510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K260041

B Applicant

Streck, LLC

C Proprietary and Established Names

MDx-Chex for BCP

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PMN	Class II	21 CFR 866.3920 - Assayed Quality Control Material For Clinical Microbiology Assays	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the MDx-Chex for BCP.

B Measurand:

Multi-analyte external quality control materials for microbiology NAAT assays.

C Type of Test:

QC materials to monitor the performance of the DiaSorin LIAISON PLEX Gram-Positive Blood Culture assay on the LIAISON PLEX System.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MDx-Chex for BCP 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 Diasorin LIAISON PLEX Gram-Positive Blood Culture assay on the LIAISON PLEX System. The MDx-Chex BCP 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 anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterococcus faecalis*, *Enterococcus faecium*; genus: *Bacillus* spp., *Listeria* spp., *Staphylococcus* spp., *Streptococcus* spp.; antimicrobial resistance genes: mecA/mecC, vanA, and vanB. Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

DiaSorin LIAISON PLEX System.

IV Device/System Characteristics:

A Device Description:

MDx-Chex for BCP is a cellular-based external quality control containing stabilized blood components (erythrocytes and leukocytes), simulated blood culture media, and inactivated microorganisms. The control simulates positive and negative blood culture samples and is processed in "control mode" per the assay IFU. Use of full-process cellular controls enables evaluation of the entire analytical workflow for sample-to-result tests, including lysis, nucleic acid isolation/purification, hybridization, detection, and analysis, and provides assessment of the impact of inhibitors and pre-analytical variables. The device is intended to be used by trained laboratory professionals.

Kit configurations

MDx-Chex for BCP is packaged in a chipboard box containing a 10-hole insert. Each package contains five (5) Positive Control vials and five (5) Negative Control vials. Each control kit is

supplied with 5 violet-capped 0.5mL microtubes, each containing 300µL of the Positive Control formulation, and 5 white-capped 0.5mL microtubes, each containing 300µL of the Negative Control formulation. Each tube contains enough reagent for 1 test.

MDx-Chex for BCP Verification Kit is packaged in the same chipboard box and contains a 20-hole insert. Each package contains ten (10) Positive Sample vials and ten (10) Negative Sample vials. Each packaged verification kit is supplied with 10 violet-capped 0.5mL microtubes, each containing 300µL of the Positive Control formulation, and 10 white-capped 0.5mL microtubes, each containing 300µL of the Negative Control formulation.

Catalog Number	Product Name	Kit Configuration
250084	MDx-Chex for BCP	(5) Positive Control vials and (5) Negative Control vials
250087	MDx-Chex for BCP Verification Kit	(10) Positive Sample vials and (10) Negative Sample vials

The analyte composition for the Control set is described in Table 1, below.

Table 1: MDx-Chex for BCP Positive Control and Negative Control Results Summary.

Gram-Positive Bacteria*		
Target	**Positive Control**	**Negative Control**
Staphylococcus aureus	Detected	Not Detected
Staphylococcus epidermidis	Detected	Not Detected
Staphylococcus lugdunensis	Detected	Not Detected
Streptococcus agalactiae	Detected	Not Detected
Streptococcus anginosus group	Detected	Not Detected
Streptococcus pneumoniae	Detected	Not Detected
Streptococcus pyogenes	Detected	Not Detected
Enterococcus faecalis	Detected	Not Detected
Enterococcus faecium	Detected	Not Detected
Bacillus spp.	Detected	Not Detected
Listeria spp.	Detected	Not Detected
Staphylococcus spp.	Detected	Not Detected
Streptococcus spp	Detected	Not Detected
Antimicrobial Resistance Genes*		
mecA/mecC	Detected	Not Detected
VanA	Detected	Not Detected
VanB	Detected	Not Detected

*All Bacteria analytes are sourced from ATCC, American Type Culture Collection

B Principle of Operation:

Not applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):

MDx-Chex for BC-GP

B Predicate 510(k) Number(s):

K231221

C Comparison with Predicate:

Device & Predicate Device(s):	K260041	K231221
Device Trade Name	MDx-Chex for BCP	MDx-Chex for BC-GP
General Device Characteristic Similarities		
Intended Use/Indications For Use	MDx-Chex for BCP 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 Diasorin LIAISON PLEX Gram-Positive Blood Culture assay on the LIAISON PLEX System. The MDx-Chex BCP 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 anginosus group, Streptococcus pneumoniae, Streptococcus pyogenes, Enterococcus faecalis, Enterococcus faecium; genus: Bacillus* spp., *Listeria* spp., *Staphylococcus* spp., *Streptococcus* spp.; antimicrobial resistance genes: mecA/mecC, vanA, and vanB. Negative Control: buffered solution only. This product is not	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*; 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.

	intended to replace manufacturer controls provided with the device.	
Physical Format	Ready-to-Use Liquid	Same
Indications for Use	Process like patient sample	Same
Composition	MDx-Chex for BCP contains stabilized human leukocytes and erythrocytes, and the inactivated bacteria and bacteria components in simulated blood culture media as identified on table 1 above.	Same
Assay Steps Monitored	Lysis, nucleic acid isolation/purification/inhibitor removal, DNA hybridization, detection, identification/data reporting	Same
General Device Characteristic Differences		
Number of targets monitored in one assay	Multiple, 16 Targets	Multiple, 15 Targets

VI Standards/Guidance Documents Referenced:

Special Controls under 21 CFR 866.3920

ISO 15223-1:2021. Symbols to be used with information to be supplied by the manufacturer.

ISO 14971:2019. Medical Devices-Application of risk management to medical devices.

CLSI EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A. Single-site precision.

Within-laboratory precision was evaluated at one site, using three lots of positive and negative QC material, over 20 days, producing a total of 60 results per control type. Samples were prepared according to the MDx-Chex for BCP Instructions for Use (IFU) and tested using at least three Liaison PLEX BCP test cartridges on at least two DiaSorin LIAISON PLEX systems by at least two operators. The results from the initial run were

analyzed as percent agreement between the observed and expected value (positive or negative) for each run, with one or more discordant analyte rendering "unexpected" result for the entire run. The results are summarized in Table 2 below.

Table 2. Single-site precision of MDx-Chex for Blood Culture GP QC material.

Category	Observed / Expected Results	Percent Agreement	95% Confidence Interval
MDx-Chex for Blood Culture GP Positive Control	59/60	98%	91%-100%
MDx-Chex for Blood Culture GP Negative Control	60/60	100%	94%-100%

B. Multisite reproducibility.

Reproducibility was evaluated at three sites using three lots (one lot per site) of positive and negative QC material at each site and 10 samples per lot per control type, producing a total of 30 results per site per control type. Samples were prepared according to the MDx-Chex for BCP IFU and analyzed with the DiaSorin LIAISON PLEX BCP assay and DiaSorin LIAISON PLEX systems. The results from the initial run were analyzed as percent agreement between the observed and expected value (positive or negative) for each run, with one or more discordant analyte rendering "unexpected" result for the entire run. The results are summarized in Table 3 below.

Table 3. Multisite reproducibility of MDx-Chex for Blood Culture GP QC material.

Category	Site #1		Site #2		Site #3		Combined Percent Agreement (observed/ expected)	95% Confidence Interval
	Observed/ Expected Results	Percent Agreement	Observed/ Expected Results	Percent Agreement	Observed/ Expected Results	Percent Agreement		
MDx-Chex for BCP Positive Control	29/30	97%	30/30	100%	30/30	100%	99% (89/90)	94% - 100%
MDx-Chex for BCP Negative Control	30/30	100%	29/30	97%	29/30	97%	98% (88/90)	92% - 100%

2. Linearity:

N/A

3. Analytical Specificity/Interference:

N/A

4. Assay Reportable Range:

N/A

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Closed-Vial Stability.
Closed-Vial Stability was evaluated using three lots of QC material, two conditions (storage temperature 2-8°C or 20-25°C), and 20 samples for each combination of lot, condition, and QC type. The results demonstrated at least 90% agreement with the expected outcomes, and supported a claimed shelf-life of 365 days when stored at 2-25°C.

Shipping Stability.
Shipping Stability was evaluated using one lot of QC material, two conditions (simulated shipping during summer or winter), and 20-25 samples for each QC type. Samples were stored at 2-8°C or 20-25°C prior to shipping simulation, exposed to extreme temperature profiles (summer: between 22°C and 40°C; winter: between -10°C and -22°C) for five days, then returned to their respective storage temperatures for seven days. Samples were tested within the 75-day close-vial stability testing period. The results demonstrated at least 90% agreement with the expected outcomes. Additional stability assessment may be performed at end-of-shelf-life to confirm product shelf-life claim after exposure to extreme shipping temperatures.

6. Detection Limit:

N/A

7. Assay Cut-Off:

N/A

B Comparison Studies:

1. Method Comparison with Predicate Device:

N/A

2. Matrix Effect:

To evaluate the effect of the simulated blood culture matrix on the performance of the DiaSorin LIAISON PLEX BCP assay, one lot of *Staphylococcus aureus* (4,000,000 cells/mL final concentration) was spiked into MDx-Chex for BCP matrix and into BD BACTEC Plus Aerobic/F culture medium supplemented with negative whole blood to simulate a clinical sample. The simulated samples were tested in triplicate using DiaSorin LIAISON PLEX BCP assay. Additionally, non-spiked simulated samples were tested in triplicate using BCP assay serving as negative controls. The results are summarized in Table 4 below.

Table 4. Matrix effect on results of MDx-Chex for Blood Culture GP QC material.

Matrix type	Observed/ Expected results	Percent Agreement	95% Confidence Interval
MDx-Chex for BCP Matrix + Staphylococcus aureus	3/3	100%	29% - 100%

Clinical Matrix + Staphylococcus aureus	3/3	100%	29% - 100%
MDx-Chex for BCP Matrix	3/3	100%	29% - 100%
Clinical Matrix	3/3	100%	29% - 100%

C Clinical Studies:

1. Clinical Sensitivity:

   N/A

2. Clinical Specificity:

   N/A

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   N/A

D Clinical Cut-Off:

N/A

E Expected Values/Reference Range:

The expected values for each analyte are either "detected" or "not detected". Refer to section IV.A. Device Description, Table 1.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.