Cepheid
Wei Zhang
Senior Regulatory Affairs Specialist
904 Caribbean Drive
Sunnyvale, California 94089

June 7, 2022

Re: K221160
Trade/Device Name: Xpert Xpress MVP, GeneXpert Dx System, GeneXpert Infinity System
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, OOI
Dated: April 20, 2022
Received: April 21, 2022

Dear Wei Zhang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Noel J. Gerald, Ph.D.
Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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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Section 5

510(k) Summary
for
Xpert Xpress MVP

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5.0 510(k) Summary

As required by 21 CFR Section 807.92(c).

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (425) 420-8349 Fax number: (408) 541-4192
Contact:	Wei Zhang, PhD RAC
Date of Preparation:	April 20, 2022
Device:	
Trade name:	Xpert® Xpress MVP
Common name:	Xpert Xpress MVP
Type of Test:	Qualitative real-time polymerase chain reaction (PCR) and detection test
Regulation number, Classification name, Product code Definition	21 CFR 866.3975, Vaginitis and Bacterial Vaginosis Nucleic Acid Detection System, PQA 21 CFR 862.2570, Real Time Nucleic Acid Amplification System, OOI
Classification Advisory Panel	Microbiology (83)
Prescription Use	Yes
Predicate Device:	Xpert Xpress MVP (K212213)

5.1 Device Description

The Xpert® Xpress MVP test is an automated *in vitro* diagnostic test for qualitative detection of DNA targets from anaerobic bacteria associated with bacterial vaginosis, *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis*, the agent of trichomoniasis. The Xpert Xpress MVP test is performed on GeneXpert Instrument Systems. The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.

The Xpert Xpress MVP test includes reagents for the detection of DNA from BV organisms, *Candida* species, and *Trichomonas vaginalis* from vaginal swab samples. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert System instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the PCR reaction. The SPC also ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The Xpert Xpress MVP test is designed for use with the following specimens collected from symptomatic individuals: self-collected vaginal swabs (collected in a clinical setting) and clinician-collected vaginal swabs. The swab transport reagent included in the Xpert Swab Specimen Collection Kit is designed to collect and preserve patient specimens to allow transport to the laboratory prior to analysis with the Xpert Xpress MVP test.

5.2 Device Intended Use

The Xpert® Xpress MVP test, performed on the GeneXpert® Instrument Systems, is an automated qualitative *in vitro* diagnostic test for the detection of DNA targets from anaerobic bacteria associated with bacterial vaginosis (BV), *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis*. The Xpert Xpress MVP test uses clinician-collected and self-collected vaginal swabs (collected in a clinical setting) from patients who are symptomatic for vaginitis/vaginosis. The Xpert Xpress MVP test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- Organisms associated with bacterial vaginosis (detected organisms not reported individually)
  - *Atopobium* spp. (*Atopobium vaginae*, *Atopobium* novel species CCUG 55226)
  - Bacterial Vaginosis-Associated Bacterium 2 (BVAB2)
  - *Megasphaera*-1
- *Candida* spp. (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*, species not differentiated)
- *Candida glabrata/Candida krusei* (species not differentiated)
- *Trichomonas vaginalis*

The Xpert Xpress MVP test is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis, or trichomoniasis.

5.3 Substantial Equivalence

The new design of the Xpert Xpress MVP test is substantially equivalent to the original design of the Xpert Xpress MVP (K212213, the predicate device).

The following tables compare the new design of the Xpert Xpress MVP test to the original design of the Xpert Xpress MVP test (K212213). Table 5-1 shows similarities between the new design and the original design (K212213).

Table 5-1: Similarities between New Device and Predicate Device

Comparison		
Attribute	**New Device**	**Predicate Device**
	Xpert Xpress MVP (New Design)	**Xpert Xpress MVP (K212213)**
Regulation	Same	**21CFR 866.3975** Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis
Product Code	Same	PQA Vaginitis and bacterial vaginosis nucleic acid detection system
Device Class	Same	II

Intended Use	Same	The Xpert® Xpress MVP test, performed on the GeneXpert® Instrument Systems, is an automated qualitative *in vitro* diagnostic test for the detection of DNA targets from anaerobic bacteria associated with bacterial vaginosis (BV), *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis*. The Xpert Xpress MVP test uses clinician-collected and self-collected vaginal swabs (collected in a clinical setting) from patients who are symptomatic for vaginitis/ vaginosis. The Xpert Xpress MVP test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:
		• Organisms associated with bacterial vaginosis (detected organisms not reported individually)
		  ○ *Atopobium* spp. (*Atopobium vaginae, Atopobium* novel species CCUG 55226)
		  ○ Bacterial Vaginosis-Associated Bacterium 2 (BVAB2)
		  ○ *Megasphaera*-1
		• *Candida* spp. (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*, species not differentiated)

Comparison		
Attribute	**New Device**	**Predicate Device**
	Xpert Xpress MVP (New Design)	**Xpert Xpress MVP (K212213)**
		• *Candida glabrata/Candida krusei* (species not differentiated) • *Trichomonas vaginalis* The Xpert Xpress MVP test is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis, or trichomoniasis.
Laboratory Users	Same	CLIA Moderate Complexity
Specimen Type	Same	Clinician-collected and self-collected vaginal swabs (collected in a clinical setting)
Assay Technology	Same	Real-Time PCR
Organisms Detected	Same	• Organisms associated with bacterial vaginosis (detected organisms not reported individually) o *Atopobium* spp. (*Atopobium vaginae*, *Atopobium* novel species CCUG 55226) o Bacterial Vaginosis-Associated Bacterium 2 (BVAB2) o *Megasphaera*-1 o *Candida* spp. (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis,* species not differentiated) • *Candida glabrata/Candida krusei* (species not differentiated) • *Trichomonas vaginalis*
Test Cartridge Technology	Same	Disposable single-use, multi-chambered fluidic cartridge
Sample Preparation	Same	Self-contained and automated after mixed specimen is added to cartridge. All other reagents are contained in the cartridge.
Assay Type	Same	Qualitative
Instrument Systems	Same	Cepheid GeneXpert Instrument Systems
Collection Device	Same	Cepheid Xpert Swab Specimen Collection kit
Time to Result	Same	Within 60 minutes

Table 5-2 shows the differences between the new device and the predicate.

Table 5-2: Differences between New Device and Predicate Device

Comparison		
Attribute	**New Device**	**Predicate Device**
	Xpert Xpress MVP (New Design)	**Xpert Xpress MVP (K212213)**
Reagents in Cartridge	Cartridge Version 2 (Minor modifications to the reagents in the self-contained, single-use disposable cartridges)	Cartridge Version 1
Assay Definition File (ADF)	ADF Version 2 (Minor command modifications to accommodate reagent changes)	ADF Version 1

The new design of the Xpert Xpress MVP test has the same intended use and the same technological characteristics as the original design (K212213, the predicate device). The differences between the new design of the Xpert Xpress MVP test and the original design include minor cartridge and ADF modifications, which do not raise different questions of safety and effectiveness. The risk analysis and equivalency study demonstrate that performance of the new design of Xpert Xpress MVP is acceptable for its intended use and is substantially equivalent to the original design of Xpert Xpress MVP (K212213) described above.

5.4 Non-Clinical Study

Analytical Sensitivity

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for Analytical Sensitivity of the Xpert Xpress MVP test.

Analytical Sensitivity Equivalency Study

To determine if the analytical sensitivity of the new design was equivalent to that of the original design, an equivalency study was conducted comparing the limit of detection (LoD) and the near cut-off concentration of the original design (K212213) and the new design of the Xpert Xpress MVP test. The LoD is defined as the lowest concentration of organism sample that can be reproducibly distinguished from negative samples with 95% confidence. The near cut-off concentration for the BV targets is defined as the lowest concentrations of *Atopobium vaginae* and *Megasphaera*-1, or *A. vaginae* and BVAB2, or *A. vaginae* and *Megasphaera*-1 and BVAB2, or *A. vaginae* in the absence of *Megasphaera*-1 and BVAB2 that result in BV POSITIVE test results and can be reproducibly distinguished from negative samples with a 95% confidence level.

For BV organisms, testing at LoD and near cut-off concentrations was performed in simulated vaginal swab matrix (SVM) only. For Candida group, Candida glab-krus and TV targets, testing was conducted with samples diluted in both SVM and pooled negative natural clinical vaginal swab matrix (VS) independently.

The analytical sensitivity of the two designs were deemed equivalent when both the original design (K212213) and the new design reported 19/20 or 20/20 POSITIVE/DETECTED results when tested at LoD/Near Cut-off concentration for each testing condition/target organism, and statistical analysis comparing the difference of mean Ct values of the original design (K212213) and the new design using a two-sample t-test with a marginal difference of 1.0 Ct value and the assumption of equal variances demonstrated that the results were not statistically different (p-value of ≥ 0.05).

Results from the equivalency study at LoD concentrations are shown in Table 5-3. The number of positive results obtained out of the total number of replicates tested for each target at the LoD concentrations, the difference in the mean Cts between the two designs, and the t-test statistical analysis of the mean Ct values are presented.

Table 5-3: Mean Ct Values and Differences Between the Two Designs of Xpert Xpress MVP Test at LoD Concentrations

Organism	Concentration Tested (1× LoD)	Matrix	Design	Replicates reported positive results/ Total Replicates	Difference in Mean Cts of Two Designs	t-test p-value
Atopobium vaginae	32 CFU/mL	SVM	Original design (K212213)	20/20	0.1	>0.999
			New design	20/20		
Megasphaera-1	338 copies/mL	SVM	Original design (K212213)	19/20	0.1	0.999
			New design	19/20		
BVAB2	50 copies/mL	SVM	Original design (K212213)	19/20	0.6	0.916
			New design	19/20		

Organism	Concentration Tested (1× LoD)	Matrix	Design	Replicates reported positive results/ Total Replicates	Difference in Mean Cts of Two Designs	t-test *p*-value
Candida albicans	30 CFU/mL	SVM	Original design (K212213)	19/20	0.5	0.911
			New design	20/20		
		VS	Original design (K212213)	19/20	0.4	0.965
			New design	20/20		
Candida dubliniensis	1,316 CFU/mL	SVM	Original design (K212213)	20/20	0.9	0.620
			New design	20/20		
		VS	Original design (K212213)	20/20	0.2	>0.999
			New design	20/20		
Candida tropicalis	750 CFU/mL	SVM	Original design (K212213)	19/20	0.7	0.826
			New design	20/20		
		VS	Original design (K212213)	20/20	0.1	>0.999
			New design	20/20		
Candida parapsilosis	1,339 CFU/mL	SVM	Original design (K212213)	20/20	0.3	>0.999
			New design	20/20		
		VS	Original design (K212213)	20/20	0.0	>0.999
			New design	20/20		
Candida glabrata	20 CFU/mL	SVM	Original design (K212213)	20/20	0.3	0.936
			New design	20/20		
		VS	Original design (K212213)	20/20	0.3	0.999
			New design	20/20		
Candida krusei	656 CFU/mL	SVM	Original design (K212213)	20/20	0.3	>0.999
			New design	20/20		
		VS	Original design (K212213)	20/20	0.2	>0.999
			New design	20/20		
Trichomonas vaginalis	5 cells/mL	SVM	Original design (K212213)	20/20	0.3	0.989
			New design	19/20		
		VS	Original design (K212213)	19/20	0.1	0.993
			New design	20/20		

Results from the equivalency study at near cut-off concentrations are shown in Table 5-4. The number of positive results obtained out of the total number of replicates tested for each BV organism at the near cut-off concentrations, the difference in the mean Cts between the two designs, and the t-test statistical analysis of the mean Ct values are presented.

Table 5-4: Mean Ct Values and Differences Between the Two Designs of Xpert Xpress MVP at Near Cut-off Concentrations of BV Organisms

Organism	Concentration tested (1× near Cut-off Concentration)	Matrix	Design	Replicates reported BV positive results/ Total Replicates	Difference in Mean Atop gp Cts	t-test *p*-value	Difference in Mean Mega1-BVAB2 Cts	t-test *p*-value
A. vaginae	3.2×10^5 CFU/mL	SVM	Original design (K212213)	19/20	0.1	>0.999	N/A	N/A
			New design	20/20				
A. vaginae; Megasphaera-1	2,750 CFU/mL; 390 copies/mL	SVM	Original design (K212213)	20/20	0.1	>0.999	0.4	0.993
			New design	19/20				
A. vaginae; BVAB2	2,750 CFU/mL; 50 copies/mL	SVM	Original design (K212213)	20/20	0.1	>0.999	0.4	0.999
			New design	20/20				
A. vaginae; Megasphaera-1; BVAB2	2,750 CFU/mL; 390 copies/mL; 50 copies/mL	SVM	Original design (K212213)	20/20	0.2	>0.999	0.3	0.996
			New design	20/20				

The Xpert Xpress MVP original design (K212213) and new design both verified the LoD and near cut-off concentrations with at least 19 of 20 replicates reported POSITIVE/DETECTED results in the head-to-head testing. In addition, the differences in mean target Cts were within the marginal difference of 1.0 Ct value, and no statistically significant differences in the mean Ct values were observed for all test targets between the two designs, demonstrating that the analytical sensitivity of the two designs of Xpert Xpress MVP is equivalent.

Equivalency Study using Clinical Specimens

A study using prospectively collected clinician-collected vaginal swab specimens was performed to demonstrate equivalence in performance of the Xpert Xpress MVP test between the original design (K212213) and the new design. The positive percent agreement (PPA) and negative percent agreement (NPA) of the new design of Xpert Xpress MVP for Bacterial Vaginosis (BV), Candida group, *Candida glabrata/Candida krusei* and *Trichomonas vaginalis* (TV) targets were determined relative to the original design (K212213) using clinical specimens to further support the equivalency claim for the two designs of the Xpert Xpress MVP test. Three sites in the United States participated in the prospective specimen collection, and one clinician-collected vaginal swab was collected from each symptomatic patient, defined as female patients ≥ 14 years of age who presented with signs and/or symptoms of vaginitis/vaginosis (including abnormal vaginal discharge; dysuria; vulvar/vaginal itching, burning, irritation, pain or vulvar edema; coital pain; or vaginal odor). The specimens were transported to Cepheid (Sunnyvale, CA) and all testing was performed by a trained operator at Cepheid.

A total of 174 participants were enrolled and provided 174 clinician-collected vaginal swabs (VS) for this study. Two VS specimens were not tested, as there was not enough volume in the specimen tubes upon receipt of the specimens to support testing with both the original design (K212213) and the new design of the Xpert Xpress MVP test. After initial testing,

three runs provided non-determinate results (2 INVALID and 1 ERROR). One specimen could not be retested as there was insufficient specimen volume remained. One run still resulted in a non-determinate result (INVALID) upon retesting. After retesting, one run yielded a valid result and was included in the final data analysis. The first two specimens could not be included in the final data analysis, as there were no valid results from both the original design (K212213) and the new design of the test for comparison. Therefore, a total of 170 prospectively collected ("fresh") VS specimens was included in the final data analysis for all targets. In addition, there were 20 contrived *C. glabrata* and *C. krusei* specimens for the Candida glab-krus target, and 20 contrived *T. vaginalis* specimens for the TV target.

As an attempt to further investigate specimens with discordant results (i.e. difference in test results between Xpert Xpress MVP original design (K212213) and new design), specimens were retested with both the original design (K212213) and the new design if enough specimen volume remained. The retest results were for information only and were not included in the final data analysis.

The overall performance of the Xpert Xpress MVP new design relative to the original design (K212213) is presented in Table 5-5. The results of the repeat testing are provided as footnotes to the table.

Table 5-5: Overall Performance of Xpert Xpress MVP New Design relative to the Original Design (K212213)

	PPA (95% CI)	**NPA (95% CI)**
BV	98.3% 56/57 [a] (90.6% - 100%)	99.1% 112/113 [b] (95.2% - 100%)
Candida group	97.4% 38/39 [c] (86.5% - 99.9%)	98.5% 129/131 [d] (94.6% - 99.8%)
Candida glab-krus Overall	100% 31/31 (90.8% - 100%)	100% 159/159 (98.1% - 100%)
Fresh	100% 11/11 (76.2% - 100%)	100% 159/159 (98.1% - 100%)
Contrived	100% 20/20 (86.1% - 100%)	N/A
TV Overall	100% 32/32 (91.1% - 100%)	100% 158/158 (98.1% - 100%)
Fresh	100% 12/12 (77.9% - 100%))	100% 158/158 (98.1% - 100%)

Contrived	100% 20/20 (86.1% - 100%)	N/A

N/A: Not Applicable

[a] There was one specimen that reported BV NEGATIVE test result with Xpert Xpress MVP new design but was BV POSITIVE with Xpert Xpress MVP original design (K212213). Upon retesting of this specimen, both the original design (K212213) and the new design reported BV POSITIVE test results.

[b] There was one specimen that reported BV POSITIVE test result with Xpert Xpress MVP new design but was BV NEGATIVE with Xpert Xpress MVP original design (K212213). Upon retesting of this specimen, the original design (K212213) reported BV POSITIVE test result and the new design reported BV NEGATIVE test result.

[c] There was one specimen that reported Candida group NOT DETECTED test result with Xpert Xpress MVP new design but was Candida group DETECTED with Xpert Xpress MVP original design (K212213). Upon retesting of this specimen, both the original design and the new design reported Candida group NOT DETECTED test results.

[d] There were two specimens that reported Candida group DETECTED test results with Xpert Xpress MVP new design but were Candida group NOT DETECTED with Xpert Xpress MVP original design (K212213). Upon retesting, both the original design (K212213) and the new design reported Candida group NOT DETECTED test results for these two specimens.

The investigation of both the false positive and false negative results showed that these specimens had Ct values close to the assay cut-off. This suggested that the discrepancies were most likely due to specimens which were near LoD or sub-LoD levels.

Of the 456 runs in this study (including external controls), four runs (4/456, 0.88%) provided non-determinate GeneXpert results (3 INVALID, 1 ERROR). Of these four non-determinates (ND), one run was from the 236 runs of the original design (K212213) and the overall non-determinate rate was 0.42% (1/236); three runs were from the 220 runs of the new design and the overall non-determinate rate was 1.4% (3/220).

Analytical Reactivity (Inclusivity)

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for Analytical Reactivity (Inclusivity) of the Xpert Xpress MVP test. No additional testing was conducted.

Analytical Specificity (Exclusivity)

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for Analytical Specificity (Exclusivity) of the Xpert Xpress MVP test. No additional testing was conducted.

Microbial Interference

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for Microbial Interference of the Xpert Xpress MVP test. No additional testing was conducted.

Competitive Interference

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for Competitive Interference of the Xpert Xpress MVP test. No additional testing was conducted.

Interfering Substances

The potentially inhibitory effects of substances encountered in vaginal specimens on the performance of the original design of the Xpert Xpress MVP test were evaluated in the absence or presence of MVP targets. Among all potentially interfering substances tested, clinically significant inhibitory effects were previously observed in the positive samples containing mucin at a concentration of 5.5% when tested with the original design of the Xpert Xpress MVP test. A retest at 4% concentration of mucin showed no interfering effect when tested with the original design of the Xpert Xpress MVP test. Refer to the Xpert Xpress MVP 510(k) #K212213 (Section 18.8 Potentially Interfering Substances Study Summary) for details.

The test conditions that had previously produced clinically and/or statistically significant inhibitory effects on the performance of the Xpert Xpress MVP original design (K212213) were also evaluated with the new design of the Xpert Xpress MVP test. The substances and concentrations tested are listed in Table 5-6. Potential interferents were tested in simulated vaginal swab matrix in the presence and absence of Xpert Xpress MVP test targets at 3× LoD or at 3× near cut-off concentrations (for BV analytes). With the exception of the 5.5% concentration of mucin (from porcine stomach), no clinically significant inhibitory effects from substances that may be encountered in vaginal specimens were observed on the performance of the new design of the Xpert Xpress MVP test. When mucin was tested at a concentration of 4.0%, no clinically significant inhibitory effect was observed on the performance of the new design of the Xpert Xpress MVP test. A limitation is included in the instructions for use indicating that interference was observed in samples containing mucin (≥5.5% v/v).

Table 5-6: Potential Interfering Substances Tested

Substance/Class	Active Ingredient	Concentration Tested
Blood	Blood	5.0% v/v
Mucus	Mucin	**5.5% v/v (Interference Observed)**
		4.0% v/v (No interference Observed)
Buffy Coat	Leukocytes	1.0×10^5 cells/mL
Intravaginal Hormones	Estradiol; Progesterone	7mg/mL Progesterone + 0.07mg/mL Beta Estradiol
Seminal Fluid	Semen	5.0% v/v
Over the Counter (OTC) Vaginal Products; Contraceptives; Vaginal treatments	Nonoxynol-9 12.5%	0.25% w/v
	Clotrimazole 2%	0.25% w/v
	Tioconazole 6.5%	0.25% w/v
	Benzocaine 5%; Resorcinol 2%	0.25% w/v
	5% w/w Acyclovir	0.25% w/v
	Glycerin; Carbomer	0.25% w/v
	Glycerin; Sodium Hydroxide; Carbomer	0.25% w/v
	Berberis Vulgaris 6X HPUS (Barberry), Borax 3X HPUS (Sodium Borate), Collinsonia Canadensis 3X HPUS (Stone Root), Hamamelis Virginiana 6X HPUS (Witch Hazel), Bacillus coagulans (Lactospore®)	0.25% w/v

Substance/Class	Active Ingredient	Concentration Tested
	Povidone-iodine 0.3%	0.25% v/v
	Povidone-iodine 10%	0.25% v/v
Hemorrhoidal Cream	Glycerin 14%; Pramoxine HCl 1%	0.25% w/v

Carry-Over Contamination

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for Carry-Over Contamination of the Xpert Xpress MVP test. No additional testing was conducted.

Time to Result

The time to result is defined as the time from the initiation of cartridge processing on the GeneXpert system to the time a result is displayed on the test screen. The time to result for the Xpert Xpress MVP test was determined by evaluating the test time of 50 random tests that were conducted as part of the Xpert Xpress MVP equivalency study with clinical specimens. The Xpert Xpress MVP test has a time to result of within 60 minutes, and the data from this study is representative for the GeneXpert Instrument Systems.

Reproducibility and Precision

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for reproducibility/precision of the Xpert Xpress MVP test. No additional testing was conducted.

5.5 Clinical Studies

Refer to the previously FDA-cleared 510(k) Premarket Notification, K212213 for clinical evaluation of the Xpert Xpress MVP test. Other than the Equivalency Study using Clinical Specimens presented in non-clinical study section, no additional clinical testing was conducted.

5.6 Conclusions

The results of the verification and validation studies summarized above demonstrated that the new design of the Xpert Xpress MVP test is substantially equivalent to the original design of the Xpert Xpress MVP (K212213, the predicate device).