

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY**

A. 510(k) Number:

K083536

B. Purpose for Submission:

New instrument added to the Vitek® and VITEK®2 Systems

C. Manufacturer and Instrument Name:

BioMérieux Inc DensiCHECK™ Plus

D. Type of Test or Tests Performed:

Growth based

E. System Descriptions:

1. Device Description:

The DensiCHEK™ Plus instrument is designed for use with the VITEK® and VITEK®2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to microorganism concentrations. It is intended for use with the VITEK and VITEK 2 Systems during the inoculum preparation phase of the identification (ID) and Antimicrobial Susceptibility Test (AST) card testing process.

2. Principles of Operation:

The DensiCHEK™ Plus generates a McFarland value using basic colorimetry, which is a method of measurement that relates the amount of color in a transparent medium (liquid) to the amount of a particular substance in the liquid. In the general the concentration of the substance being measured is proportional to the intensity of the color of the solution. The darker the color is, the higher the concentration.

The DensiCHEK™ Plus measures the turbidity of the saline and microorganism suspension using a single wavelength, 580 nm. The absorption of light determines the McFarland value generated by the instrument. The more turbid the suspension is, the higher the McFarland standard measurement. The light source in the DensiCHEK™ Plus is an LED that emits a narrow range of wavelengths, and an interference filter is used between the LED and the test tube (sample) to further narrow the wavelength of 580 nm. There are 2 calibration curves pre-programmed

into the DensiCHEK™ Plus, one for glass tubes and one for plastic tubes. The absorbance is different for glass and plastic. The instrument is first zeroed using a test tube filled with saline (blank). A well-mixed organism suspension is placed into the instrument and the test tube is slowly rotated. The instrument will display a series of dashes followed by a McFarland reading.

A set of verification standards consisting of a 0.0 McFarland (McF), 0.5 McF, 2.0 McF, and 3.0 McF are provided with the DensiCHEK™ Plus to verify instrument measurement performance. After zeroing the instrument with the 0.0 McF standard (blank), one or all of the standards may be used to verify the accuracy of measurements before using the DensiCHEK™ Plus to prepare inoculum suspension for VITEK® and VITEK® 2 Test cards.

3. Modes of Operation:

Manual, only one test tube can be read with the DensiCHEK™ Plus at a time.

4. Specimen Identification:

Not applicable

5. Specimen Sampling and Handling:

Not applicable

6. Calibration:

Instrument verification is performed using one or more of the McFarland standards (0.5, 2.0, or 3.0) after zeroing the instrument with the 0.0 McFarland Standard blank.

7. Quality Control:

Not applicable

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes___X___ or No_____

F. Regulatory Information:

1. Regulation section:

21 CFR 866. 1645

2. Classification:

II

3. Product code:

LON

4. Panel:

83 Microbiology

G. Intended Use:

1. Indication(s) for Use:

The DensiCHEK™ Plus instrument is intended for use with the VITEK® and VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to microorganism concentrations. DensiCHEK™ Plus is indicated for use with polystyrene and glass test tubes and the reading range is 0.0 – 4.0 McFarland. The DensiCHEK™ Plus has applications as an *in vitro* diagnostic device.

2. Special Conditions for Use Statement(s):

VITEK® and VITEK® 2 Systems

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

VITEK2 Compact k050002

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	measure the amount of bacteria suspended in liquid medium and convert that optical density into a McFarland standard	Same
Light source	LED	Same
Display	digital reading	Same
Differences		
Item	Device	Predicate
LED	580 nm	590 nm
Instrument	designed to prepare inoculum suspensions for the VITEK® and VITEK®2 systems	designed to prepare inoculum suspensions for the VITEK®2 systems
Power supply	4 AAA batteries, either alkaline or nickel-metal hydride (NIMH)	AC/DC power supply source or a lithium battery
Test tube	glass or plastic (polystyrene) test tubes	polystyrene only
Reading Range	0 to 4.0 McFarland	0 to 4.5 McFarland

I. Special Control/Guidance Document Referenced (if applicable):

“Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA”; CLSI M7 (M100-S18) “Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard.”

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

Quality Control - VITEK® System

Quality control testing of the DensiCHEK™ Plus was conducted and its performance was compared to that of the Colorimeter, the designated method of reference. More specifically, antimicrobial susceptibility results obtained from the use of bacterial suspensions prepared using the DensiCHEK™ Plus in conjunction with the VITEK® GNS-140 and GPS-119 test cards, were

compared to the antimicrobial results obtained from the use of bacterial suspensions prepared using the Colorimeter in conjunction with the VITEK® GNS-140 and GPS-119 test cards. Both glass and polystyrene 12 X 75mm tubes were evaluated. The quality control organisms tested for each test card type were as follows:

VITEK GNS-140

- *E. coli* ATCC 25922
- *P. aeruginosa* ATCC 27853
- *E. coli* ATCC 35218
- *E. faecalis* ATCC 29212
- *E. coli* ATCC 51446

VITEK GPS-119

- *E. faecalis* ATCC 29212
- *S. aureus* ATCC 29213
- *E. coli* ATCC 35218
- *K. pneumoniae* ATCC 700603

Quality control testing of glass and polystyrene tubes was conducted at individual clinical sites. The results for the GNS-140 test card with glass tubes revealed 100% quality control within acceptable range for the DensiCHEK™ Plus and the Colorimeter for all QC organisms tested.

The results of the GNS-140 test card with the polystyrene tubes revealed the following:

- 98.3% of QC results fell within acceptable range for the DensiCHEK™ Plus with QC *P. aeruginosa*, ATCC 27853. One out of a total of 60 QC results was out of range high with Cefotaxime.
- 100% of QC results fell within acceptable range for the DensiCHEK™ Plus with QC *E. coli* ATCC 25922, *E. coli* ATCC 35218, *E. coli* ATCC 51446 and *E. faecalis* ATCC 29212.
- 100% of QC results fell within acceptable range for the Colorimeter for all QC organisms tested.

The results of the GPS-119 test card with the glass tubes revealed the following:

- 96.7% of QC results fell within acceptable range for the DensiCHEK™ Plus with QC *S. aureus* ATCC 29213. Two out of a

total of 60 QC results fell one 2-fold dilution out of range high with Oxacillin.

- 98.1% of QC results fell within acceptable range for the DensiCHEK™ Plus with QC *E. faecalis* ATCC 29212. One out of a total of 52 QC results was found to be resistant for high-level Gentamicin.
- 100% of QC results fell within acceptable range for the DensiCHEK™ Plus with QC *E. coli* ATCC 35218 and *E. faecalis* ATCC 51299.
- 100% of QC results fell within acceptable range for the Colorimeter for all QC organisms tested.

In summary, all quality control testing of designated bacterial isolates using the VITEK® System, glass and polystyrene tubes, in conjunction with the gram-negative and gram-positive susceptibility cards, fell within acceptable range greater than or equal to 95% of the time.

Quality Control – VITEK® 2 System

Quality control testing of the DensiCHEK™ Plus was conducted and its performance was compared to that of the DensiCHEK™, the designated method of reference. More specifically, antimicrobial susceptibility results obtained from the use of bacterial suspensions prepared using the DensiCHEK™ Plus in conjunction with the VITEK 2 AST-GN13 test cards and AST-GP66 test cards, were compared to the antimicrobial results obtained from the use of bacterial suspensions prepared using the DensiCHEK™ in conjunction with the VITEK 2 AST-GN13 test cards and AST-GP66 test cards. In accordance with the product labeling, only polystyrene 12 X 75mm tubes were evaluated. The quality control organisms tested for each test card type were as follows:

VITEK® 2 AST-GN13

- *E. coli* ATCC 25922
- *P. aeruginosa* ATCC 27853
- *E. coli* ATCC 35218
- *K. pneumoniae* ATCC 700603

VITEK® 2 AST-GP66

- *E. faecalis* ATCC 29212
- *S. aureus* ATCC 29213
- *E. faecalis* ATCC 51299
- *S. aureus* ATCC BAA-1026

Quality control testing of the polystyrene tubes was each conducted at one clinical site. The results for the AST-GN13 test card with polystyrene tubes revealed 100% quality control within acceptable range for the DensiCHEK™ Plus and the DensiCHEK™ for all QC organisms tested.

The results for the AST-GP66 test card with polystyrene tubes revealed 100% quality control within acceptable range for the DensiCHEK™ Plus and the DensiCHEK™ for all QC organisms tested.

In summary, all quality control testing of designated bacterial isolates using the VITEK® 2 System, polystyrene tubes, in conjunction with the gram-negative and gram-positive susceptibility cards, fell within acceptable range greater than or equal to 95% of the time.

b. Precision/Reproducibility:

VITEK® System

Reproducibility testing was performed using isolate suspensions prepared using the DensiCHEK™ Plus in conjunction with the VITEK® System with both glass and polystyrene 12 X 75mm tubes. A panel of 10 gram negative isolates and 10 gram positive isolates were tested at each of three study sites, in triplicate, each of three days. The VITEK® GNS-140 and VITEK® GPS-119 test cards were used for the testing of the gram negative and gram positive organisms, respectively. A representative drug from each test card was analyzed to assess device performance. More specifically, Ampicillin/Sulbactam was evaluated on the VITEK® GNS-140 test card and Levofloxacin was evaluated on the VITEK® GPS-119 test card.

Evaluation of the results from all sites of Ampicillin/Sulbactam on the VITEK® GNS-140 test card revealed an overall best-case reproducibility of 99.6% and worst-case reproducibility of 97.8% agreement for glass tubes. Results revealed, for polystyrene tubes, an overall best-case reproducibility of 100% and worst-case reproducibility of 97.8% agreement.

Evaluation of the results from all sites of Levofloxacin on the VITEK® GPS-119 test card revealed an overall best-case reproducibility of 99.6% and worst-case reproducibility of 97.8% agreement for glass tubes. Results revealed, for polystyrene tubes, an overall best-case reproducibility of 100% and worst-case reproducibility of 98.5% agreement.

VITEK® 2 System

Reproducibility testing was performed using isolate suspensions prepared using the DensiCHEK™ Plus in conjunction with the VITEK® 2 System with 12 X 75mm polystyrene tubes. A panel of 10 gram negative isolates and 10 gram positive isolates were tested at each of three study sites, in triplicate, each of three days. The VITEK® 2 AST-GN13 and VITEK® 2 AST-GP66 test cards were used for the testing of the gram negative and gram positive organisms, respectively. A representative drug from each test card was analyzed to assess device performance. More specifically, Levofloxacin was evaluated on the VITEK® 2 AST-GN13 test card and Vancomycin was evaluated on the VITEK® 2 AST-GP66 test card.

Evaluation of the results from all sites of Levofloxacin on the VITEK® 2 AST-GN13 test card revealed an overall best-case reproducibility of 100% and worst-case reproducibility of 100% agreement.

Evaluation of the results from all sites of Vancomycin on the VITEK® 2 AST-GP66 test card revealed an over all best-case reproducibility of 100% and worst-case reproducibility of 95.2% agreement.

Note: VITEK® 2 reproducibility testing was conducting utilizing 12 X 75mm polystyrene tubes only. Glass tubes cannot be used with VITEK® 2 Systems per product labeling.

c. *Linearity*: Not Applicable

d. *Carryover*: Not Applicable

e. *Interfering Substances*: Not Applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

Not applicable

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.