

SPECIAL 510(k): Device Modification
 ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K_092919

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
MicroScan® Synergies plus® Gram-Positive MIC/Combo Panels k060312
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The modification was

- Updating of the product labeling with *S. aureus* interpretive criteria of $S \leq 2$; $I = 4 - 8$; $R \geq 16$

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

Similarities		
Item	Current	Modified
Product Name	MicroScan® Synergies plus® Gram-Positive MIC/Combo Panels	Same
Intended use	Determination of susceptibility to Vancomycin with gram-positive enterococci and staphylococci	Same
Technologies	Fully Automated Short-Term (16 hours) Incubation Cycle Microdilution MIC Susceptibility Tests Overnight Microdilution MIC Susceptibility Tests	Same
Antibiotic	Vancomycin 0.25 – 64 µg/mL	Same
Labeling Limitations	<i>S. aureus</i> isolates with MICs of 8 – 16 µg/mL on MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panels will be held to 16/18 hours for overnight instrument or visual reporting of vancomycin.	Same
Differences		
Item	Current	Modified
<i>S. aureus</i> Interpretive Criteria	≤ 4 (S), $8 - 16$ (I), ≥ 32 (R)	$S \leq 2$; $I = 4 - 8$; $R \geq 16$

5. A **Design Control Activities Summary** which includes:

- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
- c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The design control activities performed

Vancomycin, on MicroScan® Synergies plus™ Gram-Positive Panels, was evaluated and cleared (K060312) with three read methods Rapid (WalkAway® SI, <16 hours), Overnight Instrument (WalkAway® SI, 16/18 hours) and Overnight Manual (manual/visual read, 16-20 hours), by comparing Dried panel performance with frozen Reference Panels using stock and fresh isolates (Efficacy phase), challenge strains (Challenge phase), and QC strains (QC testing). Challenge strains were compared to Expected Results determined prior to the evaluation.

Data collected from the external validation of vancomycin (K060312) was processed using the modified *S. aureus* interpretive criteria ($S \leq 2$, $I = 4 - 8$, $R \geq 16$). The Microdilution Inhibitory Concentration (MIC) interpretive standards for vancomycin were modified by the Clinical Laboratory Standards Institute (CLSI) in January 2006. Reference CLSI Document M100 – S16 (*Performance Standards for Antimicrobial Susceptibility Testing; Sixteenth Informational Supplement*). These revised interpretive criteria were approved by the FDA for drug manufacturer, Baxter Healthcare, Inc., in April of 2008.

The gram-positive Vancomycin Efficacy phase was conducted with a total of five hundred and forty nine (549) isolates, including seventy three (73) stock and four hundred and seventy six (476) fresh clinical isolates. The Challenge phase was conducted with 78 challenge isolates. The combined Rapid Read results, from the Efficacy and Challenge studies, demonstrated overall Essential Agreement of 97.6% (565/579) and Categorical Agreement of 97.9% (567/579) when processed using the modified *S. aureus* interpretive criteria ($S \leq 2$, $I = 4 - 8$, $R \geq 16$).

Below is a summary of the performance of *S. aureus* with the **new interpretive criteria** using the different read methods

Read Method	Organism	No. Tested	Essential Agreement	Categorical Agreement	Min Errors	Maj Errors	Very Maj Errors
Rapid Dried <16 hours	All	579	565/579 (97.6)	567/579 (97.9)	7 (1.2)	5 (1.0)	0
Dried Overnight Instrument	All	627	613/627 (97.8)	615/627 (98.1)	9 (1.4)	3 (0.6)	0
Dried Overnight Manual	All	627	616/627 (98.2)	618/627 (98.6)	7 (1.1)	2 (0.4)	0
Rapid Dried <16 hours	<i>S. aureus</i> only	208	205/208 (98.6)	205/208 (98.6)	2 (1.0)	1 (0.5)	0
Dried Overnight Instrument	<i>S. aureus</i> only	208	205/208 (98.6)	204/208 (98.1)	3 (1.4)	1 (0.5)	0
Dried Overnight Manual	<i>S. aureus</i> only	208	207/208 (99.5)	206/208 (99)	2 (1.0)	0	0

NOTE: Efficacy and Challenge total for the Rapid Instrument Read Method equaled 579 isolates. Results for 42 Efficacy isolates and 6 Challenge isolates were not reported due to read times ≥ 16 hours. The 3 VRSA isolates are included in the Combined Efficacy and Challenge data.

The table below reflects performance of *S. aureus* using the **old interpretive criteria** as presented in k060312

Read Method	Organism	No. Tested	Essential Agreement	Categorical Agreement	Min Errors	Maj Errors	Very Maj Errors
Rapid Dried <16 hours	<i>S. aureus</i> only	208	204/207 (98.6)	205/208 (98.6)	0	1 (0.5)	0
Dried Overnight Instrument	<i>S. aureus</i> only	208	205/208 (98.6)	204/207 (98.6)	0	1 (0.5)	0
Dried Overnight Manual	<i>S. aureus</i> only	208	208/208 (100)	206/207 (99.2)	0	0	0

There were more minor errors observed with the new interpretive criteria for *S. aureus*, specifically, there were 2 minor errors with the Rapid read method (<16 hours), 3 minor errors with the dried overnight instrument method, and 2 minor errors with the dried overnight manual method. However, the number of minor errors is within the acceptable limits as recommended in the Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems. There were no minor errors observed with *S. aureus* using the old interpretive criteria. The number of major errors did not change when either the old or new interpretive criteria were used with all read methods. Considering the EA and CA of >97%, the overall performance of *S. aureus* with the new interpretive criteria is acceptable.

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.