**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 23, 2017

Accelerate Diagnostics Inc.
% Ms. Maureen Mende
Head of Regulatory
3950 S. Country Club Road #470
Tuscan, AZ 85714

Re: DEN160032
Accelerate PhenoTest BC Kit
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 866.1650
Regulation Name: A cellular analysis system for multiplexed antimicrobial susceptibility testing
Regulatory Classification: Class II
Product Code: PRH, NSU, PEO, PAM, PEN, LON
Dated: July 13, 2016
Received: July 14, 2016

Dear Ms. Mende:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Accelerate PhenoTest BC Kit, a prescription device. The Accelerate PhenoTest BC Kit is indicated for use as follows:

> 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.
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> The Accelerate PhenoTest BC kit identifies the following Gram-positive and Gram-negative bacteria and yeasts utilizing FISH probes targeting organism-specific ribosomal RNA sequences: *Staphylococcus aureus*, *Staphylococcus lugdunensis*, Coagulase-negative S*taphylococcus* species (i.e., *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus capitis*, *Staphylococcus lugdunensis*, *Staphylococcus warneri*, not differentiated), *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus* spp. (i.e., *Streptococcus mitis*, *Streptococcus oralis*, *Streptococcus gallolyticus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, not

differentiated), *Pseudomonas aeruginosa, Acinetobacter baumannii, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli*, *Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri*, not differentiated), *Serratia marcescens, Candida albicans* and *Candida glabrata.*

The Accelerate PhenoTest BC kit tests the following antimicrobial agents with the specific target organisms identified below:

- Amikacin: *Pseudomonas aeruginosa, Acinetobacter baumannii, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli*, *Enterobacter* spp. (i.e., *Enterobacter cloacae,* Enterobacter *aerogenes,* not differentiated), Proteus *spp*. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri*, not differentiated) and *Serratia marcescens*
- Ampicillin: *Enterococcus faecalis* and *Enterococcus faecium*
- Ampicillin/Sulbactam: *Escherichia coli, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), and *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated)
- Aztreonam: *Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Ceftazidime: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and Serratia *marcescens*
- Ceftaroline : *Staphylococcus aureus*
- Cefepime: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Ceftriaxone: *Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Ciprofloxacin: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not

differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*

- Daptomycin: *Staphylococcus aureus,* Coagulase-negative *Staphylococcus* species (i.e., *Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus capitis, Staphylococcus lugdunensis, Staphylococcus warneri,* not differentiated), *Enterococcus faecalis* and *Enterococcus faecium*
- Erythromycin: *Staphylococcus aureus*
- Ertapenem: *Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Gentamicin: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Linezolid: *Staphylococcus aureus, Enterococcus faecalis* and *Enterococcus faecium*
- Meropenem: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Piperacillin/Tazobactam: *Pseudomonas aeruginosa, Acinetobacter baumannii, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Tobramycin: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Vancomycin: *Staphylococcus aureus, Staphylococcus lugdunensis,* Coagulase-negative *Staphylococcus* species (i.e., *Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus capitis, Staphylococcus lugdunensis, Staphylococcus warneri,* not differentiated), *Enterococcus faecalis* and *Enterococcus faecium*

The following resistance phenotypes are reported based on qualitative tests: Methicillin-resistance (*S. aureus S. lugdunensis*, coagulase negative staphylococci) and macrolide-lincosamide-streptogramin B resistance (MLSb) (*S. lugdunensis* and coagulase negative staphylococci).

The Accelerate PhenoTest BC kit is indicated as an aid in the diagnosis of bacteremia and fungemia. It is also indicated for susceptibility testing of specific pathogenic bacteria as identified above commonly associated with or causing bacteremia. 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 identification and susceptibility testing of: organisms not identified by the Accelerate PhenoTest BC kit, organisms present in polymicrobial samples, organisms for which species identification is critical for patient care (e.g. speciation of *Streptococcus* spp.), samples for which an "indeterminate" result for any probe was obtained, for testing antimicrobial agents not included on the Accelerate panel and for epidemiologic testing.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Accelerate PhenoTest BC Kit, and substantially equivalent devices of this generic type, into class II under the generic name, "A cellular analysis system for multiplexed antimicrobial susceptibility testing."

FDA identifies this generic type of device as: **A cellular analysis system for multiplexed antimicrobial susceptibility testing**.

A cellular analysis system for multiplexed antimicrobial susceptibility testing is a multiplex qualitative and/or quantitative in vitro device intended for the identification and determination of the antimicrobial susceptibility results of organisms detected in samples from patients with suspected microbial infections. This device is intended to aid in the determination of antimicrobial susceptibility or resistance when used in conjunction with other laboratory findings.

Section 513(f)(2) of the Food, Drug & Cosmetic Act (FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for de novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the FD&C Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an

order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On July 14, 2016, FDA received your *de novo* requesting classification of the Accelerate PhenoTest BC Kit into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Accelerate PhenoTest BC Kit into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Accelerate PhenoTest BC Kit indicated for use as follows:

> 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.
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- Ampicillin: *Enterococcus faecalis* and *Enterococcus faecium*
- Ampicillin/Sulbactam: *Escherichia coli, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), and *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated)
- Aztreonam: *Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and *Serratia marcescens*
- Ceftazidime: *Pseudomonas aeruginosa, Klebsiella* spp. (i.e., *Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), *Escherichia coli, Enterobacter* spp. (i.e., *Enterobacter cloacae, Enterobacter aerogenes,* not differentiated), *Proteus* spp. (i.e., *Proteus mirabilis, Proteus vulgaris,* not differentiated), *Citrobacter* spp. (i.e., *Citrobacter freundii, Citrobacter koseri,* not differentiated) and Serratia *marcescens*
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- Erythromycin: *Staphylococcus aureus*
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"indeterminate" result for any probe was obtained, for testing antimicrobial agents not included on the Accelerate panel and for epidemiologic testing.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with applicable general controls, including the design controls under 21 CFR part 820, provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health and identified mitigations associated with the device type are summarized in Table 1.

**Table 1 – Identified Risks to Health and Identified Mitigations**

| **Identified Risks to Health** | **Identified Mitigations** |
|---|---|
| If identification assay is included, false positive or false negative results or incorrect identifications can lead to<br>• a delay in determining the true cause of the infection<br>• unnecessary, ineffective or lack of antimicrobial therapy<br>• delayed or skipped treatments or diagnostic procedures<br>• inappropriate infection prevention and control measures/and or public health procedures<br>• interference with antimicrobial stewardship efforts<br>Failure to perform appropriate AST testing may result in<br>• unnecessary, ineffective or lack of antimicrobial therapy<br>• interference with antimicrobial stewardship efforts<br>• development of antimicrobial resistance<br>An organism determined to be resistant when it is susceptible may lead to<br>• treatment with an ineffective antibiotic<br>• administration of unnecessary broad spectrum drugs<br>• side effects from potent antimicrobials<br>• costly implementation of infection control measures<br>An organism determined to be susceptible when it is resistant may lead to | General controls and special controls (1), (2), (3), (4), and (5) |

| Identified Risks to Health | Identified Mitigations |
|---|---|
| • treatment with an ineffective antibiotic<br>• increased morbidity or death | |
| Errors in Interpretation | General controls and special control (6) |
| Failure to correctly operate the test system | General controls and special control (7) |

In combination with the general controls of the FD&C Act, a cellular analysis system for multiplexed antimicrobial susceptibility testing is subject to the following special controls:

1. Premarket notification submissions must include detailed device description documentation, including the device components, ancillary reagents required but not provided, a detailed explanation of the methodology including primer/probe sequence, design, rationale for sequence selection and details of the antimicrobial agents, as applicable.

2. Premarket notification submissions must include detailed documentation from the following analytical and clinical performance studies: limit of detection, inclusivity, precision, reproducibility, interference, cross reactivity, carry-over, and cross contamination, quality control and additional studies as applicable to specimen type and assay claims.

3. Premarket notification submissions must include detailed documentation from an appropriate clinical study. The study, performed on a study population consistent with the intended use population, must compare the device performance to results obtained from well-accepted reference methods.

4. Premarket notification submissions must include detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.

5. The 21 CFR 809.10(b) compliant labeling must include limitations and protocols regarding the need for correlation of results by standard laboratory procedures as applicable.

6. A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.

7. A detailed explanation of the principles of operation and procedures for assay performance and troubleshooting must be included in the device's 21 CFR 809.10(b) compliant labeling.

This device is subject to the premarket notification requirements under section 510(k) of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the cellular analysis system for multiplexed antimicrobial susceptibility

testing they intend to market and receive clearance to market from FDA prior to marketing the device.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Patricia Conville at 301-796-6942.

Sincerely,

Steven R. Gitterman -S

for Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health