January 19, 2022

Streck, Inc
Deborah Kipp
Regulatory Affairs Manager
7002 S. 109th Street
La Vista, Nebraska 68128

Re: K212576
Trade/Device Name: MDx-Chex for BCID2
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed Quality Control Material For Clinical Microbiology Assays
Regulatory Class: Class II
Product Code: PMN
Dated: August 13, 2021
Received: August 16, 2021

Dear Deborah Kipp:

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/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 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 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, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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)*
K212576

Device Name
MDx-Chex for BCID2

Indications for Use *(Describe)*

MDx-Chex for BCID2 is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of yeast, Gram positive and Gram negative bacteria, as well as associated antimicrobial resistance genes, by the BioFire FilmArray Blood Culture Identification 2 (BCID2) Panel on FilmArray systems. Control 1 - GN: Gram negative bacteria: *Acinetobacter colcoaceticus-baumannii* complex, *Bacteroides fragilis, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., *Serratia marcescens, Haemophilus influenza, Neisseria meningitides, Pseudomonas aeruginosa, Stenotrophomonas maltophilia*; antimicrobial resistance genes: KPC, CTX-M, IMP, NDM, OXA-48-like, VIM, *mcr- 1*. Control 2 - GPY: Gram positive bacteria: *Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunesis, Streptococcus agalactiae, Streptococcus pneumonia, Streptococcus pyogenes*; yeast: *Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Cryptococcus neoformans/gatti*; antimicrobial resistance genes *mecA/C* and MREJ, *vanA/B*. This product is not intended to replace manufacturer controls provided with the device.

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

510(k) Submitter	Streck, Inc. 7002 S. 109th Street La Vista, NE 68128
Official Correspondent:	Deborah Kipp, Regulatory Affairs Manager
Address:	7002 S. 109th Street La Vista, NE 68128
Phone	402-537-5215
Fax	402-537-5317
Email	dkipp@streck.com
Date Prepared	August 6, 2021

Names

Trade Name:	MDx-Chex™ for BCID2
Common Name:	Quality Control Material for Microbiology Assays
Device Type	Assayed external control material for microbiology nucleic acid amplification (NAT) assays
Product Code:	PMN (866.3920)
Panel	Microbiology

Predicate Device:

K200010-Maine Molecular FilmArray BCID2 Control Panel M416

Device Description

MDx-Chex for BCID2 Control 1 - GN is positive for certain pathogens and antimicrobial resistance genes in the FilmArray BCID 2 panel and negative for those contained in MDx-Chex for BCID2 Control 2 - GPY. MDx-Chex for BCID2 Control 2 - GPY is positive for the remaining pathogen and antimicrobial resistance genes and negative for those present in MDx-Chex for BCID2 Control 1 - GN (see Table 1 below). Each control mix also contains and controls for blood and blood culture media components that have been identified as PCR inhibitors – namely hemoglobin, leukocyte DNA, and anticoagulants.

Table 1 – Pathogens and antimicrobial resistance genes detected by MDx-Chex for BCID2 Control

Gram-Negative Bacteria		
Pathogen	**MDx-Chex for BCID2 Control 1 - GN**	**MDx-Chex for BCID2 Control 2 - GPY**
Acinetobacter colcoaceticus-baumannii complex	Detected	Not Detected
Bacteroides fragilis	Detected	Not Detected
Enterobacter cloacae complex	Detected	Not Detected
Escherichia coli	Detected	Not Detected
Klebsiella aerogenes	Detected	Not Detected
Klebsiella oxytoca	Detected	Not Detected
Klebsiella pneumoniae group	Detected	Not Detected
Proteus spp.	Detected	Not Detected
Salmonella spp.	Detected	Not Detected
Serratia marcescens	Detected	Not Detected
Haemophilus influenzae	Detected	Not Detected
Neisseria meningitides	Detected	Not Detected
Pseudomonas aeruginosa	Detected	Not Detected
Stenotrophomonas maltophilia	Detected	Not Detected
Gram-Positive Bacteria		
Pathogen	**MDx-Chex for BCID2 Control 1 - GN**	**MDx-Chex for BCID2 Control 2 - GPY**
Enterococcus faecalis	Not Detected	Detected
Enterococcus faecium	Not Detected	Detected
Listeria monocytogenes	Not Detected	Detected
Staphylococcus aureus	Not Detected	Detected
Staphylococcus epidermidis	Not Detected	Detected
Staphylococcus lugdunesis	Not Detected	Detected
Streptococcus agalactiae	Not Detected	Detected
Streptococcus pneumoniae	Not Detected	Detected
Streptococcus pyogenes	Not Detected	Detected
Yeast		
Pathogen	**MDx-Chex for BCID2 Control 1 - GN**	**MDx-Chex for BCID2 Control 2 - GPY**
Candida albicans	Not Detected	Detected
Candida auris	Not Detected	Detected
Candida glabrata	Not Detected	Detected
Candida krusei	Not Detected	Detected
Candida parapsilosis	Not Detected	Detected
Candida tropicalis	Not Detected	Detected
Cryptococcus neoformans/gatti	Not Detected	Detected

MDx-Chex for BCID2 is a quality control containing stabilized blood components, blood culture media components, and inactivated microorganisms resulting in a full-process, cellular-based control for the BioFire BCID2 Panel. Use of full-process cellular controls are necessary to evaluate the entire analytical process, including sample lysis, nucleic acid isolation and purification, amplification, detection, and analysis, as well as the impact of PCR inhibitors and preanalytical variables. Routine use of full process quality controls can help identify variations in the test system that can lead to incorrect results.

Intended Use

MDx-Chex for BCID2 is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of yeast, Gram positive and Gram negative bacteria, as well as associated antimicrobial resistance genes, by the BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel on FilmArray® systems. **Control 1 - GN**: Gram negative bacteria: *Acinetobacter colcoaceticus-baumannii* complex, *Bacteroides fragilis, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp.*, Serratia marcescens, Haemophilus influenza, Neisseria meningitides, Pseudomonas aeruginosa, Stenotrophomonas maltophilia*; antimicrobial resistance genes: KPC, CTX-M, IMP, NDM, OXA-48-like, VIM, *mcr-1*. **Control 2 - GPY**: Gram positive bacteria: *Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunesis, Streptococcus agalactiae, Streptococcus pneumonia, Streptococcus pyogenes*; yeast: *Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Cryptococcus neoformans/gatti*; antimicrobial resistance genes: *mec*A/C and MREJ, *van*A/B. This product is not intended to replace manufacturer controls provided with the device.

Comparison to Predicate Device

Device & Predicate Device(s):	K212576	K200010
Device Trade Name	MDx-Chex for BCID2	FilmArray BCID2 Control Panel M416
General Device Characteristic Similarities		
Intended Use/Indications For Use	MDx-Chex for BCID2 is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of yeast, Gram positive and Gram negative bacteria, as well as associated antimicrobial resistance genes, by the BioFire FilmArray Blood Culture Identification 2 (BCID2) Panel on FilmArray systems. Control 1 - GN: Gram negative bacteria: *Acinetobacter colcoaceticus-baumannii* complex, *Bacteroides fragilis, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae* group, *Proteus spp., Salmonella spp., Serratia marcescens, Haemophilus influenza, Neisseria meningitides, Pseudomonas aeruginosa, Stenotrophomonas maltophilia*; antimicrobial resistance genes: KPC, CTX-M, IMP, NDM, OXA-48-like, VIM, *mcr-1*. Control 2 - GPY: Gram positive bacteria: *Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunesis, Streptococcus agalactiae, Streptococcus pneumonia, Streptococcus pyogenes*; yeast: *Candida albicans, Candida auris, Candida glabrata, Candida krusei*, *Candida parapsilosis, Candida tropicalis, Cryptococcus neoformans/gatti*; antimicrobial resistance genes: *mecA/C* and MREJ, *vanA/B*. This product is not intended to replace manufacturer controls provided with the device.	FilmArray BCID2 Control Panel M416 is intended for use as an external positive and negative assayed quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of antimicrobial resistance genes: CTX-M, IMP, KPC, *mcr*-1, *mec*A/C, *mec*A/C and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM; Gram positive and Gram-negative bacteria: *Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus* spp., *Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunensis, Streptococcus* spp., *Streptococcus agalactiae* (Group B), *Streptococcus pneumoniae*, *Streptococcus pyogenes* (Group A), *Acinetobacter calcoaceticus baumannii* complex, *Bacteroides fragilis*, Enteric bacteria, *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., *Serratia marcescens, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa* and *Stenotrophomonas maltophilia*; and yeast pathogens: *Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis*, *Candida tropicalis*, and *Cryptococcus neoformans/gattii* on the BioFire Blood Culture Identification 2 (BCID2) Panel assay on FilmArray systems. FilmArray BCID2 Control Panel M416 is composed of synthetic DNA specifically designed for and intended to be used solely with the BioFire BCID2 Panel assay. This product is not intended to replace

		manufacturer controls provided with the device.
Physical Format	Ready-to-Use Liquid	Same
Direction for Use	Process like patient sample	Same
Number of targets monitored in one assay	Multiple, >30 targets	Same
General Device Characteristic Differences		
Composition	Intact inactivated bacteria, human erythrocytes and leukocytes, and relevant components of blood culture media	Synthetic DNA
Assay Steps Monitored	Lysis, nucleic acid isolation/purification/PCR inhibitor removal, amplification, detection, identification/data reporting	Reverse transcription, amplification, detection

Discussion of Tests and Test Results

To substantiate the product performance claims for MDx-Chex for BCID2, Streck collected product performance data for the following studies. Results of studies are summarized below.:

- Multi-Site Precision (Reproducibility)
- Single-Site Precision (Repeatability)
- Lot-to-Lot Reproducibility
- Closed-Vial Stability
- Open-Vial Stability
- Matrix Effect
- Shipping Stability

Multi-Site Precision (Reproducibility)

Ten samples per control level (20 samples total per lot) were tested using the BCID2 panel by users at each site over a 10-day period. Three lots were used for this study. All samples were prepared and analyzed on the BioFire FilmArray Instrument per the control and BCID2 Instructions for Use. Samples were analyzed internally at Streck (La Vista, NE). External studies were conducted at UNMC (Omaha, NE), Children's Hospital and Medical Center (Omaha, NE), and Mary Lanning Healthcare (Hastings, NE). All MDx-Chex lots passed with an overall positive and negative percent agreement of ≥ 95%. The results therefore support the conclusion that MDx-Chex for BCID2 shows reproducibility across three separately manufactured control lots between sites, days, and operators when used with the BioFire FIlmArray BCID2 panel on the BioFire Film Array Torch and 2.0 Systems.

Multi-site Precision (Reproducibility) Positive Percent Agreement

Category	Site #1		Site #2		Site #3		Site #4		Percent Agreement (all sites combined)
	# Observed Results/# Expected Results [1]	Positive Percent Agreement	# Observed Results/# Expected Results [1]	Positive Percent Agreement	# Observed Results/# Expected Results [1]	Positive Percent Agreement	# Observed Results/# Expected Results [1]	Positive Percent Agreement	
SMC Level 1 (GN) and Level 2 (GPY), Combined	59/60*	98.3%	57/60*	95%	58/60*	96.7%	56/60*	93.3%	95.8% (230/240)

* 10 Positive controls gave initial false negative results; all produced the correct results upon a single retest.
[1] Expected result for the Positive Control is positive. Denominator = total # of results for Level 1-GN and Level 2-GPY controls. GPY = Gram-positive and yeast control, GN = Gram-negative control.

Multi-site Precision (Reproducibility) Negative Percent Agreement

Category	Site #1		Site #2		Site #3		Site #4		Percent Agreement (all sites combined)
	# Observed Results/# Expected Results [1]	Negative Percent Agreement	# Observed Results/# Expected Results [1]	Negative Percent Agreement	# Observed Results/# Expected Results [1]	Negative Percent Agreement	# Observed Results/# Expected Results [1]	Negative Percent Agreement	
SMC Level 1 (GN) and Level 2 (GPY), Combined	60/60	100%	60/60	100%	60/60	100%	59/60*	98.3%	99.6% (239/240)

* 1 Negative control gave initial false positive result and produced correct result upon a single retest.
[1] Expected result for the Negative Control is negative. Denominator = total # of results for Level 1-GN and Level 2-GPY controls. GPY = Gram-positive and yeast control, GN = Gram-negative control.

Single-Site Precision (Repeatability)

The repeatability of MD-Chex for BCID2 was evaluated using three separately manufactured lots of control. Each lot was tested across two BioFire FilmArray Torch instruments (2 modules per instrument). A minimum of three BCID2 pouch lots were used.

Twenty samples per lot per level were tested by four operators over a period of 20 non-consecutive days at Streck. The first time point was also used as the Day 0, replicate 1 for the closed-vial stability testing summarized below. The remainder of the data points were independently run and analyzed. Samples and pouches were prepared according to BCID2 and control instructions. Samples were analyzed on the BioFire FilmArray Torch per the BioFire BCID2 Panel Instructions for Use. All MDx-Chex lots passed with an overall positive and negative percent agreement of ≥ 95%. The data supports that there are no significant differences between operators on different days when testing different SMC lots. The results support the conclusion that MDx-Chex for BCID2 shows repeatability across three separately manufactured control lots when used with the BioFire FilmArray BCID2 panel.

Single-site Precision (Repeatability) Positive Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Positive Percent Agreement
SMC Level 1-GN and Level 2-GPY, Combined	114/120*	95%

* 6 Positive controls gave initial false negative results; all produced the correct results upon a single retest.
[1] Expected result for the Positive Control is positive. Denominator = total # of results for GN (Level 1) and GPY (Level 2) controls. GPY = gram-positive and yeast control, GN = gram negative control.

Single-site Precision (Repeatability) Negative Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Negative Percent Agreement
SMC Level 1- GN and Level 2-GPY, Combined	120/120	100%

[1] Expected result for the Negative Control is negative. Denominator = total # of results for GN (Level 1) and GPY (Level 2) controls. GPY = gram-positive and yeast control, GN = gram negative control.

Lot-to-Lot Reproducibility

The reproducibility of MDx-Chex for BCID2 was evaluated using three separately manufactured lots of control. Each lot was removed from 2-8 °C storage and allowed to warm to room temperature per the control Instructions for Use (IFU) prior to testing with the BCID2 panel. Multiple lots of BCID2 pouches were used for testing. Pouches were prepared according to the BCID2 assay instructions. Samples were prepared in accordance with the control IFU.

Testing consisted of 6 samples per control lot and level (12 total samples per lot). A total of 36 complete runs were generated for the data analysis from all control lots. Data from the first 6 timepoints in the repeatability study above were also used for the lot-to-lot precision analysis. For within-run precision analysis, data from the first 6 control vials tested, per control level, for closed-vial stability below were used for analysis of one control lot collected on the same day. All MDx-Chex lots passed with an overall positive and negative percent agreement of ≥ 90%. The results support that MDx-Chex for BCID2 is reproducible across three separately manufactured lots when used with the BioFire FilmArray BCID2 panel. The results also demonstrate that there are no significant differences in results within-run and between different control lots.

Lot-to-Lot Reproducibility Positive Percent Agreement

Category	SMC Lot	# Observed Results/# Expected Results [1]	Positive Percent Agreement
SMC Level 1(GN) and Level 2 (GPY), Combined	20363	11/12*	91.7%
	20366	12/12	100%
	21129	12/12	100%

* 1 Positive control gave an initial false negative result; it produced the correct result upon a single retest.

[1] Expected result for the Positive Control is positive. Denominator = total # of expected positive result sets for Level 1-GN and Level 2-GPY controls. GN = gram negative control, GPY = gram-positive and yeast control.

Lot-to-Lot Reproducibility Negative Percent Agreement

Category	SMC Lot	# Observed Results/ # Expected Results [1]	Negative Percent Agreement
SMC Level 1(GN) and Level 2 (GPY), Combined	20363	12/12	100%
	20366	12/12	100%
	21129	12/12	100%

[1] Expected result for the Negative Control is negative. Denominator = total # of expected negative result sets for Level 1-GN and Level 2-GPY controls. GN = gram negative control, GPY = gram-positive and yeast control.

Within-run Reproducibility Positive Percent Agreement

Category	SMC Lot	# Observed Results/ # Expected Results [1]	Positive Percent Agreement
SMC Level 1(GN) and Level 2 (GPY), Combined	21129	12/12	100%

[1] Expected result for the Positive Control is positive. Denominator = total # of expected positive result sets for Level 1-GN and Level 2-GPY controls. GN = gram negative control, GPY = gram-positive and yeast control.

Within-run Reproducibility Negative Percent Agreement

Category	SMC Lot	# Observed Results/ # Expected Results [1]	Negative Percent Agreement
SMC Level 1(GN) and Level 2 (GPY), Combined	21129	12/12	100%

[1] Expected result for the Negative Control is negative. Denominator = total # of expected negative result sets for Level 1-GN and Level 2-GPY controls. GN = gram negative control, GPY = gram-positive and yeast control.

Closed-Vial Stability

The closed-vial stability study assessed the real-time stability of MDx-Chex for BCID2 using the BioFire FilmArray Torch system. Three separately manufactured lots were stored at 2-8°C (refrigerated) and 20-25°C (room temperature). Ten samples per control lot and level were tested with the BCID2 panel at Day 0 and a minimum of 61 days per each lot and storage condition. Prior to sample analysis, BCID2 pouches were prepared according to the BCID2 assay instructions. Samples were prepared and analyzed on the BioFire FilmArray Torch per MDx-Chex for BCID2 and BCID2 assay Instructions for Use. This summary contains results that support a 60 day closed-vial stability claim for MDx-Chex for BCID2 when stored at 2-25°C. All MDx-Chex lots passed with an overall positive and negative percent agreement of ≥ 95%.

Closed-Vial Stability Positive Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Positive Percent Agreement	PPA ≥ 90% Acceptance
Day 0*	NA	115/120**	95.8%	Pass
Day 61+	2-8°C	58/60***	96.7%	Pass
Day 61+	20-25°C	60/60	100%	Pass

[1] Expected result for the Positive Control is positive. Denominator = total combined # of expected positive results for Level 1-GN and Level 2-GPY controls. GPY = gram-positive and yeast control, GN = gram negative control.
* 120 tubes were completed for Day 0 (baseline). Tubes were divided in half for storage.
** 5 Positive controls gave false negative results on the first test; all reruns produced correct results upon a single retest.
*** 2 Positive controls gave false negative results on the first test; all reruns produced correct results upon a single retest.
+ Indicates that each lot was tested for at least 61 days. Lot 20263 (77 days); Lot 20366 (75 days); and Lot 21129 (63 days).

Closed-Vial Stability Negative Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	NPA ≥ 90% Acceptance
Day 0*	NA	117/120**	97.5%	Pass
Day 61+	2-8°C	59/60***	98.3%	Pass
Day 61+	20-25°C	59/60****	98.3%	Pass

[1] Expected result for the Negative Control is negative. Denominator = total combined # of expected negative results for Level 1-GN and Level 2-GPY controls. GPY = Gram-positive and yeast control, GN = Gram-negative control.
* 120 tubes were completed for Day 0 (baseline). Tubes were divided in half for storage.
** 3 negative controls gave false positive results on the first test; all reruns produced correct results upon a single retest.
*** 1 negative control gave a false positive result on the first test; all reruns produced correct results upon a single retest.
**** 1 negative control gave false positive result on the first test; rerun produced correct result upon a single retest.
+ Indicates that each lot was tested for at least 61 days. Lot 20263 (77 days); Lot 20366 (75 days); and Lot 21129 (63 days).

Open-Vial Stability

The open-vial stability study assessed the real-time stability of MDx-Chex for BCID2 using the BioFire FilmArray Torch system. Three separately manufactured lots were stored at 2-8°C (refrigerated) and 20-25°C (room temperature). Ten samples per lot per level were tested with the BCID2 panel at Day 0 (baseline) and a minimum of 61 days for each lot and storage condition. At baseline, 120 total tubes were tested then divided in half for storage. The same data set collected for closed-vial stability at Day 0 was used for analysis of opened-vial stability at Day 0 for each respective temperature. This summary contains results that support a 60 day open-vial stability claim for MDx-Chex for BCID2 when stored at 2-25°C. All MDx-Chex lots passed with an overall positive and negative percent agreement of ≥ 95%.

Open-Vial Stability Positive Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Positive Percent Agreement	PPA ≥ 90% Acceptance
Day 0*	NA	115/120**	95.8%	Pass
Day 61+	2-8°C	60/60	100%	Pass
Day 61+	20-25°C	57/60***	95%	Pass

[1] Expected result for the Positive Control is positive. Denominator = total combined # of expected positive results for Level 1-GN and Level 2-GPY controls. GPY = gram-positive and yeast control, GN = gram negative control.
* 120 tubes were completed for Day 0 (baseline). Tubes were divided in half for storage.
** 5 Positive controls gave false negative results on the first test; all reruns produced correct results upon a single retest.
*** 3 positive controls gave false negative results on the first test; all reruns produced correct results upon a single retest.
+ Indicates that each lot was tested for at least 61 days. Lot 20263 (77 days); Lot 20366 (75 days); and Lot 21129 (63 days).

Open-Vial Stability Negative Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	NPA ≥ 90% Acceptance
Day 0*	NA	117/120**	97.5%	Pass
Day 61+	2-8°C	60/60	100%	Pass
Day 61+	20-25°C	60/60	100%	Pass

[1] Expected result for the Negative Control is negative. Denominator = total combined # of expected negative results for Level 1-GN and Level 2-GPY controls. GPY = Gram-positive and yeast control, GN = Gram-negative control.
* 120 tubes were completed for Day 0 (baseline). Tubes were divided in half for storage.
** 3 negative controls gave false positive results on the first test; all reruns produced correct results upon a single retest.
+ Indicates that each lot was tested for at least 61 days. Lot 20263 (77 days); Lot 20366 (75 days); and Lot 21129 (63 days).

Matrix Effect

To assess the MDx-Chex matrix effect on the BioFire FilmArray BCID2 panel, inactivated *Streptococcus pneumoniae* was spiked into the control matrix (containing RBCs, WBCs, and simulated blood culture media). *Streptococcus pneumoniae* was also spiked into a BD BACTEC Plus Aerobic/F culture bottle with negative whole blood to simulate a clinical sample. These samples were tested in triplicate using the BCID2 Panel. Three replicates of each simulated matrix with no spike-in organism were also tested to serve as negative controls. BCID2 pouches were prepared according to the BCID2 assay instruction. Samples were prepared and analyzed on the BioFire FilmArray Torch per the control and BCID2 Instructions for Use. The MDx-Chex matrix passed with an overall positive and negative percent agreement of 100% to the analytes tested. The results demonstrated that samples prepared with the MDx-Chex matrix showed no inhibition and/or false negative results when used with the FilmArray BCID2 panel. The data therefore support the conclusion that MDx-Chex performs identically to a clinical BCID2 panel sample, positive blood culture sample.

Matrix Effect of MDx-Chex and Clinical Samples Spiked with *S. pneumonia*, Tested on BCID-2 panel

Matrix type	# Expected results / # tested [1]	Percent Agreement
MDx-Chex, Positive Matrix	3/3	100%
Clinical, Positive Matrix	3/3	100%

[1] Expected result for the Positive Matrix is positive.

Matrix Effect of Negative MDx-Chex and Negative Clinical Samples, Tested on BCID-2 panel

Matrix type	# Expected results / #tested [1]	Percent Agreement
MDx-Chex, Negative Matrix	3/3	100%
Clinical, Negative Matrix	3/3	100%

[1] Expected result for Negative Matrix is negative.

Shipping Stability

The purpose of this study was to validate the stability of MDx-Chex for BCID2 after shipment during simulated summer and winter shipping conditions. Two sets of samples from one control lot were exposed to summer and winter temperature profiles using an environmental chamber.

Samples exposed to Winter and Summer profiles were then stored at 2 -8 °C prior to being tested on the BioFire FilmArray Torch. For each temperature profile, ten samples of each level of control (Control 1 and Control 2) from the same lot were tested using BCID2 pouches according to the BCID2 assay instruction. All pouches were prepared according to the BCID2 assay instructions before analysis. All samples were prepared and analyzed on the BioFire FilmArray Torch per MDx-Chex for BCID2 and BCID2 assay Instructions for Use. All summer and winter shipping conditions passed with ≥ 95% positive and negative agreement. The data supports the claim that MDx-Chex for BCID2 remains functional after exposure to extreme temperature (winter, summer) shipping conditions.

Shipping Stability Study Positive Percent Agreement

Category	# Expected results / # Tested [1]	Positive Percent Agreement
Summer	19/20*	95%
Winter	20/20	100%

[1] Expected result for the Positive Control is positive.
* 1 Positive control gave initial false negative result; it produced the correct result upon a single retest.

Shipping Stability Study Negative Percent Agreement

Category	# Expected results / # Tested [1]	Negative Percent Agreement
Summer	19/20*	95%
Winter	20/20	100%

[1] Expected result for the Negative Control is negative.
* 1 Negative control gave initial false positive result; it produced correct result upon a single retest.

Conclusions of Performance Tests

Study results show MDx-Chex for BCID2 to be consistently reproducible, substantially equivalent to the predicate product, and stable for the product dating. MDx-Chex for BCID2 is a safe and effective product, which fulfills its intended use when used as instructed in the Instructions for Use.