March 23, 2026

Streck
Iris Servellon
Regulatory Affairs Coordinator
7002 S. 109th St.
La Vista, Nebraska 68128

Re: K254166
Trade/Device Name: MDx-Chex for BCN
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 17, 2025
Received: December 23, 2025

Dear Iris Servellon:

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

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

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

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

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

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,

BRYAN M. GRABIAS -S
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Bryan Grabias, Ph.D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures 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)*
K254166

Device Name
MDx-Chex for BCN

Indications for Use *(Describe)*

MDx-Chex for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the Diasorin LIAISON PLEX Gram-Negative Blood Culture assay on the LIAISON PLEX System. MDx-Chex for BCN Control 1 and Control 2 are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 1: Gram-negative bacteria: Acinetobacter baumannii, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Stenotrophomonas maltophilia; genus: Acinetobacter spp., Pseudomonas spp.; antimicrobial resistance genes: KPC, NDM, and VIM. Control 2: Gram-negative bacteria: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Klebsiella variicola, Morganella morganii, Serratia marcescens; family/genus: Enterobacteriaceae/ Morganellaceae, Citrobacter spp., Enterobacter spp., Proteus spp., Salmonella spp.; antimicrobial resistance genes: CTX-M, IMP, MCR, OXA, and SME. 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: **Address:**	Iris Servellon 7002 S. 109th Street La Vista, NE 68128
Phone: **Fax:** **Email:** **Date Prepared:**	402-537-5216 402-537-5317 iservellon@Streck.com December 19, 2025
Names **Trade Name:** **Common Name:**	 MDx-Chex® for BCN Quality Control Material for Microbiology Assays
Device Type:	Assayed external control material for microbiology nucleic acid amplification (NAT) assays
Product Code: **Panel:**	PMN (21CFR 866.3920) Microbiology
Predicate Device:	K231223 - MDx-Chex for BC-GN

Device Description

MDx-Chex® for BCN is a quality control kit consisting of two controls for the Diasorin LIAISON-PLEX Gram-Negative Blood Culture Assay (BCN). The MDx-Chex for BCN Control 1 is positive for certain pathogens and resistance mechanisms in the LIAISON-PLEX Gram-Negative Blood Culture assay and negative for those contained in MDx-Chex for BCN Control 2. The MDx-Chex for BCN Control 2 is positive for the remaining pathogen and antimicrobial resistance genes in the LIAISON-PLEX Gram-Negative Blood Culture assay and negative for those present in MDx-Chex for BCN Control 1 (See Table 1). 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 BCN is also configured as a verification kit (MDx-Chex for BCN Verification Kit) for use at equipment installation, in the development of workflow procedures and for operator proficiency evaluation.

Table 1 – MDx-Chex for BCN Control 1 and Control 2 Results Summary

Gram-Negative Bacteria		
Target	**Control 1**	**Control 2**
Enterobacteriaceae / Morganellaceae	Not Detected	Detected
Acinetobacter spp.	Detected	Not Detected
Acinetobacter baumannii	Detected	Not Detected
Citrobacter spp.	Not Detected	Detected
Enterobacter spp.	Not Detected	Detected
Escherichia coli	Not Detected	Detected
Haemophilus influenzae	Detected	Not Detected
Klebsiella oxytoca	Not Detected	Detected
Klebsiella pneumoniae	Not Detected	Detected
Klebsiella variicola	Not Detected	Detected
Morganella morganii	Not Detected	Detected
Neisseria meningitidis	Detected	Not Detected
Proteus spp.	Not Detected	Detected
Pseudomonas spp.	Detected	Not Detected
Pseudomonas aeruginosa	Detected	Not Detected
Salmonella spp.	Not Detected	Detected
Serratia marcescens	Not Detected	Detected
Stenotrophomonas maltophilia	Detected	Not Detected
Antimicrobial Resistance Genes		
Gene	**Control 1**	**Control 2**
CTX-M	Not Detected	Detected
IMP	Not Detected	Detected
KPC	Detected	Not Detected
MCR	Not Detected	Detected
NDM	Detected	Not Detected
OXA	Not Detected	Detected
SME	Not Detected	Detected
VIM	Detected	Not Detected

Intended Use

MDx-Chex® for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of gram-negative bacteria and associated antimicrobial resistance genes, by the Diasorin LIAISON PLEX® Gram-Negative Blood Culture assay on the LIAISON PLEX System. MDx-Chex for BCN Control 1 and Control 2 are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 1: gram-negative bacteria: Acinetobacter baumannii, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Stenotrophomonas maltophilia; genus: Acinetobacter spp., Pseudomonas spp.; antimicrobial resistance genes: KPC, NDM, and VIM. Control 2: gram-negative bacteria: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Klebsiella variicola, Morganella morganii, Serratia marcescens; family/genus: Enterobacteriaceae/Morganellaceae, Citrobacter spp., Enterobacter spp., Proteus spp., Salmonella spp.; antimicrobial resistance genes: CTX-M, IMP, MCR, OXA, and SME. This product is not intended to replace manufacturer controls provided with the device.

Comparison to Predicate Device

Device and Predicate Device:		**K231223**
Device Trade Name	**Candidate Device: MDx-Chex for BCN**	**Predicate Device: MDx-Chex for BC-GN**
General Device Characteristic Similarities		
Intended use	MDx-Chex for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the Diasorin LIAISON PLEX Gram-Negative Blood Culture assay on the DiaSorin LIAISON PLEX system. Positive and Negative Controls are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 1: Gram-negative bacteria: *Acinetobacter spp.* *Acinetobacter baumannii* *Haemophilus influenzae* *Neisseria meningitidis*	MDx-Chex for BC-GN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the Luminex VERIGENE Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) on Luminex VERIGENE systems. The MDx-Chex for BC-GN 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: Gram-negative bacteria: Escherichia coli, Klebsiella pneumoniae, Klebsiella

	Pseudomonas spp. *Pseudomonas aeruginosa* *Stenotrophomonas maltophilia*; antimicrobial resistance genes: KPC, NDM, and VIM. Control 2: *Enterobacteriaceae / Morganellaceae* *Citrobacter spp.* *Enterobacter spp.* *Escherichia coli* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Klebsiella variicola* *Morganella morganii* *Proteus spp.* *Salmonella spp.* *Serratia marcescens;* Antimicrobial resistance genes: CTX-M, IMP, MCR, OXA and SME. This product is not intended to replace manufacturer controls provided with the device.	oxytoca, Pseudomonas aeruginosa, Species: Acinetobacter spp., Citrobacter spp., Enterobacter spp., Proteus spp.; antimicrobial resistance genes: CTX-M, IMP, KPC, NDM, OXA, and VIM. Negative Control: buffered solution only. 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 a patient sample	Same
Number of targets monitored	18 Gram-negative organisms 8 Resistant Genes	8 Gram-negative organisms 6 Resistance Genes
Composition	Intact inactivated bacteria, human erythrocytes and leukocytes, and relevant components of blood culture media.	Same
Assay Steps Monitored	Lysis, nucleic acid isolation/purification/inhibitor removal, DNA hybridization, detection, identification/data reporting	Same

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

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

Multi-Site Precision (Reproducibility)

A multi-site reproducibility study assessed performance of MDx-Chex for BCN, with the DiaSorin LIAISON PLEX BCN test, using DiaSorin LIAISON PLEX systems at three separate sites. Three MDx-Chex for BCN lots, at least three LIAISON PLEX BCN test cartridge lots, and at least three operators were included in the study. Testing at each site consisted of 10 Level 1 and 10 Level 2 Control samples for each MDx-Chex for BCN lot for a total of 30 samples per control type (Level 1 and Level 2 control tubes), 60 samples per lot, tested on different days (2 tubes x 1 lot x 1 day, for 10 days and 3 different sites). A total of 180 runs (90 runs per MDx-Chex for BGN control type; control type = Level 1 and Level 2 controls) were generated for data analysis from all testing sites and all MDx-Chex for BCN lots. Controls were stored at 2C prior to testing.

All MDx-Chex for BCN Control lots passed with ≥ 90% agreement with expected results. Reproducibility data collected from three MDx-Chex for BCN Control Level 1 and Level 2 lots passed with **≥** 90% positive agreement with expected results. Reproducibility data collected from three MDx-Chex for BCN Control Level 1 and Level 2 lots passed with **≥** 90% negative agreement with expected results. All results met predefined acceptance criteria.

Table1: Reproducibility of MDx-Chex for BCN: 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 BCN (Level 1 and Level 2 combined)	58/60*	97%	60/60	100%	60/60	100%	99% (178/180 total runs)	96 – 100%

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control Level 1 and Level 2.
* One Positive Control Level 1 and one Positive Control Level 2 produced unexpected results.

Table 2: Reproducibility of MDx-Chex for BCN: 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 BCN (Level 1 and Level 2 combined)	60/60	100%	60/60	100%	60/60	100%	100% (180/180 total runs)	98 – 100%

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control Level 1 and Level 2.

Single-Site Precision (Repeatability)

A repeatability study was conducted to assess performance of MDx-Chex for BCN using at least two DiaSorin LIAISON PLEX systems. Three MDx-Chex for BCN lots, at least three LIAISON PLEX BCN test cartridge lots and a minimum of two operators were included in the study.

Testing consisted of 20 samples per control type (Control level 1 and level 2), 40 samples per MDx-Chex for BCN lot, tested over 20 days. A total of 120 runs (20 runs per MDx-Chex for BCN control type; control type = Level 1 and Level 2 controls) were generated for data analysis for all MDx-Chex for BCN lots (2 BCN control types x 1 control type/day x 3 lots x 20 days = 120 runs). Controls were stored at 2C prior to testing.

Table 1: Repeatability of MDx-Chex® for BCN: Positive Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
MDx-Chex for BCN (Level 1 and Level 2 combined)	118/120*	98%	91% - 100%	Pass

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control Level 1 and Level 2.
*One Positive Control Level 1 and one Positive Control Level 2 produced unexpected results.

Table 2: Repeatability of MDx-Chex® for BCN: Negative Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
MDx-Chex for BCN (Level 1 and Level 2 combined)	120/120	100%	97% - 100%	Pass

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control Level 1 and Level 2.

Lot-to-Lot Reproducibility

A Lot-to-Lot reproducibility study was conducted to evaluate the performance of three MDx-Chex for BCN lots, using the same DiaSorin LIAISON PLEX BCN test cartridge lot tested on one DiaSorin LIAISON PLEX system over multiple days.

The within-run precision study was performed to assess performance of one MDx-Chex® for BCN lot, using the same DiaSorin LIAISON PLEX BCN test cartridge lot tested on the same day with one DiaSorin LIAISON PLEX System.

For the Lot-to-lot study, data from 10 Control Level 1 and Level 2 tubes, tested on the same DiaSorin LIAISON PLEX System, was used for data analysis for each control tube per MDx-Chex® for BCN lot (30 data points per control type) for a total of 60 data points from three MDx-Chex® for BCN lots.

The within-run precision study consisted of 10 tests for each Control Level 1 and Level 2 tubes generated from one MDx-Chex® for BCN 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 BCN Level 1 and Level 2 lots passed with ≥ 90% positive agreement with expected results. Similarly, all MDx-Chex® for BCN Control Level 1 and Level 2 lots passed with ≥ 90% negative agreement with expected results.

The results support that MDx-Chex® for BCN is reproducible across three separately manufactured lots when used with the DiaSorin LIAISON PLEX BCN 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 BCN: Positive Percent Agreement

Category	MDx-Chex for BCN	# Observed Results/# Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex for BCN (Level 1 and Level 2 combined)	5202	20/20	100%	83 – 100%
	5209	20/20	100%	83 – 100%
	5223	20/20	100%	83 – 100%

1 Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control Level 1 and Level 2.

Table 2: Lot-to-Lot Precision Summary of MDx-Chex® for BCN: Negative Percent Agreement

Category	MDx-Chex for Blood Culture GN	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex for BCN (Level 1 and Level 2 combined)	5202	20/20	100%	83 – 100%
	5209	20/20	100%	83 – 100%
	5223	20/20	100%	83 – 100%

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control Level 1 and Level 2.

Table 3: Within-Run Precision Summary for MDx-Chex® for BCN: Positive Percent Agreement

Category	MDx-Chex for Blood Culture GN	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex for BCN (Level 1 and Level 2 combined)	5223	19/20*	95%	76 – 100%

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control Level 1 and Level 2.
* One Positive Control Level 1 produced an unexpected result.

Table 4: Within-Run Precision Summary for MDx-Chex for BCN Negative Control: Negative Percent Agreement

Category	MDx-Chex for BCN	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex for BCN (Level 1 and Level 2 combined)	5223	20/20	100%	84 – 100%

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control Level 1 and Level 2.

Closed-Vial Stability

A closed-vial stability study was conducted to assess the performance of three MDx-Chex for BCN lots with the LIAISON PLEX BCN Test using DiaSorin LIAISON PLEX systems. Testing consisted of 20 BCN Level 1 and 20 BCN Level 2 control samples, per MDx-Chex for BCN lot, collected at different data collection timepoints at room (25C) and at refrigerated (2C) temperatures.

Closed-vial stability (Day 0 and Day 75), all MDx-Chex for BCN Level 1 and Level 2 lot passed with ≥ 90% positive agreement with expected results at Day 0 and Day 75. Similarly, all MDx-Chex for BCN Level 1 and Level 2 lot passed with ≥ 90% negative agreement with expected results at Day 0 and Day 75.

The data support MDx-Chex® for BCN is stable for at least 75 days and results meet acceptance criteria.

Table 1. Closed-vial stability of MDx-Chex® for BCN: Positive Percent Agreement

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
Day 0	NA	118/120*	98 %	94% - 100 %	Pass
Day 75+	2-8°C	120/120	100 %	97 % - 100 %	Pass
	20-25°C	120/120	100 %	97 % - 100 %	Pass

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex® for BCN Control Level 1 and Level 2.
+ Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 80 days, Level 2: 83 Days), Lot 5223 (Level 1: 84 days, Level 2: 85 Days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 83 days, Level 2: 84 Days), Lot 5223 (Level 1: 85 days, Level 2: 88 Days).
* Two GN Control Level 1 produced unexpected results.

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

Shelf-Life	Storage Temperature	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Day 0	NA	120/120	100 %	97 % - 100 %	Pass
Day 75+	2-8°C	120/120	100 %	97 % - 100 %	Pass
	20-25°C	120/120	100 %	97 % - 100 %	Pass

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control Level 1 and Level 2.
+ Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 80 days, Level 2: 83 Days), Lot 5223 (Level 1: 84 days, Level 2: 85 Days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 83 days, Level 2: 84 Days), Lot 5223 (Level 1: 85 days, Level 2: 88 Days).

Table 3. Closed-vial stability of MDx-Chex for BCN: 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	39/40*	98%	87% - 100%	Pass
		5209	40/40	100%	91% - 100%	Pass
		5223	39/40*	98%	87% - 100%	Pass
Day 75	2-8°C	5202	40/40	100%	91% - 100%	Pass
		5209	40/40	100%	91% - 100%	Pass
		5223	40/40	100%	91% - 100%	Pass
	20-25°C	5202	40/40	100%	91% - 100%	Pass
		5209	40/40	100%	91% - 100%	Pass
		5223	40/40	100%	91% - 100%	Pass

[1] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for BCN Control Level 1 and Level 2.
[+] Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 80 days, Level 2: 83 Days), Lot 5223 (Level 1: 84 days, Level 2: 85 Days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 83 days, Level 2: 84 Days), Lot 5223 (Level 1: 85 days, Level 2: 88 Days).
* One GN Control Level 1 from Lot 5202 and one GN Control Level 1 from Lot 5223 produced unexpected results.

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

Category	Storage Temperature	# Lot	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Day 0	NA	5202	40/40	100%	91% - 100%	Pass
		5209	40/40	100%	91% - 100%	Pass
		5223	40/40	100%	91% - 100%	Pass
Day 75[+]	2-8°C	5202	40/40	100%	91% - 100%	Pass
		5209	40/40	100%	91% - 100%	Pass
		5223	40/40	100%	91% - 100%	Pass
	20-25°C	5202	40/40	100%	91% - 100%	Pass
		5209	40/40	100%	91% - 100%	Pass
		5223	40/40	100%	91% - 100%	Pass

[1] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control Level 1 and Level 2.
[+] Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 80 days, Level 2: 83 Days), Lot 5223 (Level 1: 84 days, Level 2: 85 Days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (Level 1: 82 days, Level 2: 83 Days), Lot 5209 (Level 1: 83 days, Level 2: 84 Days), Lot 5223 (Level 1: 85 days, Level 2: 88 Days).

STRECK

Shipping Stability MDx-Chex for BCN

For the shipping stability study, one MDx-Chex for BCN lot was subjected to simulated winter and summer shipping temperature profiles over 5 days. Data was collected from 20 samples per control level for each simulated shipping profile, 20 samples per control level were tested within the 75-day CVS testing period. Additional 20 samples per control level will be tested at the end of shelf-life. Temperature stress conditions for Summer 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 BCN Test.

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

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

Table 1. Shipping Study of MDx-Chex for BCN: 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	40/40	100%	91% - 100%	Pass
	20-25°C	40/40	100%	91% - 100%	Pass
Winter	2-8°C	39/40 *	98%	87% - 100%	Pass
	20-25°C	40/40	100%	91% - 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 LIASON PLEX system.
[2] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for Blood Culture GN Control 1 and Control 2.
* One Positive Control Level 1 had unexpected result.
Note: Shipping data were collected within the 75-day CVS testing period.

Table 2. Shipping Study of MDx-Chex for BCN: 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	40/40	100%	91% - 100%	Pass
	20-25°C	40/40	100%	91% - 100%	Pass
Winter	2-8°C	40/40	100%	91% - 100%	Pass
	20-25°C	40/40	100%	91% - 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 LIAISON PLEX system.
[2] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Control 1 and Control 2. Note: Shipping data were collected within the 75-day CVS testing period.

STRECK

Shipping Stability MDx-Chex for BCN Verification Kit

For the shipping stability study, one MDx-Chex for BCN Verification lot was subjected to simulated winter and summer shipping temperature profiles over 5 days. For each simulated shipping condition, 5 samples per control type (i.e., Level 1 and 2) were tested within the 75-day CVS testing period. Additional 5 samples per control type may be tested at the end of shelf-life. 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 BCN Test.

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

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

Table 1. Shipping Study of MDx-Chex for BCN Verification Kit: 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	10/10	100%	69% - 100%	Pass
	20-25°C	10/10	100%	69% - 100%	Pass
Winter	2-8°C	10/10	100%	69% - 100%	Pass
	20-25°C	15/15	100%	78% - 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 LIAISON PLEX system.
[2] Expected result for the Positive Control is positive. Denominator = total number of expected positive results combined from MDx-Chex for BCN Verification Kit Control 1 and Control 2.
Note: Shipping data were collected within the 75-day CVS testing period.

Table 2. Shipping Study of Blood Culture GN Verification Kit: 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	10/10	100%	69% - 100%	Pass
	20-25°C	10/10	100%	69% - 100%	Pass
Winter	2-8°C	10/10	100%	69% - 100%	Pass
	20-25°C	14/15*	93%	68% - 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 LIAISON PLEX system.
[2] Expected result for the Negative Control is negative. Denominator = total number of expected negative results combined from MDx-Chex for BCN Verification Kit Control 1 and Control 2.
[*] One Control 2 run had false-positive for a single target. The entire dataset (5 replicates) was re-tested, and all runs passed confirming the stability of product exposed to shipping conditions (refer to study protocol # 24-0005-1 under "Study Design and Sample Size" section".
Note: Shipping data were collected within the 75-day CVS testing period.

Matrix Effect

A matrix effect study was completed to verify the simulated blood culture matrix does not have a negative impact on performance of the DiaSorin LIAISON PLEX BCN assay and produced results consistent with contrived positive blood culture samples.

To verify that the simulated blood culture matrix does not impact performance of the DiaSorin LIAISON PLEX BCN assay, one lot of E. coli (3 x 10^8 cells/mL final concentration) was spiked into MDx-Chex for BCN 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 1 x 10^7-1 10^9 CFU/mL).

The simulated samples were tested in triplicate using DiaSorin LIAISON PLEX BCN test. Additionally, non-spiked simulated samples were tested in triplicate using BCN test serving as negative controls.

The simulated positive MDx-Chex for BCN matrix and simulated positive clinical sample passed with ≥ 90% agreement for positive detection of analyte. The simulated positive MDx-Chex for BCN matrix and simulated positive clinical sample passed with ≥ 90% agreement for negative detection of analyte. The results demonstrate that MDx-Chex for BCN matrix has no effect on target detection (no inhibition and/or false negative results) when tested with the LIAISON PLEX system panel. Data was consistent with the results of simulated blood culture samples.

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

Matrix type	# Expected results / # tested [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex for BCN matrix + E. coli	3/3	100%	29 – 100%
Clinical Matrix + E. coli	3/3	100%	29 – 100%

[1] Expected result for the Spiked-in matrices are positive for E. coli and CTX-M resistance gene.

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

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

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

Conclusions of Performance Tests

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