July 27, 2023

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

Re: K231221
Trade/Device Name: MDx-Chex for BC-GP
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed Quality Control Material For Clinical Microbiology Assays
Regulatory Class: Class II
Product Code: PMN
Dated: April 26, 2023
Received: April 28, 2023

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 (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,

Bryan M. Grabias -S

Digitally signed by Bryan M. Grabias -S
Date: 2023.07.27 11:10:57 -04'00'

for

Noel J. Gerald, Ph. D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231221

Device Name
MDx-Chex™ for BC-GP

Indications for Use *(Describe)*

MDx-Chex™ for BC-GP is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-positive bacteria and associated antimicrobial resistance genes, by the Luminex VERIGENE® Gram-Positive Blood Culture Nucleic Acid Test (BC-GP) on Luminex VERIGENE® systems. The MDx-Chex™ for BC-GP 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-positive bacteria: Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Enterococcus faecalis, Enterococcus faecium, Streptococcus anginosus group; Species: Staphylococcus spp., Streptococcus spp., Listeria spp.; antimicrobial resistance genes: mecA, vanA and vanB. 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.

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510(k) Summary

510(k) Submitter: Streck
7002 S. 109th Street
La Vista, NE 68128

Official Correspondent: Megan Hiveley
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La Vista, NE 68128

Phone: 402-537-5208
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Date Prepared: July 24, 2023

Names
Trade Name: MDx-Chex™ for BC-GP
Common Name: Quality Control Material for Microbiology Assays

Device Type: Assayed external control material for microbiology nucleic acid amplification (NAT) assays

Product Code: PMN (21 CFR 866.3920)
Panel: Microbiology

Predicate Device: K212576 - MDx-Chex™ for BCID2

Device Description

MDx-Chex™ for BC-GP is a quality control kit consisting of positive and negative controls for the Luminex VERIGENE® Gram-Positive Blood Culture Test (BC-GP). The MDx-Chex™ for BC-GP Positive Control is positive for pathogens and resistance mechanisms in the VERIGENE BC-GP test (See Table 1). The MDx-Chex™ for BC-GP Negative Control is negative for pathogens and resistance mechanisms in the VERIGENE BC-GP test. Each control mix also contains controls for blood and blood culture media components that have been identified is inhibitors to DNA hybridization assays, namely hemoglobin, leukocyte DNA, and anticoagulants.

Table 1 – Pathogens and antimicrobial resistance genes detected by MDx-Chex™ for BC-GP Control Kit.

Gram-positive bacteria and resistance genes		
Pathogen/Resistance gene	**Positive Control**	**Negative Control**
Enterococcus faecalis	Detected	Not Detected
Enterococcus faecium	Detected	Not Detected
Listeria spp.	Detected	Not Detected
Staphylococcus spp.	Detected	Not Detected
Staphylococcus aureus	Detected	Not Detected

Staphylococcus epidermidis	Detected	Not Detected
Staphylococcus lugdunensis	Detected	Not Detected
Streptococcus spp.	Detected	Not Detected
Streptococcus agalactiae	Detected	Not Detected
Streptococcus anginosus group	Detected	Not Detected
Streptococcus pneumoniae	Detected	Not Detected
Streptococcus pyogenes	Detected	Not Detected
mecA (methicillin)	Detected	Not Detected
vanA (vancomycin)	Detected	Not Detected
vanB (vancomycin)	Detected	Not Detected

The MDx-Chex™ for BC-GP quality control kit contains stabilized blood components, blood culture media components, and inactivated, intact microorganisms resulting in a full-process, cellular-based control for the Luminex VERIGENE BC-GP panel. Use of full-process cellular controls are necessary to evaluate the entire analytical process, including sample lysis, nucleic acid isolation, DNA hybridization detection, and analysis, as well as the impact of inhibitors present in blood culture samples 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 BC-GP is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-positive bacteria and associated antimicrobial resistance genes, by the Luminex VERIGENE® Gram-Positive Blood Culture Nucleic Acid Test (BC-GP) on Luminex VERIGENE® systems. The MDx-Chex™ for BC-GP 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-positive bacteria: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus agalactia*e, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus anginosus* group; Species: *Staphylococcus spp*., *Streptococcus spp*., *Listeria spp*.; antimicrobial resistance genes: *mecA*, *vanA*, *vanB*. Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.

Comparison to Predicate Device

Device & Predicate Device(s):	**K231221**	**K212576**
Device Trade Name	MDx-Chex™ for BC-GP	MDx-Chex™ for BCID2
General Device Characteristic Similarities		
Intended Use / Indication For Use	MDx-Chex™ for BC-GP is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative	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

	detection of Gram-positive bacteria and associated antimicrobial resistance genes, by the Luminex VERIGENE® Gram-Positive Blood Culture Nucleic Acid Test (BC-GP) on Luminex VERIGENE® systems. The MDx-Chex™ for BC-GP 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-positive bacteria: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus anginosus* group; Species: *Staphylococcus spp*., *Streptococcus spp*., *Listeria spp*.; antimicrobial resistance genes: *mecA*, *vanA*, *vanB*. Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.	and Gram-negative bacteria, as well as associated antimicrobial resistance genes, by the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel on BIOFIRE FilmArray® systems. Control 1-GN: Gram-negative bacteria: Acinetobacter calcoaceticus-baumannii complex, Bacteroides fragilis, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus spp., Salmonella spp., Serratia marcescens, Haemophilus influenzae, Neisseria meningitidis, 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 lugdunensis, Streptococcus agalactiae, Streptococcus pneumoniae, 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 a patient sample	Same
Composition	Intact inactivated bacteria, human erythrocytes and leukocytes, and relevant components of blood culture media	Same

General Device Characteristic Differences		
Assay Steps Monitored	Lysis, nucleic acid isolation/purification/inhibitor removal, DNA hybridization, detection, identification/data reporting	Lysis, nucleic acid isolation/purification/PCR inhibitor removal, amplification, detection, identification/data reporting
Number of Targets monitored in one assay	Multiple, 15 targets	Multiple, > 30 targets (12 gram-positive)

Discussion of Tests and Test Results

To substantiate the product performance claims for MDx-Chex™ for BC-GP, 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 and Shipping Stability
- Matrix Effect

Multi-Site Precision (Reproducibility)

Testing was completed at three (3) sites and consisted of 10 positive control samples and 10 negative control samples for each MDx-Chex™ for BC-GP lot for a total of 30 samples per control type (positive and negative control tubes), 60 samples per lot, tested on different days (2 vials x 1 lot x 1 day, for 10 days and 3 different lots). A total of 180 runs (90 runs per MDx-Chex™ for BC-GP control type; control type = positive or negative control) were generated for data analysis from all testing sites and all MDx-Chex™ for BC-GP lots.

Three lots were used for this study, (#22343, #22353, #22355), at least three Luminex BC-GP panel lots, three locations and at least three operators were included in the study.
All samples were prepared and analyzed on the Luminex VERIGENE System Instrument per the control Instructions for Use.

All MDx-Chex™ for BC-GP Positive and Negative Control lots passed with ≥ 90% agreement with expected results. The results support the conclusion that MDx-Chex™ for BC-GP shows reproducibility across three separately manufactured control lots between sites, days, and operators when used with the Luminex BC-GP panels on different Luminex VERIGENE systems.

Table 1: Reproducibility of MDx-Chex for BC-GP 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 BC-GP Positive Control	30/30	100%	30/30	100%	30/30	100%	100% (90/90)	96% - 100%

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

Table 2: Reproducibility of MDx-Chex for BC-GP 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 BC-GP Negative Control	30/30	100%	30/30	100%	30/30	100%	100% (90/90)	96% - 100%

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

Single-Site Precision (Repeatability)

The repeatability of MD-Chex™ for BC-GP was evaluated using three separately manufactured lots of control. Each lot was tested using the Luminex VERIGENE System. A minimum of three Luminex BC-GP panel lots were used.

Three MDx-Chex™ for BC-GP lots (#22343, #22353, #22355), at least three Luminex BC-GP panel 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 BC-GP lot, tested over 20 days. A total of 120 runs (20 runs per MDx-Chex™ for BC-GP control type; control type = positive or negative control) were generated for data analysis for all MDx-Chex™ for BC-GP lots.

Samples were prepared according to MDx-Chex™ for BC-GP control instructions. Samples were analyzed on the Luminex VERIGENE System per the Instructions for Use.
All MDx-Chex™ for BC-GP Positive and Negative Control lots passed with ≥ 90% agreement with expected results. The results support the conclusion that MDx-Chex™ for BC-GP shows repeatability across three separately manufactured control lots when used with the Luminex BC-GP panels.

Table 1: Repeatability of MDx-Chex™ for BC-GP Positive Control: Positive Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP, Positive Control	60/60	100%	94% - 100%

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

Table 2: Repeatability of MDx-Chex™ for BC-GP Negative Control: Negative Percent Agreement

Category	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP, Negative Control	60/60	100%	94% - 100%

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

Lot-to-Lot Reproducibility

The reproducibility of MDx-Chex™ for BC-GP was evaluated using three separately manufactured lots of control (#22343, #22353, #22355). Samples were prepared per the control Instructions for Use (IFU) prior to testing with the same Luminex BC-GP panel lot on one Luminex VERIGENE System over multiple days.

The within-run precision study was performed to assess performance of one MDx-Chex™ for BC-GP lot (#22343), using the same Luminex BC-GP panel lot tested on the same day with one Luminex VERIGENE System.

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

The within-run precision study consisted of 10 tests for each positive and negative control tube generated from one MDx-Chex™ for BC-GP lot (total of 20 tests per control kit). For this study, Day 60 (2C) closed-vial stability data were used to demonstrate the within-run precision.

All MDx-Chex™ for BC-GP Positive and Negative Control lots passed with ≥ 90% agreement with expected results. The results support that MDx-Chex™ for BC-GP is reproducible across three separately manufactured lots when used with the Luminex VERIGENE BC-GP panel. 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 for MDx-Chex™ for BC-GP Positive Control: Positive Percent Agreement

Category	# Lot	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP, Positive Control	22343	9/10*	90%	55% - 100%
	22353	10/10	100%	69% - 100%
	22355	9/10*	90%	55% - 100%

* One Positive Control for Lots #22343 and #22355 gave initial false negative results which produced the expected results upon a single retest. The retest runs are not included in the above calculations.

Table 2: Lot-to-Lot Precision Summary for MDx-Chex™ for BC-GP Negative Control: Negative Percent Agreement

Category	# Lot	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP, Negative Control	22343	10/10	100%	69% - 100%
	22353	10/10	100%	69% - 100%
	22355	10/10	100%	69% - 100%

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

Table 3: Within-Run Precision Summary for MDx-Chex™ for BC-GP Positive Control: Positive Percent Agreement

Category	# Lot	# Observed Results/ # Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP, Positive Control	22343	10/10	100%	69% - 100%

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

Table 4: Within-Run Precision Summary for MDx-Chex™ for BC-GP Negative Control: Negative Percent Agreement

Category	# Lot	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP, Negative Control	22343	10/10	100%	69% - 100%

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

Closed-Vial Stability and Shipping Stability

A closed-vial stability study was conducted to assess performance of three MDx-Chex™ for BC-GP lots (#22343, #22353, #22355) with the Luminex BC-GP panel using Luminex VERIGENE systems. Testing consisted of 20 positive and 20 negative control samples, per MDx-Chex™ for BC-GP lot, collected at different data collection timepoints and stored at room (25˚C) and at refrigerated (2˚C) temperatures.

For the shipping stability study, one of the MDx-Chex™ for BC-GP lots (RPL #22355) from each storage temperature (2˚C and 25˚C) was subjected to simulated winter and summer shipping temperature profiles over 5 days. Data was collected from 20 samples per control type (i.e., positive and negative), for each simulated shipping profile, within the 61-day CVS testing period.

Samples were prepared and analyzed on the Luminex VERIGENE systems per MDx-Chex™ for BC-GP assay Instructions for Use. All MDx-Chex™ for BC-GP Positive and Negative Control lots passed closed-vial stability, and summer and winter shipping conditions with ≥ 90% agreement with expected results. The data supports that MDx-Chex™ for BC-GP Control kit is stable for a minimum of 60 days for use with the Luminex BC-GP panel lot when stored at 2-25°C. The data also supports that the Control kit is stable and functional after exposure to extreme summer and winter shipping temperature conditions.

Table 1. Closed-vial stability of MDx-Chex™ for BC-GP 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 61+	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.
+ Indicates that lots stored at 2-8°C were tested for at least 61 days; Lot 22343 (71 days), Lot 22353 (75 days), and Lot 22355 (79 days). Lots stored at 20-25°C were also tested for at least 61 days; Lot 22343 (73 days), Lot 22353 (77 days), and Lot 22355 (81 days).

Table 2. Closed-vial stability of MDx-Chex™ for BC-GP 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 61+	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.
+ Indicates that lots stored at 2-8°C were tested for at least 61 days; Lot 22343 (71 days), Lot 22353 (75 days), and Lot 22355 (79 days). Lots stored at 20-25°C were tested for at least 61 days; Lot 22343 (73 days), Lot 22353 (77 days), and Lot 22355 (81 days).

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

Shelf-Life	Storage Temperature	# Lot	#Observed Results/ #Expected Results [1]	Positive Percent Agreement	95% Confidence Interval	PPA ≥ 90% Acceptance
Day 0	NA	22343	20/20	100%	83% - 100%	Pass
		22353	20/20	100%	83% - 100%	Pass
		22355	20/20	100%	83% - 100%	Pass
Day 61+	2-8°C	22343	20/20	100%	83% - 100%	Pass
		22353	20/20	100%	83% - 100%	Pass
		22355	20/20	100%	83% - 100%	Pass
	20-25°C	22343	20/20	100%	83% - 100%	Pass
		22353	20/20	100%	83% - 100%	Pass
		22355	20/20	100%	83% - 100%	Pass

[1] Expected result for the Positive Control is positive.
+ Indicates that lots stored at 2-8°C were tested for at least 61 days; Lot 22343 (71 days), Lot 22353 (75 days), and Lot 22355 (79 days). Lot stored at 20-25°C were also tested for at least 61 days; Lot 22343 (73 days), Lot 22353 (77 days), and Lot 22355 (81 days).

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

Shelf-Life	Storage temperature	# Lot	#Observed Results/ #Expected Results [1]	Negative Percent Agreement	95% Confidence Interval	NPA ≥ 90% Acceptance
Day 0	NA	22343	20/20	100%	83% - 100%	Pass
		22353	20/20	100%	83% - 100%	Pass
		22355	20/20	100%	83% - 100%	Pass
Day 61+	2-8°C	22343	20/20	100%	83% - 100%	Pass
		22353	20/20	100%	83% - 100%	Pass
		22355	20/20	100%	83% - 100%	Pass
	20-25°C	22343	20/20	100%	83% - 100%	Pass
		22353	20/20	100%	83% - 100%	Pass
		22355	20/20	100%	83% - 100%	Pass

[1] Expected result for the Negative Control is negative.
+ Indicates that lots stored at 2-8°C were tested for at least 61 days; Lot 22343 (71 days), Lot 22353 (75 days), and Lot 22355 (79 days). Lots stored at 20-25°C were also tested for at least 61 days; Lot 22343 (73 days), Lot 22353 (77 days), and Lot 22355 (81 days).

Table 1. Shipping Study of MDx-Chex™ for BC-GP Positive Control: Positive Percent Agreement.

Category	Storage Temperature*	#Observed Results/ #Expected Results [1]	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

* Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions. After exposure to simulated summer and winter conditions, samples were returned to each respective storage temperature prior to testing on the Luminex system.
[1] Expected result for the Positive Control is positive.

Table 2. Shipping Study of MDx-Chex™ for BC-GP Negative Control: Negative Percent Agreement.

Category	Storage Temperature*	#Observed Results/ #Expected Results [1]	Negative 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

* Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions. After exposure to simulated summer and winter conditions, samples were returned to each respective storage temperature prior to testing on the Luminex system. [1] Expected result for the Negative Control is negative.

Matrix Effect

A matrix effect study was completed to demonstrate that the matrix of the MDx-Chex™ for BC-GP has no effect on target detection by the VERIGENE Gram Positive Blood Culture (BC-GP) panel and produces results consistent with contrived positive blood culture samples.

To verify that the simulated blood culture matrix does not impact performance of the Luminex BC-GP panel, one lot (Lot# 23026) of *Streptococcus agalactiae* (5.0E7 cells/mL final concentration) was spiked into MDx-Chex™ for BC-GP 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 (i.e., Positive Control) were tested in triplicate using Luminex BC-GP panel. Additionally, non-spiked simulated samples were tested in triplicate using Luminex BC-GP panel serving as negative controls.

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

Table 1: Effect of MDx-Chex™ for BC-GP and clinical sample matrices, spiked with *Streptococcus agalactiae*, tested on Luminex Gram-Positive Blood Culture (BC-GP) Test

Matrix type	# Observed Results/# Expected Results [1]	Positive Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP Matrix, Positive Control	3/3	100%	29% - 100%
Clinical Matrix, Positive Control	3/3	100%	29% - 100%

[1] Expected result for the spiked-in matrices are positive for Streptococcus agalactiae.

Table 2: Effect of negative MDx-Chex™ for BC-GP and clinical sample matrices tested on Luminex Gram-Positive Blood Culture (BC-GP) Test

Matrix type	# Observed Results/ # Expected Results [1]	Negative Percent Agreement	95% Confidence Interval
MDx-Chex™ for BC-GP Matrix, Negative Control	3/3	100%	29% - 100%
Clinical Matrix, Negative Control	3/3	100%	29% - 100%

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

Conclusion of Performance Tests

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