March 17, 2026

Streck, LLC
Megan Hiveley
Regulatory Affairs Coordinator
7002 S 109th St.
La Vista, Nebraska 68128

Re: K254167
Trade/Device Name: MDx-Chex for BCY
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: December 22, 2025
Received: December 23, 2025

Dear Megan Hiveley:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254167

Device Name
MDx-Chex for BCY

Indications for Use *(Describe)*
MDx-Chex for BCY is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of yeast by the Diasorin LIAISON PLEX Yeast Blood Culture assay on the LIAISON PLEX System. The MDx-Chex for BCY Positive and Negative Controls are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Positive Control: Yeast: Candida albicans, Candida dubliniensis, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida auris, Candida kefyr, Candida lipolytica, Candida lusitaniae, Candida guilliermondii, Cryptococcus neoformans/gattii, Candida famata, Candida haemulonii/duobushamulonii. Negative Control: buffered solution only. 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.

510(k) Summary

510(k) Submitter:	Streck 7002 S. 109th Street La Vista, NE 68128
Official Correspondent	Megan Hiveley
Address:	7002 S. 109th Street La Vista, NE 68128
Phone:	402-537-5208
Email:	mhiveley@streck.com
Date Prepared:	December 05, 2025
Names, Trade Name:	MDx-Chex for BCY
Common Name:	Quality Control Material for Microbiology Assays
Device Type:	Assayed external control material for microbiology nucleic acid amplification (NAT) assays
Product Code:	PMN
Panel:	Microbiology
Predicate Device:	MDx-Chex for BCID2 (K212576)

Device Description:

MDx-Chex for BCY is a quality control kit consisting of two controls for the Diasorin LIAISON-PLEX® Yeast Blood Culture Assay (BCY). The MDx-Chex for BCY Positive Control is positive for pathogens in the LIAISON-PLEX Yeast Blood Culture assay (See Table 1). The MDx-Chex for BCY Negative Control is negative for pathogen in the LIAISON-PLEX Yeast Blood Culture assay. Each control mix also contains and controls for blood and blood culture media components that have been identified as assay inhibitors, namely hemoglobin, leukocyte DNA, and anticoagulants.

MDx-Chex for BCY is also configured as a verification kit (MDx-Chex for BCY Verification Kit) for use at equipment installation, in the development of workflow procedures and for operator proficiency evaluation.

Yeasts		
Target	**Positive Control**	**Negative Control**
Candida albicans	Detected	Not Detected
Candida dubliniensis	Detected	Not Detected
Candida glabrata	Detected	Not Detected
Candida krusei	Detected	Not Detected
Candida parapsilosis	Detected	Not Detected
Candida tropicalis	Detected	Not Detected
Candida auris	Detected	Not Detected
Candida kefyr	Detected	Not Detected
Candida lipolytica	Detected	Not Detected
Candida lusitaniae	Detected	Not Detected
Candida guilliermondii	Detected	Not Detected
Cryptococcus neoformans/C. gattii	Detected	Not Detected
Candida famata	Detected	Not Detected
Candida haemulonii/C. duobushaemulonii	Detected	Not Detected

Intended Use

MDx-Chex® for BCY is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of yeast by the Diasorin LIAISON PLEX® Yeast Blood Culture assay on the LIAISON PLEX System. The MDx-Chex for BCY Positive and Negative Controls are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Positive Control: Yeast: *Candida albicans*, *Candida dubliniensis*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, *Candida auris*, *Candida kefyr*, *Candida lipolytica*, *Candida lusitaniae*, *Candida guilliermondii*, *Cryptococcus neoformans/gattii*, *Candida famata*, *Candida haemulonii/duobushamulonii*. Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.

Comparison to Predicate Device

Characteristics	Candidate Device: MDx-Chex for BCY	Predicate Device: Streck MDx-Chex for BCID2 (K212576)
Device & Predicate Device(s):		K212576
Device Trade Name	MDx-Chex for BCY	MDx-Chex for BCID2
Device Similarities		
Intended Use/Indications For Use	MDx-Chex for BCY is a quality control kit consisting of two controls for the Diasorin LIAISON-PLEXÒ Yeast Blood Culture Assay (BCY). The MDx-Chex for BCY Positive Control is positive for pathogens in the LIAISON-PLEX Yeast Blood Culture assay (See Table 1). The MDx-Chex for BCY Negative Control is negative for pathogen in the LIAISON-PLEX Yeast Blood Culture assay. Each control mix also contains and controls for blood and blood culture media components that have been identified as assay inhibitors, namely hemoglobin, leukocyte DNA, and anticoagulants.	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.
Physical Format	Ready-to-Use Liquid	Same
Direction for Use	Process like patient sample	Same
Number of targets monitored in one assay	Multiple, 14 targets	Multiple, >30 targets

Assay Steps Monitored	Lysis, nucleic acid isolation/purification/PCR inhibitor removal, amplification, detection, identification/data reporting	Same
Composition	Buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components	Same

Discussion of Tests and Test Results
To substantiate the product performance claims for MDx-Chex for BCY, Streck collected product performance data for the following studies:

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

Multi-Site Precision (Reproducibility)
A multi-site reproducibility study assessed performance of MDx-Chex for BCY, with the DiaSorin LIAISON PLEX BCY assay, using DiaSorin LIAISON PLEX systems at three separate sites. Three MDx-Chex for BCY lots, at least three LIAISON PLEX BCY test cartridge lots, and at least three operators were included in the study. Testing at each site consisted of 10 positive control samples and 10 negative control samples for each MDx-Chex for BCY lot for a total of 30 samples per control type (positive and negative control tubes), 60 samples per lot, tested on different days (2 tubes x 1 lot x 1 day, for 10 days and 3 different lots). A total of 180 runs (90 runs per MDx-Chex for BCY control type; control type = positive or negative control) were generated for data analysis from all testing sites and all MDx-Chex for BCY lots.

An effective statistical sample size of n = 90 tests per control type (positive or negative) produced a two-sided 95% confidence interval with a width equal to 0.058 and a lower limit of 93.2% when the positive or negative percent agreement with expected results was assumed 99%. The total sample size for this multi-site evaluation was N = 180 samples tested using the DiaSorin LIAISON PLEX system.

All MDx-Chex for BCY Positive and Negative Control lots passed with ≥ 90% agreement with expected results. The results support the conclusion that MDx-Chex for BCY shows reproducibility across three separately manufactured control lots between sites, days, and operators when used with the LIAISON PLEX BCT assay on different DiaSorin LIAISON PLEX system.

Table 1: Reproducibility of **MDx-Chex for BCY -** Positive Control: Positive Percent Agreement

Category	Site #1		Site #2		Site #3		Percent Agreement (all sites combined)	95% Confidence Interval
	# Observed Results/# Expected Results [1]	Positive Percent Agreement	# Observed Results/# Expected Results [1]	Positive Percent Agreement	# Observed Results/# Expected Results [1]	Positive Percent Agreement		
MDx-Chex for BCY Positive Control	30/30	100%	30/30	100%	30/30	100%	100% (90/90 total runs)	96% - 100%

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

Table 2: Reproducibility of **MDx-Chex for BCY -** Negative Control: Negative Percent Agreement

Category	Site #1		Site #2		Site #3		Percent Agreement (all sites combined)	95% Confidence Interval
	# Observed Results/# Expected Results [1]	Negative Percent Agreement	#Observed Results/# Expected Results [1]	Negative Percent Agreement	# Observed Results/# Expected Results [1]	Negative Percent Agreement		
MDx-Chex for BCY Negative Control	30/30	100%	30/30	100%	30/30	100%	100% (90/90 total runs)	96% - 100%

[1] Expected result for the Negative Control is negative.

Single-Site Precision (Repeatability)

An internal repeatability study was conducted to assess performance of MDx-Chex for BCYusing at least two DiaSorin LIAISON PLEX systems. Three MDx-Chex for BCY lots, at least three LIAISON PLEX BCY test cartridge lots and a minimum of two operators were included in the study. Testing consisted of 20 samples per control type (positive and negative control tubes), 40 samples per MDx-Chex for BCY lot, tested over 20 days. A total of 120 runs (20 runs per MDx-Chex for BCY control type; control type = positive or negative control) were generated for data analysis for all MDx-Chex for BCY lots (2 BCY control types x 1 control type/day x 3 lots x 20 days = 120 runs). Controls were stored at 2 degrees C prior to testing.

An effective statistical sample size of n = 60 tests for each control vials produced a two-sided 95% confidence interval with width equal to 0.077 and a lower limit of 90.3% when the percent positive or negative agreement with expected results was 98%. The total sample size for this study was N =120 samples tested using the DiaSorin LIAISON PLEX system. Repeatability data collected from three MDx-Chex for BCY Positive and Negative Control lots passed with ≥ 90% positive agreement with expected results.

All results met predefined acceptance criteria. The results support the conclusion that MDx-Chex for BCY shows repeatability across three separately manufactured control lots when used with the LIAISON PLEX BCY Test.

Table 1: Repeatability of MDx-Chex for BCY - Positive Control: Positive Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
MDx-Chex for BCY Positive Control	60/60	100%	94% - 100%	Pass

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

Table 2: Repeatability of MDx-Chex for BCY - Negative Control: Negative Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
MDx-Chex for BCY Negative Control	60/60	100%	94% - 100%	Pass

[1] Expected result for the Negative Control is negative.

Lot-to-Lot Reproducibility

A lot-to-lot reproducibility study was conducted to assess performance of three MDx-Chex for BCY lots, using the same DiaSorin LIAISON PLEX BCY test cartridge lot tested on one DiaSorin LIAISON PLEX system over multiple days. The within-run precision study was conducted to assess performance of one MDx-Chex for BCY lot, using the same DiaSorin LIAISON PLEX BCY test cartridge lot tested on the same day with one DiaSorin LIAISON PLEX System.

For the Lot-to-lot study, data from 10 positive and 10 negative control tubes, tested on the same DiaSorin LIAISON PLEX System, was used for data analysis for each control tube per MDx-Chex for BCY lot (30 data points per control type) for a total of 60 data points from three MDx-Chex for BCY lots.

The Within-Run Precision study consisted of 10 tests for each positive and negative control tube generated from one MDx-Chex for BCY lot (total of 20 tests per control kit). For this study, closed-vial stability data was used to demonstrate the within-run precision.

All MDx-Chex for BCY Positive and Negative Control lots passed with ≥ 90% positive agreement with expected results. All results met predefined acceptance criteria. The results support that MDx-Chex for BCY is reproducible across three separately manufactured lots when used with the DiaSorin LIAISON PLEX BCY Test. The results also demonstrate that there are no significant differences in results within runs of a control lot.

Table 1: Lot-to-Lot Precision Summary of MDx-Chex for BCY - Positive Control: Positive Percent Agreement

Category	MDx-Chex for BCY Lot	# Observed Results/# Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex for BCY Positive Control	5202	10/10	100%	69% - 100%
	5209	10/10	100%	69% - 100%
	5223	10/10	100%	69% - 100%

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

Table 2: Lot-to-Lot Precision Summary of MDx-Chex for BCY - Negative Control: Negative Percent Agreement

Category	MDx-Chex for BCY Lot	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex for BCY Negative Control	5202	10/10	100%	69% - 100%
	5209	10/10	100%	69% - 100%
	5223	10/10	100%	69% - 100%

[1] Expected result for the Negative Control is negative.

Table 3: Within-run Precision Summary of MDx-Chex for BCY - Positive Control: Positive Percent Agreement

Category	MDx-Chex for BCY Lot	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex for BCY Positive Control	5223	10/10	100%	69% - 100%

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

Table 4: Within-run Precision Summary of MDx-Chex for BCY - Negative Control: Negative Percent Agreement

Category	MDx-Chex for BCY Lot	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex for BCY Negative Control	5223	10/10	100%	69% - 100%

[1] Expected result for the Negative Control is negative.

Closed-Vial Stability and Shipping Stability

For closed-vial stability, three (3) MDx-Chex for BCY lots were tested using the LIAISON PLEX BCY Test. Testing consisted of 20 positive and 20 negative control samples from each MDx-Chex for BCY lot, collected at various timepoints at room temperature (25 °C) and refrigerated temperature (2 °C). The first data collection timepoint was on Day 0 (ship date) and Day 75. Day 0 and Day 75 are being submitted for FDA review. Note: Data will be collected on three previously manufactured lots using the final product formulation to substantiate a one year shelf-life prior to product launch.

Closed-vial stability (Day 0 and Day 75): All MDx-Chex for BCY Positive and Negative Control lots passed with ≥ 90% positive agreement with expected results at Day 0 and Day 75. The data support MDx-Chex for BCY is stable for at least 75 days and results meet acceptance criteria.

Table 1. Closed-vial stability of MDx-Chex for BCY Positive Control: Positive Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
Day 0	NA	60/60	100 %	94 % - 100 %	Pass
Day 75[+]	2-8°C	60/60	100 %	94 % - 100 %	Pass
	20-25°C	60/60	100 %	94 % - 100 %	Pass

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results for BCY Positive Control.

[+] Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (80 days), Lot 5209 (83 days), Lot 5223 (78 days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (80 days), Lot 5209 (83 days), Lot 5223 (79 days).

Table 2. Closed-vial stability of MDx-Chex for BCY Negative Control: Negative Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Day 0	NA	60/60	100%	94% - 100%	Pass
Day 75[+]	2-8°C	60/60	100 %	94 % - 100 %	Pass
	20-25°C	60/60	100 %	94 % - 100 %	Pass

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results for BCY Negative Control.
[+] Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (80 days), Lot 5209 (83 days), Lot 5223 (79 days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (83 days), Lot 5209 (84 days), Lot 5223 (80 days).

Table 3. Closed-vial stability of MDx-Chex for BCY Positive Control: Positive Percent Agreement for each MDx-Chex Lot.

Category	Storage Temperature	# Lot	#Observed Results/ #Expected Results [1]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
Day 0	NA	5202	20/20	100%	83% - 100%	Pass
	20-25°C	5209	20/20	100%	83% - 100%	Pass
		5223	20/20	100%	83% - 100%	Pass
Day 75 [+]	2-8°C	5202	20/20	100%	83% - 100%	Pass
	20-25°C	5209	20/20	100%	83% - 100%	Pass
		5223	20/20	100%	83% - 100%	Pass
	20-25°C	5202	20/20	100%	83% - 100%	Pass
		5209	20/20	100%	83% - 100%	Pass
		5223	20/20	100%	83% - 100%	Pass

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results for BCY Positive Control.
[+] Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (80 days), Lot 5209 (83 days), Lot 5223 (78 days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (80 days), Lot 5209 (83 days), Lot 5223 (79 days).

Table 4. Closed-vial stability of MDx-Chex for BCY Negative Control: Negative Percent Agreement for each MDx-Chex Lot.

Category	Storage Temperature	# Lot	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Day 0	NA	5202	20/20	100%	83% - 100%	Pass
		5209	20/20	100%	83% - 100%	Pass
		5223	20/20	100%	83% - 100%	Pass
Day 75 [+]	2-8°C	5202	20/20	100%	83% - 100%	Pass
		5209	20/20	100%	83% - 100%	Pass
		5223	20/20	100%	83% - 100%	Pass
	20-25°C	5202	20/20	100%	83% - 100%	Pass
		5209	20/20	100%	83% - 100%	Pass
		5223	20/20	100%	83% - 100%	Pass

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results for BCY Negative Control.

[+] Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (80 days), Lot 5209 (83 days), Lot 5223 (79 days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (83 days), Lot 5209 (84 days), Lot 5223 (80 days).

Shipping Stability (Control)

For shipping study, one MDx-Chex for BCY lot was subjected to simulated winter and summer shipping temperature profiles over 5 days. For each simulated shipping condition (Summer and Winter), 20 samples per control type (i.e., positive and negative) were tested within the 75-day CVS testing period. Additional 20 samples per control type will be tested at the end of shelf-life. Temperature stress conditions for Summer and Winter include a 120-hour exposure periods. Samples at each storage temperature (2C and 25C) were exposed to Winter and Summer Temperature extremes and then were stored back at each respective storage temperature (2C and 25C) for a week prior to being tested using LIAISON PLEX BCY Test.

All summer and winter shipping conditions passed with ≥ 90% positive and negative agreement with expected results.

The data support that MDx-Chex for BCY Control kit is stable for 75 days for use with the DiaSorin LIAISON PLEX BCY Test when stored at 2-25°C. In addition, data support that the Control kit is stable and functional for 75 days after exposure to extreme summer and winter shipping temperature conditions.

Table 1. Shipping Study of MDx-Chex for BCY Positive Control: Positive Percent Agreement.

Category	Storage Temperature[1]	#Observed Results/ #Expected Results [2]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
Summer [+]	2-8°C	20/20	100%	83% - 100%	Pass
	20-25°C	20/20	100%	83% - 100%	Pass
Winter [+]	2-8°C	20/20	100%	83% - 100%	Pass
	20-25°C	20/20	100%	83% - 100%	Pass

[1] Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions and incubated back at each respective storage temperature prior to testing on the DiaSorin LIAISON PLEX system.

[2] Expected result for the Positive Control is positive.

[+] Indicates initial dataset for shipping study which was collected within the 75-day CVS testing period.

Table 2. Shipping Study of MDx-Chex for BCY Negative Control: Negative Percent Agreement.

Category	Storage Temperature[1]	#Observed Results/ #Expected Results [2]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Summer [+]	2-8°C	20/20	100%	83% - 100%	Pass
	20-25°C	20/20	100%	83% - 100%	Pass
Winter [+]	2-8°C	20/20	100%	83% - 100%	Pass
	20-25°C	20/20	100%	83% - 100%	Pass

[1] Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions and incubated back at each respective storage temperature prior to testing on the DiaSorin LIAISON PLEX system.
[2] Expected result for the Negative Control is negative.
[+] Indicates initial dataset for shipping study which was collected within the 75-day CVS testing period.

Shipping Stability (MDx-Chex for BCY Verification Kit)
To verify simulated shipping performance, one lot of MDx-Chex for BCY Verification Kit was subjected to simulated shipping conditions. Vials were packaged in the MDx-Chex for BCY Verification Kit configuration (see Design Input section for details) and exposed to winter and summer shipping temperature profiles over a 5-day period. Data were collected from 5 samples per control type under each simulated profile within the 75-day CVS testing window. Data may be collected again at end-of-shelf-life to confirm product stability.

All summer and winter shipping conditions passed with ≥ 90% positive and negative agreement with expected results. The data supports that the MDx-Chex for BCY Verification Kit is stable for 75 days for use with the DiaSorin LIAISON PLEX BCY Test when stored at 2-25°C. In addition, data supports that the MDx-Chex for BCY Verification Kit is stable and functional for 75 days after exposure to extreme summer and winter shipping temperature conditions.

Table 1. Shipping Study of MDx-Chex for BCY Verification Kit Positive Control: Positive Percent Agreement.

Category	Storage Temperature [1]	#Observed Results/ #Expected Results [2]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
Summer	2°C	5/5	100%	48% - 100%	Pass
	25°C	5/5	100%	48% - 100%	Pass
Winter	2°C	5/5	100%	48% - 100%	Pass
	25°C	5/5	100%	48% - 100%	Pass

[1] Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions and incubated back at each respective storage temperature prior to testing on the DiaSorin Liaison Plex system.
[2] Expected result for the Positive Control is positive.
Note: Shipping data were collected within the 75-day CVS testing period.

Table 2. Shipping Study of MDx-Chex for BCY Verification Kit Negative Control: Negative Percent Agreement.

Category	Storage Temperature [1]	#Observed Results/ #Expected Results [2]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Summer	2°C	5/5	100%	48% - 100%	Pass
	25°C	5/5	100%	48% - 100%	Pass
Winter	2°C	5/5	100%	48% - 100%	Pass
	25°C	5/5	100%	48% - 100%	Pass

[1] Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions and incubated back at each respective storage temperature prior to testing on the DiaSorin Liaison Plex system.
[2] Expected result for the Negative Control is negative.
Note: Shipping data were collected within the 75-day CVS testing period.

Matrix Effect

To verify that the simulated blood culture matrix does not impact performance of the DiaSorin LIAISON PLEX BCY assay, one lot of Candida tropicalis (1E6 cells/mL final concentration) was spiked into MDx-Chex for BCY matrix and also into BD BACTEC Plus Aerobic/F culture medium supplemented with negative whole blood to simulate a clinical sample (note: spike-in concentration is within the clinical bottle positivity range of approximately 1E7-1E9 CFU/mL). The simulated samples were tested in triplicate using DiaSorin LIAISON PLEX BCY assay. Additionally, non-spiked simulated samples were tested in triplicate using BCY assay serving as negative controls.

The simulated positive and negative MDx-Chex for BCY matrix and simulated positive clinical sample passed with ≥ 90% agreement for positive detection of analyte. All results met predefined acceptance criteria. The results demonstrate that MDx-Chex for BCY matrix has no effect on target detection (i.e., no inhibition and/or false negative results) when tested with the LIAISON PLEX BCY Test. Data for MDx-Chex for BCY was identical to the results for the simulated clinical blood culture sample.

Table 1: Comparison of MDx-Chex for BCY Matrix and Clinical Sample matrix tested on DiaSorin LIAISON PLEX BCY Assay – Spiked-in samples

Matrix type	# Expected results / # tested [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex for BCY Matrix + Candida tropicalis	3/3	100%	29% - 100%
Clinical Matrix + Candida tropicalis	3/3	100%	29% - 100%

[1] Expected result for the Spiked-in matrices are positive for Candida tropicalis.

Table 2: Comparison of MDx-Chex for BCY Matrix and Clinical Sample matrix tested on DiaSorin LIAISON PLEX BCY Assay – non-spiked samples

Matrix type	# Expected results / # tested [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex for BCY Matrix	3/3	100%	29% - 100%
Clinical Matrix	3/3	100%	29% - 100%

[1] Expected result for non-spiked matrices are negative.

Conclusion of Performance Tests

The study results demonstrate MDx-Chex for BCY to be consistently stable, to demonstrate reproducibility, repeatability, and is substantially equivalent to the predicate device (MDx-Chex for BCID2) through product expiration dating. MDx-Chex for BCY is a safe and effective product, which fulfills its intended use when used as instructed in the Instructions for Use.