



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K254167

B Applicant

Streck, LLC

C Proprietary and Established Names

MDx-Chex for BCY

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 BCY.

B Measurand:

Multi-analyte quality control materials

C Type of Test:

MDx-Chex for BCY is intended for *in vitro* diagnostic use as an external assayed quality 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.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):

Rx-For Prescription Use Only

For *in vitro* diagnostic use only

D Special Instrument Requirements:

MDx-Chex for BCY is to be used on the Diasorin LIAISON PLEX system only.

IV Device/System Characteristics:

A Device Description:

MDx-Chex for BCY is a quality control kit consisting of positive and negative controls for the Diasorin LIAISON PLEX Yeast Blood Culture assay (BCY) on the LIAISON PLEX System. The MDx-Chex for BCY Positive Control is positive for 14 different yeast species (Table 1) that can cause bloodstream infections. The MDx-Chex for BCY Negative Control is negative for all yeast targets in the LIAISON PLEX BCY test.

Each control mix contains stabilized human blood components (erythrocytes and leukocytes) and blood culture media components that have been identified as inhibitors to nucleic acid purification and hybridization assays (e.g., hemoglobin, leukocyte DNA, and sodium polyanetholesulfonate anticoagulant). The MDx-Chex for BCY quality control kit contains stabilized blood components, simulated blood culture media components, and inactivated, intact yeast microorganisms resulting in a full-process, cellular-based control for the Diasorin

LIAISON PLEX Yeast Blood Culture panel. Full-process controls evaluate the entire analytical workflow, including sample lysis, nucleic acid isolation and purification, hybridization, detection, and analysis, as well as the impact of inhibitors present in blood culture samples and pre-analytical variables.

Table 1: Yeast in MDx-Chex for BCY and detected by the Diasorin LIAISON PLEX Yeast Blood Culture assay on the LIAISON PLEX System

<i>Candida albicans</i>	<i>Candida krusei</i>
<i>Candida auris</i>	<i>Candida lipolytica</i>
<i>Candida dubliniensis</i>	<i>Candida lusitaniae</i>
<i>Candida famata</i>	<i>Candida parapsilosis</i>
<i>Candida glabrata</i>	<i>Candida tropicalis</i>
<i>Candida guilliermondii</i>	<i>Candida haemulonii/duobushaemulonii</i>
<i>Candida kefyr</i>	<i>Cryptococcus neoformans/gattii</i>

B Principle of Operation:

Not Applicable

V Substantial Equivalence Information:

A Predicate Device Name(s):

MDx-Chex for BCID2

B Predicate 510(k) Number(s):

K212576

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K254167</u> (candidate device)	<u>K212576</u> (predicate)
Device Trade Name	MDx-Chex for BCY	MDx-Chex for BCID2
General Device Characteristic Similarities		
Intended Use/ Indications For 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	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

Device & Predicate Device(s):	<u>K254167</u> (candidate device)	<u>K212576</u> (predicate)
	<p>stabilized erythrocytes and leukocytes in a matrix of blood culture media components.</p> <p>Positive Control: Yeast: <i>Candida albicans</i>, <i>Candida dubliniensis</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, <i>Candida tropicalis</i>, <i>Candida auris</i>, <i>Candida kefyr</i>, <i>Candida lipolytica</i>, <i>Candida lusitaniae</i>, <i>Candida guilliermondii</i>, <i>Cryptococcus neoformans/gattii</i>, <i>Candida famata</i>, <i>Candida haemulonii/duobushamulonii</i>.</p> <p>Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.</p>	<p>FilmArray Blood Culture Identification 2 (BCID2) Panel on FilmArray systems.</p> <p>Control 1 - GN: Gram negative bacteria: <i>Acinetobacter colcoaceticus-baumannii</i> complex, <i>Bacteroides fragilis</i>, <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella aerogenes</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group, <i>Proteus</i> spp., <i>Salmonella</i> spp., <i>Serratia marcescens</i>, <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i>, <i>Pseudomonas aeruginosa</i>, <i>Stenotrophomonas maltophilia</i>; antimicrobial resistance genes: KPC, CTX-M, IMP, NDM, OXA-48-like, VIM, <i>mcr-1</i>.</p> <p>Control 2 - GPY: Gram positive bacteria: <i>Enterococcus faecalis</i>, <i>Enterococcus faecium</i>, <i>Listeria monocytogenes</i>, <i>Staphylococcus aureus</i>, <i>Staphylococcus epidermidis</i>, <i>Staphylococcus lugdunensis</i>, <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i>; yeast: <i>Candida albicans</i>, <i>Candida auris</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, <i>Candida tropicalis</i>, <i>Cryptococcus neoformans/gattii</i>; antimicrobial resistance genes: <i>mecA/C</i> and MREJ,</p>

Device & Predicate Device(s):	<u>K254167</u> (candidate device)	<u>K212576</u> (predicate)
		<i>vanA/B</i> . 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
Assay Steps Monitored	Lysis, nucleic acid isolation/purification/PCR inhibitor removal, amplification, detection, identification/data reporting	Same
General Device Characteristic Differences		
Number of targets monitored in one assay	Multiple - 14 yeast organisms	Multiple, >30 targets
Composition	Intact inactivated yeast, human erythrocytes and leukocytes, and relevant components of blood culture media	Intact inactivated bacteria, antimicrobial resistance genes, human erythrocytes and leukocytes, and relevant components of blood culture media

VI Standards/Guidance Documents Referenced:

- ISO 14971,2019: Medical devices - Application of risk management to medical devices
- ISO 15223,2021: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Note: The results for all analytical studies described below represent percent agreement based on comparing the expected call to the obtained test result (positive or negative). The terms, PPA (positive percent agreement) and NPA (negative percent agreement) were used to describe this agreement.

1. Precision/Reproducibility:

Reproducibility

A multi-site reproducibility study was conducted with the MDx-Chex for BCY where testing was completed at three sites with seven operators and consisted of ten positive control samples and ten negative control samples for each of three lots of MDx-Chex for BCY for a total of 30 samples per control type and 60 samples per lot. Both positive and negative controls were tested on different days (2 tubes x 1 lot x 1 day, for 10 days and 3 different lots) for a total of 180 runs (90 runs per MDx-Chex for BCY control type) from all testing sites and all MDx-Chex for BCY lots.

All samples were prepared and analyzed on the DiaSorin LIAISON PLEX System per the Instructions for Use. This resulted in a positive percent agreement (PPA) of 100% (90/90) for the MDx-Chex for BCY Positive Control (Table 2) and a negative percent agreement (NPA) of 100% (90/90) for the MDx-Chex for BCY Negative Control (Table 3).

Table 2: MDx-Chex for BCY Positive Control Multi-Site Reproducibility Summary

Category	Site #1		Site #2		Site #3		PPA for All Sites Combined	95% Confidence Interval
	# Observed/# Expected Results ¹	PPA	# Observed/# Expected Results ¹	PPA	# Observed/# Expected Results ¹	PPA		
MDx-Chex for BCY 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 3: MDx-Chex for BCY Negative Control Multi-Site Reproducibility Summary

Category	Site #1		Site #2		Site #3		NPA for All Sites Combined	95% Confidence Interval
	# Observed/# Expected Results ¹	NPA	# Observed/# Expected Results ¹	NPA	# Observed/# Expected Results ¹	NPA		
MDx-Chex for BCY 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.

The results support the reproducibility of the MDx-Chex for BCY across three separately manufactured control lots between sites, days, and operators when used with the DiaSorin LIAISON PLEX BCY test on different DiaSorin LIAISON PLEX systems.

Repeatability

An internal repeatability study was conducted to assess performance of MDx-Chex for Blood Culture Yeast (BCY) using at least two DiaSorin LIAISON PLEX systems. The testing schedule consisted of evaluating two MDx-Chex for BCY control types (1 control type per day) from three lots over 20 days for a total of 120 runs. Samples were analyzed on the

DiaSorin LIAISON PLEX System per the Instructions for Use. Three operators tested each control type using three LIAISON PLEX BCY test cartridge lots and two LIAISON PLEX systems. This resulted in a PPA of 100% (60/60) for the MDx-Chex for BCY Positive Control (Table 4) and a NPA of 100% (60/60) for the MDx-Chex for BCY Negative Control (Table 5).

Table 4: MDx-Chex for BCY Positive Control Repeatability Study Summary

Category	# Observed/ #Expected Results ¹	PPA	95% Confidence Interval
MDx-Chex for BCY Positive Control	60/60	100%	94%-100%

¹ Expected result for the Positive Control is positive.

Table 5: MDx-Chex for BCY Negative Control Repeatability Summary

Category	# Observed/ #Expected Results ¹	NPA	95% Confidence Interval
MDx-Chex for BCY Negative Control	60/60	100%	94%-100%

¹ Expected result for the Negative Control is negative.

The results support the conclusion that MDx-Chex for Blood Culture Yeast shows repeatability across three separately manufactured control lots when used with the LIAISON PLEX BCY Test on the DiaSorin LIAISON PLEX system.

Lot-to-Lot Reproducibility

Lot-to-lot reproducibility was demonstrated by testing three lots of MDx-Chex for BCY. Samples were prepared per the control Instructions for Use and tested using the same DiaSorin LIAISON PLEX BCY test cartridge lot tested on one DiaSorin LIAISON PLEX system over ten days. Ten positive and ten negative MDx-Chex for BCY control tubes were tested on the same DiaSorin LIAISON PLEX system for 60 data points total (30 per lot per positive and negative control). All MDx-Chex for BCY positive and negative control lots passed with $\geq 90\%$ positive or negative agreement with expected results, respectively. Results are presented in Tables 6 and 7.

Table 6: Lot-to-Lot Reproducibility for MDx-Chex for BCY Positive Controls

Category	Lot #	# Observed/ # Expected Results ¹	PPA	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 7: Lot-to-Lot Reproducibility for MDx-Chex for BCY Negative Controls

Category	Lot #	# Observed/ # Expected Results ¹	PPA	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.

The results support that MDx-Chex for BCY is reproducible across three separately manufactured lots when used with the DiaSorin LIAISON PLEX BCY Test.

Within-run Precision

A 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. The 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). All MDx-Chex for BCY positive and negative control lots passed with $\geq 90\%$ positive or negative agreement with expected results, respectively. Results are presented in Tables 8 and 9.

Table 8: Within-run Precision Summary for MDx-Chex for BCY Positive Controls

Category	Lot #	# Observed/ # Expected Results ¹	PPA	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 9: Within-run Precision Summary for MDx-Chex for BCY Negative Controls

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

¹ Expected result for the Negative Control is negative.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Not applicable.

4. Detection Limit and Assay Reportable Range:

Not applicable.

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

Closed-vial Stability

A real-time closed-vial stability study is ongoing using three lots of MDx-Chex for BCY with currently available data summarized below. Twenty positive and 20 negative control samples from each MDx-Chex for BCY lot were stored at room temperature (20-25 °C) and refrigerated temperature (2-8 °C) and collected at different timepoints for testing. The first

data collection timepoint was on Day 0 (ship date), followed by Day 75 for each lot and storage condition. Samples were prepared and analyzed on the DiaSorin LIAISON PLEX System per the MDx-Chex for BCY Instructions for Use. Data collected on Days 0 and at a minimum of 75 days are presented in Tables 10 and 11.

Table 10: Closed-vial Stability of MDx-Chex for BCY Positive Control- PPA

Shelf-Life	Storage Temperature	# Observed/ # Expected Results ¹	PPA	95% Confidence Interval	PPA ≥ 90% Acceptance
Day 0	N/A	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.

⁺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 11: Closed-vial Stability of MDx-Chex for BCY Negative Control- NPA

Shelf-Life	Storage Temperature	# Observed/ # Expected Results ¹	NPA	95% Confidence Interval	NPA ≥ 90% Acceptance
Day 0	N/A	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.

⁺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).

The data for the ongoing closed-vial stability study support the conclusion that MDx-Chex for BCY has a closed-vial stability for 75 days when stored at 2-25°C. The study is ongoing to support the use of the MDx-Chex for BC-GN control kit throughout the labeled shelf life.

Shipping Stability

A shipping stability study was performed to validate the stability of MDx-Chex for BCY during shipment. One MDx-Chex for BCY lot was subjected to simulated winter and summer shipping temperature profiles over 5 days. Temperature stress conditions for summer include a 120-hour exposure period with the following temperature profile: 5h at 22°C, 14h at 26°C, 5.5h at 22°C, 5.5h at 25°C, 10h at 22°C, 2h at 40°C, 15h at 29°C, 5h at 40°C, 17.5h at 26°C, 11.5h at 29°C, 10h at 22°C, 7.5h at 30°C, and 11.5h at 24°C. Temperature stress conditions for winter include a 120-hour exposure period with the following temperature profile: 5h at 22°C, 14h at 15°C, 5.5h at 22°C, 5.5h at 17°C, 10h at 22°C, 2h at -10°C, 15h at 10°C, 5h at -10°C, 17.5h at 15°C, 11.5h at 10°C, 10h at 22°C, 7.5h at 8°C, and 11.5h at 18°C.

Samples at each storage temperature (2°C and 25°C) were exposed to winter and summer temperature extremes and then were stored back at each respective storage temperature (2°C and 25°C) for a week prior to being tested using LIAISON PLEX BCY Test. Data were collected from 20 samples per positive and negative control for each simulated shipping profile within the 75-day closed-vial stability testing period. An additional 20 samples per control type will be tested at the end of shelf-life.

All summer and winter shipping conditions passed with $\geq 90\%$ positive and negative agreement with expected results and presented in Tables 12 and 13.

Table 12: Shipping Stability Study Results for the MDx-Chex for BCY Positive Control

Category	Storage Temperature ¹	# Observed/ # Expected Results ²	PPA	95% Confidence Interval
Summer ⁺	2-8°C	20/20	100%	83-100%
	20-25°C	20/20	100%	83-100%
Winter ⁺	2-8°C	20/20	100%	83-100%
	20-25°C	20/20	100%	83-100%

¹Samples 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.

²Expected result for the positive Control is positive.

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

Table 13: Shipping Stability Study Results for the MDx-Chex for BCY Negative Control

Category	Storage Temperature ¹	# Observed/ # Expected Results ²	NPA	95% Confidence Interval
Summer ⁺	2-8°C	20/20	100%	83-100%
	20-25°C	20/20	100%	83-100%
Winter ⁺	2-8°C	20/20	100%	83-100%
	20-25°C	20/20	100%	83-100%

¹Samples 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.

²Expected result for the negative Control is negative.

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

Results support that the MDx-Chex for BCY control kit is stable and functional for 75 days after exposure to extreme summer and winter shipping temperature conditions. The study is ongoing to support the shipping stability of the MDx-Chex for BC-GN control kit throughout the labeled shelf life.

6. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable.

2. Matrix Comparison:

The matrix of MDx-Chex for BCY is made of stabilized blood components (erythrocytes and leukocytes) in a simulated blood culture media. Since the matrix is not identical to that of the routine DiaSorin LIAISON PLEX BCY assay sample, blood culture media, a test was performed to investigate the effect of the matrix on the assay.

To confirm that the simulated blood culture matrix does not impact performance of the DiaSorin LIAISON PLEX BCY assay, *Candida tropicalis* (1×10^6 cells/mL final

concentration) was spiked into MDx-Chex for BCY matrix as well as into BD BACTEC Plus Aerobic/F culture vial with negative whole blood to simulate a clinical sample. These samples were then tested in triplicate using DiaSorin LIAISON PLEX BCY assay. Three replicates of each simulated matrix with no spike-in organism were also tested to serve as negative controls. The results presented in Tables 14 and 15 showed PPA and NPA of 100%, respectively.

Table 14: Matrix Equivalency Study Results for Control and Clinical Matrix Spiked with *Candida tropicalis*, tested on DiaSorin LIAISON PLEX BCY Assay

Matrix Type	# Observed/# Expected Results ¹	PPA	95% Confidence Interval
MDx-Chex for BCY Matrix + <i>Candida tropicalis</i>	3/3	100%	29-100%
Clinical Matrix + <i>Candida tropicalis</i>	3/3	100%	29-100%

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

Table 15: Matrix Equivalency Study Results for Unspiked Control and Clinical Matrix, tested on DiaSorin LIAISON PLEX BCY Assay

Matrix Type	# Observed/# Expected Results ¹	NPA	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.

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.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off:

Not applicable.

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

Not applicable.

D Expected Values/Reference Range:

MDx-Chex for BCY is a qualitative control and the expected results are listed in Table 16 below.

Table 16: Pathogens detected by MDx-Chex for BCY Control

Pathogen	Positive Control	Negative control
<i>Candida albicans</i>	Detected	Not detected
<i>Candida auris</i>	Detected	Not detected
<i>Candida dubliniensis</i>	Detected	Not detected
<i>Candida famata</i>	Detected	Not detected
<i>Candida glabrata</i>	Detected	Not detected
<i>Candida guilliermondii</i>	Detected	Not detected
<i>Candida kefyr</i>	Detected	Not detected
<i>Candida krusei</i>	Detected	Not detected
<i>Candida lipolytica</i>	Detected	Not detected
<i>Candida lusitaniae</i>	Detected	Not detected
<i>Candida parapsilosis</i>	Detected	Not detected
<i>Candida tropicalis</i>	Detected	Not detected
<i>Candida haemulonii/duobushaemulonii</i>	Detected	Not detected
<i>Cryptococcus neoformans/gattii</i>	Detected	Not detected

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.