.9%/40.1%); (95%CI: 0.702-0.890)

False Positive Rate (FPR) (SV): HR HPV = 68.1% (248/364) (95%CI: 63.2%-72.7%)
False Positive Rate (FPR) (CC): HR HPV = 59.9% (218/364) (95%CI: 54.8%-64.8%)
Ratio of False Positive Rate (FPR) (SV:CC): HR HPV = 1.138 (68.1%/59.9%); (95%CI: 1.068-1.220)

| Total | | CC | | | |
|---|---|---|---|---|---|
| | | HPV16 and/or HPV18 | Other 12 HR-HPV | HR-HPV Negative | Total |
| SV | HPV16 and/or HPV18 | 57 | 6 | 13 | 76 |
| | Other 12 HR-HPV | 3 | 214 | 38 | 255 |

| | | | | | |
|---|---|---|---|---|---|
| | **HR-HPV Negative** | 4 | 19 | 108 | 131 |
| | **Total** | 64 | 239 | 159 | 462 |
| PPA (HR HPV) = 92.4% (280/303); 95%CI: 88.9%, 94.9%<br>NPA (HR HPV) = 67.9% (108/159); 95%CI: 60.3%, 74.7% | | | | | |

The final HPV assay invalid rate for SV is 1.63% (8/490; 95% CI: 0.83, 3.19%). The final HPV assay invalid rate for CC is 0.83% (4/480; 95% CI: 0.32, 2.12%).

A total of 17 Adverse Device Effects (ADEs) were reported in the study. All were mild and all resolved. No serious adverse events (SAEs) or unanticipated ADEs (UADEs) were reported.

*Study #2*

A second prospective clinical study was conducted to provide data supporting the performance of Onclarity Self-Collection Kit for use with the BD Onclarity HPV Assay. This study was conducted in a simulated home environment with individuals representative of the general cervical cancer screening population. 406 subjects were enrolled at two locations in the eastern and western regions of the U.S. Subjects, aged between 25-65 years old, who met routine cervical cancer screening guidelines and had no previous history of abnormal cervical cancer screening results were consented for the study. 5 subjects were excluded due to pelvic pain and not meeting the required age range. Each participant was provided with an individually packaged self-collection kit and an instruction sheet on how to collect the vaginal specimen. No instruction was provided by the study staff. After collecting the vaginal swab, subjects broke the swab off into the empty BD Onclarity HPV Self Collection Tube. A clinician then collected a cervical specimen using a cervical broom and expressed it in 20 mL of PreservCyt liquid-based-cytology (LBC) medium (Hologic, Inc., Bedford, MA, USA). The vaginal specimens were transported dry at ambient temperature to the laboratory where they were resuspended in 3mL of BD Onclarity HPV Assay diluent and tested on the BD COR System. The clinician-collected specimens were shipped to a laboratory and tested with BD Onclarity HPV Assay on BD COR System.

The final HPV assay invalid rate for SV and CC is 0%. No adverse events were reported in the study.

The Positive Percent Agreement was 93.1% (95% CI: 85.8%; 96.8%). The Negative Percent Agreement was 83.1% (95% CI: 78.6%; 86.9%). The age distribution of the participants and study results are presented in tables below.

**Age Distribution of Study Participants**

| **Age category (years)** | **Subjects**<br>**N (%)** |
|---|---|
| **Total** | 401 |
| **24-29** | 19 (4.74%) |
| **30-39** | 62 (15.46%) |
| **40-49** | 98 (24.44%) |
| **50-59** | 141 (35.16%) |

| | |
|---|---|
| **60+** | 81 (20.20%) |

**Concordance: Cross-Tabulation of CC vs. SV Results and Key Performance Metrics**

| Total | | CC | | |
|---|---|---|---|---|
| | | **HR HPV Positive** | **HR HPV Negative** | **Total** |
| **SV** | **HR HPV Positive** | **81** | **53** | **134** |
| | **HR HPV Negative** | **6** | **261** | **267** |
| | **Total** | **87** | **314** | **401** |
| **PPA (HR HPV) =93.1% (81/87); 95% CI: 85.8%, 96.8%<br>NPA (HR HPV) =83.1% (261/314); 95% CI: 78.6%, 86.9** | | | | |

Please refer to P160037-S017 and P160037-S024 for additional information on self-collected vaginal specimen testing.

## D Expected Values/Reference Range:

Not applicable

## F Other Supportive Performance Characteristics Data:

*Usability and Comprehension study*

Device usability and user comprehension of the Onclarity Self-Collection Kit was assessed in female participants aged 25 to 64 years old in a simulated home environment to evaluate users' ability to unbox the contents of the Onclarity Self-collection Kit, collect a simulated vaginal sample and prepare the vaginal sample for mailing according to the provided instructions. The study involved 60 participants representing a range of educational levels. Usability and comprehension study results demonstrated high user comprehension and ability to execute procedural steps across the study participants. A second usability study was conducted in 58 female participants aged at 25 or above to evaluate the users' ability to follow the collection instructions to self-collect vaginal swab at home. All participants demonstrated success in completing the at home collection tasks. Vaginal self-collection procedure has been demonstrated to be easy to perform and safe for the users.

Hazard Analysis and Mitigations

A comprehensive hazard analysis of the Onclarity Self-Collection Kit was conducted in accordance with ISO 14971:2019, to identify known and foreseeable hazards and hazardous situations and ensure that their risks are appropriately assessed and controlled when used under the conditions of intended use. Specific risks associated with human factors, sample and device handling, storage, and environmental factors were evaluated. Risk control measures have been implemented to reduce the risks.

Tests Evaluating Onclarity Self-Collection Kit Robustness

To demonstrate that Onclarity Self-Collection Kit (both COR and Viper LT configurations) can withstand shipping without affecting product integrity, the kits were challenged and tested in accordance with ISTA 3A 2018 standard testing, and the packages and components within the collection kit were inspected for damage after challenge. No damage was found to the Onclarity

Self-Collection Kit and its components, and the results demonstrate the robustness of the Onclarity Self-Collection Kit.

Frequently Asked Questions

A Frequently Asked Questions (FAQ) section has been included in the Instruction for Use for the BD Onclarity Self-Collection Kit to provide educational information regarding the safety, benefit, and precautions of self-collection using the BD Onclarity Self-Collection Kit.

Biocompatibility

Biocompatibility safety testing was conducted with the BD Onclarity Self-Collection Kit and yielded acceptable results.

## 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.