February 8, 2024

Regulatory Affairs Specialist
MDC Associates
180 Cabot Street
Beverly, Massachusetts 01915

Re: K231536
Trade/Device Name: eQUANT System
Regulation Number: 21 CFR 866.1650
Regulation Name: A Cellular Analysis System For Multiplexed Antimicrobial Susceptibility Testing
Regulatory Class: Class II
Product Code: QZX, JTN
Dated: May 26, 2023
Received: May 30, 2023

Dear Katie Hahnemann:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K231536

Device Name
eQUANT System

Indications for Use *(Describe)*
The eQUANT System is an automated inoculum preparation system that uses potentiometric sensing of oxidation-reduction potential changes due to pathogen metabolism to generate a 0.5 McFarland-equivalent suspension (the eMcFarland or eMcF) from positive blood culture samples that can be used for direct, qualitative *in vitro* susceptibility testing by the agar disk diffusion test method (Kirby-Bauer). Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system and confirmed as Gram-negative rods by Gram stain. Organism identification must be confirmed by an FDA cleared device for direct testing from positive blood culture before processing samples on the eQUANT System.

Evaluation of the eQUANT System's inoculum preparation was conducted for use with agar disk diffusion susceptibility testing and performance was demonstrated for the following antimicrobial agents with Enterobacterales species, Acinetobacter species and Pseudomonas aeruginosa as identified below:

Amoxicillin/clavulanate- *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis*

Ampicillin- *Escherichia coli*

Aztreonam- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and P*seudomonas aeruginosa*

Cefazolin- *Klebsiella pneumoniae*

Cefepime- *Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and *Pseudomonas aeruginosa*

Ceftriaxone- C*itrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

Ertapenem- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

Gentamicin- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and *Pseudomonas aeruginosa*

Levofloxacin- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and *Pseudomonas aeruginosa*

Meropenem- *Acinetobacter* spp., *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and *Pseudomonas aeruginosa*

Piperacillin/tazobactam- *Acinetobacter* spp., *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and *Pseudomonas aeruginosa*

Tobramycin- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca*,

*Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*, and *Pseudomonas aeruginosa*

Susceptibility test results are intended to be used in conjunction with other clinical and laboratory findings. Standard laboratory protocols for processing positive blood cultures should be followed to ensure availability of isolates for supplemental testing as needed. Additionally, subculture of positive blood culture is necessary for the susceptibility testing of organisms present in polymicrobial samples, for testing antimicrobial agents and species not indicated for testing with the device, for epidemiologic testing, and for recovery of organisms present in microbial samples.

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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# 510(k) Summary

The summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

## 1. Contact Details

**Sponsor:** Avails Medical, Inc.
1455 Adams Drive
Menlo Park, CA 94025

**Correspondent:** MDC Associates, Inc.
Katie Hahnemann, Ph.D.
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Beverly, MA 01915
(978) 927-3808
avails@mdcassoc.com

## 2. Device

**Device Trade Name:** eQUANT™ System

**Common Name:** eQUANT™ System

**Classification Name:** Class II (special controls)

**Regulation Number:** 866.1650

Device Type: A cellular analysis system for multiplexed antimicrobial susceptibility testing

**Product Code:** QZX, JTN

**Predicate Device:** Accelerate Pheno System, Accelerate PhenoTest BC Kit (K192665)

### 3. Device Description Summary

The eQUANT™ System is an automated system that uses potentiometric sensing of changes in oxidation-reduction potential (ORP) during pathogen metabolism to prepare an organism concentration equivalent to a 0.5 McFarland (1-2e8 CFU/ml ± 0.6 log) directly from a positive blood culture. The eQUANT™ System consists of four components: the eQUANT™ Instrument, a single use eTube™ Disposable, a single use eQUANT™ Reagent tube (CAMHB with antifoam), and a workflow tray.

The eQUANT™ System processes a single positive blood culture sample at a time. Before processing on the eQUANT™ System, the positive blood culture is confirmed as Gram-negative rods by Gram stain, and a rapid FDA-cleared identification (ID) method for testing from positive blood culture is performed to confirm organism ID. Mixed cultures or organisms identified that are not included in the eQUANT™ System indications for use should not be processed on the eQUANT™ System. Positive blood cultures must be processed immediately on the eQUANT™ System or within 12 hours of blood culture bottle positivity should delays be unavoidable. Once the organism ID is confirmed, 1 mL of eQUANT™ Reagent (cation-adjusted Mueller Hinton broth (CAMHB) supplemented with antifoam (0.0015%) to reduce air bubble formation) is added to the eTube™ Disposable, followed by the addition of 34 µL of the positive blood culture. The eTube™ Disposable with diluted sample is vortexed and then placed in the eQUANT™ System for incubation.

Once inserted, the eTube™ Disposable sits in a thermal module which is heated to 37°C ± 2°C to grow the bacteria to a concentration equivalent to a 0.5 McFarland (eMcFarland, or eMcF). The eQUANT™ Sensor located in the eTube™ Disposable is an ORP sensor consisting of two electrode components, which both come into direct contact with the diluted positive blood culture sample. The eQUANT™ ORP sensor responds to changes in the ORP during pathogen growth/metabolism. As the concentration of microorganisms in the sample increases, the growth media becomes reduced, and the voltage measured by the ORP sensor becomes more negative. With the organism ID of the tested sample and the blood culture bottle type as inputs to the system, the algorithm is applied to the real-time voltage measurements to determine the point in time at which the organism concentration reaches a level equivalent to a standard 0.5 McFarland. At the endpoint, the sample immediately starts to cool down to 15°C ± 2°C to inhibit further growth. The sample can be held for up to one (1) hour on the instrument, before being used for downstream Disk Diffusion AST testing.

**4. Intended Use/Indications for Use**

**Intended Use**:

The eQUANT™ System is an automated inoculum preparation system that uses potentiometric sensing of oxidation-reduction potential changes due to pathogen metabolism to generate a 0.5 McFarland-equivalent suspension (the eMcFarland or eMcF) from positive blood culture samples. Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system and confirmed as Gram-negative rods by Gram stain. Organism identification, as determined by an FDA cleared device for direct testing from positive blood culture, must be available before processing samples on the eQUANT™ System.

**Indications for Use**:

The eQUANT™ System is an automated inoculum preparation system that uses potentiometric sensing of oxidation-reduction potential changes due to pathogen metabolism to generate a 0.5 McFarland-equivalent suspension (the eMcFarland or eMcF) from positive blood culture samples that can be used for direct, qualitative *in vitro* susceptibility testing by the agar disk diffusion test method (Kirby-Bauer). Samples are processed directly from blood culture samples identified as positive by a continuous

monitoring blood culture system and confirmed as Gram-negative rods by Gram stain. Organism identification must be confirmed by an FDA cleared device for direct testing from positive blood culture before processing samples on the eQUANT™ System.

Evaluation of the eQUANT™ System's inoculum preparation was conducted for use with agar disk diffusion susceptibility testing and performance was demonstrated for the following antimicrobial agents with Enterobacterales species, *Acinetobacter* species and *Pseudomonas aeruginosa* as identified below:

Amoxicillin/clavulanate- *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis*

Ampicillin- *Escherichia coli*

Aztreonam- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens* and *Pseudomonas aeruginosa*

Cefazolin- *Klebsiella pneumoniae*

Cefepime- *Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens* and *Pseudomonas aeruginosa*

Ceftriaxone- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

Ertapenem- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens*

Gentamicin- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens* and *Pseudomonas aeruginosa*

Levofloxacin- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens*, and *Pseudomonas aeruginosa*

Meropenem- *Acinetobacter* spp., *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens,* and *Pseudomonas aeruginosa*

Piperacillin/tazobactam- *Acinetobacter spp*., *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, and Pseudomonas aeruginosa*

Tobramycin- *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris*, *Serratia marcescens,* and *Pseudomonas aeruginosa*

Susceptibility test results are intended to be used in conjunction with other clinical and laboratory findings. Standard laboratory protocols for processing positive blood cultures should be followed to ensure availability of isolates for supplemental testing as needed. Additionally, subculture of positive blood culture is necessary for the susceptibility testing of organisms present in polymicrobial samples, for testing antimicrobial agents and species not indicated for testing with the device, for epidemiologic testing, and for recovery of organisms present in microbial samples.

## 5. Technology Comparison with the Predicate Device

| **Feature** | **Subject Device**<br>Avails Medical, Inc. eQUANT™ System **K231536** | **Predicate Device**<br>Accelerate PhenoSystem, Accelerate PhenoTest BC Kit **K192665** |
|---|---|---|
| **Intended Use** | The eQUANT™ System is an automated inoculum preparation system that uses potentiometric sensing of oxidation-reduction potential changes due to pathogen metabolism to generate a 0.5 McFarland-equivalent suspension (the eMcFarland or eMcF) from positive blood culture samples. Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system and confirmed as Gram-negative rods by Gram stain. Organism identification, as determined by an FDA cleared device for direct testing from positive blood culture, must be available before processing samples on the eQUANT™ System. | The Accelerate PhenoTest BC kit is a multiplexed in vitro diagnostic test utilizing both qualitative nucleic acid fluorescence in situ hybridization (FISH) identification and quantitative, antimicrobial susceptibility testing (AST) methods and is intended for use with the Accelerate Pheno system. The Accelerate PhenoTest BC kit is capable of simultaneous detection and identification of multiple microbial targets followed by susceptibility testing of the appropriate detected bacterial organisms. The Accelerate PhenoTest BC kit is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results. |
| **Similarities** | | |
| **Antibiotics** | Amoxicillin/clavulanate<br>Ampicillin<br>Aztreonam<br>Cefazolin<br>Cefepime | Amikacin<br>Ampicillin<br>Ampicillin/Sulbactam<br>Aztreonam<br>Ceftazidime |

| **Feature** | **Subject Device**<br>Avails Medical, Inc. eQUANT™ System<br>**K231536** | **Predicate Device**<br>Accelerate PhenoSystem, Accelerate PhenoTest BC Kit **K192665** |
|---|---|---|
| | Ceftriaxone<br>Ertapenem<br>Gentamicin<br>Levofloxacin<br>Meropenem<br>Piperacillin/Tazobactam<br>Tobramycin | Ceftaroline<br>Cefepime<br>Ceftriaxone<br>Ciprofloxacin<br>Daptomycin<br>Ertapenem<br>Gentamicin<br>Linezolid<br>Meropenem<br>Piperacillin/Tazobactam<br>Tobramycin<br>Vancomycin |
| **Indicated Organisms** | *Acinetobacter* spp.<br>*Citrobacter freundii*<br>*Enterobacter cloacae*<br>*Escherichia coli*<br>*Klebsiella aerogenes*<br>*Klebsiella pneumoniae*<br>*Klebsiella oxytoca*<br>*Proteus mirabilis*<br>*Proteus vulgaris*<br>*Pseudomonas aeruginosa*<br>*Serratia marcescens* | Gram-negative species:<br>*Acinetobacter baumannii*<br>*Citrobacter* spp.<br>*Enterobacter* spp.<br>*Escherichia coli*<br>*Klebsiella* spp.<br>*Proteus* spp.<br>*Pseudomonas aeruginosa*<br>*Serratia marcescens*<br><br>Additional Gram-positive bacteria and yeast are also included on the Accelerate PhenoTest BC kit. |
| **Sample** | Positive blood culture aliquot | Positive blood culture aliquot |
| **Differences** | | |
| **Technology** | Measure pathogen concentration via potentiometric sensing of changes in oxidation-reduction potential (ORP) during pathogen metabolism. Uses species-specific and blood culture bottle specific algorithms to determine when a 0.5 McFarland equivalent concentration is reached. | Microscopy-based, single cell analysis. Identification via fluorescence *in situ* hybridization (FISH); AST via microscopic observation of individual growing bacterial cells in the presence of antimicrobial agents. |

| **Feature** | **Subject Device**<br>Avails Medical, Inc. eQUANT™ System **K231536** | **Predicate Device**<br>Accelerate PhenoSystem, Accelerate PhenoTest BC Kit **K192665** |
|---|---|---|
| **Output/Results Reporting** | Liquid suspension of bacteria (0.5 McFarland equivalent) suitable for Disk Diffusion susceptibility testing; no result reported | Microbial identification and MIC-based susceptibility test results |

Any differences between the subject device and the predicate device shown in the table above do not affect the safety and effectiveness of the subject device.

## 6. Performance Characteristics

**Reproducibility**

The Reproducibility Study was performed to demonstrate that the eQUANT™ System reproducibly prepares an 0.5 McFarland equivalent inoculum, the eMcFarland, at an organism concentration of 2.51e7 – 7.96e8 CFU/mL from a positive blood culture (PBC). The reproducibility of the eQUANT™ System was assessed across sites (one internal and two external), operators (6), runs (6), instruments (12), and consumable lots. A panel of six (6) organisms was contrived in blood culture bottles with human blood added and incubated on a blood culture monitoring system until positivity. From each positive blood culture, eQUANT™ System testing was performed in duplicate by two (2) operators at each site for a total of four (4) eMcFarlands per PBC. The resulting eMcFarlands were plated to confirm colony counts met the defined concentration specifications. Due to agreement below defined acceptance criteria (≥95%) for *A. baumannii* in initial testing (93.1%), an additional 30 replicates were tested at the internal site (5 days x 3 replicates x 2 operators). All repeat testing passed. Final overall agreement based on eMcFarland concentration across sites, operators, runs, instruments, and lots was 98.9%, demonstrating that the eQUANT™ System prepares a 0.5 McFarland equivalent inoculum with a high degree of reproducibility (see Table 1 below).

**Table 1.** eQUANT™ System Reproducibility Results Summary

| **Organism** | **Isolate ID** | **Agreement** |
|---|---|---|
| *Escherichia coli* | ATCC 25922 | **72/72 (100%)** |
| *Pseudomonas aeruginosa* | ATCC 27853 | **72/72 (100%)** |
| *Klebsiella pneumoniae* | ATCC 700603 | **72/72 (100%)** |
| *Acinetobacter baumannii* | ATCC 19606 | **97/102 (95.1%)** |
| *Proteus vulgaris* | ATCC 6380 | **72/72 (100%)** |
| *Serratia marcescens* | ATCC 14756 | **72/72 (100%)** |
| **Total** | | **457/462 (98.9%)** |

**Sample Stability**

The Sample Stability Study was performed to determine the stability of positive blood culture samples when testing on the eQUANT™ System and to establish the stability of the eQUANT™ System generated eMcFarland. A panel of five (5) organisms was contrived in blood culture bottles with human blood added

and incubated on a blood culture monitoring system until positivity. Positive blood culture bottles were held for different lengths of time either on the blood culture instrument (35°C) or on the benchtop (room temperature) until processing on the eQUANT™ System. From the T0 bottles, the resulting eMcFarlands were held for one (1) hour on the eQUANT™ Instrument at 15°C, then removed and plated to confirm colony counts. Additionally, colony count plates were prepared at various timepoints (up to 30 minutes) after removal from the eQUANT™ Instrument when stored at room temperature. All conditions were tested in triplicate. A sample was considered stable if the eMcFarland concentration met the defined acceptance criteria of 2.51e7 – 7.96e8 CFU/mL. All eMcFarland colony counts met defined acceptance criteria, supporting that positive blood culture bottles are stable for use on the eQUANT™ System for up to 12 hours (Table 2). eQUANT™ System generated eMcFarlands are stable for up to one (1) hour on the eQUANT™ Instrument, held at 15°C, and for up to 10 minutes after removal, held at room temperature (Table 3).

**Table 2.** eQUANT™ System PBC Stability Results

| Organism | PBC Storage Condition | Time Point (hours) | Average eMcFarland Concentration after 1 hour hold at 15°C (CFU/mL) |
|---|---|---|---|
| *E. coli* | RT | T0 | $1.04 \times 10^8$ |
| *E. coli* | RT | T12 | $1.19 \times 10^8$ |
| *E. coli* | RT | T14 | $1.09 \times 10^8$ |
| *E. coli* | 35°C | T0 | $9.80 \times 10^7$ |
| *E. coli* | 35°C | T12 | $1.09 \times 10^8$ |
| *E. coli* | 35°C | T14 | $1.00 \times 10^8$ |
| *E. cloacae* | RT | T0 | $1.71 \times 10^8$ |
| *E. cloacae* | RT | T12 | $1.38 \times 10^8$ |
| *E. cloacae* | RT | T14 | $1.59 \times 10^8$ |
| *E. cloacae* | 35°C | T0 | $1.71 \times 10^8$ |
| *E. cloacae* | 35°C | T12 | $1.77 \times 10^8$ |
| *E. cloacae* | 35°C | T14 | $1.79 \times 10^8$ |
| *S. marcescens* | RT | T0 | $1.83 \times 10^8$ |
| *S. marcescens* | RT | T12 | $1.92 \times 10^8$ |
| *S. marcescens* | RT | T14 | $2.14 \times 10^8$ |
| *S. marcescens* | 35°C | T0 | $1.71 \times 10^8$ |
| *S. marcescens* | 35°C | T12 | $1.83 \times 10^8$ |
| *S. marcescens* | 35°C | T14 | $1.90 \times 10^8$ |
| *P. aeruginosa* | RT | T0 | $8.76 \times 10^7$ |
| *P. aeruginosa* | RT | T12 | $8.89 \times 10^7$ |
| *P. aeruginosa* | RT | T14 | $9.14 \times 10^7$ |
| *P. aeruginosa* | 35°C | T0 | $8.92 \times 10^7$ |
| *P. aeruginosa* | 35°C | T12 | $9.61 \times 10^7$ |
| *P. aeruginosa* | 35°C | T14 | $9.27 \times 10^7$ |

| Organism | PBC Storage Condition | Time Point (hours) | Average eMcFarland Concentration after 1 hour hold at 15°C (CFU/mL) |
|---|---|---|---|
| *A. baumannii* | RT | T0 | $8.82 \times 10^7$ |
| *A. baumannii* | RT | T12 | $9.06 \times 10^7$ |
| *A. baumannii* | RT | T14 | $8.05 \times 10^7$ |
| *A. baumannii* | 35°C | T0 | $1.32 \times 10^8$ |
| *A. baumannii* | 35°C | T12 | $8.62 \times 10^7$ |
| *A. baumannii* | 35°C | T14 | $8.76 \times 10^7$ |

**Table 3.** eQUANT™ System eMcFarland Stability Results

| Organism | Avg. eMcF Concentration after 0 min hold (CFU/mL) | Avg. eMcF Concentration after 5 min hold (CFU/mL) | Avg. eMcF Concentration after 10 min hold (CFU/mL) | Avg. eMcF Concentration after 15 min hold (CFU/mL) | Avg. eMcF Concentration after 20 min hold (CFU/mL) | Avg. eMcF Concentration after 30 min hold (CFU/mL) |
|---|---|---|---|---|---|---|
| *E. coli* | $1.01 \times 10^8$ | $1.06 \times 10^8$ | $1.02 \times 10^8$ | $1.06 \times 10^8$ | $1.08 \times 10^8$ | $1.24 \times 10^8$ |
| *E. cloacae* | $1.71 \times 10^8$ | $1.69 \times 10^8$ | $1.79 \times 10^8$ | $1.90 \times 10^8$ | $1.99 \times 10^8$ | $2.24 \times 10^8$ |
| *S. marcescens* | $1.77 \times 10^8$ | $1.80 \times 10^8$ | $1.90 \times 10^8$ | $1.94 \times 10^8$ | $2.12 \times 10^8$ | $2.14 \times 10^8$ |
| *P. aeruginosa* | $8.84 \times 10^7$ | $9.28 \times 10^7$ | $1.09 \times 10^8$ | $9.57 \times 10^7$ | $1.02 \times 10^8$ | $9.33 \times 10^7$ |
| *A. baumannii* | $1.10 \times 10^8$ | $1.48 \times 10^8$ | $1.33 \times 10^8$ | $1.60 \times 10^8$ | $1.80 \times 10^8$ | $1.33 \times 10^8$ |

**Blood Culture Bottle Equivalency**

The Blood Culture Bottle Equivalency Study was performed to demonstrate that the eQUANT™ System generates a standardized inoculum, the eMcFarland, meeting the defined concentration specifications, from a variety of blood culture bottle media types (Table 4). A panel of eight (8) organisms was contrived into various bioMérieux BACT/ALERT® and BD BACTEC™ blood culture bottle types with human blood added and incubated on the respective blood culture monitoring system until positivity. Each organism/blood culture bottle type was tested in triplicate on the eQUANT™ System within 12 hours of positivity, and the resulting eMcFarlands were plated to confirm colony counts met defined concentration specifications. The concentrations of all eMcFarlands for all organisms and bottle types evaluated met defined acceptance criteria (2.51e7 – 7.96e8 CFU/mL).

The eMcFarlands were also used for downstream Disk Diffusion AST testing, and results were compared to results generated from a standard 0.5 McFarland inoculum prepared from isolated colonies (Table 4). For *A. baumannii,* disk diffusion was performed and expected AST results (>95% CA) were obtained for all bottle types assessed. For *P. aeruginosa,* disk diffusion was performed and >95% CA was obtained for all bottle types except BD BACTEC Aero Plus, which demonstrated performance of 90.5% CA with two minor errors with levofloxacin. However, the two minor error eQUANT™ zone diameters were less than 3 mm difference when compared to the zone diameters obtained by the standard method, which was considered acceptable. For Enterobacterales, >95% CA was only obtained for the bottle type BACT/ALERT

SN; the remaining CA performance was 90-93% CA. The minor errors were spread across all bottle types. The zone diameter of the majority (60/64 = 93.8%) of the error results were ≤3 mm compared to the standard method zone diameter, which was considered acceptable. In addition, 63/64 of the minor errors were due to a single isolate of *K. pneumoniae* with minor errors detected across bottle types and among 6 of the 12 tested drugs (i.e., levofloxacin, piperacillin/tazobactam, cefepime, ceftriaxone, gentamicin, tobramycin). These results demonstrate that all blood culture bottle types evaluated are suitable for use with the eQUANT™ System.

**Table 4.** Compatibility of the eQUANT™ System with Different Blood Culture Bottle Types

| Org. Group | Bottle System | Bottle Type | Total | CA # | CA % | VME | ME | mE |
|---|---|---|---|---|---|---|---|---|
| Enterobacterales[a] | BD BACTEC | Aero Plus | 96 | 87 | 90.6* | 0 | 0 | 9 |
| | | STD AERO | 96 | 88 | 91.7* | 0 | 0 | 8 |
| | | STD ANA | 96 | 89 | 91.7* | 0 | 0 | 7 |
| | | LYTIC | 96 | 89 | 92.7* | 0 | 0 | 7 |
| | | ANA PLUS | 96 | 88 | 91.7* | 0 | 0 | 8 |
| | BACT/ALERT | SA | 96 | 89 | 92.7* | 0 | 0 | 7 |
| | | FA | 96 | 89 | 92.7* | 0 | 0 | 7 |
| | | FN | 96 | 88 | 91.7* | 0 | 0 | 8 |
| | | SN | 96 | 93 | 96.9 | 0 | 0 | 3 |
| *P. aeruginosa*[b] | BD BACTEC | Aero Plus | 21 | 19 | 90.5* | 0 | 0 | 2 |
| | | STD AERO | 21 | 20 | 95.2 | 0 | 0 | 1 |
| | BACT/ALERT | SA | 21 | 21 | 100 | 0 | 0 | 0 |
| | | FA | 21 | 20 | 95.2 | 0 | 0 | 1 |
| *A. baumannii*[c] | BD BACTEC | Aero Plus | 24 | 24 | 100 | 0 | 0 | 0 |
| | | STD AERO | 24 | 24 | 100 | 0 | 0 | 0 |
| | BACT/ALERT | SA | 24 | 24 | 100 | 0 | 0 | 0 |
| | | FA | 24 | 24 | 100 | 0 | 0 | 0 |

[a]Disk diffusion results with amoxicillin/clavulanate, ampicillin, aztreonam, cefazolin, cefepime, ceftriaxone, ertapenem, gentamicin, levofloxacin, meropenem, piperacillin/tazobactam, and tobramycin

[b]Disk diffusion results with aztreonam, cefepime, gentamicin, levofloxacin, meropenem, piperacillin/tazobactam and tobramycin

[c]Meropenem and piperacillin/tazobactam disk diffusion results

*<95% CA due to minor errors of which the majority were from eQUANT™ zone diameters that were ≤3mm difference compared to the zone diameters obtained by the standard method

**Interfering Substances**

The Interfering Substances Study was performed to determine if the eQUANT™ System generates a standard inoculum (eMcFarland) suitable for downstream AST testing in the presence of substances commonly found in positive blood cultures. A panel of nine (9) organisms was contrived into blood culture bottles with and without potential interferents at high concentrations, including endogenous substances, exogenous substances, and a representative antibiotic from each of the main classes of antibiotics that target Gram-negative organisms (Tables 5-6). Antibiotic interferents were tested on one (1) test isolate resistant to the test interferent to allow for growth in the PBC. Contrived blood culture bottles were

incubated on a blood culture monitoring system until positivity and tested on the eQUANT™ System within 12 hours. The resulting eMcFarlands were plated to confirm colony counts met defined concentration specifications and were also used for downstream Disk Diffusion AST testing. Results from eMcFarlands prepared from positive blood culture bottles containing interferents were compared to results from eMcFarlands prepared from PBCs without interferents. When acceptance criteria were not met, repeat testing was performed in triplicate. All resulting eMcFarland concentrations met defined acceptance criteria (2.51e7 – 7.96e8 CFU/mL). No reproducible interference was observed in downstream AST testing. High concentrations of two substances, hemoglobin (*A. baumannii, P. aeruginosa*) and platelets (*P. aeruginosa*), resulted in aborted eQUANT™ System runs due to aeration blockage errors detected by the instrument. At decreased interferent concentrations, valid eMcFarlands were successfully generated and AST results were as expected.

**Table 5.** eQUANT™ System Interfering Substances Disk Diffusion Results

| Interferent | Concentration | Overall CA |
|---|---|---|
| Conjugated Bilirubin | 475 μmol/L | 97.8% (176/180) |
| Gamma Globulin* | 50 mg/mL | 100% (177/177) |
| Hemoglobin* | 20 g/dL (Enterobacterales)<br>2 g/dL – 8 g/dL (*A. baumannii* and *P. aeruginosa*) | 98.9% (175/177) |
| Hematocrit* | 50% | 97.2% (172/177) |
| Heparin | 3 units/mL | 98.3% (174/177) |
| Platelets | 1,000,000/μL<br>900,000/μL (*P. aeruginosa)* | 100% (191/191) |
| Sodium Polyanetholesulfonate (SPS) | 0.1% w/v | 99.4% (176/177) |
| Triglycerides | 37 mmol/L | 97.7% (173/177) |
| Unconjugated Bilirubin | 684 μmol/L | 98.3% (174/177) |
| WBCs (Buffy Coat)* | 12,000/μL | 100% (177/177) |

*Endogenous substances added directly into the eTube as acceptable interferent concentrations in the blood culture bottle were not achieved.

**Table 6.** eQUANT™ System Interfering Antibiotics Disk Diffusion Results

| Interferent | Drug Class | Concentration | Overall CA |
|---|---|---|---|
| Ampicillin | Penicillins | 75 μg/mL | 95.2% (63/66) |
| Cefazolin | 1st generation Cephalosporins | 1201 μg/mL | 100% (33/33) |
| Cefepime | 4th generation Cephalosporins | 492 μg/mL | 100% (36/36) |
| Ceftriaxone | 3rd generation Cephalosporins | 837 μg/mL | 100% (36/36) |

| | | | |
|---|---|---|---|
| Chloramphenicol | Macrolides | 78 μg/mL | 90.9%[1] (33/36) |
| Ciprofloxacin | Fluroquinolones | 1.2 μg/mL | 100% (36/36) |
| Gentamicin | Aminoglycosides | 3 μg/mL | 100% (6/6) |
| Piperacillin/Tazobactam | Beta-lactam combination agents | 1100/31 μg/mL | 100% (36/36) |
| Tetracycline | Tetracyclines | 2.4 μg/mL | 100% (27/27) |
| Trimethoprim/ Sulfamethoxazole | Sulfonamides | 41/405 μg/mL | 100% (33/33) |

[1] Acceptable performance since 3/3 minor errors ≤ 3 mm difference in zone diameter when compared to the control replicate (i.e., no potential interferent).

**Carryover**

The Carryover Study was performed to demonstrate that no bacterial carryover occurs between runs on the eQUANT™ System. Two organisms with distinct morphologies, *E. coli* and *P. aeruginosa,* were contrived into blood culture bottles with human blood added and incubated on a blood culture system until positivity. The resulting positive blood cultures were run on the same eQUANT™ System within 12 hours of positivity in an alternating pattern for a total of three (3) runs per species. The resulting eMcFarlands were subcultured to ensure no carryover occurred between runs. No carryover was observed, as evidenced by monomicrobial cultures and the expected organism morphology.

**Method Comparison**

A method comparison study was performed to evaluate the performance of the eQUANT™ System in preparing a 0.5 McFarland equivalent inoculum (eMcFarland) from positive blood cultures containing Gram-negative bacteria for use in downstream Disk Diffusion AST testing. Performance was based on eQUANT™ System-generated eMcFarland concentrations meeting defined specifications (2.51e7 – 7.96e8 CFU/mL) and on AST results (categorical interpretations and error rates) generated from the eMcFarland as compared to AST results generated from a traditional 0.5 McFarland standard prepared from isolated colonies.

Samples were enrolled and tested at three (3) US clinical sites and one (1) internal site. Samples enrolled in the study included leftover, deidentified clinical positive blood culture samples (prospective) and contrived positive blood culture samples, contrived with either stock or challenge isolates. Prior to enrollment, prospective positive blood culture samples were confirmed by Gram strain to contain Gram-negative rods followed by organism identification (ID) using an ID method FDA-cleared for use with positive blood cultures. Polymicrobial samples or those identified as containing species not supported by the eQUANT™ System were not eligible for enrollment. Contrived stock isolates were provided by the clinical site or Avails Medical and contrived challenge isolates with known antimicrobial resistance were provided by Avails Medical. All positive blood cultures were processed on the eQUANT™ System within 12 hours of positivity.

For comparative testing, the positive blood culture sample was subcultured overnight, and isolated colonies were used to prepare a standard 0.5 McFarland equivalent inoculum for Disk Diffusion testing

according to CLSI guidelines (CLSI M02-A12). For eQUANT™ System testing, 34 μL of the positive blood culture sample was diluted into 1 mL of eQUANT™ Reagent in the eTube Disposable and processed on the eQUANT™ System according to Instructions for Use. After the run was successfully completed, the resulting eMcFarland was used to prepare colony count plates for select samples and for direct Disk Diffusion testing for all samples.

Performance of the eQUANT™ System was based on both eMcFarland concentrations and on Disk Diffusion AST results. eMcFarland concentrations were assessed based on the defined concentration range of 2.51e7 – 7.96e8 CFU/mL. AST performance was assessed by comparing the results generated from the eMcFarland inoculum to results generated from the standard (std) inoculum. Agreement and acceptance criteria were defined based on FDA guidance. The primary endpoints were Categorical Agreement (CA) and error rates (Very Major Error (VME), Major Error (ME) and Minor Error (MIN)) for each antimicrobial agent (≥95% CA, ≤1% VME, ≤1.5% ME). Categorical agreement (Susceptible/Intermediate/Resistant, S/I/R) was assessed using FDA-recognized breakpoints (Antimicrobial Susceptibility Test Interpretive Criteria/STIC) and CLSI M100, when applicable.

A total of 578 positive blood culture samples were enrolled in the study with 567 (98.1%) included in performance analysis. Eleven (11) samples were excluded for the following reasons: not meeting eQUANT™ System stability requirements for testing (4), non-target organism (2), eQUANT™ runtime exceeded (2), polymicrobial sample (1), insufficient growth (1), or sample mix-up (1).

Of the 567 samples included in clinical performance analysis, 42 were prospective positive blood cultures (7.4%), 515 were contrived with stock isolates (90.8%) and 10 were contrived with challenge isolates (1.8%). There was broad representation of the organisms that can be processed on the eQUANT™ System. These included 41 *Acinetobacter* spp., 41 *Citrobacter freundii*, 2 *Citrobacter* spp., 45 *Enterobacter cloacae*, 182 *Escherichia coli*, 43 *Klebsiella aerogenes*, 19 *Klebsiella oxytoca*, 41 *Klebsiella pneumoniae*, 52 *Proteus mirabilis,* 18 *Proteus vulgaris,* 1 *Proteus* spp., 41 *Serratia marcescens,* and 41 *Pseudomonas aeruginosa*.

Of the 567 samples included in clinical performance analysis, colony counts were performed on 221 samples. eMcFarland colony counts from eQUANT™ System samples were within the expected colony count range of 2.51e7 to 7.96e8 CFU/mL for 99.1% of PBC samples and therefore met the acceptance criteria for overall samples of ≥95% (Table 8). The two (2) samples outside the expected colony count range were one (1) contrived *Acinetobacter* spp. and one (1) contrived *P. aeruginosa* sample. For these two (2) samples, there were no errors observed with Disk Diffusion results.

**Table 8**. eQUANT™ System Colony Count Performance (All Sites)
*Target range is between 2.51e7 and 7.96e8 CFU/mL; colony counts were not performed on all samples enrolled

| | **eMcFarland Colony Counts # in Expected Range/Total (%)** | | | | |
|---|---|---|---|---|---|
| **Organism Group** | **Site #1** | **Site #2** | **Site #3** | **Site #4** | **Overall** |
| Enterobacterales | 50/50 | 36/36 | 25/25 | 54/54 | 165/165 |

| | | | | | |
|---|---|---|---|---|---|
| | (100.0) | (100.0) | (100.0) | (100.0) | (100.0) |
| *Acinetobacter* spp. | 7/8 (87.5) | 8/8 (100.0) | 3/3 (100.0) | 6/6 (100.0) | 24/25 (96.0) |
| *P. aeruginosa* | 4/4 (100.0) | 12/13 (92.3) | 8/8 (100.0) | 6/6 (100.0) | 30/31 (96.8) |
| **Total** | **61/62 (98.4)** | **56/57 (98.2)** | **36/36 (100.0)** | **66/66 (100.0)** | **219/221 (99.1)** |

Qualitative AST performance for Disk Diffusion was assessed with 12 antimicrobials and overall performance is summarized in Table 9, below. All antibiotic/group combinations met overall acceptance criteria of ≥95% CA with the following exceptions: amoxicillin_clavulanate/Enterobacterales, cefazolin/Enterobacterales, cefepime/Enterobacterales, and piperacillin_tazobactam/Enterobacterales. One combination did not meet acceptance criteria for %VME, gentamicin/Enterobacterales, and one combination did not meet acceptance criteria for %ME, cefepime/*Pseudomonas aeruginosa.* The following combinations were removed from the eQUANT™ System Indications for Use based on performance <90% CA: cefazolin/*Escherichia coli,* cefazolin/*Proteus mirabilis,* cefepime/*Citrobacter freundii,* and cefepime/*Klebsiella aerogenes.* Limitations are included in product labeling, as appropriate.

**Table 9.** eQUANT™ System Disk Diffusion Performance Summary by Antimicrobial – All Sites, All Samples

| Antimicrobial Agent | Organism Group | N | Std S | Std I | Std R | Total CA | CA | % CA | VMJ | MAJ | MIN |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Amoxicillin/ Clavulanate | Enterobacterales | 223 | 150 | 13 | 60 | 223 | 210 | 94%[1] | 0 (0.00%) | 1 (0.67%) | 12 (5.38%) |
| Ampicillin | Enterobacterales | 33 | 9 | 1 | 23 | 33 | 33 | 100% | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| Aztreonam | Enterobacterales | 189 | 141 | 3 | 45 | 189 | 183 | 97% | 0 (0.00%) | 1 (0.71%) | 5 (2.65%) |
| | *Pseudomonas aeruginosa* | 25 | 10 | 4 | 11 | 25 | 24 | 96% | 0 (0.00%) | 0 (0.00%) | 1 (4.00%) |
| Cefazolin | Enterobacterales[2] | 213 | 71 | 44 | 98 | 213 | 181 | 85%[1] | 0 (0.00%) | 1 (1.41%) | 31 (14.55%) |
| Cefepime | Enterobacterales[3] | 237 | 162 | 33 | 42 | 237 | 218 | 92%[1] | 0 (0.00%) | 1 (0.62%) | 18 (7.59%) |
| | *Pseudomonas aeruginosa* | 41 | 21 | 0 | 20 | 41 | 39 | 95% | 0 (0.00%) | 2[4] (9.52%) | 0 (0.00%) |
| Ceftriaxone | Enterobacterales | 223 | 134 | 5 | 84 | 223 | 216 | 97% | 0 (0.00%) | 2[5] (1.49%) | 5 (2.24%) |
| Ertapenem | Enterobacterales | 187 | 153 | 5 | 29 | 187 | 183 | 98% | 0 (0.00%) | 0 (0.00%) | 4 (2.14%) |
| Gentamicin | Enterobacterales | 255 | 226 | 3 | 26 | 255 | 248 | 97% | 1 (3.85%) | 1 (0.44%) | 5 (1.96%) |
| | *Pseudomonas aeruginosa* | 41 | 23 | 1 | 17 | 41 | 39 | 95% | 0 (0.00%) | 0 (0.00%) | 2 (4.88%) |
| Levofloxacin | Enterobacterales | 206 | 146 | 11 | 49 | 206 | 198 | 96% | 0 (0.00%) | 0 (0.00%) | 8 (3.88%) |
| | *Pseudomonas aeruginosa* | 25 | 8 | 6 | 11 | 25 | 24 | 96% | 0 (0.00%) | 0 (0.00%) | 1 (4.00%) |
| Meropenem | *Acinetobacter* spp. | 16 | 6 | 1 | 9 | 16 | 16 | 100% | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |
| | Enterobacterales | 206 | 180 | 3 | 23 | 206 | 200 | 97% | 0 (0.00%) | 2[6] (1.11%) | 4 (1.94%) |
| | *Pseudomonas aeruginosa* | 25 | 8 | 0 | 17 | 25 | 25 | 100% | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |

| Antimicrobial Agent | Organism Group | N | Std S | Std I | Std R | Total CA | CA | % CA | VMJ | MAJ | MIN |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Piperacillin/ Tazobactam | *Acinetobacter* spp. | 41 | 16 | 0 | 25 | 41 | 39 | 95% | 0 (0.00%) | 0 (0.00%) | 2 (4.88%) |
| | Enterobacterales | 239 | 166 | 27 | 46 | 239 | 225 | 94%[1] | 0 (0.00%) | 0 (0.00%) | 14 (5.86%) |
| | *Pseudomonas aeruginosa* | 25 | 14 | 2 | 9 | 25 | 24 | 96% | 0 (0.00%) | 0 (0.00%) | 1 (4.00%) |
| Tobramycin | Enterobacterales | 203 | 164 | 6 | 33 | 203 | 196 | 97% | 0 (0.00%) | 0 (0.00%) | 7 (3.45%) |
| | *Pseudomonas aeruginosa* | 25 | 16 | 1 | 8 | 25 | 25 | 100% | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) |

[1]Categorical agreement was 90-95% due to minor errors for the following drug/organism combinations and considered acceptable since the eQUANT™ zone diameters of a significant number of the errors were ≤3 mm difference compared to the standard disk diffusion zone diameters:
Amoxicillin/Clavulanate: *Escherichia coli*, *Proteus mirabilis*; Cefazolin: *Klebsiella pneumoniae;* Cefepime: *Enterobacter cloacae, Klebsiella oxytoca, Proteus mirabilis;* Ceftriaxone: *Klebsiella aerogenes*, *Proteus mirabilis*; Levofloxacin: *Proteus mirabilis*; Piperacillin/Tazobactam: *Escherichia coli.*

[2] Two combinations are removed from product labeling due to %CA <90%: cefazolin/*E. coli* and cefazolin/*P. mirabilis.*

[3] Two combinations are removed from product labeling due to %CA <90%: cefepime/*C. freundii* and cefepime/*K. aerogenes.*

[4]The major error rate was ≥1.5% and considered acceptable since the eQUANT™ zone diameters for the major errors were ≤3 mm difference compared to the standard disk diffusion zone diameters.

[5]A single major error was observed for the following drug/organism combinations which may be due to eQUANT™ zone diameters tending to be smaller than the standard disk diffusion zone diameters: Ceftriaxone/*Klebsiella aerogenes, Proteus mirabilis.*

[6] The categorical agreement was ≥95% for the following drug/organism combination; however, a single major error was observed which may be due to eQUANT™ zone diameters tending to be smaller than the standard disk diffusion zone diameters: Meropenem/*Serratia marcescens.*

## 7. Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (807.92(b)(3)).