November 25, 2024

Hologic, Inc.
Gabriela Mccoole
Regulatory Affairs Specialist
10210 Genetic Center Dr
San Diego, California 92121

Re: K243345
Trade/Device Name: Aptima BV Assay; Aptima CV/TV Assay
Regulation Number: 21 CFR 866.3975
Regulation Name: Device That Detects Nucleic Acid Sequences From Microorganisms Associated With Vaginitis And Bacterial Vaginosis
Regulatory Class: Class II
Product Code: PQA
Dated: October 23, 2024
Received: October 28, 2024

Dear Gabriela Mccoole:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S

Digitally signed by Bryan M. Grabias -S
Date: 2024.11.25 12:19:01 -05'00'

Bryan Grabias, Ph. D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243345

Device Name
Aptima BV Assay; Aptima CV/TV Assay

Indications for Use *(Describe)*

Aptima BV Assay
The Aptima BV Assay is an in vitro nucleic acid amplification test that utilizes real time Transcription-Mediated Amplification (TMA) technology for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including Lactobacillus (L. gasseri, L. crispatus, and L. jensenii), Gardnerella vaginalis (G. vaginalis), and Atopobium vaginae (A. vaginae). The assay reports a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther System using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.

Aptima CV/TV Assay
The Aptima CV/TV Assay is an in vitro nucleic acid amplification test for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis. The assay utilizes real time Transcription-Mediated Amplification (TMA) technology to detect and qualitatively report results for the following organisms:
• Candida species group (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis)
• Candida glabrata (C. glabrata)
• Trichomonas vaginalis (TV)
The assay differentiates between C. glabrata and the Candida species group (C spp) by targeting the RNA component of RNAse P ribonucleoprotein; the assay does not differentiate among C spp. For TV, the assay targets ribosomal RNA (rRNA) and differentiates the result from results for C. glabrata and C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis on the automated Panther System using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis or vulvovaginitis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

HOLOGIC®

510(k) SUMMARY
Aptima BV Assay

I. SUBMITTER

Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Contact Person:
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Regulatory Affairs Specialist
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Date Prepared:
October 25, 2024

II. DEVICE

Proprietary Name of Device: Aptima BV Assay
Classification Name: Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis.
Regulation Number: 21 CFR 866.3975
Regulatory Class: Class II
Product Code: PQA, NSU, and PMN

III. PREDICATE DEVICE

The predicate device is the Aptima BV Assay (K190452; cleared May 23, 2019), which is a 100 test kit configuration.

IV. DEVICE DESCRIPTION

Like the Aptima BV assay 100 test kit, the Aptima BV assay 250 test kit is an in vitro nucleic acid amplification test for the detection and quantitation of rRNA from bacteria associated with bacterial vaginosis in women with a clinical presentation consistent with vaginitis/vaginosis. The Aptima BV assay utilizes the automated Panther system to provide qualitative results to aid in the diagnosis of bacterial vaginosis.

Principles of the Procedure

The Aptima BV assay involves three main steps, all of which take place in a single tube on the Panther system: target capture, target amplification by TMA, and detection of the amplification products (amplicon) by fluorescent labeled probes (torches). The assay incorporates an internal control (IC) in every test to monitor nucleic acid capture, amplification and detection.

Specimens are collected in a tube containing specimen transport media (STM) that lyses the cells, releases the RNA, and protects it from degradation during storage. When the Aptima BV assay is performed, capture oligonucleotides hybridize to highly conserved regions of the target RNA, if present, in the test specimen. The hybridized target is then captured onto magnetic microparticles that are separated from the specimen in a magnetic field. Wash steps remove extraneous components from the reaction tube.

Target amplification occurs via TMA, a transcription-based nucleic acid amplification method that utilizes two enzymes, Moloney murine leukemia virus (MMLV) reverse transcriptase and T7 RNA polymerase. The reverse transcriptase is used to generate a DNA copy of the target RNA sequence, adding a promoter sequence for T7 RNA polymerase. T7 RNA polymerase produces multiple copies of RNA amplicon from the DNA copy template.

Detection is achieved using single-stranded nucleic acid torches that are present during the amplification of the target and hybridize specifically to the amplicon in real time. Each torch has a fluorophore and a quencher. The quencher suppresses the fluorescence

of the fluorophore when the torch is not hybridized to the amplicon. When the torch binds to the amplicon, the fluorophore is separated from the quencher and emits a signal at a specific wavelength when excited by a light source. The Panther system detects and discriminates between four fluorescent signals corresponding to Lactobacillus group, *Atopobium vaginae, Gardnerella vaginalis* and IC amplification products. The Panther system software compares signal emergence times for each target organism to calibration information in order to determine the BV Positive or Negative status of each sample.

Assay Components

The Aptima BV 250 test kit provides enough reagents to run 250 tests. Like the Aptima BV assay 100 test kit, the Aptima BV assay 250 test kit master kit contains 8 reagents, 1 calibrator, and 2 controls required for sample processing. There are 4 boxes that make up the assay master kit. Boxes 1 and 2 contain the Aptima BV assay reagents packaged according to storage conditions. Box 3 contains the calibrator, and Box 4 contains the controls when provided as part of the master kit. The Aptima BV Calibrator and Controls kit may also be procured separately if customers need additional calibrators or controls. A listing of the components that are required to perform the Aptima BV assay are detailed in **Table 1.** In addition, there is one ancillary kit (Aptima Assay Fluids Kit) required to run the assay, and one collection kit (Aptima Multitest Swab Specimen Collection Kit) utilized for collection of specimens.

Table 1 Reagents Required to Perform the Aptima BV Assay 250 test kit

Box	Components Description
1	Amplification Reagent
	Enzyme Reagent
	Promoter Reagent
	Internal Control
2	Amplification Reconstitution Solution
	Enzyme Reconstitution Solution
	Promoter Reconstitution Solution
	Target Capture Reagent
3	Positive Calibrator
4	Negative Control
	Positive Control

Instrumentation

Like the Aptima BV assay 100 test kit, the 250 test kit configuration has been designed for and validated on the Panther system. The Panther system is an integrated hardware and software system that together with the Aptima BV assay fully automates all the steps necessary to perform the assay from sample preparation through amplification of nucleic acid, detection, data reduction and amplicon inactivation.

V. INDICATIONS FOR USE

The Aptima® BV Assay is an *in vitro* nucleic acid amplification test that utilizes real time Transcription-Mediated Amplification (TMA®) technology for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including *Lactobacillus (L. gasseri, L. crispatus, and L. jensenii*), *Gardnerella vaginalis* (*G. vaginalis*), and *Atropbium vaginae (A. vaginae*). The assay reports a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther® System using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTCS WITH THE PREDICATE DEVICE

Table 2 displays a comparison of the Aptima BV Assay 250 Test Kit (subject device) with the Aptima BV Assay 250 Test Kit (predicate device).

Table 2 Comparison of Predicate and Subject Device

Feature	**Aptima BV Assay 100 Test Kit (Predicate Device, K190452)**	**Aptima BV Assay 250 Test Kit (Subject Device) Comparison to the Predicate**	**Predicate and Subject Device Comparison**
Intended Use	The Aptima BV assay is an in vitro nucleic acid amplification test that utilizes real time transcription-mediated amplification (TMA) for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including *Lactobacillus* (*L. gasseri, L.* crispatus, and L. jensenii), *Gardnerella vaginalis*, and *Atopobium vaginae*. The assay reports a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther system using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.	The Aptima® BV Assay is an *in vitro* nucleic acid amplification test that utilizes real time Transcription-Mediated Amplification (TMA®) technology for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including *Lactobacillus (L. gasseri, L. crispatus, and L. jensenii*), *Gardnerella vaginalis* (*G. vaginalis*), and *Atropbium vaginae (A. vaginae*). The assay reports a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther® System using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.	Same; some editorial changes were made to the intended use statement (added trademark symbols and abbreviations for *Gardnerella vaginalis* and *Atropbium vaginae*).
Organisms Detected	*Lactobacillus (L. gasseri, L. crispatus,* and *L. jensenii), Gardnerella vaginalis,* and *Atopobium vaginae*	*Lactobacillus (L. gasseri, L. crispatus,* and *L. jensenii), Gardnerella vaginalis,* and *Atopobium vaginae*	Same
Test Quantity	100 Tests	250 Tests	Different; The subject device quantity is 250 Tests.
Assay Controls	Incorporates an Internal Control in every test. Uses external positive and negative controls.	Incorporates an Internal Control in every test. Uses external positive and negative controls.	Same

Feature	**Aptima BV Assay 100 Test Kit (Predicate Device, K190452)**	**Aptima BV Assay 250 Test Kit (Subject Device) Comparison to the Predicate**	**Predicate and Subject Device Comparison**
Patient Population	Women with a clinical presentation of vaginitis/vaginosis	Women with a clinical presentation of vaginitis/vaginosis	Same
Specimen Types	Vaginal swabs in patients who are symptomatic for vaginitis/vaginosis	Vaginal swabs in patients who are symptomatic for vaginitis/vaginosis	Same
Analyte	ribosomal RNA	ribosomal RNA	Same
Assay Calibrators	Positive Calibrator	Positive Calibrator	Same
Technology Principle of Operation	Real-time Transcription Mediated Amplification (TMA)	Real-time Transcription Mediated Amplification (TMA)	Same
User Complexity	High	High	Same
Platform	Panther System	Panther System	Same
Platform Software	Panther System Software	Panther System Software	Same
Assay Software	Panther Aptima BV 100 Test Kit Assay Software	Panther Aptima BV 250 Test Kit Assay Software.	Different. The subject device uses the Panther Aptima BV 250 Test Kit Assay Software.

VII. PERFORMANCE DATA

The Aptima BV assay 100 Test Kit and the 250 Test Kit (subject device) share the same intended use, operating principle, formulation, and accessories. Based on these similarities, a risk analysis determined the analytical and clinical studies performed for the 100 Test Kit also support the Aptima BV 250 Test Kit configuration performance. A Limit of Detection (LoD) Confirmation study was performed to verify that the Aptima BV 250 Test Kit configuration meets the established Aptima BV 100 Test Kit LoD. The Aptima BV 100 Test Kit LoD was confirmed in the Aptima BV 250 Test Kit configuration, and thus all other previously validated analytical and clinical performance testing performed with the Aptima BV 100 Test Kit configuration is valid and appropriate to show performance for the Aptima BV 250 Test Kit configuration.

Analytical Sensitivity

To confirm the Limit of Detection (LoD) for *L. crispatus* (LC), *L. gasseri* (LG), *L. jensenii* (LJ) and the BV Positivity Limit (C95) for *A.vaginae* (AV) and *G.vaginalis* (GV), dilutions of cell lysates were prepared in SVSM. Dilutions were then tested with at least 20 replicates per concentration, per reagent lot, using three lots over the course of three days (7 replicates per day) for a total of at least 60 replicates per strain.
The results verified that the LoD for each strain is as follows: LC is 143 CFU/mL, LG is 2,207 CFU/mL, and LJ is 10 CFU/mL. The BV Positivity Limit (C95) for AV and GV were verified to be 5.10 log CFU/mL (128,397 CFU/mL), and 4.86 log CFU/mL (72,836 CFU/mL) respectively.

VIII. CONCLUSIONS

The performance study results demonstrate that the Aptima BV assay 250 Test Kit on the Panther system performs comparably to the predicate device that is currently marketed for the same intended use. Hardware and software verification and validation demonstrate that the Aptima BV assay 250 Test Kit on the Panther system will perform as intended.

HOLOGIC®

510(k) SUMMARY
Aptima CV/TV Assay

I. SUBMITTER

Hologic, Inc.
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Contact Person:
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Date Prepared:
October 25, 2024

II. DEVICE

Proprietary Name of Device: Aptima CV/TV Assay
Classification Name: Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis.
Regulation Number: 21 CFR 866.3975
Regulatory Class: Class II
Product Code: PQA, NSU

III. PREDICATE DEVICE

The predicate device is the Aptima CV/TV Assay (K190472; cleared February 26, 2019), which is a 100 test kit configuration.

IV. DEVICE DESCRIPTION

Like the Aptima CV/TV assay 100 test kit, the Aptima CV/TV assay 250 test kit is an in vitro nucleic acid amplification test for the detection and quantitation of RNA from microorganisms associated with vaginitis, trichomoniasis, and vulvovaginitis, in women with a clinical presentation consistent with vaginitis, trichomoniasis, and vulvovaginitis. The Aptima CV/TV assay utilizes the automated Panther system to provide qualitative results to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis.

Principles of the Procedure

The Aptima CV/TV assay involves three main steps, all of which take place in a single tube on the Panther system: target capture, target amplification by TMA, and detection of the amplification products (amplicon) by fluorescent labeled probes (torches). The assay incorporates an internal control (IC) in every test to monitor nucleic acid capture, amplification and detection.

Specimens are collected in a tube containing specimen transport media (STM) that lyses the organisms, releases the RNA, and protects it from degradation during storage. When the assay is performed, capture oligonucleotides hybridize to highly conserved regions of the target RNA, if present, in the test specimen. The hybridized target is then captured onto magnetic microparticles that are separated from the specimen in a magnetic field. Wash steps remove extraneous components from the reaction tube.

Target amplification occurs via TMA, a transcription-based nucleic acid amplification method that utilizes two enzymes, Moloney murine leukemia virus (MMLV) reverse transcriptase and T7 RNA polymerase. The reverse transcriptase is used to generate a DNA copy of the target RNA sequence, adding a promoter sequence for T7 RNA polymerase. T7 RNA polymerase produces multiple copies of RNA amplicon from the DNA copy template.

Detection is achieved using single-stranded nucleic acid torches that are present during the amplification of the target and hybridize specifically to the amplicon in real time.

Each torch has a fluorophore and a quencher. The quencher suppresses the fluorescence of the fluorophore when the torch is not hybridized to the amplicon. When the torch binds to the amplicon, the fluorophore is separated from the quencher and emits a signal at a specific wavelength when excited by a light source. The Panther system detects and discriminates between four fluorescent signals corresponding to Cspp, *C. glabrata*, *T. vaginalis* and IC amplification products. The Panther system software uses an Aptima CV/TV assay-specific algorithm that interprets the amplification signal emergence times to generate a Positive or Negative status for each target organism in the sample

Assay Components

The Aptima CV/TV 250 test kit provides enough reagents to run 250 tests. Like the Aptima CV/TV assay 100 test kit, the Aptima CV/TV assay 250 test kit master kit contains 8 reagents, 1 calibrator, and 2 controls required for sample processing. There are 4 boxes that make up the assay master kit. Boxes 1 and 2 contain the Aptima CV/TV assay reagents packaged according to storage conditions. Box 3 contains the calibrator, and Box 4 contains the controls when provided as part of the master kit. The Aptima CV/TV Calibrator and Controls kit may also be procured separately if customers need additional calibrators or controls. A listing of the components that are required to perform the Aptima CV/TV assay are detailed in **Table 1.** In addition, there is one ancillary kit (Aptima Assay Fluids Kit) required to run the assay, and one collection kit (Aptima Multitest Swab Specimen Collection Kit) utilized for collection of specimens.

Table 1 Reagents Required to Perform the Aptima CV/TV Assay 250 test kit

Box	Components Description
1	Amplification Reagent
	Enzyme Reagent
	Promoter Reagent
	Internal Control
2	Amplification Reconstitution Solution
	Enzyme Reconstitution Solution
	Promoter Reconstitution Solution
	Target Capture Reagent
3	Positive Calibrator
4	Negative Control
	Positive Control

Instrumentation

Like the Aptima CV/TV assay 100 test kit, the 250 test kit configuration has been designed for and validated on the Panther system. The Panther system is an integrated hardware and software system that together with the Aptima CV/TV assay fully automates all the steps necessary to perform the assay from sample preparation through amplification of nucleic acid, detection, data reduction and amplicon inactivation.

V. INDICATIONS FOR USE

The Aptima® CV/TV Assay is an *in vitro nucleic* acid amplification test for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis. The assay utilizes real time Transcription-Mediated Amplification (TMA®) technology to detect and qualitatively report results for the following organisms:

- *Candida* species group (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*)
- *Candida glabrata (C. glabrata*)
- *Trichomonas vaginalis (TV*)

The assay differentiates between *C. glabrata* and the Candida species group (C spp) by targeting the RNA component of RNAse P ribonucleoprotein; the assay does not differentiate among C spp. For TV, the assay targets ribosomal RNA (rRNA) and

differentiates the result from results for *C. glabrata* and C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis on the automated Panther® System using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis or vulvovaginitis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTCS WITH THE PREDICATE DEVICE

Table 2 displays a comparison of the Aptima CV/TV Assay 250 Test Kit (subject device) with the Aptima CV/TV Assay 250 Test Kit (predicate device).

Table 2 Comparison of Predicate and Subject Device

Item	Aptima CV/TV Assay 100 Test Kit (Predicate Device, K190472)	Aptima CV/TV Assay 250 Test Kit (Subject Device)	Predicate and Subject Device Comparison
Intended Use	The Aptima CV/TV assay is an *in vitro* nucleic acid amplification test for the detection of RNA from microorganisms associated with vaginitis, trichomoniasis, and vulvovaginitis. The assay utilizes real time transcription-mediated amplification (TMA) to detect and qualitatively report results for the following organisms: • *Candida* species group (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*) • *Candida glabrata* • *Trichomonas vaginalis* The assay differentiates between *Candida glabrata* and the *Candida* species group (C spp) by targeting the RNA component of RNAse P ribonucleoprotein; the assay does not differentiate among C spp. For *Trichomonas vaginalis*, the assay targets ribosomal RNA (rRNA) and differentiates the result from results for *Candida glabrata* and C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis on the automated Panther system using clinician-collected and patient-collected vaginal swab specimens from women with a clinical presentation consistent with vaginitis, trichomoniasis, and/or vulvovaginitis.	The Aptima® CV/TV Assay is an *in vitro nucleic* acid amplification test for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis. The assay utilizes real time Transcription-Mediated Amplification (TMA®) technology to detect and qualitatively report results for the following organisms: • *Candida* species group (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*) • *Candida glabrata (C. glabrata*) • *Trichomonas vaginalis (TV*) The assay differentiates between *C. glabrata* and the Candida species group (C spp) by targeting the RNA component of RNAse P ribonucleoprotein; the assay does not differentiate among C spp. For TV, the assay targets ribosomal RNA (rRNA) and differentiates the result from results for *C. glabrata* and C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis on the automated Panther® System using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis or vulvovaginitis.	Same. Added trademarks and *Candida glabrata* and *Trichomonas vaginalis* abbreviations.

Item	**Aptima CV/TV Assay 100 Test Kit (Predicate Device, K190472)**	**Aptima CV/TV Assay 250 Test Kit (Subject Device)**	**Predicate and Subject Device Comparison**
Organisms Detected	*Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis); Candida glabrata; Trichomonas vaginalis*	*Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis); Candida glabrata; Trichomonas vaginalis*	Same
Test Quantity	100 Tests	250 Tests	Different. The subject device quantity is 250 Tests.
Assay Controls	Incorporates an Internal Control in every test. Uses external positive and negative controls.	Incorporates an Internal Control in every test. Uses external positive and negative controls.	Same
Patient Population	Women with a clinical presentation of vaginitis, trichomoniasis, or vulvovaginitis	Women with a clinical presentation of vaginitis, trichomoniasis, or vulvovaginitis	Same
Specimen Types	Vaginal swabs in patients who are symptomatic for vaginitis, trichomoniasis, or vulvovaginitis	Vaginal swabs in patients who are symptomatic for vaginitis, trichomoniasis, or vulvovaginitis	Same
Analyte	ribosomal RNA	ribosomal RNA	Same
Assay Calibrators	Positive Calibrator	Positive Calibrator	Same
Technology Principle of Operation	Real-time Transcription Mediated Amplification (TMA)	Real-time Transcription Mediated Amplification (TMA)	Same
User Complexity	High	High	Same

Item	**Aptima CV/TV Assay 100 Test Kit (Predicate Device, K190472)**	**Aptima CV/TV Assay 250 Test Kit (Subject Device)**	**Predicate and Subject Device Comparison**
Platform	Panther System	Panther System	Same
Platform Software	Panther System Software	Panther System Software	Same
Assay Software	Panther Aptima CV/TV 100 Test Kit Assay Software	Panther Aptima CV/TV 250 Test Kit Assay Software	Different. The subject device uses Panther Aptima CV/TV 250 Test Kit Assay Software.

VII. PERFORMANCE DATA

The Aptima CV/TV assay 100 Test Kit and the 250 Test Kit (subject device) share the same intended use, operating principle, formulation, and accessories. Based on these similarities, a risk analysis determined the analytical and clinical studies performed for the 100 Test Kit also support the Aptima CV/TV 250 Test Kit configuration performance. A Limit of Detection (LoD) Confirmation study was performed to verify that the Aptima CV/TV 250 Test Kit configuration meets the established Aptima CV/TV 100 Test Kit LoD. The Aptima CV/TV 100 Test Kit LoD was confirmed in the Aptima CV/TV 250 Test Kit configuration, and thus all other previously validated analytical and clinical performance testing performed with the Aptima CV/TV 100 Test Kit configuration is valid and appropriate to show performance for the Aptima CV/TV 250 Test Kit configuration.

Analytical Sensitivity

To confirm the Limit of Detection (LoD) or C95 of C. albicans, C. glabrata, and T. vaginalis, cell lysates were diluted into Natural Vaginal Swab Matrix (NVSM). Cell lysates of *C. tropicalis* and *C. dubliniensis* and suspension of *C. parapsilosis* were diluted into Simulated Vaginal Swab Matrix (SVSM). Dilutions were then tested with at least 20 replicates per concentration, per reagent lot, using three lots for a total of at least 60 replicates per strain.

The results verified that the LoD for each strain is as follows: The C95 (LoD) for C. albicans is 4439 CFU/mL, *for C. parapsilosis* is 9416 CFU/mL, for *C. tropicalis* is 811 CFU/mL, for *C. dubliniensis* is 1176 CFU/mL. The LoD for *C. glabrata* is 41 CFU/mL, and for *T. vaginalis* is 0.0024 cells/mL.

VIII. CONCLUSIONS

The performance study results demonstrate that the Aptima CV/TV assay 250 Test Kit on the Panther system performs comparably to the predicate device that is currently marketed for the same intended use. Hardware and software verification and validation

demonstrate that the Aptima CV/TV assay 250 Test Kit on the Panther system will perform as intended.