EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390) DECISION SUMMARY

I Background Information:

A De Novo Number

DEN230092

B Applicant

DiaSorin Molecular LLC

C Proprietary and Established Names

Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SBT	Class II	21 CFR 866.3967 - Device to detect microbial colonization directly from clinical specimens	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

De Novo request for evaluation of automatic class III designation for the Simplexa C. auris Direct, Simplexa C. auris Positive Control Pack, Simplexa C. auris Sample Prep Kit (MOL3950, MOL3960, MOL5390)

B Measurand:

Nucleic acids from *Candida auris*

C Type of Test:

Real-Time PCR nucleic acid amplification test

III Indications for Use:

A Indication(s) for Use:

The Simplexa C. auris Direct is a real-time polymerase chain reaction (RT-PCR) assay intended for use on the LIAISON MDX instrument for the direct in vitro qualitative detection of Candida auris DNA from a composite swab of bilateral axilla/groin from patients suspected of C. auris colonization.

The test is intended to aid in the prevention and control of C. auris infection in healthcare settings by detecting C. auris from colonized patients.

Positive results indicate that the patient is colonized with C. auris. A positive result cannot rule out co-colonization with other pathogens. A negative result does not preclude C. auris colonization or infection and should not be used as the sole basis for treatment or other patient management decisions. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory information available to the clinician evaluating the patient. The test is not intended to diagnose or monitor treatment for C. auris infection. Concomitant cultures are necessary to recover organisms for epidemiological typing or for antimicrobial susceptibility testing.

B Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostic use

C Special Instrument Requirements:

The LIAISON MDX (with LIAISON MDX Studio Software, version 2.3)

IV Device/System Characteristics:

A Device Description:

The Simplexa C. auris RT-PCR system is intended for the amplification and qualitative detection of nucleic acid from *Candida auris* in composite bilateral axilla/groin swab specimens and consists of the following:

1. The **Simplexa C. auris Direct** is the RT-PCR assay kit that contains all the reagents for the amplification reaction, including the primers and fluorescent probes for the detection of nucleic acid from *Candida auris*. The primers and fluorescent probes amplifies the *C. auris* DNA and Internal Control DNA. In addition, the kit comes with a barcode card, which contains assay specific parameters and lot information.

2. The **Simplexa C. auris Positive Control Pack** is the separately packaged external positive quality control kit for use with the Simplexa C. auris Direct assay.

3. The **Simplexa C. auris Sample Prep Kit** is the enzymatic buffer solution to receive the sample solution (bilateral axilla/groin swab in Amies transport media) from the patient.

The Simplexa C. auris RT-PCR system is for use with the **LIAISON MDX instrument** (with **LIAISON MDX Studio Software**), the RT-PCR thermocycler that amplifies the nucleic acid from biological specimens and uses real-time fluorescence detection to identify targets, and the **Direct Amplification Disc (DAD)**, which is the accessory containing the input sample wells for use on the LIAISON MDX. The instrument and accessory were previously cleared under K102314 and K120413. The instrument is controlled by an external laptop running the software. The DAD consumable is compartmentalized into eight (8) separate wedges and can process up to eight (8) separate specimens or controls on each disc. Each wedge contains sample and reagent input wells, microfluidic channels and laser activated valves to control the fluid flow as well as a reaction/detection chamber.

B Principle of Operation

The Simplexa C. auris RT-PCR system is a molecular nucleic acid amplification test (NAAT) that utilizes RT-PCR technology for the qualitative detection of *Candida auris* nucleic acids. The assay target primers amplify the conserved region of the internal transcribed spacer 2 (ITS2) gene to identify *C. auris*, and the assay fluorescent probes allow real-time detection of the amplification reaction. The Internal Control monitors PCR failure/inhibition.

Patient samples are collected into the ESwab Collection and Transport System solution (composite bilateral axilla/groin swabs in Amies transport media). To process a patient sample, the user scans the barcode on the Reaction Mix Vial or on the barcode card and on the DAD. A foil seal is lifted and the user adds 50 µL of Reaction Mix to the reagent input well (R) of the DAD using a fixed volume pipette. Next, the user adds 50 µL of the patient sample to the Sample Prep Solution vial and mixes, and 50 µL of the sample preparation is then transferred to the sample well of the DAD. After loading, the wells of the individual wedge are resealed with the original top foil and the tab is removed at the perforation. The LIAISON MDX performs the movement of fluids, mixing of samples and reagents, thermocycling and real-time detection of fluorophores. A sample is considered positive for a particular target if intensity of the optical reading crosses a Ct threshold of 40 for both targets before a predetermined cut-off cycle.

C Instrument Description Information

1. Instrument Name:
   LIAISON MDX (with LIAISON MDX Studio Software, version 2.3)

2. Specimen Identification:
   Barcodes on the reagent kit and the barcode card contain the assay definition protocol and parameters for identification for the test and specimen type.

3. Specimen Sampling and Handling:
   Samples are collected using the ESwab collection and transport system, which are composite bilateral axilla/groin swabs in 1mL Liquid Amies. When the sample has been collected, the swab is immediately inserted directly into the transport media and can be stored up to 48 hours at room temperature or up to 7 days at 2 to 8°C. For longer storage, samples may be stored frozen at ≤ -70°C for up to 30 days. Once the Simplexa C. auris Direct Reaction Mix and Sample Prep Kit vials have thawed, the samples should be processed within 30 minutes.

4. Calibration:
   Not applicable.

5. Quality Control:
   Internal Control (DNA IC) and Simplexa C. auris Positive Control Pack. An external positive and negative (no template) control are required to be run but not included with the Simplexa C. auris Direct Assay. The Simplexa C. auris Positive Control Pack, which is comprised of inactivated whole cells of *C. auris,* is available as a separate kit. The instructions for the Simplexa C. auris Direct informs the user that Liquid Amies transport media (from the BD or Copan ESwab) should be used as a No Template Control (NTC).

V Standards/Guidance Documents Referenced:

Table 1. Referenced Standards and Guidance Documents

Document #	Title	Publishing Organization
14971 Third Edition 2019-12	Application of Risk Management to Medical Devices	ISO
15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	ISO
EP05-A3 (Reaffirmed: September 2019)	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline —Third Edition	CLSI
EP07 3rd Edition	Interference Testing in Clinical Chemistry	CLSI
EP12-A2	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition	CLSI
EP15-A3 (Reaffirmed: September 2019)	User Verification of Precision and Estimation of Bias; Approved Guideline - Third Edition	CLSI
EP25-A (Replaces EP25-P)	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline	CLSI
EP35 1st Edition	Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures	CLSI
62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	IEC

VI Performance Characteristics:

Analytical Performance:

1. Precision/Reproducibility:
   Precision/reproducibility was conducted to assess the performance of the Simplexa C. auris Direct RT-PCR system. A multisite precision study was conducted at three external testing sites on a total of six (6) panel members: a positive control sample (PC), a negative control sample (No Template Control in Liquid Amies transport media, NTC), and four (4) test samples contrived in negative clinical matrix (NCM), comprised of pooled axilla/groin swabs in Liquid Amies transport media. Contrived samples consisted of a low positive sample (LP)

contrived at < 2x the limit of detection (LoD) and a moderate positive (MP) sample contrived at approximately 3x LoD. Both Clade I (South Asian) AR382 and Clade IV (South American) Z485 *C. auris* strains were used for each LoD level for a total of four (4) contrived samples within the panel. Each panel member was tested by two (2) different operators at each site, and each operator tested each panel member in three (3) replicates each day for five (5) non-consecutive testing days for a total of ninety (90) replicates per panel member (3 replicates × 2 operators × 3 sites × 5 days). At least one (1) set of controls (PC and NTC) were tested on each instrument being used in the study per day for a total of sixty (60) evaluable controls across all sites. One lot each of Reaction Mix (RM), Sample Prep Solution (SPS), and Positive Control (PC) were used. A total of six (6) LIAISON MDX instruments (2 per site) were used, and all runs were performed on LIAISON MDX Studio Software, version 2.3. Results were calculated of the overall mean and overall variability utilizing Ct values, standard deviation (SD) and coefficient of variance (%CV) as well as % agreement of the qualitative result. These studies are summarized in **Tables 2 and 3** and demonstrate acceptable results.

Table 2. Summary Results of Multisite Precision Study by Site

Panel Member	Site 1		Site 2		Site 3		All Sites		
	Agreement (%)	Avg. Ct ± SD (%CV)	Agreement (%)	Avg. Ct ± SD (%CV)	Agreement (%)	Avg. Ct ± SD (%CV)	Agreement (%)	Avg. Ct ± SD (%CV)	95% CI
Clade I South Asian (LP)	100.0 (30/30)	28.4 ± 1.99 (7.0)	96.7 (29/30) [a]	28.3 ± 1.53 (5.4)	100.0 (30/30)	29.6 ± 2.21 (7.5)	**98.9 (89 /90)**	**28.8 ± 1.99 (6.9)**	**94.0 - 99.8**
Clade I South Asian (MP)	100.0 (30/30)	27.0 ± 0.97 (3.6)	100.0 (30/30)	27.4 ± 1.11 (4.1)	100.0 (30 /30)	28.7 ± 1.04 (3.6)	**100.0 (90 /90)**	**27.7 ± 1.26 (4.6)**	**95.9 - 100**
Clade IV South American (LP)	100.0 (30/30)	27.6 ± 0.55 (2.0)	100.0 (30/30)	27.8 ± 0.80 (2.9)	100.0 (30 /30)	28.5 ± 0.69 (2.4)	**100.0 (90/90)**	**28.0 ± 0.78 (2.8)**	**95.9 - 100**
Clade IV South American (MP)	100.0 (30/30)	26.7 ± 0.63 (2.4)	100.0 (30/30)	27.1 ± 0.99 (3.7)	100.0 (30 /30)	27.6 ± 0.70 (2.5)	**100.0 (90/90)**	**27.1 ± 0.86 (3.2)**	**95.9 - 100**
NTC	100.0 (30/30)	0.0 ± 0.00 (N/A)	100.0 (30/30)	0.0 ± 0.00 (N/A)	100.0 (30 /30)	0.0 ± 0.00 (N/A)	**100.0 (90/90)**	**0.0 ± 0.00 (N/A)**	**95.9 - 100**
PC	100.0 (30/30)	25.8 ± 0.82 (3.2)	100.0 (30/30)	26.4 ± 0.97 (3.7)	100.0 (30 /30)	27.1 ± 0.85 (3.1)	**100.0 (90/90)**	**26.4 ± 1.02 (3.9)**	**95.9 - 100**

LP= Low Positive, MP= Moderate Positive, PC= Positive Control, NTC= No Template Control, Ct= Cycle Threshold, SD= Standard Deviation, %CV= Percent Coefficient of Variation

[a] One (1) Clade I South Asian (LP) replicate gave a false negative result (C. auris Not Detected).

Table 3. Summary Variance Results by Component

Panel Member	N	Mean Ct	Between-day (inter-assay)		Between-operator (between-run)		Between Sites		Repeatability (intra-assay)		Total Reproducibility	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Clade I South Asian (LP)	89 [a]	28.78	0.85	2.9	0.47	1.6	0.54	1.9	2.08	7.2	2.35	8.2
Clade I South Asian (MP)	90	27.67	0.58	2.1	0.28	1.0	0.84	3.0	1.03	3.7	1.48	5.3
Clade IV South American (LP)	90	27.95	0.29	1.0	0.45	1.6	0.31	1.1	0.65	2.3	0.90	3.2
Clade IV South American (MP)	90	27.13	0.40	1.5	0.31	1.1	0.37	1.4	0.78	2.9	1.00	3.7
NTC	90	0.0	0.0	N/A	0.0	N/A	0.0	N/A	0.0	N/A	0.0	N/A
PC	90	26.43	0.49	1.8	0.63	2.4	0.43	1.6	0.72	2.7	1.16	4.4

LP= Low Positive, MP= Moderate Positive, PC= Positive Control, NTC= No Template Control, Ct= Cycle Threshold, SD= Standard Deviation, %CV= Percent Coefficient of Variation

[a] One (1) Clade I South Asian (LP) replicate gave a false negative result (C. auris Not Detected).

A lot-to-lot precision study was also performed on the six (6) panel members using three test lots to evaluate inter-lot variability. Four (4) runs per day were performed by one (1) operator with one (1) LIAISON MDX instrument with LIAISON MDX Studio Software version 2.3. The study included one (1) lot of Candidate Device Positive Control (PC), three (3) lots of Reaction Mix (RM), one (1) lot of Sample Prep Solution (SPS), and one (1) lot of Direct Amplification Disc (DAD). A total of twenty-four (24) runs were performed across six (6) non-consecutive days for each sample panel member: each was tested eight (8) times on each lot as duplicates of two (2) runs per day over the course of two (2) days. Results of the study were analyzed for overall mean, SD, and %CV for repeatability, inter-lot reproducibility, inter-day reproducibility, inter-run reproducibility and total and presented in **Table 4** below.

Table 4. Summary Results of Lot-to-Lot Precision Study

Panel Member	RM Lot 1		RM Lot 2		RM Lot 3		Combined	
	% Detected (#/#)	Mean Ct ± SD (%CV)	% Detected (#/#)	Mean Ct ± SD (%CV)	% Detected (#/#)	Mean Ct ± SD (%CV)	% Detected (#/#)	Mean Ct ± SD (%CV)
Clade I South Asian (LP)	100.0 (8/8)	27.5 ± 1.0 (3.5)	100.0 (8/8)	28.5 ± 2.5 (8.9)	100.0 (8/8)	28.6 ± 2.0 (7.0)	100.0 (24/24)	28.2 ± 1.9 (6.9)
Clade I South Asian (MP)	100.0 (8/8)	26.3 ± 0.9 (3.3)	100.0 (8/8)	27.2 ± 2.1 (7.8)	100.0 (8/8)	26.6 ± 0.5 (1.8)	100.0 (24/24)	26.7 ± 1.3 (5.0)
Clade IV South American (LP)	100.0 (8/8)	27.3 ± 0.7 (2.4)	100.0 (8/8)	27.2 ± 1.1 (4.0)	100.0 (8/8)	27.8 ± 0.7 (2.5)	100.0 (24/24)	27.4 ± 0.8 (3.1)
Clade IV South American (MP)	100.0 (8/8)	26.4 ± 0.9 (3.4)	100.0 (8/8)	26.4 ± 0.3 (1.1)	100.0 (8/8)	26.7 ± 0.6 (2.1)	100.0 (24/24)	26.5 ± 0.6 (2.4)
NTC	0.0 (0/8)	0.0 ± 0.0 (N/A)	0.0 (0/8)	0.0 ± 0.0 (N/A)	0.0 (0/8)	0.0 ± 0.0 (N/A)	0.0 (0/24)	0.0 ± 0.0 (N/A)
PC	100.0 (8/8)	25.7 ± 0.7 (2.7)	100.0 (8/8)	25.7 ± 0.9 (3.4)	100.0 (8/8)	26.5 ± 0.6 (2.1)	100.0 (24/24)	26.0 ± 0.8 (3.0)

LP= Low Positive, MP= Moderate Positive, PC= Positive Control, NTC= No Template Control, Ct= Cycle Threshold, SD= Standard Deviation, %CV= Percent Coefficient of Variation

For the multisite study, the test device showed ≥ 98.9% agreement of the qualitative result and ≤ 8.2% CV for each of the variance components, which is acceptable. For the lot-to-lot study, there was 100% agreement between the expected results and the qualitative results. The combined performance for all three lots is %CV of ≤ 7.2% for all panel members, which is acceptable. Lot-to-lot precision studies were also performed with three (3) lots of Positive Control (PC) and three (3) lots of Sample Preparation Solution (SPS). For PC, there was 100% agreement to expected results for all panel members and %CV of ≤ 8.2% for all three lots. For SPS, there was 100% agreement to expected results for all panel members and %CV of ≤ 6.7% for all three lots.

2. Linearity:
   This study is not applicable as the test device is a qualitative assay.

3. Analytical Specificity/Interference:
   a. *Cross-reactivity and Microbial Interference*
      The candidate device was evaluated for analytical specificity/cross-reactivity and interference by testing forty-seven (47) different bacteria and fungi that could be found in axilla/groin swabs. Thirty-four (34) microorganisms were subjected to wet testing and were prepared by spiking each potentially cross-reacting organism into NCM (pooled axilla/groin swabs in Liquid Amies transport media). The testing concentration was 1×10^6 CFU/mL. For microbial interference testing, samples were further contrived with

either *C. auris* Clade I AR382 or Clade IV Z485 at 3x LoD. **Table 5** shows the results for cross-reactivity and microbial interference testing. Cross-reactivity and microbial interference was not observed with any of the organisms tested.

Table 5. Summary Results of Cross-reactivity and Microbial Interference Studies

Organism	Cross-Reactivity % Detection (# Detected/# Tested)	Clade I	Clade IV
		Interference % Detection (# Detected/# Tested)	Interference % Detection (# Detected/# Tested)
Aspergillus fumigatus	0.0% (0/3)	100% (3/3)	100% (3/3)
Bacillus cereus	0.0% (0/3)	100% (3/3)	100% (3/3)
Bacillus subtilis	0.0% (0/3)	100% (3/3)	100% (3/3)
Campylobacter coli	0.0% (0/3)	100% (3/3)	100% (3/3)
Campylobacter jejuni	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida albicans	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida blankii	0.0% (0/3)	100% (3/3)	100% (3/3)
Diutina catenulata (Candida catenulata)	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida dublinensis	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida duobushaemulonii	0.0% (0/3)	100% (3/3)	100% (3/3)
Debaryomyces hansenii (Candida famata)	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida glabrata	0.0% (0/3)	100% (3/3)	100% (3/3)
Pichia guilliermondii (Candida guilliermondii)	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida haemulonii	0.0% (0/3)	100% (3/3)	100% (3/3)
Pichia kudriavzevii (Candida krusei)	0.0% (0/3)	100% (3/3)	100% (3/3)
Clavispora lusitaniae (Candida lusitaniae)	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida parapsilosis	0.0% (0/3)	100% (3/3)	100% (3/3)
Diutina rugosa (Candida rugosa)	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida sake	0.0% (0/3)	100% (3/3)	100% (3/3)
Candida tropicalis	0.0% (0/3)	100% (3/3)	100% (3/3)
Clostridioides difficile (Clostridium difficile)	0.0% (0/3)	100% (3/3)	100% (3/3)
Corynebacterium jeikeium	0.0% (0/3)	100% (3/3)	100% (3/3)
Cryptococcus neoformans serotype A	0.0% (0/3)	100% (3/3)	100% (3/3)
Escherichia coli	0.0% (0/3)	100% (3/3)	100% (3/3)
Kodameae ohmeri	0.0% (0/3)	100% (3/3)	100% (3/3)
Listeria monocytogenes serotype 1/2b	0.0% (0/3)	100% (3/3)	100% (3/3)
Cutibacterium acnes (Propionibacterium acnes)	0.0% (0/3)	100% (3/3)	100% (3/3)
Saccharomyces cerevisiae	0.0% (0/3)	100% (3/3)	100% (3/3)
Salmonella enterica Group B	0.0% (0/3)	100% (3/3)	100% (3/3)
Salmonella enterica Group E	0.0% (0/3)	100% (3/3)	100% (3/3)
Shigella flexneri	0.0% (0/3)	100% (3/3)	100% (3/3)
Staphylococcus aureus	0.0% (0/3)	100% (3/3)	100% (3/3)
Staphylococcus epidermidis	0.0% (0/3)	100% (3/3)	100% (3/3)
Yersinia enterocolitica	0.0% (0/3)	100% (3/3)	100% (3/3)

The following organisms were not available for testing: *Rhodotorula* spp., *Microsporum audouinii*, *Microsporum canis*, *Microsporum gypseum*, *Microsporum nanum*, *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, *Trichophyton equinum*, *Trichophyton tonsurans*, *Trichophyton verracosum*, *Trichophyton violaceum*, *Epicoccum* spp., and *Malassezia furfur*. For these organisms, *in silico* analyses were performed to predict potential cross-reactivity of the assay oligos through a BLAST comparison of the oligo sequences to the GenBank nt sequence database. No cross-reactivity was predicted based on this analysis.

b. *Interfering Substances*

An interfering substances study was conducted to assess the performance of the candidate device in the presence of medically and/or physiologically relevant concentrations of potentially interfering substances that may be present in axilla/groin swabs. The study evaluated thirty-six (36) potentially interfering endogenous and exogenous substances. Samples were prepared by spiking each potential interferent into a baseline sample consisting of *C. auris* Clade IV, strain Z485 spiked into NCM (pooled axilla/groin swabs in Liquid Amies transport media) at 3x LoD. **Table 6** lists the concentrations of interferents tested and shows the results of interference testing. Interference was observed with anti-breathable deodorant cream at 10% v/v, and the antiseptic Benzalkonium chloride at 0.07% v/v resulting in an invalid result; however, detection is restored when anti-breathable deodorant cream is tested at 5% v/v, and the antimicrobial Benzalkonium chloride is tested at 0.04% v/v. No other interference was observed. This information is noted in the package insert.

Table 6. Summary Results of Interfering Substances Testing

Potential Interferent	Active Ingredient	Concentration	% Detection (#detected/#tested)
Mineral Oil	N/A	10% (v/v)	100.0% (3/3)
Deodorant cream	N/A	10% (v/v)	0% (0/3) Invalid result: IC failure
Deodorant cream	N/A	5% (v/v)	100.0% (3/3)
Balneal lotion	N/A	10% (v/v)	100.0% (3/3)
Detergent pH5	N/A	0.1% (v/v)	100.0% (3/3)
Detergent pH7	N/A	1% (v/v)	100.0% (3/3)
Baby powder	N/A	10% (w/v)	100.0% (3/3)
Cornstarch	N/A	10% (w/v)	100.0% (3/3)
Bovine submaxillary gland mucin, type I-S	Mucin	5mg/mL	100.0% (3/3)
Whole blood EDTA	N/A	10% (v/v)	100.0% (3/3)
Urine	N/A	10% (v/v)	100.0% (3/3)
Stool	N/A	10% (w/v)	100.0% (3/3)
Human genome DNA	N/A	10% (v/v)	100.0% (3/3)
Sweat	N/A	10% (v/v)	100.0% (3/3)
Disinfectant	Benzocaine	7% (w/v)	100.0% (3/3)
Antiseptic	Benzalkonium chloride	0.07% (v/v)	0% (0/3) Invalid result: IC failure
Antiseptic	Benzalkonium chloride	0.04% (v/v)	100.0% (3/3)
Topical corticosteroid	Triamcinolone	10% (w/v)	100.0% (3/3)
Antifungal medicine	Miconazole	2µg/ml	100.0% (3/3)

Potential Interferent	Active Ingredient	Concentration	% Detection (#detected/#tested)
Aminoglycoside antibiotic	Neomycin	4µg/ml	100.0% (3/3)
Antifungal medicine	Tioconazole	10% (w/v)	100.0% (3/3)
Steroid medication	Mometasone fuoroate	1µg/ml	100.0% (3/3)
Alcohol used in skincare formulations	Benzyl Alcohol	5% (v/v)	100.0% (3/3)
Antifungal medicine	Nystatin	0.3mg/ml	100.0% (3/3)
Preparation H	Phenylephrine HCl 0.25%, Pramoxine HCl 1%	10% (v/v)	100.0% (3/3)
Mupirocin	Mupirocin	10% (v/v)	100.0% (3/3)
Disinfectant	Chlorhexidine	7% (w/v)	100.0% (3/3)
Antifungal medication	Clotrimazole	2µg/ml	100.0% (3/3)
Synthetic Allylamine Antifungals	Butenafine	2µg/ml	100.0% (3/3)
Antifungal medication	Terbinafine	2µg/ml	100.0% (3/3)
Skin care product additive	Cyclomethicone	10% (v/v)	100.0% (3/3)
Antibacterial and Antifungal agent	Triclosan	2µg/ml	100.0% (3/3)
Skin care product additive	Lavender oil	10% (v/v)	100.0% (3/3)
Skin care product additive	Tea tree oil	10% (v/v)	100.0% (3/3)
Preservative	Methylparaben	10% (v/v)	100.0% (3/3)
Preservative	Propylparaben	10% (v/v)	100.0% (3/3)
Excipient	Polyethylene glycol distearates	10% (v/v)	100.0% (3/3)
Excipient	Butylated hydroxytoluene	10% (v/v)	100.0% (3/3)

4. Assay Reportable Range:
   This study is not applicable as the test device is a qualitative assay.

5. Traceability, Stability and Expected Values (Controls, Calibrators, or Methods):
   a. *Specimen Stability*
      The candidate device was evaluated for the product's ability to detect *C. auris* in axilla/groin swabs samples stored under different conditions. Samples were tested individually as negative or as contrived positive samples by spiking *C. auris* Clade I and Clade IV at different concentrations: 0.5x LoD, 2x LoD and 5x LoD. Samples were tested fresh and then stored at the following conditions: room temperature for 48 and 72 hours, refrigeration at 2 to 8°C for three (3) and eight (8) days, or frozen for a month at or below -70°C, after being held for seven (7) days at 2-8°C. Sixty (60) samples per clade were prepared at different concentration levels and tested at each storage condition, and the results are presented below. For all samples, 100% of positivity for 5x LoD, at least 95% of positivity for 2x LoD, and 10-90% for 0.5x LoD were the acceptance criteria. Based upon the study results, specimens can be stored for up to 48 hours when stored at room temperature, up to 7 days when stored at 2 to 8°C, and frozen at or below -70°C for 30 days after being stored at 2 to 8°C for 7 days. Results are shown in **Table 7**.

      Table 7. Summary Results of Specimen Stability Study

Strain	Analyte Concentration	Test Condition Detection Rate (%) (#Detected/#Tested)					
		Fresh	48h RT	72h RT	3d 2-8°C	8d 2-8°C	7d at 2-8°C 30d ≤ -70°C
C. auris Clade I AR382	5xLoD	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
	2xLoD	93% (28/30)	100% (30/30)	100% (30/30)	100% (30/30)	97% (29/30)	100% (30/30)
	0.5xLoD	20% (2/10)	100% (10/10)	100% (10/10)	70% (7/10)	70% (7/10)	40% (4/10)
	Negative samples	0% (0/10)	0% (0/10)	0% (0/10)	0% (0/10)	0% (0/10)	0% (0/10)
C. auris Clade IV Z485	5xLoD	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
	2xLoD	97% (29/30)	100% (30/30)	100% (30/30)	100% (10/10)	100% (10/10)	100% (30/30)
	0.5xLoD	50% (5/10)	100% (10/10)	100% (10/10)	80% (8/10)	90% (9/10)	70% (7/10)
	Negative samples	0% (0/10)	0% (0/10)	0% (0/10)	0% (0/10)	0% (0/10)	0% (0/10)

b. *Quality Controls*

The test device has an Internal Control (DNA IC) in the Simplexa C. auris Reaction Mix and a separately packaged external positive quality control, the Simplexa C. auris Positive Control Pack. The external positive and a negative, no template control (NTC) containing Liquid Amies are recommended to be run but not included with the Simplexa C. auris Direct Assay. These controls were run as part of the analytical and clinical validations according to the Instructions for Use. In addition, a control specificity study was performed by testing a total of forty-eight (48) replicates of No Template Control (NTC) (ESwab Liquid Amies transport media) for 3 lots each of Reaction Mix and Sample Preparation Solution for a total of 144 replicates. For this study, ESwab Liquid Amies transport media was tested directly from the manufacturer's tube as an unknown sample with no additional sample preparation or manipulation performed. The results showed an analytical specificity of 100% (0% (0/144) *C. auris* detection rate).

6. Detection Limit:

The objective of this study was to evaluate the limit of detection (LoD) of the candidate device for *C. auris* in axilla/groin swab specimen matrix. Samples were prepared by using strains from two representative *C. auris* clades. Testing was done by contriving *C. auris* Clade I AR382 or Clade IV Z485 in negative clinical matrix (NCM) composed of pooled cutaneous axilla/groin swab in Liquid Amies transport media and confirmed negative for *C. auris* by the candidate device. A preliminary LoD was established by testing six (6) replicates at seven (7) concentration levels for both *C. auris* clades using a single lot of Reaction Mix. The lowest concentration with a 100% detection rate was selected for the confirmatory LoD study. For the confirmatory LoD, sixty (60) total replicates of the preliminary LoD were tested using three (3) lots of the Reaction Mix, twenty (20) replicates for each lot. LoD is defined as the lowest concentration tested with a detection rate of at least 95%. Samples were prepared to target concentrations in CFU/mL determined by calculating the dilutions of the sample preparations according to the supplier's provided concentrations; however, final concentrations were verified by plating and colony counting quantitation. Results are summarized in **Table 8**.

Table 8. Summary Results of Limit of Detection Study

Study	C. *auris* (Clade I)		C. *auris* (Clade IV)	
	Concentration (CFU/mL)*	% Detection (#Detected/#Tested)	Concentration (CFU/mL)*	% Detection (#Detected/#Tested)
Preliminary LoD	233	100% (6/6)	533	100% (6/6)
	193	100% (6/6)	303	100% (6/6)
	113	83% (5/6)	260	100% (6/6)
	127	100% (6/6)	190	100% (6/6)
	47	100% (6/6)	143	100% (6/6)
	20	100% (6/6)	80	83% (5/6)
	10	17% (1/6)	53	17% (1/6)
Confirmatory LoD	20	5% (1/20)	143	60% (12/20)
	47	20% (4/20)	190	75% (30/40)
	127	15% (3/20)	260	98% (59/60)
2nd Confirmatory LoD for Clade I	20	55% (11/20)		
	47	90% (36/40)		
	127	98% (59/60)		

* The listed concentrations were those determined by plating and colony counting verification testing.

The preliminary LoD result for Clade I was 20 CFU/mL. Because the percentage of detection during the confirmatory LoD study was under 95%, a similar study was conducted using higher concentrations. An internal evaluation of the discordant results between preliminary and confirmatory testing found that the starting stock aliquot used to prepare the dilutions had a lower concentration than was indicated. Confirmatory testing was repeated for *C. auris* Clade I, and the LoD was determined to be 127 CFU/mL according to plating and colony counting. The preliminary LoD result for Clade IV was 143 CFU/mL. Since a detection lower than 95% was obtained during the confirmatory LoD study, a similar study was conducted using higher concentrations. The LoD of *C. auris* Clade IV is 260 CFU/mL according to plating and colony counting.

7. Inclusivity:

Analytical reactivity was evaluated to demonstrate that the candidate device could detect different clades and/or strains of *C. auris*. For this study, nine (9) strains representing six (6) clades were tested by spiking into negative clinical matrix corresponding to 3x LoD of *C. auris* Clade I as determined in the LoD study. Test samples were tested in triplicate. Strain stock concentrations provided by the supplier were verified by plating and colony counting. All replicates had a positive result for *C. auris* detection. Results are summarized in **Table 9**.

Table 9. Summary Results of Analytical Reactivity Study

Sample	Concentration (CFU/mL) By supplier	Concentration (CFU/mL) By plating and counting	Target concentration (CFU/mL)	Tested concentration (~CFU/mL)	% Detection (#Detected/#Tested)
Clade I AR382	9.58×10^8	2.57×10^8	900*	241	100% (3/3)
Clade I AR387	4.63×10^8	1.63×10^8	900*	317	100% (3/3)
Clade II AR381	4.23×10^8	2.37×10^8	400**	224	100% (3/3)
Clade II AR1101	4.47×10^8	3.47×10^8	400**	310	100% (3/3)
Clade III AR383	7.98×10^8	4.10×10^8	400**	205	100% (3/3)
Clade III AR384	1.09×10^9	4.67×10^8	900*	386	100% (3/3)

Sample	Concentration (CFU/mL) By supplier	Concentration (CFU/mL) By plating and counting	Target concentration (CFU/mL)	Tested concentration (~CFU/mL)	% Detection (#Detected/#Tested)
Clade IV Z485	2.64×10^9	1.24×10^9	900*	422	100% (3/3)
Clade IV AR386	9.27×10^8	7.60×10^7	900*	74	100% (3/3)
Clade V AR1097	3.60×10^8	4.85×10^7	900*	121	100% (3/3)

* Samples were prepared to a target concentration of 3x LoD of *C. auris* Clade I based on the supplier-provided stock concentrations for this strain.
** Samples were prepared to a target concentration of 3x LoD of *C. auris* Clade I based on the final concentration determined by plating and colony counting quantitation.

In silico inclusivity analysis was also performed of oligo sequences against NCBI GenBank and SRA databases. Percent (%) homology was assessed of each oligo sequence with full coverage of all three oligo-binding regions (forward primer, reverse primer, probe); 736 sequences were aligned, 721 demonstrated oligo identity ≥ 90% with a predicted inclusivity of 98%. The analysis also included two new clade sequences from Clade VI, which was not evaluated in wet testing, and demonstrated 100% homology. Therefore, the assay is predicted to be able to detect this new clade.

8. Assay Cut-Off:

The fluorescence and Ct thresholds for *C. auris* and Internal Control were established using 717 sample runs of No Template Control (NTC), Limit of Detection (LoD), Microbial Inhibition, Interference and Limiting Dilution samples. The established thresholds were then confirmed using an independent data set comprising 2,924 sample runs from LoD, Carry-over/Cross Contamination, Cross-reactivity, Sample Stability, Microbial Inhibition, Inter-lot Reproducibility, Analytical Reactivity, Interference, No Template Control (NTC) Specificity and Open Kit Reagent Stability samples. A sample is considered positive for a particular target if intensity of the optical reading crosses a fluorescence threshold of 5,000 or a Ct threshold of 40 for both targets before a predetermined cut-off cycle.

9. Accuracy (Instrument):
Please refer to Section VI.C (Clinical Studies) for the clinical evaluation study and data that establish clinical performance and accuracy of the test device.

10. Carry-Over:
    a. *Carry-Over/Cross Contamination*
    The candidate device was evaluated to assess carry-over contamination. *C. auris* Clade I AR382 was used to contrive the samples. Samples were prepared in a matrix consisting of pooled *C. auris* negative axilla/groin ESwab matrix at a high positive (HP) concentration (1×10^6 CFU/mL formulated to target a Ct ≤ 20). Fifty-six (56) replicates each of HP and negative samples were tested in sixteen (16) runs in which HP and negative sample replicates were alternately loaded into the DAD. The HP sample was 100% detected with a Ct average of 17.6, and the negative sample resulted in 0% detection as shown in **Table 10** below.

Table 10. Summary Results of Carry-Over Study

Samples	C. *auris* (FAM)		Internal Control (Q670)	
	% Detection (#Detected /#Tested)	Mean Ct ± SD (%CV)	% Detection (#Detected /#Tested)	Mean Ct ± SD (%CV)
HP	100% (56/56)	17.6 ± 0.71 (4.0%)	100% (56/56)	23.3 ± 0.33 (1.4%)
Negative	0% (0/56)	NA ± NA (NA%)	100% (56/56)	23.4 ± 0.35 (1.5%)

b. *DAD Reusability*
The Direct Amplification Disc (DAD) is compartmentalized into eight (8) separate wedges and may be reused until all wedges have been utilized. Therefore, a study was performed to demonstrate that the discs may be reused up to eight (8) times without carry-over contamination between runs. A customized assay definition protocol was created in the LIAISON MDX that repeated the cycling parameters for the candidate device eight (8) times with a ten (10) minute pause, or 600 seconds, between iterations. During this pause, the heating elements of the instrument are turned off, and capture steps were implemented at the end of each iteration to detect any signal loss. That is, alternating dyes in each of the eight (8) wells of the DAD were loaded to detect any cross contamination or unexpected signal loss during each iterative cycle. A total of eighteen (18) discs were used in this study, with three (3) DAD lots, six (6) discs per lot. Each DAD was loaded on a separate LIAISON MDX instrument. No fluid check failures or leakage was observed in all eighteen (18) discs by visual inspection or by data analysis.

Comparison Studies:

1. Method Comparison:
Please refer to Section VI.C (Clinical Studies) below for the clinical validation, regarding the method comparison studies.

2. Matrix Comparison:
Not applicable.

Clinical Studies:

The clinical performance of the Simplexa C. auris Direct RT-PCR system was evaluated for detection of *C. auris* in a multi-center clinical evaluation at six study sites across four geographically diverse locations within the United States and one in Italy. A prospective study was conducted from April to July 2023 which tested prospectively collected specimens from patients at risk of *C. auris* colonization tested either fresh or frozen. Demographic information of the prospectively collected specimens that met enrollment criteria and were included in the performance analysis are shown in **Table 11**.

Table 11. Demographic Summary of Prospective Cohort

Demographic Distribution (N = 1946, %)		
Gender	Female	935 (48.0%)
	Male	1011 (52.0%)
	Unknown	0 (0%)
Age Group	0-1	2 (0.1%)

(Years)	>1-5	2 (0.1%)
	>5-21	38 (2%)
	>21-65	957 (49.2%)
	>65	945 (48.6%)
	Unknown	2 (0.1%)
Patient Location	ER*	124 (6.4%)
	ICU*	572 (29.4%)
	Inpatient	1249 64.2%)
	LTCF*	1 (0.1%)

* ER= Emergency room, ICU= Intensive care unit, LTCF= Long-term healthcare facility/nursing home.

The prospective study was supplemented with frozen, archived clinical specimens and fresh, enriched specimens. Specimens were leftover, de-identified composite bilateral axilla/groin swabs in the BD ESwab Collection and Transport System/Copan ESwab Liquid Based Collection and Transport (flocked swab with 1mL of Liquid Amies transport media) stored at either ambient temperature if tested within 48 hours from collection, refrigerated (2-8°C) if tested within three (3) days, or frozen (≤ -70°C) if there was a greater than three (3)-day delay prior to testing.

Clinical performance of the Simplexa C. auris Direct was determined by comparison against the reference method, which consisted of standard of care (SOC) culture followed by matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) for identification. Bi-directional sequencing (BDS) assays were performed when the candidate assay results differed from the comparator method. The results from discordant analysis were not used to alter the original performance but are provided in footnotes to the performance tables.

A total of 1,990 prospective fresh and/or frozen swab specimens were collected, one specimen per enrolled subject. Of these, the prospective cohort consisted of 1,969 evaluable specimens that met enrollment criteria. Eleven (11) retrospective specimens identified as *C. auris* positive using the comparator method were pre-selected and tested in a randomized, blinded manner alongside prospective specimens at one site. Due to the low prevalence observed at one site, an enrichment strategy was utilized wherein 202 specimens identified as *C. auris* positive by a laboratory-verified RT-PCR test were enrolled. All enriched specimens were blinded and tested fresh on the candidate device and plated for reference method testing alongside prospective specimens. Of these, the retrospective/enriched cohort consisted of 91 evaluable specimens. Of the 2,060 evaluable clinical specimens in the combined prospective, retrospective, and enriched studies, twenty-five (25) specimens generated invalid results, six (6) specimens had failed positive controls, and nine (9) specimens gave “No identification/low confidence score” on the comparator. These samples were excluded from the performance analysis leaving 2,020 samples used to determine clinical agreement. Results are presented for the 1,930 prospective cohort samples (**Table 12**) and the 2,020 combined clinical cohort, which includes 90 enriched and retrospective/pre-selected samples (**Table 13**). **Table 14** provides a summary of performance by study type (prospective, enriched, retrospective) and specimen condition (fresh, frozen).

Table 12. Clinical Performance of Prospective Cohort

Reference Method (Culture/MALDI-TOF)		**Total**
Positive	**Negative**	

Simplexa C. auris Direct	**Positive**	32	22	54
	Negative	2	1874	1876
	Total	34	1896	1930

Positive Percent Agreement (PPA) = 94.1% (32/34) (95% CI: 80.9% - 98.4%)
Negative Percent Agreement (NPA) = 98.8% (1874/1896) (95% CI: 98.2% - 99.2%)

Table 13. Clinical Performance of Combined Prospective, Enriched and Retrospective Clinical Cohort

		Reference Method (Culture/MALDI-TOF)		Total
		Positive	**Negative**	
Simplexa C. auris Direct	**Positive**	55	25	80
	Negative	3	1937	1940
	Total	58	1962	2020

Positive Percent Agreement (PPA) = 94.8% (55/58) (95% CI: 85.9% - 98.2%)
Negative Percent Agreement (NPA) = 98.7% (1874/1896) (95% CI: 98.1% - 99.1%)

Table 14. Summary of Combined Clinical Performance for the Simplexa C. auris Direct

		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Prospective (n= 1930)	**Fresh**	20/22	90.9	72.2 - 97.5	1594/1610	99.0	98.4 - 99.4
	Frozen	12/12	100.0	75.7 - 100	280/286	97.9	95.5 - 99.0
	Combined	32/34	94.1	80.9 - 98.4	1874/1896[a]	98.8	98.2 - 99.2
Enriched and Retrospective (n=90)	**Fresh**	12/13	92.3	66.7 - 98.6	63/66	95.5	87.5 - 98.4
	Frozen	11/11	100	74.1 - 100	0/0	NA	NA
	Combined	23/24	95.8	79.8 - 99.3	63/66	95.5	87.5 - 98.4
Overall (n=2020)		**55/58[b]**	**94.8**	**85.9 - 98.2**	**1937/1962[c,d]**	**98.7**	**98.1 - 99.1**

TP= True positive; FN= False negative; TN= True negative; FP= False positive; PPA= Positive percent agreement; NPA= Negative percent agreement; CI= Confidence interval
[a] Of the prospective data, eight (8) samples gave low confidence/no ID by culture/MALDI-TOF reference method and twenty-five (25) samples gave an invalid ID by Simplexa C. auris Direct and were excluded from the analysis.
[b] Three (3) of the three (3) FN samples tested negative by BDS. Of the two (2) FN samples with available SOC laboratory-verified PCR results, one (1) tested negative and one (1) tested positive.
[c] Of the 24 FP samples that were tested by BDS, nine (9) tested positive and fifteen (15) tested negative. Of the 17 FP samples that had available SOC laboratory-verified PCR results, ten (10) tested positive and seven (7) tested negative.
Of the combined data, nine (9) samples gave low confidence/no ID by culture/MALDI-TOF reference method and twenty-five (25) samples gave an invalid ID by Simplexa C. auris Direct and were excluded from the analysis.

1. Clinical Sensitivity:
   Please refer to Section VI.C (Clinical Studies) above for the clinical validation.
   The test sensitivity/positive percent agreement (PPA) is 94.8%

2. Clinical Specificity:
   Please refer to Section VI.C (Clinical Studies) above for the clinical validation.
   The test specificity/negative percent agreement (NPA) is 98.7%

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

Clinical Cut-Off:
Not applicable.

Expected Values/Reference Range:

The prospective study was conducted from April to July 2023. Out of 1,982 prospective specimens with valid MALDI-TOF MS results, 34 were identified as *C. auris* positive for a prevalence of 1.71% (34/1982) in the prospective population of this study.

F Other Supportive Performance Characteristics Data:

Not applicable.

VII Proposed Labeling:

The labeling supports the decision to grant the De Novo request for this device.

VIII Identified Risks and Mitigations:

Identified Risks to Health	Mitigation Measures
Risk of false results	Certain labeling information including limitations, device descriptions, explanations of procedures, and performance information. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions and certain analytical and clinical studies.
Failure to correctly interpret test results	Certain labeling information including limitations, device descriptions, explanations of procedures, and performance information. Certain design verification and validation including documentation of device descriptions certain analytical and clinical studies.
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, explanations of procedures, and performance information. Use of certain specimen collection devices.

IX Benefit/Risk Assessment:

A Summary of the Assessment of Benefit:

The ability to determine colonization of *C. auris* has a major public health impact, as *C. auris* causes invasive healthcare-associated infections and is associated with high mortality rates. Several outbreaks have been described in the US, including in New York, New Jersey, Illinois, and California (*Source:* Tracking C. auris | Candida auris (C. auris) | CDC). CDC-recommended infection prevention measures to prevent transmission of *C. auris* in healthcare settings are adherence to hand hygiene, transmission-based precautions and room placement, cleaning and disinfecting patient care environment and reusable equipment with recommended products, communication about patient's *C. auris* status when a patient is transferred, screening contacts of newly identified case patients to identify colonization, and laboratory surveillance of clinical specimens to detect additional cases (*Source:* Infection Control Guidance: Candida auris | Candida auris (C. auris) | CDC). Thus, the benefit of the device is the ability to determine

colonization of *C. auris* allowing for prompt recognition of patients colonized with *C. auris* and subsequent infection prevention procedures to prevent further spread in healthcare settings.

B Summary of the Assessment of Risk:

The risks associated with the device, when used as intended, are those related to the risk of false test results, failure to correctly interpret the test results, and failure to correctly operate the device. In cases of false positive results, patients may unnecessarily undergo more strict isolation requirements than indicated. Unnecessary isolation may lead to barriers in healthcare providers accessing patient rooms. Some infection prevention practices group patients in the same area based on their colonization status. In cases of false positive results, it is also possible that non-colonized patients would be cohorted in locations with patients colonized with *C. auris* and be exposed to *C. auris* as a result of the false screening test result. While the test is intended for detection of colonization and not active infection, false positive results, when associated with clinical syndromes concerning for infection, may lead clinicians to consider use of measures to address the possibility for *C. auris* infections such as the use of systemic antifungals where this would otherwise not be considered, and in turn, face adverse events related to the antifungal exposure. In cases of false negative results, patients will not undergo appropriate isolation, and may transmit *C. auris* to healthcare workers or other patients in their healthcare setting. Failure to correctly interpret results carries the same risks as false results. Failure to correctly operate the device could lead to invalid results requiring retesting and leading to delayed test results. The risk of a delayed result is minimal, given the short time to results with the device.

C Patient Perspectives:

This submission did not include specific information on patient perspectives for this device.

D Summary of the Assessment of Benefit-Risk:

The benefits of the device to rapidly detect colonization with *C. auris* outweighs the risks in light of the required special controls. *C. auris* is an emerging pathogen with demonstrated multi-drug resistance. Prompt identification of colonized patients can result in appropriate infection prevention procedures to prevent outbreaks of this highly transmissible pathogen. False positive results run the risk of uncolonized patients being exposed to colonized patients, or being unnecessarily isolated and in turn receiving poorer care. False negative results are not expected to adversely affect an individual patient but could lead to a failure to enact infection prevention procedures and lead to spread of *C. auris* to other patients and to healthcare workers.

The risk of false results is partially mitigated by CDC-recommended infection prevention and control measures, which would minimize the risk of exposure to patients. Additionally, as colonization does not necessarily predict invasive infection, the risk of false results is mostly spread of *C. auris* to healthcare workers and other patients. The risk to the patient is further mitigated by usual clinical care, which would involve collection of conventional cultures, should the patient develop signs and/or symptoms of invasive fungal infection. In addition, the risks of false test results are mitigated by certain design verification and validation activities, including analytical and clinical studies and risk analysis strategies to reduce the likelihood of such errors. In addition, the device's performance as observed in the clinical study suggests that errors will be uncommon and will facilitate accurate assay implementation and interpretation of results.

The risks associated with false test results, failure to correctly interpret the results and failure to correctly operate the device are further mitigated by labeling information, which will assist the operator in correctly performing the test. In addition, the device's performance observed in the

analytical and clinical studies suggests that these errors will be uncommon and will facilitate accurate assay implementation and interpretation of results.

X Conclusion:

The De Novo request is granted and the device is classified under the following and subject to the special controls identified in the letter granting the De Novo request:

Product Code(s): SBT
Device Type: Device to detect microbial colonization directly from clinical specimens.
Class: II (special controls)
Regulation: 21 CFR 866.3967