510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K213899

B Applicant

bioMérieux, Inc.

C Proprietary and Established Names

VITEK 2 AST-Yeast Caspofungin (≤0.125 - ≥8 µg/mL), VITEK 2 AST-YS Caspofungin (≤0.125 - ≥8 µg/mL), VITEK 2 AST-YS Caspofungin

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	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 update the VITEK 2 AST Yeast Caspofungin device labeling to include updated, species-specific FDA-recognized interpretive criteria (i.e., breakpoints) for *Candida* spp., as published in the FDA STIC website.

Previously obtained QC and reproducibility data is applicable to this reevaluation.

B Measurand:

Caspofungin (≤ 0.125 - ≥ 8 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 vitr*o 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 Caspofungin 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 Caspofungin is a quantitative test. Caspofungin 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 albicans
Candida guillermondii
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

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Caspofungin (cas02n): *Candida krusei* when the MIC is 0.25-0.5 µg/mL (if critical to patient care)
- Caspofungin (cas02n): *Candida albicans* when the MIC is 0.25 µg/mL (if critical to patient care)
- Caspofungin (cas02n): *Candida tropicalis* when the MIC is 0.25 µg/ with the VITEK 2 and when the MIC is ≤0.125 µg/mL with the VITEK 2 Compact (if critical to patient care)"

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:

- Caspofungin (cas02n): *Candida albicans , C. guilliermondii, C. krusei, C. parapsilosis, C. tropicalis*

D Special Instrument Requirements:

For use with the VITEK 2 and VITEK 2 Compact Systems using VITEK 2 Systems 8.01 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 0.50% 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 Caspofungin has the following concentrations in the card: 0.125, 0.5, 2, and 8 (equivalent standard method concentration by efficacy in μg/mL). The caspofungin MIC result range for the VITEK 2 card is ≤0.125 – ≥8 μg/mL. For all species, the VITEK 2 system is capable of reporting the following MIC results: ≤0.125, 0.25, 0.5, 1, 2, 4 and ≥8 μg/mL for the AST-YS Caspofungin test.

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 Caspofungin ≤0.125 - ≥8 μg/mL

B Predicate 510(k) Number(s):
K151817

C Comparison with Predicate(s):

Device & Predicate Device(s):	**Device: K213899**	**Predicate: K151817**
Device Trade Name	VITEK 2 AST-YS Caspofungin	VITEK 2 AST-YS Caspofungin
General Device Characteristic Similarities		
Intended Use	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.	Same
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
Antimicrobial Agent	Caspofungin	Same
Inoculum	Saline suspension of organism	Same
Test Card	VITEK 2 Yeast Susceptibility Test Card	Same
Analysis Algorithms	Growth pattern Analysis	Same
Instrument	VITEK 2 and VITEK 2 Compact Systems	Same
Concentrations	0.125, 0.5, 2, 8	Same
Reporting Range	≤0.125 - ≥ 8 µg/mL	Same
General Device Characteristic Differences		
Claimed species	Active *in vitro* and in clinical infections: *Candida albicans* *Candida guilliermondii* *Candida krusei* *Candida parapsilosis* *Candida tropicalis*	Active *in vitro* and in clinical infections: *Candida albicans* *Candida glabrata* *Candida guilliermondii* *Candida krusei* *Candida parapsilosis* *Candida tropicalis*
Breakpoints for *Candida* spp.	*Candida albicans:* ≤0.25 (S), 0.5 (I), ≥1 (R) *Candida guilliermondii:*	*Candida* spp.: ≤2 (S), - (I),- (R)

Device & Predicate Device(s):	Device: K213899	Predicate: K151817
	≤2 (S), 4 (I), ≥8 (R) *Candida krusei:* ≤0.25 (S), 0.5 (I), ≥1 (R) *Candida parapsilosis:* ≤2 (S), 4 (I), ≥8 (R) *Candida tropicalis:* ≤0.25 (S), 0.5 (I), ≥1 (R)	

VI Standards/Guidance Documents Referenced:

- CLSI Document M27, "*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts*"; Fourth Edition (November 2017)
- CLSI Document M60, "*Performance Standards for Antifungal Susceptibility Testing of Yeast*"; Second Edition (June 2020)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Reproducibility of the VITEK 2 AST-YS Caspofungin was previously evaluated during review of K151817 and was determined to be acceptable.

   In summary, an 18-isolate panel representing species included in the intended use were tested at four sites using both inoculation methods (manual and automatic) for testing with the VITEK 2 and the manual inoculation method for testing with the VITEK 2 Compact.

2. Linearity:

   N/A

3. Analytical Specificity/Interference:

   N/A

4. Assay Reportable Range:

   N/A

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

   Quality Control (QC) testing, Inoculum and Growth failure for the VITEK 2 AST-YS Caspofungin were previously evaluated during review of K151817 and were determined to be acceptable. QC specific to the change in breakpoints was not performed since the QC

ranges used in K151817 were not changed.

In summary, the FDA and CLSI recommended QC strains, *Candida krusei* (ATCC 6258) and *Candida parapsilosis* (ATCC 22019), were tested a minimum of 20 times at each site by the reference broth microdilution method, the VITEK 2 (auto- and manual dilution methods), and the VITEK 2 Compact using the manual dilution method.

The quality control results for the VITEK 2 AST-YS Caspofungin were within the expected range ≥95% of the time, which is acceptable.

6. Detection Limit:
   N/A

7. Assay Cut-Off:
   N/A

B Comparison Studies:

1. Method Comparison with Predicate Device:

Performance after reanalysis and additional testing:
The VITEK 2 AST-YS Caspofungin was originally cleared in premarket submission K151817. Since there were no changes to the design or dilution range of the VITEK 2 AST card, performance evaluation was achieved via reanalysis of the MIC data provided in the original 510(k) submission (K151817) using revised interpretive criteria currently recognized by FDA for caspofungin against *Candida* spp. In summary, performance data for the five currently claimed *Candida* species (599 clinical isolates and 50 challenge isolates of *C. candida, C. guilliermondii, C. krusei, C. parapsilosis,* and *C. tropicalis*) were reanalyzed. An additional 31 challenge isolates were tested with both the automatic and manual dilution methods on the VITEK 2 and with the manual dilution method on the VITEK 2 Compact to address the insufficient number of challenge isolate results due to the removal of *C. glabrata* from the intended use and exclusion of the corresponding data, for a total of 75 challenge isolate results.

Table 1. Overall Performance Data of the Reanalyzed Original Clinical and Challenge Isolates and Additional Challenge Isolates with the VITEK 2 - Automatic Dilution.

	Tot	# EA	% EA	Eval Tot	# Eval EA	% Eval EA	CA Tot	% CA	# R	# Min	# Maj	# Vmj
***C. albicans* (Breakpoints (µg/mL): ≤0.25 S, 0.5 I, ≥1 R)**												
Clinical	452	451	99.8	7	6	85.7	450	99.6	1	1	0	1
Challenge	44	44	100.0	2	2	100.0	43	97.7	0	1	0	0
Total	496	495	99.8	9	8	88.9	493	99.4	1	2	0	1
***C. guilliermondii* (Breakpoints (µg/mL): ≤2 S, 4 I, ≥8 R)**												
Clinical	7	7	100.0	7	7	100.0	7	100.0	0	0	0	0
Challenge	3	3	100.0	3	3	100.0	3	100.0	0	0	0	0
Total	10	10	100.0	10	10	100.0	10	100.0	0	0	0	0
***C. krusei* (Breakpoints (µg/mL): ≤0.25 S, 0.5 I, ≥1 R)**												
Clinical	24	24	100.0	4	4	100.0	16	66.7	0	8	0	0
Challenge	6	6	100.0	1	1	100.0	3	50.0	0	3	0	0
Total	30	30	100.0	5	5	100.0	19	63.3	0	11	0	0

	Tot	# EA	% EA	Eval Tot	# Eval EA	% Eval EA	CA Tot	% CA	# R	# Min	# Maj	# Vmj
***C. parapsilosis* (Breakpoints (µg/mL): ≤2 S, 4 I, ≥8 R)**												
Clinical	75	75	100.0	71	71	100.0	75	100.0	0	0	0	0
Challenge	17	17	100.0	17	17	100.0	17	100.0	0	0	0	0
Total	92	92	100.0	88	88	100.0	92	100.0	0	0	0	0
***C. tropicalis* (Breakpoints (µg/mL): ≤0.25 S, 0.5 I, ≥1 R)**												
Clinical	41	41	100.0	1	1	100.0	41	100.0	0	0	0	0
Challenge	11	11	100.0	1	1	100.0	8	72.7	1	2	0	1
Total	52	52	100.0	2	2	100.0	49	94.2	1	2	0	1
***Candida* spp. (all)**												
Clinical	599	598	99.8	90	89	98.9	589	98.3	1	9	0	1
Challenge	81	81	100.0	24	24	100.0	74	91.4	1	6	0	1
Total	**680**	**679**	**99.9**	**114**	**113**	**99.1**	**663**	**97.5**	**2**	**15**	**0**	**2**

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

Essential Agreement (EA) occurs when there is agreement between the MIC result of the reference method and that of the VITEK 2 test card within plus or minus two serial two-fold dilutions of the antibiotic. Evaluable results are those that are on scale for both the VITEK 2 test card and the reference method or those in which an off scale result is at least two doubling dilutions from the on scale result. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the VITEK 2 test card.

Table 2. Overall Performance Data of the Reanalyzed Original and Additional Challenge Isolates with the VITEK 2 and VITEK 2 Compact - Manual Dilution.

	Tot	# EA	% EA	Eval Tot	# Eval EA	% Eval EA	CA Tot	% CA	# R	# Min	# Maj	# Vmj
***C. albicans* (Breakpoints (µg/mL): ≤0.25 S, 0.5 I, ≥1 R)**												
VITEK 2	44	44	100.0	1	1	100.0	43	97.7	0	1	0	0
VITEK 2 Compact	44	44	100.0	0	0	-	43	97.7	0	1	0	0
***C. guilliermondii* (Breakpoints (µg/mL): ≤2 S, 4 I, ≥8 R)**												
VITEK 2	3	3	100.0	3	3	100.0	3	100.0	0	0	0	0
VITEK 2 Compact	3	3	100.0	3	3	100.0	3	100.0	0	0	0	0
***C. krusei* (Breakpoints (µg/mL): ≤0.25 S, 0.5 I, ≥1 R)**												
VITEK 2	6	6	100.0	3	3	100.0	3	50.0	0	3	0	0
VITEK 2 Compact	6	6	100.0	4	4	100.0	4	66.7	0	2	0	0
***C. parapsilosis* (Breakpoints (µg/mL): ≤2 S, 4 I, ≥8 R)**												
VITEK 2	17	17	100.0	17	17	100.0	17	100.0	0	0	0	0
VITEK 2 Compact	17	17	100.0	17	17	100.0	17	100.0	0	0	0	0
***C. tropicalis* (Breakpoints (µg/mL): ≤0.25 S, 0.5 I, ≥1 R)**												
VITEK 2	11	10	90.9	1	0	0.0	8	72.7	1	2	0	1
VITEK 2 Compact	11	10	90.9	1	0	0.0	8	72.7	1	2	0	1

	Tot	# EA	% EA	Eval Tot	# Eval EA	% Eval EA	CA Tot	% CA	# R	# Min	# Maj	# Vmj
***Candida* spp. (all)**												
VITEK 2	**81**	**80**	**98.8**	**25**	**24**	**96.0**	**74**	**91.4**	**1**	**6**	**0**	**1**
VITEK 2 Compact	**81**	**80**	**98.8**	**25**	**24**	**96.0**	**75**	**92.6**	**1**	**5**	**0**	**1**

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

Essential Agreement (EA) occurs when there is agreement between the MIC result of the reference method and that of the VITEK 2 test card within plus or minus two serial two-fold dilutions of the antibiotic. Evaluable results are those that are on scale for both the VITEK 2 test card and the reference method or those in which an off scale result is at least two doubling dilutions from the on scale result. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the VITEK 2 test card.

The updated breakpoints for casponfungin with *Candida* spp. lowered the susceptible breakpoint by three-fold dilutions for some species and established the intermediate and resistant breakpoints for all *Candida* spp. As summarized in Table 1, applying the updated breakpoints with the VITEK 2 automatic dilution method for *Candida* spp. and excluding data from *C. glabrata* did not affect the combined Essential Agreement, but did reduce the combined Category Agreement from 99.8% in K151817 to 97.5% in the current submission due to an increase in minor errors from 0 (0%) to 15 (2.2%). As summarized in Table 2, applying the updated breakpoints with the VITEK 2 and VITEK 2 Compact with the manual dilution method for *Candida* spp. and excluding data from *C. glabrata* reduced the combined Essential Agreement from 100% in K151817 to 98.8% in the current submission as well as the Category Agreement from 100% to 91.4% for the VITEK 2 and 92.6% for the VITEK 2 Compact due to an increase in minor errors from 0 (0%) to 5 (6.3%) and very major errors from 0 (0%) to 1 (100%).

When evaluating performance data at the individual species-level, *C. krusei* had 11 (36.7%) minor errors with the VITEK 2 automatic dilution method, three (50%) minor errors with the VITEK 2 manual dilution method, and two (33%) minor errors with the VITEK 2 Compact. All *C. krusei* minor errors occurred at a VITEK MIC value of ≤0.125 or 0.25 µg/mL and were in essential agreement with the reference method.

C. albicans had one (100%) very major error at a VITEK MIC value of 0.25 µg/mLwith the VITEK 2 automatic dilution method and one minor error with both the VITEK 2 and VITEK 2 Compact with the manual dilution method.

C. tropicalis had two minor errors with the VITEK 2 (automatic and manual dilution) and VITEK 2 Compact and one (100%) very major error at a VITEK MIC value of 0.25 µg/mL with the VITEK 2 (automatic and manual dilution methods) and a VITEK MIC value of ≤0.125 µg/mL with the VITEK 2 Compact.

The following limitation was added to the package insert to address the minor and very major errors errors observed:

"Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Caspofungin (cas02n): *Candida krusei* when the MIC is 0.25-0.5 µg/mL (if critical to patient care)
- Caspofungin (cas02n): *Candida albicans* when the MIC is 0.25 µg/mL (if critical to patient care)
- Caspofungin (cas02n): *Candida tropicalis* when the MIC is 0.25 µg/ with the VITEK 2 and when the MIC is ≤0.125 µg/mL with the VITEK 2 Compact (if critical to patient care)"

In addition, to explain the very major errors observed, the following statement is included as a footnote to the performance table in the device labeling:

"One very major error was observed for *C. albicans* and one very major error was observed for *C. tropicalis* using the VITEK 2 (both the automatic and manual dilution methods). Each very major error was the only resistant isolate tested and was within essential agreement with the reference method. One very major error was observed for *C. tropicalis* using the VITEK 2 Compact. This very major error was the only resistant isolate tested and was not within essential agreement with the reference method."

Due to the lack of resistant organisms available for testing, the following limitation statement was added to the package insert:

"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:

- Caspofungin (cas02n): *Candida albicans, C. guilliermondii, C. krusei, C. parapsilosis, C. tropicalis"*

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."

MIC Trending Analysis:

An analysis of trending was conducted using the combined clinical and challenge data. This trending calculation considers MIC values that are determined to be one or more doubling dilutions lower or higher compared to 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.

Species for which the difference between the percentage of isolates with higher vs. lower MIC values 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 labeling.

Table 3. Trending Analysis for VITEK 2 Caspofungin.

Trending Analysis VITEK 2 Caspofungin (Clinical and Challenge Isolates) Automatic Dilution						
Organism	**Total Evaluable for Trending**	**≥ 1 Dilution lower No. (%)**	**Exact No. (%)**	**≥ 1 Dilution Higher No. (%)**	**Percent Difference (CI)**	**Trending Noted**
C. albicans	168	161 (95.8%)	2 (1.2%)	5 (3.0%)	-92.9% (-95.6%, -87.2%)	Yes
C. guilliermondii	10	7 (70.0%)	3 (30.0%)	0 (0.0%)	-70.0% (-89.2%, -28.9%)	Yes
C. krusei	21	18 (85.7%)	3 (14.3%)	0 (0.0%)	-85.7% (-95.0%, -60.2%)	Yes
C. parapsilosis	91	65 (71.4%)	23 (25.3%)	3 (3.3%)	-68.1% (-76.7%, -56.5%)	Yes
C. tropicalis	17	16 (94.1%)	0 (0.0%)	1 (5.9%)	-88.2% (-95.1%, -5.8%)	Yes
All *Candida* spp.	307	267 (87.0%)	31 (10.1%)	9 (2.9%)	-84.0% (-87.6%, -79.1%)	Yes

A trend toward lower MIC values was observed for *C. albicans, C. guilliermondii, C. krusei, C parapsilosis, and C. tropicalis* when compared to the CLSI broth microdilution reference method, as summarized in Table 3. The following statement is included as a footnote to the performance table in the device labeling to address the observed trending:

> "VITEK 2 Caspofungin MIC values tended to be in exact agreement or at least one doubling dilution lower when testing *Candida albicans, Candida guiliermondii, Candida krusei, Candida parapsilosis, and Candida tropicalis* compared to the broth microdilution reference method."

2. Matrix Comparison:
   N/A

C Clinical Studies:

1. Clinical Sensitivity:
   N/A

2. Clinical Specificity:
   N/A

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

D Clinical Cut-Off:
N/A

E Expected Values/Reference Range:
The FDA and CLSI susceptibility interpretive criteria for Caspofungin are as listed in Table 4.

Table 4. FDA Recognized Interpretive Criteria for Caspofungin

	Minimum Inhibitory Concentrations (µg/mL)[a]		
Organisms	**S**	**I**	**R**
Candida albicans	≤0.25	0.5	≥1
Candida krusei	≤0.25	0.5	≥1
Candida tropicalis	≤0.25	0.5	≥1
Candida guilliermondii	≤2	4	≥8
Candida parapsilosis	≤2	4	≥8

S = Susceptible; I = Intermediate; R = Resistant
[a]According to CLSI M60-Ed2 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 complete and supports a substantial equivalence decision.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a breakpoint change protocol that was reviewed and accepted by FDA. This 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/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The protocol outlined the specific procedures and acceptance criteria that bioMérieux intends to use to evaluate the BioMerieux VITEK2 AST-Yeast Caspofungin (≤0.125 - ≥8 µg/mL) when revised breakpoints for Caspofungin are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, BioMerieux will update the Caspofungin 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.