December 21, 2018

GenMark Diagnostics, Incorporated
Beth Stofka
Sr. Regulatory Affairs Specialist
5964 La Place Court
Carlsbad, California 92008

Re: K182690
Trade/Device Name: ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel
Regulation Number: 21 CFR 866.3365
Regulation Name: Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures
Regulatory Class: Class II
Product Code: PEO
Dated: September 26, 2018
Received: September 27, 2018

Dear Beth Stofka:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182690

Device Name
ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel

Indications for Use *(Describe)*

The GenMark ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel is a qualitative nucleic acid multiplex *in vitro* diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous detection and identification of multiple potentially pathogenic fungal organisms in positive blood culture. The ePlex BCID-FP Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain fungal organism.

The following fungal organisms are identified using the ePlex BCID-FP Panel: *Candida albicans, Candida auris*, *Candida dubliniensis, Candida famata, Candida glabrata, Candida guilliermondii, Candida kefyr, Candida krusei, Candida lusitaniae, Candida parapsilosis, Candida tropicalis, Cryptococcus gattii, Cryptococcus neoformans, Fusarium* and *Rhodotorula*.

The detection and identification of specific fungal nucleic acids from individuals exhibiting signs and/or symptoms of bloodstream infection aids in the diagnosis of bloodstream infection when used in conjunction with other clinical information. The results from the ePlex BCID-FP Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-FP Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by ePlex BCID-FP Panel, susceptibility testing and differentiation of mixed growth) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.

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

Summary of Safety and Effectiveness

Submitter Information

Submitter: GenMark Diagnostics, Incorporated
5964 La Place Court
Carlsbad, CA 92008

Manufacturer: GenMark Diagnostics, Incorporated
5964 La Place Court
Carlsbad, CA 92008

Establishment Registration Number: 3008632402

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Date Prepared: September 27, 2018

Name of Device and Classification

Product Name: ePlex® Blood Culture Identification Fungal Pathogen (BCID-FP) Panel

Device Classification: 866.3980, Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures, Class II

Product Code(s): PEO

Predicate Device

Predicate: FilmArray Blood Culture Identification Panel; BioFire Diagnostics; K130914

Device Description

The ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel is based on the principles of competitive nucleic acid hybridization using a sandwich assay format, wherein a single-stranded target binds concurrently to a sequence-specific solution-phase signal probe and a solid-phase electrode-bound capture probe. The test employs nucleic acid extraction, target amplification via polymerase chain reaction (PCR) or reverse transcription PCR (RT-PCR) and hybridization of target DNA. In the process, the double-stranded PCR amplicons are digested with exonuclease to generate single-stranded DNA suitable for hybridization.

Nucleic acid extraction from biological samples occurs within the cartridge via cell lysis, nucleic acid capture onto magnetic beads, and release for amplification. The nucleic acid extraction is processed through microfluidic liquid handling. Once the nucleic acid targets are captured and inhibitors are washed away, the magnetic particles are delivered to the electrowetting environment on the printed circuit board (PCB) and the targets are eluted from the particles and amplified.

During hybridization, the single-stranded target DNA binds to a complementary, single-stranded capture probe immobilized on the working gold electrode surface. Single-stranded signal probes (labeled with electrochemically active ferrocenes) bind to specific target sequence / region adjacent to the capture probe. Simultaneous hybridization of target to signal probes and capture probe is detected by alternating current voltammetry (ACV). Each working electrode on the array contains specific capture probes, and sequential analysis of each electrode allows detection of multiple analyte targets.

Intended Use/Indications for Use

The GenMark ePlex® Blood Culture Identification Fungal Pathogen (BCID-FP) Panel is a qualitative nucleic acid multiplex *in vitro* diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous detection and identification of multiple potentially pathogenic fungal organisms in positive blood culture. The ePlex BCID-FP Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain fungal organism.

The following fungal organisms are identified using the ePlex BCID-FP Panel: *Candida albicans, Candida auris, Candida dubliniensis, Candida famata, Candida glabrata, Candida guilliermondii, Candida kefyr, Candida krusei, Candida lusitaniae, Candida parapsilosis, Candida tropicalis, Cryptococcus gattii, Cryptococcus neoformans, Fusarium* and *Rhodotorula.*

The detection and identification of specific fungal nucleic acids from individuals exhibiting signs and/or symptoms of bloodstream infection aids in the diagnosis of bloodstream infection when used in conjunction with other clinical information. The results from the ePlex BCID-FP Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-FP Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by ePlex BCID-FP Panel, susceptibility testing and differentiation of mixed growth) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.

Summary of Technological Characteristics of the Device Compared to the Predicate Device

The GenMark ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel ("Subject Device") and the legally marketed device, FilmArray Blood Culture Identification Panel, K130914, ("Predicate Device") are described below:

Characteristic	Subject Device	Predicate Device
Product Name	ePlex BCID-FP Panel	FilmArray BCID Panel
Manufacturer	GenMark Diagnostics, Inc.	BioFire Diagnostics, Inc.
Organisms Detected	• *Candida albicans* • *Candida auris* • *Candida dubliniensis,* • *Candida famata* • *Candida glabrata* • *Candida guilliermondii* • *Candida kefyr* • *Candida krusei* • *Candida lusitaniae* • *Candida parapsilosis* • *Candida tropicalis* • *Cryptococcus gattii* • *Cryptococcus neoformans* • *Fusarium* • *Rhodotorula*	*Enterococci, Listeria monocytogenes,* commonly encountered *Staphylococci* (including specific differentiation of *Staphylococcus aureus),* commonly encountered *Streptococci* (with specific differentiation of *Streptococcus agalactiae, Streptococcus pneumoniae,* and *Streptococcus pyogenes), Acinetobacter baumannii,* commonly encountered *Enterobacteriaceae* (including specific differentiation of the *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus,* and *Serratia marcescens), Haemophilus influenzae, Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis,* and *Candida tropicalis.*
Indication for Use	The ePlex BCID-FP Panel is indicated as an aid in the diagnosis of bloodstream infections. The use of additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by the ePlex BCID-FP Panel and for susceptibility testing, differentiation of mixed growth) and clinical presentation must be taken into consideration in the final diagnosis of blood stream infection.	FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings.

Characteristic	Subject Device	Predicate Device
Specimen Type	Blood culture samples identified as positive by a continuous monitoring blood culture system and which contain fungal organism.	Blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as confirmed by Gram stain.
Chemistry	Reagents on cartridge include: sample lysis and nucleic acid extraction, PCR amplification and hybridization-based electrochemical detection reagents.	The FilmArray BCID pouch contains freeze-dried reagents to perform nucleic acid purification and nested, multiplex PCR with DNA melt analysis.
Hardware	GenMark ePlex Instrument & Single Use Cartridge	FilmArray Instrument and assay pouch
Software Interface Result Reporting	• GenMark ePlex System Software • GenMark ePlex BCID-FP Panel Software	The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism and antimicrobial resistance gene on the panel.

Summary of Performance Data

EXPECTED VALUES

A prospective, multicenter clinical study was conducted to evaluate the clinical performance of the ePlex BCID-FP Panel in positive blood culture samples. A total of 447 positive blood culture samples were collected at 6 clinical sites in 2 phases from patients of all ages and genders. Samples were collected and frozen for future testing from May 2015 through July 2016. Samples were collected from July through August 2018 and tested fresh (never frozen). Of these 447 samples, 21 had a Gram stain result indicating fungal organism. The expected values of individual analytes based on the ePlex BCID-FP Panel results in the 21 prospective samples are summarized by age group and by site in **Tables 1** and **2** below.

Table 1: Expected Value by Age Group (Prospective Samples)

Target	All Ages (N=21) n (%)	Age <1 (N=1) n (%)	Age 1-17 (N=2) n (%)	Age 18-44 (N=4) n (%)	Age 45-64 (N=11) n (%)	Age 65-84 (N=2) n (%)	Age 85+ (N=1) n (%)
Candida albicans	4 (19.0)	1 (100)	0 (0.0)	0 (0.0)	2 (18.2)	1 (50.0)	0 (0.0)
Candida auris	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida dubliniensis	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
Candida famata	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida glabrata	6 (28.6)	0 (0.0)	1 (50.0)	1 (25.0)	3 (27.3)	1 (50.0)	0 (0.0)
Candida guilliermondii	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida kefyr	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida krusei	2 (9.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (18.2)	0 (0.0)	0 (0.0)
Candida lusitaniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida parapsilosis	2 (9.5)	0 (0.0)	1 (50.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
Candida tropicalis	2 (9.5)	0 (0.0)	0 (0.0)	1 (25.0)	1 (9.1)	0 (0.0)	0 (0.0)
Cryptococcus gattii	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cryptococcus neoformans	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fusarium	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhodotorula	1 (4.8)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 2: Expected Value by Collection Site (Prospective Samples)

Target	All Sites (N=21) n (%)	Site 1 (N=1) n (%)	Site 2 (N=8) n (%)	Site 3 (N=2) n (%)	Site 4 (N=4) n (%)	Site 5 (N=4) n (%)	Site 6 (N=2) n (%)
Candida albicans	4 (19.0)	1 (100)	0 (0.0)	2 (100)	1 (25.0)	0 (0.0)	0 (0.0)
Candida auris	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida dubliniensis	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)
Candida famata	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida glabrata	6 (28.6)	0 (0.0)	2 (25.0)	0 (0.0)	1 (25.0)	2 (50.0)	1 (50.0)
Candida guilliermondii	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida kefyr	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida krusei	2 (9.5)	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida lusitaniae	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Candida parapsilosis	2 (9.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	1 (50.0)
Candida tropicalis	2 (9.5)	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cryptococcus gattii	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cryptococcus neoformans	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fusarium	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhodotorula	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)

PERFORMANCE CHARACTERISTICS

Clinical Performance

Samples with a Gram stain result indicating fungal organism, a final, valid investigational test result, and a valid comparator result were evaluable and included in summaries and analyses of demographics, expected values (positivity rate), and performance characteristics. Evaluable samples included 11 prospective fresh and 10 prospective frozen samples as well as 120 retrospective samples and 725 contrived samples.

Comparator Method

The performance of the ePlex BCID-FP Panel was compared to standard laboratory procedures, including traditional and automated culture, MALDI-TOF IVD, and microbiological and biochemical techniques. In addition, all prospective samples were tested with analytically validated PCR assays followed by bi-directional sequencing to determine the presence or absence of *Candida auris*, *Fusarium*, and *Rhodotorula*. Identification for samples with *Candida parapsilosis* identified by standard laboratory procedures was confirmed using analytically validated PCR assays followed by bi-directional sequencing.

The comparator method(s) results were used to determine the Detected / Not Detected status for each target organism on the ePlex BCID-FP Panel. The comparator methods for each target are summarized in **Table 3**.

Table 3: Comparator Method(s) by ePlex BCID-FP Panel Target

Target	Comparator Method
Candida albicans	Standard laboratory procedures for organism identification.
Candida dubliniensis	
Candida famata	
Candida glabrata	
Candida guilliermondii	
Candida kefyr	
Candida krusei	
Candida lusitaniae	
Candida tropicalis	
Cryptococcus gattii	
Cryptococcus neoformans	
Candida parapsilosis	Standard laboratory procedures for organism ID. PCR/sequencing to confirm *C. parapsilosis* or identify *C. metapsilosis, C. orthopsilosis.*
Candida auris, Fusarium, and Rhodotorula	Standard laboratory procedures for organism identification. PCR/sequencing in prospective samples.

Demographics of Clinical Samples

Clinical performance was evaluated in samples prospectively and retrospectively collected. Prospective samples were collected at 6 clinical sites, with 21 evaluable samples. Sample with final, valid, ePlex BCID-FP Panel results and valid comparator results were considered evaluable. Demographic information for prospectively-collected samples is described in **Table 4.** Subjects enrolled in this study were from a diverse demographic distribution and represent the intended patient population.

To supplement the results of the prospective collection, 120 samples were collected retrospectively from a total of 9 sites, and 725 evaluable samples were contrived for organisms with low prevalence. Demographic information for retrospectively-collected samples is described in **Table 5**.

Table 4: Demographic Data for Clinical Samples by Collection Site (Prospective Collection)

	All Sites (N=21) n (%)	**Site 1 (N=1) n (%)**	**Site 2 (N=8) n (%)**	**Site 3 (N=2) n (%)**	**Site 4 (N=4 n (%))**	**Site 5 (N=4) n (%)**	**Site 6 (N=2) n (%)**
Sex, n (%)							
Male	14 (66.7)	1 (100)	7 (87.5)	1 (50.0)	3 (75.0)	1 (25.0)	1 (50.0)
Female	7 (33.3)	0 (0.0)	1 (12.5)	1 (50.0)	1 (25.0)	3 (75.0)	1 (50.0)
Age (years)							
<1 yr	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)
1-17 yrs	2 (9.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (50.0)	0 (0.0)
18-44 yrs	4 (19.0)	0 (0.0)	2 (25.0)	0 (0.0)	1 (25.0)	1 (25.0)	0 (0.0)
45-64 yrs	11 (52.4)	1 (100)	4 (50.0)	1 (50.0)	2 (50.0)	1 (25.0)	2 (100)
65-84 yrs	2 (9.5)	0 (0.0)	1 (12.5)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
85+ yrs	1 (4.8)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 5: Demographic Data for Clinical Samples by Collection Site (Retrospective Collection)

	All Sites (N=120) n (%)	Site 1 (N=13) n (%)	Site 2 (N=14) n (%)	Site 3 (N=17) n (%)	Site 4 (N=4) n (%)	Site 5 (N=3) n (%)	Site 6 (N=13) n (%)	Site 7 (N=16) n (%)	Site 8 (N=5) n (%)	Site 9 (N=35) n (%)
Sex, n (%)										
Male	68 (56.7)	10 (76.9)	8 (57.1)	8 (47.1)	1 (25.0)	2 (66.7)	8 (61.5)	9 (56.3)	3 (60.0)	19 (54.3)
Female	52 (43.3)	3 (23.1)	6 (42.9)	9 (52.9)	3 (75.0)	1 (33.3)	5 (38.5)	7 (43.8)	2 (40.0)	16 (45.7)
Age (years)										
<1 yr	2 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.7)
1-17 yrs	8 (6.7)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (38.5)	0 (0.0)	0 (0.0)	2 (5.7)
18-44 yrs	27 (22.5)	4 (30.8)	2 (14.3)	2 (11.8)	1 (25.0)	0 (0.0)	3 (23.1)	3 (18.8)	1 (20.0)	11 (31.4)
45-64 yrs	39 (32.5)	2 (15.4)	6 (42.9)	6 (35.3)	1 (25.0)	2 (66.7)	2 (15.4)	7 (43.8)	1 (20.0)	12 (34.3)
65-84 yrs	39 (32.5)	6 (46.2)	6 (42.9)	8 (47.1)	2 (50.0)	0 (0.0)	2 (15.4)	5 (31.3)	2 (40.0)	8 (22.9)
85+ yrs	5 (4.2)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	1 (33.3)	1 (7.7)	1 (6.3)	1 (20.0)	0 (0.0)

Clinical Performance

Sensitivity or positive percent agreement (PPA) was calculated by dividing the number of true positive (TP) results by the sum of TP and false negative (FN) results, while specificity or negative percent agreement (NPA) was calculated by dividing the number of true negative (TN) results by the sum of TN and false positive (FP) results. A TP result being defined as a sample where the detected ePlex BCID-FP Panel result matched the detected comparator method result, while a TN result was one where a negative ePlex BCID-FP Panel result matched a negative comparator method result. The two-sided 95% confidence interval was also calculated.

A total of 866 positive blood culture samples with a Gram stain result indicating fungal organism consisting of 11 fresh prospective, 10 frozen prospective, 120 retrospective, and 725 contrived samples were evaluated for the ePlex BCID-FP Panel targets. Contrived samples were prepared by spiking an isolate into a blood culture bottle and growing until flagged positive by a continuously monitoring blood culture system. Samples were removed from the system within 8 hours of positivity and stored frozen until the time of testing. PPA and NPA results are summarized by target in **Tables 6-20** below and the strains used to contrive samples are summarized in **Table 21**.

Table 6: Clinical Performance for *Candida albicans*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida albicans	Prospective (Fresh)	2/2	100 (34.2-100)	9/9	100 (70.1-100)
	Prospective (Frozen)	2/2	100 (34.2-100)	8/8	100 (67.6-100)
	Prospective (All)	**4/4**	**100 (51.0-100)**	**17/17**	**100 (81.6-100)**
	Retrospective	49/50	98.0 (89.5-99.6)	70/70	100 (94.8-100)
	Prospective/Retrospective	**53/54**	**98.1 (90.2-99.7)**	**87/87**	**100 (95.8-100)**
	Contrived	13/14	92.9 (68.5-98.7)	710/711	99.9 (99.2-100)
	Overall	**66/68**	**97.1 (89.9-99.2)**	**797/798**	**99.9 (99.3-100)**

CI= Confidence Interval

Table 7: Clinical Performance for *Candida auris*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida auris	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	0/0	---	120/120	100 (96.9-100)
	Prospective/Retrospective	**0/0**	**---**	**141/141**	**100 (97.3-100)**
	Contrived	49/49	100 (92.7-100)	676/676	100 (99.4-100)
	Overall	**49/49**	**100 (92.7-100)**	**817/817**	**100 (99.5-100)**

Table 8: Clinical Performance for *Candida dubliniensis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida dubliniensis	Prospective (Fresh)	1/1	100 (20.7-100)	10/10	100 (72.2-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**1/1**	**100 (20.7-100)**	**20/20**	**100 (83.9-100)**
	Retrospective	3/3	100 (43.9-100)	117/117	100 (96.8-100)
	Prospective/Retrospective	**4/4**	**100 (51.0-100)**	**137/137**	**100 (97.3-100)**
	Contrived	48/48	100 (92.6-100)	677/677	100 (99.4-100)
	Overall	**52/52**	**100 (93.1-100)**	**814/814**	**100 (99.5-100)**

Table 9: Clinical Performance for *Candida famata*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida famata	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	0/0	---	120/120	100 (96.9-100)
	Prospective/Retrospective	**0/0**	**---**	**141/141**	**100 (97.3-100)**
	Contrived	51/51	100 (93.0-100)	674/674	100 (99.4-100)
	Overall	**51/51**	**100 (93.0-100)**	**815/815**	**100 (99.5-100)**

Table 10: Clinical Performance for *Candida glabrata*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida glabrata	Prospective (Fresh)	4/4	100 (51.0-100)	7/7	100 (64.6-100)
	Prospective (Frozen)	2/2	100 (34.2-100)	8/8	100 (67.6-100)
	Prospective (All)	**6/6**	**100 (61.0-100)**	**15/15**	**100 (79.6-100)**
	Retrospective	37/38	97.4 (86.5-99.5)	80/82	97.6 (91.5-99.3)
	Prospective/Retrospective	**43/44**	**97.7 (88.2-99.6)**	**95/97[A]**	**97.9 (92.8-99.4)**
	Contrived	16/16	100 (80.6-100)	709/709	100 (99.5-100)
	Overall	**59/60**	**98.3 (91.1-99.7)**	**804/806**	**99.8 (99.1-99.9)**

A. *C. glabrata* was detected in 2/2 false positive clinical samples using PCR/sequencing.

Table 11: Clinical Performance for *Candida guilliermondii*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida guilliermondii	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	0/0	---	120/120	100 (96.9-100)
	Prospective/Retrospective	**0/0**	**---**	**141/141**	**100 (97.3-100)**
	Contrived	49/50	98.0 (89.5-99.6)	675/675	100 (99.4-100)
	Overall	**49/50**	**98.0 (89.5-99.6)**	**816/816**	**100 (99.5-100)**

Table 12: Clinical Performance for *Candida kefyr*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida kefyr	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	0/0	---	120/120	100 (96.9-100)
	Prospective/Retrospective	**0/0**	**---**	**141/141**	**100 (97.3-100)**
	Contrived	51/51	100 (93.0-100)	672/674	99.7 (98.9-99.9)
	Overall	**51/51**	**100 (93.0-100)**	**813/815**	**99.8 (99.1-99.9)**

Table 13: Clinical Performance for *Candida krusei*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida krusei	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	2/2	100 (34.2-100)	8/8	100 (67.6-100)
	Prospective (All)	**2/2**	**100 (34.2-100)**	**19/19**	**100 (83.2-100)**
	Retrospective	2/2	100 (34.2-100)	118/118	100 (96.8-100)
	Prospective/Retrospective	**4/4**	**100 (51.0-100)**	**137/137**	**100 (97.3-100)**
	Contrived	46/46	100 (92.3-100)	679/679	100 (99.4-100)
	Overall	**50/50**	**100 (92.9-100)**	**816/816**	**100 (99.5-100)**

Table 14: Clinical Performance for *Candida lusitaniae*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida lusitaniae	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	3/4	75.0 (30.1-95.4)	116/116	100 (96.8-100)
	Prospective/Retrospective	**3/4**	**75.0 (30.1-95.4)**	**137/137**	**100 (97.3-100)**
	Contrived	45/45	100 (92.1-100)	679/680	99.9 (99.2-100)
	Overall	**48/49**	**98.0 (89.3-99.6)**	**816/817**	**99.9 (99.3-100)**

Table 15: Clinical Performance for *Candida parapsilosis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida parapsilosis	Prospective (Fresh)	2/2	100 (34.2-100)	9/9	100 (70.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**2/2**	**100 (34.2-100)**	**19/19**	**100 (83.2-100)**
	Retrospective	16/17	94.1 (73.0-99.0)	102/103	99.0 (94.7-99.8)
	Prospective/Retrospective	**18/19**	**94.7 (75.4-99.1)**	**121/122[A]**	**99.2 (95.5-99.9)**
	Contrived	41/41	100 (91.4-100)	684/684	100 (99.4-100)
	Overall	**59/60**	**98.3 (91.1-99.7)**	**805/806**	**99.9 (99.3-100)**

A. *C. parapsilosis* was detected in 1/1 false positive clinical sample using PCR/sequencing.

Table 16: Clinical Performance for *Candida tropicalis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Candida tropicalis	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	2/2	100 (34.2-100)	8/8	100 (67.6-100)
	Prospective (All)	**2/2**	**100 (34.2-100)**	**19/19**	**100 (83.2-100)**
	Retrospective	3/3	100 (43.9-100)	116/117	99.1 (95.3-99.8)
	Prospective/Retrospective	**5/5**	**100 (56.6-100)**	**135/136[A]**	**99.3 (96.0-99.9)**
	Contrived	45/45	100 (92.1-100)	680/680	100 (99.4-100)
	Overall	**50/50**	**100 (92.9-100)**	**815/816**	**99.9 (99.3-100)**

A. *C. tropicalis* was detected in 1/1 false positive clinical sample using PCR/sequencing.

Table 17: Clinical Performance for *Cryptococcus gattii*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Cryptococcus gattii	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	0/0	---	120/120	100 (96.9-100)
	Prospective/Retrospective	**0/0**	**---**	**141/141**	**100 (97.3-100)**
	Contrived	50/50	100 (92.9-100)	675/675	100 (99.4-100)
	Overall	**50/50**	**100 (92.9-100)**	**816/816**	**100 (99.5-100)**

Table 18: Clinical Performance for *Cryptococcus neoformans*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Cryptococcus neoformans	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	5/5	100 (56.6-100)	115/115	100 (96.8-100)
	Prospective/Retrospective	**5/5**	**100 (56.6-100)**	**136/136**	**100 (97.3-100)**
	Contrived	52/52	100 (93.1-100)	673/673	100 (99.4-100)
	Overall	**57/57**	**100 (93.7-100)**	**809/809**	**100 (99.5-100)**

Table 19: Clinical Performance for *Fusarium*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Fusarium	Prospective (Fresh)	0/0	---	11/11	100 (74.1-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**0/0**	**---**	**21/21**	**100 (84.5-100)**
	Retrospective	0/0	---	120/120	100 (96.9-100)
	Prospective/Retrospective	**0/0**	**---**	**141/141**	**100 (97.3-100)**
	Contrived	69/70	98.6 (92.3-99.7)	655/655	100 (99.4-100)
	Overall	**69/70**	**98.6 (92.3-99.7)**	**796/796**	**100 (99.5-100)**

Table 20: Clinical Performance for *Rhodotorula*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Rhodotorula	Prospective (Fresh)	1/1	100 (20.7-100)	10/10	100 (72.2-100)
	Prospective (Frozen)	0/0	---	10/10	100 (72.2-100)
	Prospective (All)	**1/1**	**100 (20.7-100)**	**20/20**	**100 (83.9-100)**
	Retrospective	1/1	100 (20.7-100)	119/119	100 (96.9-100)
	Prospective/Retrospective	**2/2**	**100 (34.2-100)**	**139/139**	**100 (97.3-100)**
	Contrived	48/50	96.0 (86.5-98.9)	674/675	99.9 (99.2-100)
	Overall	**50/52**	**96.2 (87.0-98.9)**	**813/814**	**99.9 (99.3-100)**

Table 21: Contrived Sample Summary

Target	Organism	Strain	Independent Contrived Samples Tested
Candida albicans	*Candida albicans*	ATCC 10231	2
		ATCC 14053	2
		ATCC 24433	2
		ATCC 90028	5
		ATCC MYA-4441	3
	Candida albicans total		14
Candida auris	*Candida auris*	ATCC 10913	1
		ATCC 12372	1
		ATCC 12766	1
		CBS 10913	3
		CBS 12372	3
		CBS 12373	2
		CBS 12766	3
		CBS 12767	3
		CBS 12768	2
		CDC#0385	5
		CDC#0386	5
		CDC#0387	5
		CDC#0388	5
		CDC#0389	5
		CDC#0390	5
	Candida auris total		49
		ATCC MYA-577	6

Target	Organism	Strain	Independent Contrived Samples Tested
Candida dubliniensis	*Candida dubliniensis*	ATCC MYA-578	12
		ATCC MYA-579	12
		ATCC MYA-582	13
		NCPF3949	5
	Candida dubliniensis total		48
Candida famata	*Debaryomyces fabryi*	CBS 789	21
	Debaryomyces hansenii	CBS 1961	3
	Debaryomyces subglobosus	CBS 1796	27
	Candida famata total		51
Candida glabrata	*Candida glabrata*	128-4058	1
		128-4072	1
		ATCC 15126	2
		ATCC 15545	2
		ATCC 2001	1
		ATCC 66032	4
		ATCC 90030	2
		ATCC MYA-2950	3
	Candida glabrata total		16
Candida guilliermondii	*Candida guilliermondii*	ATCC 22017	13
		ATCC 6260	12
	Meyerozyma guilliermondii	ATCC 90197	10
		ATCC 90198	9
		ATCC 90199	6
	Candida guilliermondii total		50
Candida kefyr	*Candida kefyr*	ATCC 204093	4
		ATCC 2512	10
		ATCC 4135	13
		ATCC 66028	12
		ATCC 8553	12
	Candida kefyr total		51
Candida krusei	*Candida krusei*	ATCC 14243	8
		ATCC 22985	9
		ATCC 28870	9
		ATCC 32196	10
		ATCC 34135	10
	Candida krusei total		46

Target	Organism	Strain	Independent Contrived Samples Tested
Candida lusitaniae	*Candida lusitaniae*	ATCC 26287	5
		ATCC 34449	10
		ATCC 42720	9
		ATCC 66035	11
		ATCC MYA-766	10
	Candida lusitaniae total		45
Candida parapsilosis	*Candida parapsilosis*	ATCC 22019	11
		ATCC 28474	5
		ATCC 28475	10
		ATCC 58895	7
		ATCC 90018	8
	Candida parapsilosis total		41
Candida tropicalis	*Candida tropicalis*	ATCC 1369	9
		ATCC 13803	12
		ATCC 201380	9
		ATCC 201381	7
		ATCC 750	8
	Candida tropicalis total		45
Cryptococcus gattii	*Cryptococcus gattii*	ATCC 14248	11
		ATCC 76108	12
		ATCC MYA-4138	10
		ATCC MYA-4560	8
		ATCC MYA-4877	9
	Cryptococcus gattii total		50
Cryptococcus neoformans	*Cryptococcus neoformans* var. *grubii*	ATCC 14116	9
		ATCC 208821(H99)	8
		ATCC 90112	7
		NCPF8195	7
		NCPF8299	3
		NCPF8357	3
	Cryptococcus neoformans var. *neoformans* (*Filobasidiella bacillispora* Kwon-Chung, teleomorph (serotype D))	ATCC 34873	3
	Cryptococcus neoformans var. *neoformans* (serotype D)	ATCC 36556	3
		ATCC MYA-565	9
	Cryptococcus neoformans total		52
Fusarium	*Bisifusarium dimerum*	CBS 108944	3
		CBS 110317	9
		CBS 116520	3

Target	Organism	Strain	Independent Contrived Samples Tested
	Fusarium moniliforme	ATCC 38159	11
	Fusarium oxysporum	CBS 116611	1
	Fusarium sacchari	ATCC 24379	10
		CBS 119828	11
	Fusarium solani	ATCC 36031	11
	Fusarium verticillioides	CBS 100312	11
	Fusarium total		70
Rhodotorula	*Rhodotorula glutinis*	ATCC 32765	3
		ATCC 32766	3
	Rhodotorula glutinis (Fresenius) Harrison	ATCC 96365	4
	Rhodotorula mucilaginosa	ATCC 66034	21
		ATCC 9449	19
	Rhodotorula total		50

Genus and Group Assay Species Stratification

The ePlex BCID-FP Panel reports genus level results for *Fusarium* and *Rhodotorula* targets. Sensitivity/PPA of these genus and group level targets for species from all clinical and contrived samples tested are summarized in **Table 22** below.

Table 22: Species Detected by Genus Assays

Target Species Detected	All Samples	
	Sensitivity/PPA	
	TP/TP+FN	% (95% CI)
Fusarium	**69/70**	**98.6 (92.3-99.7)**
Bisifusarium dimerum	14/15	93.3 (70.2-98.8)
Fusarium moniliforme	11/11	100 (74.1-100)
Fusarium oxysporum	1/1	100 (20.7-100)
Fusarium sacchari	21/21	100 (84.5-100)
Fusarium solani	11/11	100 (74.1-100)
Fusarium verticillioides	11/11	100 (74.1-100)
Rhodotorula	**50/52**	**96.2 (87.0-98.9)**
*Rhodotorula**	2/2	100 (34.2-100)
Rhodotorula glutinis	6/6	100 (61.0-100)
Rhodotorula glutinis (Fresenius) Harrison	4/4	100 (51.0-100)
Rhodotorula mucilaginosa	38/40	95.0 (83.5-98.6)

*Results are from 2 clinical samples (1 prospective, 1 retrospective). All other *Fusarium* and *Rhodotorula* samples were contrived.

Co-detections in Clinical Samples

The ePlex BCID-FP Panel did not identify any fungal co-detections in prospective samples, and 6 fungal co-detections were identified in the retrospective samples. Of the 120 retrospective samples, 114 (95.0%) had single detections and 6 (5.0%) had double detections. In the 6 co-detections, 4 included 1 organism that comparator method(s) did not detect. See **Table 27** below for a summary of co-detections in retrospective samples.

Table 23 Co-Detections Identified by the ePlex BCID-FP Panel (Retrospective Samples)

Distinct Organism Combinations Detected by the ePlex Panel in Retrospective Samples		Number of Samples (Number Discrepant)	Discrepant Organism(s)[A,B]
Target 1	**Target 2**		
Candida albicans	*Candida dubliniensis*	1 (0)	
Candida albicans	*Candida parapsilosis*	1 (0)	
Candida dubliniensis	*Candida parapsilosis*	1 (1)	*C. parapsilosis* (1)
Candida dubliniensis	*Candida tropicalis*	1 (1)	*C. tropicalis* (1)
Candida glabrata	*Candida lusitaniae*	2 (2)	*C. glabrata* (2)

A. A discrepant organism is defined as one that was detected by the BCID-FP Panel but not by the comparator method(s).
B. 4/4 organisms were investigated using PCR/sequencing and the discrepant organism was detected in 4/4 cases.
   i. In 1/1 sample, *C. parapsilosis* was detected.
   ii. In 1/1 sample, *C. tropicalis* was detected.
   iii. In 2/2 samples, *C. glabrata* was detected.

Summaries of additional distinct fungal co-detections detected by the comparator method in prospective and retrospective samples are provided in Table 28 and Table 29. These tables include additional distinct fungal co-detections not included in the co-detections identified by the BCID-FP Panel; they have 1 or more organism not detected by the BCID-FP Panel or an off-panel fungal organism.

Table 24: Co-Detections Identified by the Comparator Method (Prospective Samples)

Distinct Organism Combinations Detected by the Comparator Method in Prospective Samples		Number of Samples (Number Discrepant)	Discrepant Organism(s)[A]
Target 1	**Target 2**		
*Candida metapsilosis**	*Trichosporon asahii**	1 (0)	

A. A discrepant organism is defined as one that was detected by the comparator method(s) but not by the BCID-FP Panel (excludes organisms not targeted by the BCID-FP Panel).
* Off-panel organism not targeted by the BCID-FP Panel.

Table 25: Co-Detections Identified by the Comparator Method (Retrospective Samples)

Distinct Organism Combinations Detected by the Comparator Method in Retrospective Samples			Number of Samples (Number Discrepant)	Discrepant Organism(s)[A]
Target 1	**Target 2**	**Target 3**		
Candida albicans	*Candida dubliniensis*	*Candida glabrata*	1 (1)	*C. glabrata* (1)
Candida albicans	*Candida parapsilosis*		1 (1)	*C. parapsilosis* (1)

A. A discrepant organism is defined as one that was detected by the comparator method(s) but not by the BCID-FP Panel (excludes organisms not targeted by the BCID-FP Panel).

Clinical Study ePlex Instrument Performance

A total of 867 samples (including prospective, retrospective, and contrived samples) were initially tested in the clinical evaluations. Of these, 7/867 (0.8%) did not complete the run and the sample was retested. After repeat testing, all 867 samples completed testing and 839/867 (96.8%, 95% CI: 95.4%-97.8%) generated valid results and 28/867 (3.2%, 95% CI: 2.2%-4.6%) generated invalid results on the first completed attempt.

Upon repeat testing of the 28 samples with initially invalid results, all completed the run and 27/28 (96.4%) generated valid results. Overall, after final testing, 1/867 (0.1%, 95% CI: 0.0%-0.7%) had final, invalid results, resulting in a final validity rate of 866/867 (99.9%, 95% CI: 99.3%-100%).

Analytical Performance Characteristics

Limit of Detection (Analytical Sensitivity)

The Limit of Detection (LOD), or analytical sensitivity, was identified and verified for each assay on the BCID-FP Panel using at least two quantified reference strains in simulated blood culture sample matrix, which is defined as whole blood with EDTA added to a blood culture bottle in the same ratio as the manufacturer recommends and incubated for 8 hours. At least 20 replicates per target were tested for each condition. The limit of detection was defined as the lowest concentration of each target that is detected in ≥95% of tested replicates. The confirmed LOD for each ePlex BCID-FP Panel organism is shown in **Table 26.**

Table 26: LOD Results Summary

Target	Organism	Strain	LOD Concentration (CFU/mL)
Candida albicans	*Candida albicans*	ATCC 14053	1×10^6
	Candida albicans	ATCC 24433	1×10^5
Candida auris	*Candida auris*	CBS 10913	1×10^5
	Candida auris	CBS 12766	1×10^5
Candida dubliniensis	*Candida dubliniensis*	ATCC MYA-577	1×10^4
	Candida dubliniensis	NCPF 3949	1×10^5
Candida famata	*Candida famata*	CBS 767	1×10^3
	Candida famata	CBS 766	1×10^4
Candida glabrata	*Candida glabrata*	ATCC 2001	1×10^6
	Candida glabrata	ATCC 15545	1×10^6
Candida guilliermondii	*Candida guilliermondii*	ATCC 22017	1×10^5
	Candida guilliermondii	ATCC 6260	1×10^5
Candida kefyr	*Candida kefyr*	ATCC 4135	1×10^3
	Candida kefyr	ATCC 8553	1×10^4
Candida krusei	*Candida krusei*	ATCC 22985	1×10^5
	Candida krusei	ATCC 28870	1×10^6
Candida lusitaniae	*Candida lusitaniae*	ATCC 34449	1×10^6
	Candida lusitaniae	ATCC 66035	1×10^5
Candida parapsilosis	*Candida parapsilosis*	ATCC 28474	1×10^4
	Candida parapsilosis	ATCC 28475	1×10^5
Candida tropicalis	*Candida tropicalis*	ATCC 13803	1×10^5
	Candida tropicalis	ATCC 1369	1×10^6
Cryptococcus gattii	*Cryptococcus gattii*	ATCC MYA-4877	1×10^3

Target	Organism	Strain	LOD Concentration (CFU/mL)
	Cryptococcus gattii	ATCC MYA-4138	1 x 10^3
Cryptococcus neoformans	*Cryptococcus neoformans*	ATCC 208821	1 x 10^5
	Cryptococcus neoformans	ATCC MYA-565	1 x 10^5
Fusarium	*Fusarium oxysporum*	CBS 116611	1 x 10^6 spores/mL
	Fusarium solani	ATCC 36301	1 x 10^6 spores/mL
Rhodotorula	*Rhodotorula mucilaginosa*	ATCC 4058	1 x 10^5
	Rhodotorula glutinis	ATCC 32765	1 x 10^5

Analytical Reactivity (Inclusivity)

A panel of 51 strains/isolates, representing the genetic, temporal and geographic diversity of each target on the ePlex BCID-FP Panel was evaluated to demonstrate analytical reactivity. Each strain was tested in triplicate at concentrations approximating bottle positivity (1 x 10^6 CFU/mL for *Candida* and *Rhodotorula*, 1 x 10^7 CFU/mL for *Cryptococcus*, and 1 x 10^8 spores/mL for *Fusarium*). All organisms tested were detected at bottle positive concentrations. Results of the analytical reactivity are summarized in **Table 27**. An additional 29 unique strains were detected as a part of the **Limit of Detection (Analytical Sensitivity)** study and are summarized in **Table 26**.

Table 27: Analytical Reactivity (Inclusivity) Results

Target	Organism	Strain
Candida albicans	*Candida albicans*	ATCC 10231
	Candida albicans	ATCC 90028
	Candida albicans	ATCC MYA-4441
Candida auris	*Candida auris*	CDC#385
	Candida auris	CDC#386
	Candida auris	CDC#387
	Candida auris	CDC#388
	Candida auris	CDC#389
	Candida auris	CDC#390
	Candida auris	CBS 12766
Candida dubliniensis	*Candida dubliniensis*	ATCC MYA-578
	Candida dubliniensis	ATCC MYA-579
	Candida dubliniensis	ATCC MYA-582
Candida famata	*Candida famata*	ATCC 20850
	Candida famata	CBA 1961
	Candida famata	CBS 789
Candida glabrata	*Candida glabrata*	ATCC 15126
	Candida glabrata	ATCC 66032
	Candida glabrata	ATCC MYA-2950
Candida guilliermondii	*Candida guilliermondii*	ATCC 90197
	Candida guilliermondii	ATCC 90198
	Candida guilliermondii	ATCC 90199
Candida kefyr	*Candida kefyr*	ATCC 204093
	Candida kefyr	ATCC 2512
	Candida kefyr	ATCC 66028
Candida krusei	*Candida krusei*	ATCC 14243
	Candida krusei	ATCC 32196
	Candida krusei	ATCC 34135
Candida lusitaniae	*Candida lusitaniae*	ATCC 42720
	Candida lusitaniae	ATCC MYA-766
	Candida lusitaniae	Z010
Candida parapsilosis	*Candida parapsilosis*	ATCC 22019
	Candida parapsilosis	ATCC 58895
	Candida parapsilosis	ATCC 90018
Candida tropicalis	*Candida tropicalis*	ATCC 201380
	Candida tropicalis	ATCC 201381

Target	Organism	Strain
	Candida tropicalis	ATCC 750
Cryptococcus gattii	*Cryptococcus gattii*	ATCC 14248
	Cryptococcus gattii	ATCC 4560
	Cryptococcus gattii	ATCC 76108
Cryptococcus neoformans	*Cryptococcus neoformans*	ATCC 14116
	Cryptococcus neoformans	ATCC 90112
	Cryptococcus neoformans	NCPF 8299
Fusarium	*Bisifusarium dimerum*	CBS 110317
	Fusarium moniliforme	ATCC 38159
	Fusarium proliferatum	CBS 131570
	Fusarium sacchari	CBS 119828
	Fusarium verticillioides	CBS 100312
Rhodotorula	*Rhodotorula glutinis*	ATCC 96365
	Rhodotorula mucilaginosa	ATCC 66034
	Rhodotorula mucilaginosa	ATCC 9449

Predicted (*in silico*) Reactivity for Genus and Group Assays

Note: the performance of the ePlex BCID-FP Panel has not been established for all of the organisms listed in the tables below. See the Analytical Reactivity (Inclusivity) and Limit of Detection (Analytical Sensitivity) sections of the package insert for data on organisms for which performance characteristics have been established (indicated with an asterisk in Tables 32 and 33). Some species were not assessed *in silico* due to lack of sequence data, though they may appear in the analytical sensitivity or specificity studies.

In addition to species-specific assays, the ePlex BCID-FP Panel contains two broader genus-level assays: *Fusarium* and *Rhodotorula*. **Table 28** and **Table 29** highlight the predicted (*in silico*) reactivity (inclusivity) for these assay targets.

Table 28: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Fusarium*

Detection Predicted for ≥95% of target sequences		
Fusarium acaciae-mearnsii	*Fusarium cortaderiae*	*Fusarium napiforme*
Fusarium acuminatum	*Fusarium culmorum*	*Fusarium nisikadoi*
Fusarium acutatum	*Fusarium denticulatum*	*Fusarium nygamai*
Fusarium aethiopicum	*Bisifusarium dimerum**	*Fusarium oxysporum**
Fusarium ananatum	*Fusarium dlaminii*	*Fusarium palustre*
Fusarium andiyazi	*Fusarium equiseti*	*Fusarium phyllophilum*
Fusarium anthophilum	*Fusarium falciforme*	*Fusarium poae*
Fusarium armeniacum	*Fusarium foetens*	*Fusarium polyphialidicum*
Fusarium asiaticum	*Fusarium fujikuroi*	*Fusarium proliferatum**
Fusarium austroamericanum	*Fusarium gaditjirri*	*Fusarium pseudoanthophilum*
Fusarium avenaceum	*Fusarium globosum*	*Fusarium pseudocircinatum*
Fusarium aywerte	*Fusarium guttiforme*	*Fusarium pseudograminearum*
Fusarium bactridioides	*Fusarium hostae*	*Fusarium pseudonygamai*
Fusarium begoniae	*Fusarium incarnatum*	*Fusarium ramigenum*
Fusarium beomiforme	*Fusarium inflexum*	*Fusarium sacchari**
Fusarium boothii	*Fusarium konzum*	*Fusarium secorum*
Fusarium brachygibbosum	*Fusarium lacertarum*	*Fusarium sinensis*
Fusarium brasilicum	*Fusarium lactis*	*Fusarium solani**
Fusarium brevicatenulatum	*Fusarium langsethiae*	*Fusarium sporotrichioides*
Fusarium bulbicola	*Fusarium lichenicola*	*Fusarium sterilihyphosum*

	(Cylindrocarpon lichenicola)	
Fusarium bullatum	*Fusarium louisianense*	*Fusarium subglutinans*
Fusarium camptoceras	*Fusarium lunulosporum*	*Fusarium temperatum*
Fusarium cerealis	*Fusarium mangiferae*	*Fusarium thapsinum*
Fusarium circinatum	*Fusarium meridionale*	*Fusarium udum*
Fusarium commune	*Fusarium mesoamericanum*	*Fusarium verticillioides**
Fusarium concentricum	*Fusarium mexicanum*	
Fusarium concolor	*Fusarium musae*	
Detection Predicted for 85%-94% of target sequences		
Fusarium torulosum	*Fusarium xylarioides*	
Detection Predicted for <85% of target sequences		
Fusarium chlamydosporum (66.7%)	*Fusarium graminearum* (59.4%)	*Fusarium longipes* (25.0%)
Fusarium coeruleum (50.0%)	*Fusarium lateritium* (50.0%)	*Fusarium nelsonii* (16.7%)
Detection Not Predicted		
Fusarium kyushuense	*Fusarium sambucinum*	*Fusarium venenatum*
Fusarium miscanthi	*Fusarium stilboides*	
Fusarium redolens	*Fusarium succisae*	

Table 29: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Rhodotorula*

Detection Predicted for ≥95% of target sequences		
Rhodotorula araucariae	*Rhodotorula graminis*	*Rhodotorula taiwanensis*
*Rhodotorula glutinis**	*Rhodotorula mucilaginosa**	
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
Rhodotorula acheniorum	*Rhodotorula fragariae*	*Rhodotorula marina*
Rhodotorula acuta	*Rhodotorula fujisanensis*	*Rhodotorula minuta*
Rhodotorula armeniaca	*Rhodotorula hinnulea*	*Rhodotorula muscorum*
Rhodotorula aurantiaca	*Rhodotorula hordea*	*Rhodotorula nothofagi*
Rhodotorula auriculariae	*Rhodotorula hylophila*	*Rhodotorula philyla*
Rhodotorula bacarum	*Rhodotorula ingeniosa*	*Rhodotorula phylloplana*
Rhodotorula bogoriensis	*Rhodotorula javanica*	*Rhodotorula pilati*
Rhodotorula buffonii	*Rhodotorula lactosa*	*Rhodotorula pustula*
Rhodotorula ferulica	*Rhodotorula lignophila*	*Rhodotorula sonckii*

Analytical Specificity (Cross-Reactivity and Exclusivity)

Cross-reactivity of on-panel and off-panel analytes was evaluated with the BCID-FP Panel. On-panel organisms were tested in triplicate at concentrations approximating bottle positivity (see **Analytical Reactivity (Inclusivity)** section of the package insert for additional details). Off-panel organisms were tested at concentrations of $\geq 1x10^9$ CFU/mL for bacteria and $\geq 1x10^7$ CFU/mL or spores/mL for fungi unless otherwise noted in **Table 30**. If the target concentration could not be reached, the organism was diluted 2-fold from stock for use.

No cross reactivity was observed for any of the organisms tested. See **Table 30** for a summary of the on-panel strains tested and **Table 31** for a summary of off-panel strains tested.

On-Panel Exclusivity

Table 30: On-Panel Organisms Assessed for Cross-reactivity with the ePlex BCID-FP Panel (Exclusivity)

Organism	Strain
Candida albicans	ATCC 10231
Candida albicans	ATCC 90028
Candida albicans	ATCC MYA-4441
Candida auris	CBS 12766
Candida auris	CDC#385
Candida auris	CDC#386
Candida auris	CDC#387
Candida auris	CDC#388
Candida auris	CDC#389
Candida auris	CDC#390
Candida dubliniensis	ATCC MYA-578
Candida dubliniensis	ATCC MYA-579
Candida dubliniensis	ATCC MYA-582
Candida famata	ATCC 20850
Candida famata	CBA 1961
Candida famata	CBS 789
Candida glabrata	ATCC 15126
Candida glabrata	ATCC 66032
Candida glabrata	ATCC MYA-2950
Candida guilliermondii	ATCC 90197
Candida guilliermondii	ATCC 90198
Candida guilliermondii	ATCC 90199
Candida kefyr	ATCC 204093
Candida kefyr	ATCC 2512
Candida kefyr	ATCC 66028
Candida krusei	ATCC 14243
Candida krusei	ATCC 32196
Candida krusei	ATCC 34135
Candida lusitaniae	ATCC 42720
Candida lusitaniae	ATCC MYA-766
Candida lusitaniae	Z010
Candida parapsilosis	ATCC 22019
Candida parapsilosis	ATCC 58895
Candida parapsilosis	ATCC 90018
Candida tropicalis	ATCC 201380
Candida tropicalis	ATCC 201381
Candida tropicalis	ATCC 750
Cryptococcus gattii	ATCC 14248
Cryptococcus gattii	ATCC 4560
Cryptococcus gattii	ATCC 76108
Cryptococcus neoformans	ATCC 14116
Cryptococcus neoformans	ATCC 90112
Cryptococcus neoformans	NCPF 8299
Bisifusarium dimerum	CBS 110317
Fusarium lichenicola (Cylindrocarpon lichenicola)	ATCC 204306
Fusarium moniliforme	ATCC 38159
Fusarium proliferatum	CBS 131570
Fusarium sacchari	CBS 119828
Fusarium verticillioides	CBS 100312
Rhodotorula glutinis	ATCC 96365
Rhodotorula mucilaginosa	ATCC 66034
Rhodotorula mucilaginosa	ATCC 9449

Off-Panel Exclusivity

Table 31: Off-Panel Organisms Assessed for Cross-Reactivity with the ePlex BCID-FP Panel (Exclusivity)

Organism	Strain
Acinetobacter Iwoffii	ATCC 15309
Acremonium kiliense	ATCC 4301
Aspergillus fumigatus	ATCC 204305[A]
Bacteroides fragilis	ATCC 25285
Bordetella pertussis	ATCC 9340
Candida bracarensis	CBS 10154
Candida carpophila	CBS 5256
Candida duobushaemulonii	CDC#394
Candida haemulonii	CDC#393
Candida inconspicua	ATCC 16783
Candida lambica	ATCC 24750
Candida lipolytica	ATCC 20177
Candida metapsilosis	ATCC 96144
Candida nivariensis	CBS 9984
Candida norvegensis	ATCC 22977
Candida orthopsilosis	ATCC 96139
Candida pelliculosa	ATCC 10262
Candida rugosa	CBS 96275
Candida sake	ATCC 22021
Candida utilis	ATCC 9256
Citrobacter freundii	ATCC 6879
Clostridium perfringens	ATCC 13124
Corynebacterium striatum	ATCC 7094
Enterobacter aerogenes	ATCC 29751
Enterobacter cloacae	ATCC 23373
Enterococcus faecium	ATCC 31282
Exophiala jeanselmei	ATCC 12734
Filobasidium elegans	CBS 7637
Filobasidium globisporum	CBS 7642
Klebsiella oxytoca	ATCC 43165
Kluyveromyces lactis	ATCC 10689

Organism	Strain
Kodamaea ohmeri	CDC#0396
Lactobacillus rhamnosus	ATCC 53103
Malassezia furfur	ATCC 12078
Malassezia furfur	ATCC 14521
Malassezia furfur	CBS 7710
Malassezia globosa	ATCC MYA-4612
Malassezia restricta	ATCC MYA-4611
Malassezia sympodialis	ATCC 44031
Meyerozyma caribbica (Candida fermentati)	ATCC 20296
Micrococcus luteus	ATCC 19212
Morganella morganii	ATCC 25830
Mucor velutinosus	ATCC MYA-4766
Penicillium marneffei	ATCC 200050
Proteus mirabilis	ATCC 35659
Rhodotorula minuta	ATCC 36236
Saccharomyces cerevisiae	ATCC 18824
Salmonella enterica (Typhi)	ATCC 19430
Scedosporium prolificans	ATCC 200543
Schizosaccharomyces pombe	LPY 02387
Serratia marcescens	ATCC 43861
Sporidiobolus salmonicolor	ATCC 24217
Sporothrix schenckii	ATCC 18616
Staphylococcus hominis	ATCC 27844
Staphylococcus intermedius	ATCC 29663
Staphylococcus saprophyticus	ATCC 15305
Streptococcus agalactiae	ATCC 12401
Streptococcus anginosus	ATCC 9895
Streptococcus pyogenes	ATCC 12384
Trichosporon asahii	ATCC 201110
Trichosporon asteroides	ATCC 90043
Trichosporon dermatis	ATCC 204094

A. Tested at 1 x 10^6 spores/mL

Bottle Positivity

Several representative fungal organisms were spiked into blood culture bottles along with the manufacturer's recommended volume of human whole blood and grown to positivity in a commercially-available continuously monitoring blood culture system. Bottles were removed from the incubator within two hours of being identified as positive as well as eight hours after bottle positivity. At least two independent positive blood culture replicates were quantified for each organism on culture plates. Organisms tested and approximate bottle positivity concentrations are summarized in **Table 32**. Concentrations shown below represent approximate levels that may be observed in a clinical setting. All estimated bottle positivity concentrations are equivalent or greater than the established Limit of Detection (LOD) for each of the assays of the ePlex BCID-FP Panel.

Table 32: Bottle Positivity Concentrations

Organism	Strain ID	Mean Bottle Positivity Concentration	Mean Bottle Positivity +8 hours Concentration
Candida albicans	ATCC 90082	1.6×10^6 CFU/mL	1.4×10^6 CFU/mL
Cryptococcus neoformans var. grubii	ATCC 14116	1.3×10^7 CFU/mL	6.5×10^7 CFU/mL
Fusarium solani	ATCC 36031	9.6×10^6 spores/mL	7.7×10^6 spores/mL
Rhodotorula mucilaginosa	ATCC 66034	1.6×10^6 CFU/mL	4.2×10^6 CFU/mL

Reproducibility

Two positive mixes including 5 on-panel organisms at two concentrations and one negative mix including an off-panel organism were tested. Concentrations in the positive mixes reflected those observed at time of bottle positivity (BP) and time of bottle positivity plus 8 hours or one log higher than that expected at bottle positivity (BP+8) and one mix containing an off-panel organism grown to bottle positivity, which is expected to yield a negative result. Bottle concentrations used in this study are summarized in **Table 32**. Testing occurred at three sites, with two operators testing the mixes over six days using three cartridge lots.

Table 32: Bottle Positivity Concentrations

Organism	Bottle Positivity Concentration	Bottle Positivity +8 Hours Concentration
Candida albicans	1 x 10^6 CFU/mL	1 x 10^7 CFU/mL
Candida kefyr	1 x 10^6 CFU/mL	1 x 10^7 CFU/mL
Cryptococcus neoformans	1 x 10^7 CFU/mL	1 x 10^8 CFU/mL
Fusarium sacchari	6.5 x10^6 spores/mL	6.1 x10^6 spores/mL
Rhodotorula mucilaginosa	1 x 10^6 CFU/mL	1 x 10^7 CFU/mL

The percent agreement of each target with the expected result is summarized in **Tables 33-37**.

Table 33: Percent Agreement for *Candida albicans*

Concentration of *Candida albicans*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours ($1x10^7$ CFU/mL)	1	34/35	97.1	(85.5-99.5)
	2	35/36	97.2	(85.8-99.5)
	3	36/36	100	(90.4-100)
	All	**105/107**	**98.1**	**(93.4-99.5)**
Bottle Positive ($1x10^6$ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**108/108**	**100**	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	108/108	100	(96.6-100)
	All	**324/324**	**100**	**(98.8-100)**

Table 34: Percent Agreement for *Candida kefyr*

Concentration of *Candida kefyr*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours ($1x10^7$ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**108/108**	**100**	**(96.6-100)**
Bottle Positive ($1x10^6$ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**108/108**	**100**	**(96.6-100)**
Negative	1	107/107	100	(96.5-100)
	2	108/108	100	(96.6-100)
	3	108/108	100	(96.6-100)
	All	**323/323**	**100**	**(98.8-100)**

Table 35: Percent Agreement for *Cryptococcus neoformans*

Concentration of *Cryptococcus neoformans*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours ($1x10^8$ CFU/mL)	1	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
Bottle Positive ($1x10^7$ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**108/108**	**100**	**(96.6-100)**
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	108/108	100	(96.6-100)
	All	**324/324**	**100**	**(98.8-100)**

Table 36: Percent Agreement for *Fusarium*

Concentration of *Fusarium sacchari*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours ($6.1x10^6$ spores/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**108/108**	**100**	**(96.6-100)**
Bottle Positive ($6.5x10^6$ spores/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**108/108**	**100**	**(96.6-100)**
Negative	1	107/107	100	(96.5-100)
	2	108/108	100	(96.6-100)
	3	108/108	100	(96.6-100)
	All	**323/323**	**100**	**(98.8-100)**

Table 37: Percent Agreement for *Rhodotorula*

Concentration of *Rhodotorula mucilaginosa*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours ($1x10^7$ CFU/mL)	1	36/36	100	(90.4-100)
	2	34/36	94.4	(81.9-98.5)
	3	35/36	97.2	(85.8-99.5)
	All	**105/108**	**97.2**	**(92.1-99.1)**
Bottle Positive ($1x10^6$ CFU/mL)	1	35/36	97.2	(85.8-99.5)
	2	36/36	100	(90.4-100)
	3	35/36	97.2	(85.8-99.5)
	All	**106/108**	**98.1**	**(93.5-99.5)**
Negative	1	107/107	100	(96.5-100)
	2	108/108	100	(96.6-100)
	3	108/108	100	(96.6-100)
	All	**323/323**	**100**	**(98.8-100)**

Interfering Substances and Sample Matrix Equivalency (Bottle Evaluation)

Two organism mixes consisting of 5 on-panel organisms and negative blood matrix were used to assess potentially interfering substances and bottle types for interference. The concentration of each organism tested is summarized in **Table 38.**

Table 38: Interfering Substance and Bottle Equivalency Concentrations

Organism	Concentration
Candida albicans	1 x 10^6 CFU/mL
Candida kefyr	1 x 10^6 CFU/mL
Cryptococcus neoformans	1 x 10^7 CFU/mL
Fusarium sacchari	6.5 x 10^6 spores/mL
Rhodotorula mucilaginosa	1 x 10^6 CFU/mL

Interfering Substances

Eighteen substances were used to assess the ePlex BCID-FP Panel for potential interference. The organisms in **Table 38** were spiked into negative blood matrix and tested in triplicate with and without each potentially interfering substance. Negative blood matrix was tested to control for potential positive interference. Potentially interfering substances are summarized in **Table 39**. None of the eighteen substances commonly found in blood culture specimens or as medications commonly used to treat skin or blood infections were found to inhibit the ePlex BCID-FP Panel at the clinically relevant concentrations. The effect of interfering substances has only been evaluated for the organisms listed in **Table 38**. Interference due to substances other than those described in this section can lead to erroneous results.

Table 39: Potentially Interfering Substances: Substance List

Endogenous Substances	**Testing Concentration**
Bilirubin	60 µg/mL
Hemoglobin	0.6 g/L
Human Genomic DNA	6 x 10^5 copies/mL
Triglycerides	1000 mg/dL
γ-globulin	0.85 g/dL
Exogenous Substances	**Testing Concentration**
Amoxicillin/Clavulanate	3.5 µg/mL
Amphotericin B	2 µg/mL
Caspofungin	5 µg/mL
Ceftriaxone	0.23 mg/mL
Ciprofloxacin	3 mg/L
Fluconazole	25 mg/L
Flucytosine	90 µg/mL
Gentamicin sulfate	3 µg/mL
Heparin	0.9 U/mL
Imipenem	83 µg/mL
Sodium Polyanethol Sulfonate (SPS)	0.25% w/v
Tetracycline	5 mg/L
Vancomycin	30 mg/L

Sample Matrix Equivalency (Bottle Evaluation)

Fifteen bottle types were tested for interference with each of the organisms listed in **Table 38**. Five replicates of each organism were tested in each of two bottle lots. Negative blood matrix was run as a negative control. Thirteen of the bottle types tested showed no interference for any of the targets tested. One lot of the BACT/Alert® PF Plus bottle type showed lower sensitivity for *Rhodotorula* and one lot BACT/Alert® FA Plus bottle type showed lower sensitivity for *Candida albicans*. A summary of the bottle types assessed and the study outcomes is found in **Table 40**.

Table 40: Sample Matrix Equivalency (Bottle Evaluation) Bottle Types

Manufacturer	Bottle Brand	Bottle Type	Study Outcome
BD	BACTEC™	Plus Aerobic	No interference observed
BD	BACTEC	Plus Anaerobic	No interference observed
BD	BACTEC	Standard Aerobic	No interference observed
BD	BACTEC	Standard Anaerobic	No interference observed
BD	BACTEC	Peds Plus™	No interference observed
BD	BACTEC	Lytic Anaerobic	No interference observed
BD	BACTEC	Myco	No interference observed
bioMérieux	BACT/ALERT®	SA Standard Aerobic	No interference observed
bioMérieux	BACT/ALERT	SN Standard Anaerobic	No interference observed
bioMérieux	BACT/ALERT	FA Plus	A false negative result was observed for the *Candida albicans* target in one lot.
bioMérieux	BACT/ALERT	FN Plus	No interference observed
bioMérieux	BACT/ALERT	PF Plus	False negative results were observed for the *Rhodotorula* target in one lot.
bioMérieux	BACT/ALERT	MP Mycobacteria	No interference observed
Thermo Scientific™	VersaTREK™	REDOX™ 1 EZ Draw Aerobic	No interference observed
Thermo Scientific	VersaTREK	REDOX 2 EZ Draw Anaerobic	No interference observed

Carryover and Cross-Contamination

Carryover and cross-contamination were evaluated for the ePlex BCID-FP Panel within and between runs by alternating high positive and negative samples across multiple runs over 5 rounds of testing. *Fusarium sacchari* was grown to bottle positivity +8 hours and spiked with 1 x 10^7 CFU/mL *Candida albicans* to simulate clinically relevant high positive samples for positive testing. Negative blood culture matrix was used to represent negative samples. No false positives were detected, indicating that no carryover or cross-contamination was observed between bays or within bays with the ePlex BCID-FP Panel when testing consecutively or in adjacent bays.

Competitive Inhibition Study

Competitive inhibition was evaluated for the ePlex BCID-FP Panel by pairing twelve clinically relevant organisms (including 9 off-panel organisms) in thirteen simulated dual infection sample mixes. *Candida albicans* was tested at low titer (concentration expected at bottle positivity) while in the presence of other organisms at higher titer (concentrations expected at 8 hours beyond bottle positivity, or one log higher than that expected at bottle positivity). *Candida glabrata* and *Candida parapsilosis* were also tested at the concentration expected at bottle positivity in the presence of *Candida albicans* at a higher titer concentration. No competitive inhibition was observed in any of the sample mixes evaluated at the concentrations listed in **Table 41.**

Table 41: Competitive Inhibition Organisms and Concentrations Tested

On-panel Organisms	High Concentration	Low Concentration
Candida albicans	1 x 10^7 CFU/mL	1 x 10^6 CFU/mL
Candida glabrata	1 x 10^7 CFU/mL	1 x 10^6 CFU/mL
Candida parapsilosis	1 x 10^7 CFU/mL	1 x 10^6 CFU/mL
Off-panel Organisms	**High Concentration**	
Acinetobacter baumannii	1 x 10^9 CFU/mL	
Cutibacterium acnes	1 x 10^9 CFU/mL	
Enterococcus faecalis	1 x 10^8 CFU/mL	
Escherichia coli	1 x 10^9 CFU/mL	
Klebsiella pneumoniae	1 x 10^9 CFU/mL	
Staphylococcus aureus	1 x 10^8 CFU/mL	
Staphylococcus epidermidis	1 x 10^8 CFU/mL	
Streptococcus pneumoniae	4 x 10^8 CFU/mL	
Pseudomonas aeruginosa	4 x 10^8 CFU/mL	