November 6, 2023

Hologic, Inc.
Jingwen Chen
Manager, Regulatory Affairs
10210 Genetic Center Drive
San Diego, California 92121

Re: K231316
Trade/Device Name: Aptima Trichomonas vaginalis Assay
Regulation Number: 21 CFR 866.3860
Regulation Name: Trichomonas Vaginalis Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OUY
Dated: May 5, 2023
Received: May 8, 2023

Dear Jingwen Chen:

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.

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,

Himani Bisht -S

Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV 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)*
K231316

Device Name
Aptima Trichomonas vaginalis Assay

Indications for Use *(Describe)*
The Aptima Trichomonas vaginalis (TV) assay is an in vitro qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from Trichomonas vaginalis to aid in the diagnosis of trichomoniasis using the Panther system.
The assay may be used to test the following specimens from symptomatic or asymptomatic individuals: clinician-collected endocervical swabs, clinician-collected and patient-collected vaginal swabs (in a clinical setting), female and male urine, and specimens collected in PreservCyt Solution.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Aptima Trichomonas Vaginalis Assay

Contact Details

Applicant Name: Hologic, Inc.

Applicant Address: 10210 Genetic Center Drive San Diego CA 92121 United States

Applicant Contact Telephone: 858-410-8956

Applicant Contact: Jingwen Chen

Applicant Contact Email: Jingwen.chen@hologic.com

Device Name

Device Trade Name: Aptima Trichomonas vaginalis Assay

Common Name: Trichomonas vaginalis nucleic acid assay

Classification Name: Trichomonas Vaginalis Nucleic Acid Amplification Test System

Regulation Number: 866.3860

Regulatory Class: Class II

Product Code: OUY

Legally Marketed Predicate Devices

Predicate #: K122062

Predicate Trade Name: Aptima Trichomonas vaginalis Assay

Product Code: OUY

Device Description Summary

Clearance of this pre-market application will add patient-collected vaginal swab, and male and female urine from symptomatic and asymptomatic populations as acceptable specimen types for use with the Aptima Trichomonas vaginalis (TV) assay on the Panther System.

The Aptima TV assay involves the technologies of target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA).

Specimens are collected and transferred into their respective specimen transport tubes. The transport solution in these tubes releases the rRNA target and protects it from degradation during storage. When the Aptima TV assay is performed in the laboratory, the target rRNA is isolated from the specimens using a specific capture oligomer and magnetic microparticles in a method

called target capture. The capture oligomer contains a sequence complementary to a specific region of the target molecule as well as a string of deoxyadenosine residues. During the hybridization step, the sequence-specific region of the capture oligomer binds to a specific region of the target molecule. The capture oligomer:target complex is then captured out of solution by decreasing the temperature of the reaction to room temperature. This temperature reduction allows hybridization to occur between the deoxyadenosine region on the capture oligomer and the poly-deoxythymidine molecules that are covalently attached to the magnetic particles. The microparticles, including the captured target molecule bound to them, are pulled to the side of the reaction vessel using magnets and the supernatant is aspirated. The particles are washed to remove residual specimen matrix that may contain amplification inhibitors. After the target capture steps are completed, the specimens are ready for amplification.

Intended Use

The Aptima Trichomonas vaginalis (TV) assay is an *in vitro* qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis using the Panther system.

The assay may be used to test the following specimens from symptomatic or asymptomatic individuals: clinician-collected endocervical swabs, clinician-collected and patient-collected vaginal swabs (in a clinical setting), female and male urine, and specimens collected in PreservCyt Solution.

Indications for Use Comparison

The intended use of subject device and predicate device remains the same as they both qualitatively detect ribosomal RNA (rRNA) from *T. vaginalis* to aid in the diagnosis of trichomoniasis using the Panther system. Clearance of this pre-market application will add patient-collected vaginal swab, and male and female urine (all collected in clinical settings) from symptomatic and asymptomatic populations as acceptable specimen types for use with the Aptima TV assay on the Panther system.

Technological Comparison

Both subject device and predicate device combine the technologies of target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) to streamline specimen processing, amplify target rRNA and detect amplicon. There are no changes in design, materials, chemical composition nor principle of operation. Therefore, the technological characteristics remain the same.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following studies were performed to demonstrate the performance of the Aptima TV assay with the vaginal swab and urine specimen types, using female urine as the representative urine specimen type. Female urine samples were used as the matrix to support both male and female urine sample claims since male and female samples are very similar in chemical composition and the processing of these samples into urine transport medium (UTM) prior to testing is identical.

Data for vaginal swab specimens were included in the original submission of K122062 previously reviewed by the FDA and are not provided again in the current submission. Those studies previously conducted also included urine specimens, but data for urine specimens were not submitted as Hologic did not pursue female and male urine claims at the time of the original submission. Analytical performance data for urine specimens are being provided in the current submission to support urine specimens as specimen type for use with the Aptima TV assay.

Analytical Studies

Limit of Detection (LOD)

The study was conducted to verify the analytical sensitivity (95% detection limit) in swab and urine clinical specimen matrices for use with Aptima TV assay on the Panther system. Sensitivity panels were prepared with two strains of T. vaginalis (one Metronidazole-susceptible strain and one Metronidazole-resistant strain). Testing showed greater than 95% positivity in both strains of T. vaginalis for panels containing 0.01 TV/mL in urine specimen matrix, and panels containing 0.003 TV/mL in swab specimen matrix.

Cross Reactivity of Microorganisms

The study was conducted to evaluate if various non-targeted microorganisms cross-react or interfere with the sensitivity and specificity of the Aptima TV assay. Results demonstrated that the presence of microorganisms did not interfere with the detection of TV with the exception of *P. hominis* and *T. tenax. T. tenax* is a commensal of the oral cavity and *Pentatrichomonas hominis and Dientamoeba fragilis* are commensal of the large intestine.

Interfering Substances

The study was conducted to assess the effect of potentially interfering substances (e.g., common gynecological and feminine hygiene substances, blood, and seminal fluid) on the sensitivity and specificity of the Aptima TV assay. Testing results yielded no false positive results for all substances at the tested concentrations. Lower mean RLU (<1,000,000) was observed with mucin at 1%. The mean RLU value was above 1,000,000 when testing samples with 0.5% mucin. *T. vaginalis* was detected at ≥ 95% in the presence of all substances tested with the exception of Astroglide personal lubricant, mucus, and glacial acetic acid.

Additional interference testing was conducted to evaluate the effect of Astroglide personal lubricant, mucus, and glacial acetic acid by spiking *T. vaginalis* at 0.3 and 1 *TV*/mL in STM, PreservCyt-STM and urine-UTM matrices. *T. vaginalis* at 0.3 *TV*/mL was detected at ≥ 95% in the presence of Astroglide personal lubricant. *T. vaginalis* at 1 *TV*/mL was detected at ≥ 95% in the presence of mucus and glacial acetic acid. Glacial acetic acid would only be present in PreservCyt specimens and not in urine or swab specimens.

Specimen Stability

T. vaginalis rRNA integrity (stability) in each specimen matrix is independent of the assay and platform used for evaluation, such that results from legacy studies performed on earlier platforms can be applied to the Panther system. A specimen stability study was conducted on the Tigris instrument to evaluate the stability of *T. vaginalis* rRNA target when spiked into vaginal swab specimen matrix, and female urine clinical specimens and tested with the Aptima TV assay. Samples were tested on both Tigris and Panther instruments at additional time-points. Results demonstrated that spiked swab specimens were stable for 2 months at room temperature and for 2 years frozen. Spiked urine specimens in UTM were stable for 1 month at room temperature, and storage up to 2 years frozen.

Additional studies supporting the analytical performance of Aptima TV assay on Panther system were previously included in the original submission of K122062 and reviewed by the FDA and are not provided again in the current submission.

Reproducibility Study

Reproducibility of the Aptima TV assay was evaluated on the Panther system at two external US laboratories and at Hologic. Reproducibility panel members were created by using negative urine specimens in urine transport medium (UTM) or negative PreservCyt solution liquid Pap specimens with Specimen Transport Medium (STM). The positive panel members were created by spiking the urine matrix or PreservCyt solution liquid Pap matrix with the appropriate amount of *T. vaginalis* lysate. Final *T. vaginalis* concentrations ranged from 0.002 trichomonads/mL to 1 trichomonads/mL.

Testing was performed using two lots of assay reagents and a total of six operators (two at each site). At each site, testing was performed over at least 6 days. Two operators performed testing at each site with only one operator performing testing each day. At each site, each operator performed two runs per day, each run using a different lot of reagents. Each run included three replicates of each panel member. Agreement values ranged from 90.7% to 100% in the PreservCyt panel members and agreement values were 100% in the urine panel members. Aptima TV assay demonstrated high agreement with the expected results in the negative panel member and panel members containing target levels at or above the assay LoD. Refer to K122062 for the summary of reproducibility study results in support of specimen types used with STM matrix. Updated reproducibility study results supporting the addition of urine-UTM matrix are provided below.

Aptima Trichomonas vaginalis Assay Reproducibility Study (Analysis of RLU Signal)

Conc	N	Agmt (%)	Mean RLU	Between Sites		Between Operators		Between Lots		Between Runs		Within Runs		Totals	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
PreservCyt Solution Liquid Pap Matrix Samples															
Neg	108	99.1	23.5	0.0	0.0	2.7	11.6	0.0	0.0	0.0	0.0	37.5	159.7	37.6	160.1
HNeg	108	90.7	69.3	5.0	7.3	4.5	6.5	6.1	8.8	14.8	21.4	16.0	23.1	23.6	34.1
MPos	108	97.2	348.1	30.3	8.7	33.1	9.5	33.1	9.5	77.0	22.1	62.9	18.1	114.0	32.8
HPos	108	100	1185.5	0.0	0.0	17.0	1.4	0.0	0.0	28.0	2.4	34.2	2.9	47.4	4.0
Urine Matrix Samples															
Neg	108	100	1.0	0.2	24.6	0.0	0.0	0.3	28.3	0.0	0.0	0.7	72.3	0.8	81.4
HNeg	107	100	33.1	15.9	48.1	4.9	14.8	0.0	0.0	7.1	21.6	9.3	28.0	20.3	61.5
MPos	108	100	621.9	27.2	4.4	33.5	5.4	37.3	6.0	100.6	16.2	69.4	11.2	134.9	21.7
HPos	108	100	1208.3	28.8	2.4	0.0	0.0	0.0	0.0	140.4	11.6	41.5	3.4	149.2	12.3

Agmt = agreement; **Conc** = concentration; **CV** = coefficient of variation; **HNeg** = high negative; **HPos** = high positive; **MPos** = moderate positive; **Neg** = negative; **RLU** = relative light units; **SD** = standard deviation.

Note: The RLU value reported by the software is the total measured RLU divided by 1000 with the digits after the decimal point truncated.

Variability from some factors may have been numerically negative. This occurred if the variability due to those factors was very small. In these cases, SD and CV are shown as 0.

The results indicate reproducible performance within and across all three sites for all panel members tested when compared to the expected outcome.

Clinical Studies

Clinical Performance Study

Two clinical performance studies were conducted. Aptima TV assay clinical performance was estimated with clinician-collected vaginal swab, endocervical swab, and PreservCyt solution liquid Pap specimens in Clinical Study 1, and with patient-collected vaginal swab, and female and male urine specimens in Clinical Study 2. Performance results for Clinical Study 1 were previously included in the original submission of K122062 and reviewed by the FDA and are not provided again in the current submission.

The clinical performance of the Aptima TV assay on the Panther system was evaluated using specimens collected from consenting subjects in a prospective, multicenter clinical study (Clinical Study 2). Symptomatic and asymptomatic men and women were enrolled at 11 geographically and ethnically diverse US clinical sites, including obstetrics and gynecology, family planning, and STI clinics. Subjects were classified as symptomatic if symptoms were reported by the subject. Subjects were classified as asymptomatic if the subject did not report symptoms.

Up to 5 specimens were collected from each female subject (4 patient-collected vaginal swabs, 1 first-catch urine), and 1 first catch urine specimen was collected from each male subject. All specimens were collected by the subject at the clinical sites.

Specimens were tested with the Aptima TV assay on the Panther system. Samples with initial invalid Aptima TV assay results were retested, volume permitting. Of the specimens collected, 5922 were processed in valid Aptima TV assay runs. Of these, 225 (3.8%, 95% CI: 3.3%–4.3%) had initial invalid results. Upon retest, 89 (1.5%) remained invalid and were excluded from the analyses. Urine and vaginal swabs were tested with up to three cleared NAATs to establish the specimen-specific composite comparator method result as follows:

- Male urine: The patient infected status (PIS) was derived from male urine specimens.
- Female urine: The composite comparator algorithm (CCA) interpretation was derived from female urine specimens.
- Vaginal swab: The PIS was derived from patient-collected vaginal swab specimens.

Specimens were categorized as infected (PIS) or positive (CCA) if a positive result occurred in at least two of the comparator NAATs, and as not infected or negative if at least 2 of the comparators results were negative; the third (tie-breaker) comparator was only required if the first 2 comparator results were discordant. Specimens that could not be categorized, due to missing results from the comparator assays, were excluded from the performance analyses. Performance of the Aptima TV assay was estimated relative to the PIS and reported as sensitivity and specificity for vaginal swab and male urine specimens, and was estimated relative to the CCA and reported as positive and negative percent agreement (PPA and NPA) for female urine specimens.

A total of 5502 specimens from 3820 evaluable subjects were included in the analyses comparing Aptima TV assay results to the specimen-specific PIS or CCA interpretations: 1785 patient-collected vaginal swab specimens, 1782 female urine specimens, and 1935 male urine specimens.

Overall, the calculated sensitivity is 98.8% (95% CI: 95.6-99.7) for patient-collected vaginal swab specimens, , and 100% (95% CI: 91.6-100) for male urine. The calculated PPA is 100% (95% CI: 97.6-100) for female urine. The performance of the Aptima TV assay in female urine specimens was also assessed compared to a patient-collected vaginal swab-based PIS. The data showed that the detection of *T. vaginalis* infection in female urine specimens by the Aptima TV assay is up to 2.4 % lower when using the vaginal swab PIS compared to the female urine CCA.

Overall specificity estimate is 99.4% (95% CI: 99.0-99.7) for patient-collected vaginal swab specimen, and 99.8% (95% CI: 99.5-99.9) for male urine. Overall NPA estimate is 100% (95% CI: 99.8-100) for female urine.

The study data demonstrate that performance of the Aptima TV assay on the Panther system is substantially equivalent to that of currently FDA-cleared assays for male and female urine specimens, and for patient-collected vaginal swab specimens.

Conclusion

Analytical and clinical studies performed to evaluate the added specimen types for use with the Aptima TV assay on the Panther system demonstrated that the performance of added specimen types for use with the Aptima TV assay on the Panther system is consistent with current expectations for *T. vaginalis* testing, and that the assay is safe and effective for its intended use.