510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K232967

B Applicant

bioMérieux, Inc.

C Proprietary and Established Names

VITEK 2 AST-Yeast Voriconazole (≤ 0.03125 – ≥4 µg/mL)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NGZ	Class II	21 CFR 866.1640 - Antimicrobial Susceptibility Test Powder	MI - Microbiology
LON	Class II	21 CFR 866.1645 - Fully automated short-term incubation cycle antimicrobial susceptibility system	MI - Microbiology
LRG	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology
LTT	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology
LTW	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for Voriconazole testing of *Candida* species on the VITEK 2 and VITEK 2 Compact Antimicrobial Susceptibility Test Systems.

B Measurand:

Voriconazole (≤ 0.03125 - ≥ 4 µg/mL)

C Type of Test:

Automated quantitative antifungal susceptibility test

III Intended Use/Indications for Use:

A Intended Use(s):
The VITEK 2 Fungal Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.

B Indication(s) for Use:
VITEK 2 AST-Yeast Voriconazole is designed for antifungal susceptibility testing of *Candida* species and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antifungal agents. VITEK 2 AST-Yeast Voriconazole is a quantitative test. Voriconazole has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antifungal.

Active *in vitro* and in clinical infections:
Candida krusei
Candida parapsilosis
Candida tropicalis

The VITEK 2 Fungal Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
Voriconazole (vrc02n): *Candida* spp.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination:
Voriconazole (vrc02n): *C. albicans*

D Special Instrument Requirements:

For use with the VITEK 2 and VITEK 2 Compact Systems using VITEK 2 Systems 9.04 software (or later)

IV Device/System Characteristics:

A Device Description:

The VITEK 2 AST card is a miniaturized, abbreviated and automated version of the doubling dilution technique for determining the minimum inhibitory concentration (MIC). Each VITEK 2 AST card contains 64 wells. A control well(s) which contain only nutrient medium is resident on all cards. The remaining wells contain premeasured portions of antimicrobials combined with the nutrient media. The isolate to be tested is diluted to a standardized concentration with 0.45 to 0.5% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System will automatically (or allow operator to manually) dilute the organism suspension to prepare an inoculum for susceptibility cards. Then, the VITEK 2 will fill, seal and place the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing, and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time. The analysis program determines when a well demonstrates growth based on attenuation of light measured by an optical scanner. This data is used to determine the minimum inhibitory concentration or "MIC" values for the antimicrobial agent. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK 2 AST-YS Voriconazole has the following concentrations in the card: 0.03125, 0.125, 0.25, 1, and 2 (equivalent standard method concentration by efficacy in μg/mL). The Voriconazole MIC result range for the VITEK 2 card is ≤0.03125 – ≥4 μg/mL.

B Principle of Operation:

The VITEK 2 and VITEK 2 Compact Systems utilize automated growth-based detection using attenuation of light measured by an optical scanner. The optics in the systems use visible light to directly measure organism growth within each of the 64 micro-wells. Transmittance optics is based on an initial light reading of a well before significant growth has begun. Every 15 minutes throughout the incubation cycle (defined period of time based on the VITEK 2 card), light transmittance readings of each well determine organism growth by the amount of light that is prevented from passing through the well. At the completion of the incubation period, the MIC values and their associated interpretive category results for each antimicrobial on the test card are displayed in an automatically generated report.

V Substantial Equivalence Information:

A Predicate Device Name(s):
VITEK 2 AST-YS Fluconazole (≤ 0. 5 - ≥ 64 μg/mL)

B Predicate 510(k) Number(s):
K213241

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K232967	Predicate: K213241
Device Trade Name	VITEK 2 AST-Yeast Voriconazole (≤ 0.03125 - ≥ 4 µg/mL)	VITEK 2 AST-YS Fluconazole (≤ 0. 5 - ≥ 64 µg/mL)
General Device Characteristic Similarities		
Indications for Use	VITEK 2 AST-Yeast Voriconazole is designed for antifungal susceptibility testing of *Candida* species and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antifungal agents. VITEK 2 AST-Yeast Voriconazole is a quantitative test. Voriconazole has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antifungal. The VITEK 2 Fungal Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.	VITEK 2 AST-Yeast Fluconazole is designed for antifungal susceptibility testing of *Candida* species and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antifungal agents. VITEK 2 AST-Yeast Fluconazole is a quantitative test. Fluconazole has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antifungal. The VITEK 2 Fungal Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.
Test Methodology	Automated quantitative antimicrobial susceptibility test for use with the VITEK 2 and VITEK 2 Compact Systems to determine the *in vitro* susceptibility of yeast.	Same
Inoculum	Saline suspension of organism	Same
Test card	VITEK 2 Yeast Susceptibility Test Card	Same
Instrument	VITEK 2 and VITEK 2 Compact Systems	Same
Analysis Algorithms	Discriminant Analysis	Same
General Device Characteristic Differences		
Claimed Species	Active in vitro and in clinical infections: *Candida krusei* *Candida parapsilosis* *Candida tropicalis*	Active *in vitro* and in clinical infections: *Candida albicans* *Candida parapsilosis* *Candida tropicalis*

Device & Predicate Device(s):	Device: K232967	Predicate: K213241
Antifungal Agent	Voriconazole	Fluconazole
Antimicrobial Concentrations (µg/mL)	0.03125, 0.125, 0.25, 1, 2	2, 4, 8, 16, 32, 64

VI Standards/Guidance Documents Referenced:

CLSI M27M44S, "Performance Standards for Antifungal Susceptibility Testing of Yeasts" Third Edition (August 2022)

CLSI M27, "Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeast" Fourth Edition (November 2017)

FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA (Issued August 28, 2009)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility testing for the VITEK 2 AST-Yeast Voriconazole was conducted at three sites (two external and one internal site) using a panel of ten *Candida* species consistent with the indications for use (i.e., one isolate of *Candida albicans*, two isolates of *Candida parapsilosis*, six isolates of *Candida krusei*, and one isolate of *Candida tropicalis*). Each isolate was tested in triplicate, using separate inocula, over three days for a total of 270 data points. Inocula were prepared using both the autodilution and manual dilution methods for testing with the VITEK 2 System. In addition, inocula were prepared by the manual dilution method for testing with the VITEK 2 Compact. The mode of MIC values was determined for each isolate and the reproducibility was calculated based on the number of MIC values that fell within ±1 and ± 2 doubling dilutions of the mode.

The testing resulted in overall best case reproducibility of >95% for autodilution and manual dilution in the VITEK 2 System as well as the VITEK 2 Compact System (manual dilution only) when evaluating both ±1 and ± 2 doubling dilutions of the mode. The overall worst case reproducibility was >89% for autodilution and manual dilution in the VITEK 2 System as well as the VITEK 2 Compact System (manual dilution only) when evaluating both ±1 and ± 2 doubling dilutions of the mode. The reproducibility data was acceptable.

Table 1. Reproducibility Performance

	VITEK 2				VITEK 2 Compact	
	Manual Dilution		Auto-Dilution		Manual Dilution	
	+/- 1 dilution of the mode	+/- 2 dilutions of the mode	+/- 1 dilution of the mode	+/- 2 dilutions of the mode	+/- 1 dilution of the mode	+/- 2 dilutions of the mode
Best Case	97.8%	100%	97.8%	100%	97.8%	100%
Worst Case	93.7%	95.9%	93.7%	95.9%	92.9%	95.2%

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable

4. Assay Reportable Range:

   Not applicable.

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

   Inoculum Density Check: The DensiCHEK Plus was used to standardize the inoculum to a 1.8-2 McFarland standard. The instrument was standardized daily with all results recorded at each site. Calibration values were within the expected range.

   Purity Check: A purity check of all organisms was performed on the dilution tube used to prepare the VITEK 2 card inoculum. Only those cultures that were pure were evaluated in the study.

   Growth or Device Failure: The VITEK 2 AST-YS Voriconazole trial had several device failures including isolated mechanical failures that did not repeat (card recognition, mechanical jam, failure to eject, dispenser/pipettor failure, communication errors and an optics failure). These errors did not raise concerns since they were isolated and did not reflect systematic issues. One clinical isolate of *C. parapsilosis* failed to grow.

   Quality Control Testing: The CLSI recommended QC strain *Candida krusei* (ATCC 6258) was tested a minimum of 20 times at each site by the reference method, the VITEK 2 instrument platform using both auto- and manual dilution methods, and the VITEK 2 Compact instrument platform using the manual dilution method. A summary of the QC performance is provided in **Table 2**.

   The quality control results for the VITEK 2 AST-YS Voriconazole were within the recommended range ≥95% which is acceptable.

Table 2. Quality Control Results for VITEK 2 AST-Yeast Voriconazole

Organism	VITEK 2 Result Range	BMD Result Range (µg/mL)	VITEK 2 Auto-Dilution	BMD	VITEK 2 Manual Dilution	BMD	VITEK 2 Compact Manual Dilution	BMD
C. krusei ATCC 6258 Expected Range: 0.06 – 0.5 µg/mL		≤0.004						
		0.0078						
		0.0156						
	≤0.0313	0.0313		2	2	2		2
	0.0625	0.0625	2	83	0	38		38
	0.125	0.125	119	45	63	25	66	25
	0.25	0.25	10	1	1	1		1
	0.5	0.5						
	1	1						
	2	2						
	≥4	4						
		≥8						

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Testing of Voriconazole was performed at three external sites and one internal site. Results obtained with VITEK 2 AST-Yeast Voriconazole were compared to results obtained with the CLSI broth microdilution reference panel. The MIC result range for the VITEK 2 AST-Yeast Voriconazole is ≤ 0.03125 - ≥ 4 µg/mL for all species. The testing conditions for the reference method consisted of the following:

   - Medium: RPMI 1640
   - Inoculum: Direct colony suspension
   - Incubation: 35ºC; 24 hours (up to 48 hours for isolates that are not growing well)

   The VITEK 2 cards were inoculated with test organisms using the auto-dilution method (VITEK 2) and using the manual dilution method (VITEK 2 and VITEK 2 Compact). All test inocula used for the VITEK 2 AST cards and the reference method were standardized using the DensiCHEK instruments. A total of 460 clinical isolates were evaluated using autodilution and VITEK 2. One isolate failed to grow in the VITEK 2 card. The results for the remaining 459 clinical isolates were evaluated. The majority of the isolates were recently isolated from clinical specimens and 201 of the 459 clinical isolates tested were from stock isolates (43.8%). The clinical isolates included: 257 *C. albicans* isolates, 67 *C. krusei* isolates, 61 *C. parapsilosis* isolates, and 74 *C. tropicalis* isolates.

The challenge set was composed of organisms listed in the Microbiology and Indication and Usage Sections of the FDA approved pharmaceutical package insert. A total of 76 challenge isolates including 41 *C. albicans* isolates, 9 *C. krusei* isolates, 13 *C. parapsilosis* isolates, and 13 *C. tropicalis* isolates were evaluated at two external sites and one internal site.

Clinical and Challenge Data – VITEK 2 Autodilution

The results obtained using the autodilution method of the VITEK 2 from the 535 total isolates (459 clinical isolates and 76 challenge isolates) are summarized in **Table 3**.

Table 3. Performance of *Candida* spp. for the Auto Dilution and the VITEK 2 AST-YS Voriconazole.

	Total	#EA	%EA	Eval EA Total	Eval EA #	Eval EA %	#CA	%CA	#R	#S	min	maj	vmj
Candida albicans* ≤0.125 (S), 0.25-0.5 (I), ≥1 (R)													
Clinical	216	188	87.0	32	14	43.8	181	83.4	8	200	28	3	4
Challenge	41	40	97.6	6	5	83.3	40	97.6	4	37	1	0	0
Combined	257	228	**88.7**	38	19	50.0	221	**86.0**	12	237	29	3	4
***Candida krusei* ≤0.5 (S), 1 (I), ≥2 (R)**													
Clinical	67	67	100.0	67	67	100.0	67	100.0	0	66	0	0	0
Challenge	9	9	100.0	9	9	100.0	8	88.9	0	8	1	0	0
Combined	76	76	**100.0**	76	76	100.0	75	**98.7**	0	74	1	0	0
***Candida parapsilosis* ≤0.125 (S), 0.25-0.5 (I), ≥1 (R)**													
Clinical	61	57	93.4	7	3	42.9	58	95.1	0	61	2	1	0
Challenge	13	13	100.0	2	2	100.0	12	92.3	1	11	1	0	0
Combined	74	70	**94.6**	9	5	55.6	70	**94.6**	1	72	3	1	0
***Candida tropicalis* ≤0.125 (S), 0.25-0.5 (I), ≥1 (R)**													
Clinical	74	72	97.3	16	14	87.5	66	89.2	1	67	6	2	0
Challenge	13	13	100.0	5	5	100.0	13	100.0	1	10	0	0	0
Combined	87	85	**97.7**	21	19	90.5	79	**90.8**	2	77	6	2	0

EA – Essential Agreement
CA – Category Agreement
EVAL – Evaluable isolates
R – Resistant
min – minor discrepancies
maj – major discrepancies
vmj – very major discrepancies
S – Susceptible

*Due to unacceptable performance, perform an alternative method of testing prior to reporting of results for voriconazole and *C. albicans*.

Essential agreement (EA) was calculated for when the VITEK 2 system results were within +/- two doubling dilutions of the reference method results. Evaluable results are those that are on-scale for both the reference method and VITEK 2 system or results in which an off-scale result is clearly more than two doubling dilutions from the on-scale result. Category agreement was calculated for when the VITEK 2 system result interpretations agreed exactly with the reference method result qualitative interpretations.

For *C. albicans* evaluated using VITEK 2 and autodilution, the overall EA and CA were 88.7% and 86.0%, respectively (**Table 3**) with 29 minor errors (11.3% of 257 isolates, 3 major errors (1.3% of 237 isolates), and 4 very major errors (33.3% of 12 isolates), which is not acceptable.

Due to the poor performance observed with *C. albicans*, this organism was removed from the Indications for Use.

For *C. krusei* evaluated using VITEK 2 and autodilution, the overall EA and CA were acceptable at 100% and 98.7%, respectively (**Table 3**), with one minor error (1.4% of 74 isolates). For *C. parapsilosis* evaluated using VITEK 2 and autodilution, the overall EA and CA were both acceptable at 94.6% (**Table 3**), with three minor errors (4.1% of 74 isolates) and 1 major error (1.4% of 72 susceptible isolates).or *C. tropicalis* evaluated using VITEK 2 and autodilution, the overall EA and CA were acceptable at 97.7% and 90.8%, respectively (**Table 3**), with 6 minor errors (6.9% of 87 isolates), and 2 major errors (2.6% of 77 susceptible isolates).

Challenge Data –VITEK 2 and VITEK 2 Compact Manual Dilution
The 76 challenge isolates were also evaluated with the manual dilution options of the VITEK 2 and VITEK 2 Compact systems (summarized in **Table 4**).

Table 4. Performance of *Candida* spp. for the Manual Dilution with the VITEK 2 and the VITEK 2 Compact Systems AST-YS Voriconazole

VITEK 2 Systems	Total	#EA	%EA	Eval Total	No Eval EA	Eval EA %	#CA	%CA	#R	#S	min	maj	vmj
***Candida albicans* ≤0.125 (S), 0.25-0.5 (I), ≥1 (R)**													
VITEK 2	41	40	**97.6**	6	5	83.3	39	**95.1**	4	37	1	1	0
VITEK 2 Compact	41	40	**97.6**	6	5	83.3	40	**97.6**	4	37	1	0	0
***Candida krusei* ≤0.5 (S), 1 (I), ≥2 (R)**													
VITEK 2	9	9	**100.0**	9	9	100.0	8	**88.9**	0	8	1	0	0
VITEK 2 Compact	9	9	**100.0**	9	9	100.0	8	**88.9**	0	8	1	0	0
***Candida parapsilosis* ≤0.125 (S), 0.25-0.5 (I), ≥1 (R)**													
VITEK 2	13	13	**100.0**	3	3	100.0	13	**100.0**	1	11	0	0	0
VITEK 2 Compact	13	13	**100.0**	3	3	100.0	13	**100.0**	1	11	0	0	0
***Candida tropicalis* ≤0.125 (S), 0.25-0.5 (I), ≥1 (R)**													
VITEK 2	13	12	**92.3**	5	4	80.0	12	**92.3**	1	10	1	0	0
VITEK 2 Compact	13	13	**100.0**	4	4	100.0	13	**100.0**	1	10	0	0	0

EA – Essential Agreement
CA – Category Agreement
EVAL – Evaluable isolates
R – Resistant
min – minor discrepancies
maj – major discrepancies
vmj – very major discrepancies
S – Susceptible

Essential agreement (EA) was calculated for when the VITEK 2 system results were within +/- two doubling dilutions of the reference method results. Evaluable results are those that are on-scale for both the reference method and VITEK 2 system or results in which an off-scale result is clearly more than two doubling dilutions from the on-scale result. Category agreement was calculated for when the VITEK 2 system result interpretations agreed exactly with the reference method result qualitative interpretations.

The overall EA and CA for *C. albicans* is >95% (**Table 4**), with the manual dilution option and the VITEK 2 and VITEK 2 COMPACT instruments, however due to the unacceptable overall clinical performance, this organism was removed from the Indications for Use.

The overall EA and CA for *C. parapsilosis* is >95% (**Table 4**), with the manual dilution option and the VITEK 2 and VITEK 2 COMPACT instruments, which is acceptable. For *C. krusei* and

the VITEK 2 manual dilution method, the overall EA was acceptable at 100.0%; however, the CA was 88.9% (**Table 4**), with one minor error (11.1% of 9 isolates) for both the VITEK 2 and VITEK 2 COMPACT systems. The AST guidance indicates a CA of < 90% may be acceptable if the EA of the evaluable test results is very good and the majority of the discrepancies as minor discrepancies; therefore, the CA performance was considered acceptable. For *C. tropicalis*, the overall EA and CA were >90%, with the manual dilution option and the VITEK 2 and VITEK 2 COMPACT instruments (**Table 4**), with 1 minor error (7.7% of 13 isolates), which is acceptable.

As required under 511A(b)(2)(C)(ii)(I) of the Federal Food, Drug and Cosmetic Act, the following statement was added to the package insert to address testing of non-indicated species:

> *Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.*

Resistant Strains
There were limited *Candida* spp. resistant isolates available for evaluation during clinical and challenge testing. The sponsor included the following limitation in the device labeling:

> *The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:*
> *• Voriconazole (vrc02n): Candida spp.*

MIC Trends:
A trending analysis was conducted using the combined data (clinical and challenge) obtained from the VITEK 2 auto-dilution method for each organism group. This trending calculation takes into account MIC values that are determined to be one or more doubling dilutions lower or higher than the reference method irrespective of whether the device MIC values are on-scale or not. Results that are not clearly at least one dilution lower, at least one dilution higher or in exact agreement with the CLSI reference method are not considered in the trending analysis.

Organism groups for which the difference between the percentage of isolates with higher vs. lower readings was > 30% and for which the confidence interval was determined to be statistically significant were considered to show evidence of trending. Trending that showed higher or lower MIC values compared to the reference is addressed in the labeling.

Table 5. Trending for *Candida* spp. with Voriconazole and the VITEK 2 Automated Dilution

Organism	Total Evaluable for Trending	≥ 1 Dilution lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Candida albicans	47	4 (8.5)	5 (10.6)	38 (80.9)	72.4 (54.7, 82.5)	Yes
Candida krusei	76	36 (47.4)	29 (38.2)	11 (14.5)	-32.9 (-45.6, -18.4)	Yes
Candida parapsilosis	10	0 (0.0)	2 (20.0)	8 (80.0)	60.0 (16.2, 80.3)	Yes
Candida tropicalis	33	17 (51.5)	4 (12.1)	10 (30.3)	-21.2 (41.7, -2.4)	No

A trend toward higher MIC values was observed for *C. albicans* and *C. parapsilosis* when compared to the CLSI broth microdilution reference method, as summarized in **Table 5**. The following statement is included as a footnote to the performance table in the device labeling to address the observed trending:

> *VITEK 2 Voriconazole MIC values for C. parapsilosis tended to be in exact agreement or at least one doubling dilution higher than the reference MIC values.*

A trend toward lower MIC values was observed for *C. krusei* when compared to the CLSI broth microdilution reference method, as summarized in **Table 5**. The following statement is included as a footnote to the performance table in the device labeling to address the observed trending:

> *Voriconazole MIC values for C. krusei tended to be in exact agreement or at least one doubling dilution lower than the reference MIC values*.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The FDA and CLSI susceptibility interpretive criteria for Voriconazole are as listed in **Table 6**.

Table 6. FDA Recognized Interpretive Criteria for Voriconazole

Organism	Minimum Inhibitory Concentrations (µg/mL) [1]		
	S	I	R
Candida krusei	≤0.5	1	≥2
Candida parapsilosis	≤0.125	0.25-0.5	≥1
Candida tropicalis	≤0.125	0.25-0.5	≥1

S = Susceptible; I = Intermediate; R = Resistant

[1] According to CLSI M27M44S, 3rd Edition and FDA STIC Website https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is not complete and does not support a substantial equivalence decision.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission incorporated by reference a breakpoint change protocol that was reviewed and accepted by FDA in submission K230864 cleared on July 3, 2023. The referenced protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria). The referenced protocol outlined the specific procedures and acceptance criteria that bioMérieux intends to use to evaluate the bioMérieux VITEK 2 AST-Yeast Voriconazole (≤ 0.03125 - ≥ 4 µg/mL) when revised breakpoints for Voriconazole are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, bioMérieux will update the VITEK 2 AST-Yeast Voriconazole device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.