DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 31, 2016

GREAT BASIN CORPORATION
CHUCK OWEN
DIRECTOR, REGULATORY AFFAIRS & QUALITY ASSURANCE
2441 SOUTH 3850 WEST
SALT LAKE CITY, UT 84120

Re: K143312
Trade/Device Name: Portrait™ GBS Assay
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus spp. serological reagents
Regulatory Class: I
Product Code: NJR, NSU
Dated: March 20, 2015
Received: March 23, 2015

Dear Mr. Owen:

This letter corrects our substantially equivalent letter of April 21, 2015.

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -S

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143312

Device Name
Portrait™ GBS Assay

Indications for Use *(Describe)*
The Great Basin Portrait™ GBS Assay, performed on the PA500 Portrait™ Analyzer System, is a qualitative in vitro diagnostic test (IVD) for the detection of Group B Streptococcus (GBS) DNA from vaginal/rectal swabs from antepartum women, following enrichment in LIM Broth for 18 - 29 hours. The assay utilizes automated sample preparation and polymerase chain reaction (PCR) to amplify a cfb gene sequence specific to the Streptococcus agalactiae (GBS) genome which is detected by hybridization probes immobilized on a silica chip surface.

Results from the Portrait™ GBS Assay can be used as an aid in determining colonization status in antepartum women. The Portrait™ GBS Assay does not provide susceptibility results. Cultured isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The Portrait™ GBS Assay is intended for use in clinical laboratory, hospital laboratory, and reference laboratory settings. The Portrait™ GBS Assay is not intended for point of care use.

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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April 17, 2015

510(k) Summary: Portrait GBS Assay

A. Submitted by:

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Contact Information

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B. Name of Device

Proprietary Name: Portrait™ GBS Assay

Common or Usual Names: Group B *Streptococcus* Assay
Group B Strep Assay
GBS

C. Predicate Device:

k112125, *illumigene*® Group B *Streptococcus* (GBS) DNA Amplification Assay

D. Regulatory Information:

a. Regulation Section: 21 CFR 866.3740 – Streptococcus spp. Serological reagents
b. Classification: Class I (non-exempt)
c. Classification panel: Microbiology Devices, OIVD (83) Microbiology
d. Product Code: NJR – Nucleic Acid Amplification Assay, Group B Streptococcus, Direct Specimen
NSU-Instrumentation for Clinical Multiplex Test Systems

E. Intended use(s) / Indications for Use:

The Great Basin Portrait™ GBS Assay, performed on the PA500 Portrait™ Analyzer System, is a qualitative *in vitro* diagnostic test (IVD) for the detection of Group B *Streptococcus* (GBS) DNA from vaginal/rectal swabs from antepartum women following enrichment in LIM Broth for 18 - 29 hours. The assay utilizes automated sample preparation and polymerase chain reaction (PCR) to amplify a *cfb* gene sequence specific to the *Streptococcus agalactiae* (GBS) genome which is detected by hybridization probes immobilized on a silica chip surface.

Results from the Portrait™ GBS Assay can be used as an aid in determining colonization status in antepartum women. The Portrait™ GBS Assay does not provide susceptibility results. Cultured isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The Portrait™ GBS Assay is intended for use in clinical laboratory, hospital laboratory, and reference laboratory settings. The Portrait™ GBS Assay is not intended for point of care use.

F. Device Description:

Test Principle:

The Great Basin Portrait™ GBS Assay on the PA500 Portrait™ Analyzer System utilizes automated hot-start PCR technology to amplify target nucleic acid sequences that are detected using species-specific *S. agalactiae* DNA hybridization probes immobilized on a modified silicon chip surface.

Genomic DNA is extracted from microbial cells and diluted to reduce potential inhibitors of the PCR reaction. In a duplex PCR, biotin-labeled primers enable amplification of specific nucleic acid sequences within a unique and conserved region of the *cfb* gene (CAMP factor) for identification of *S. agalactiae* species and to an additional sample processing control (SPC) bacterial construct. Following PCR, biotin-labeled, amplified target DNA sequences are hybridized to sequence specific capture probes immobilized on the silicon chip surface, then incubated with anti-biotin antibody conjugated to the horseradish peroxidase enzyme (HRP). The unbound conjugate is removed by washing and tetramethylbenzidine (TMB) is added to produce a colored precipitate at the location of the probe/target sequence complex. The resulting signal is detected by the automated Portrait™ Optical Reader within the PA500 Portrait™ Analyzer System.

Test Device:

The Great Basin PA500 Portrait Analyzer System is a fully automated system that includes the Portrait Analyzer, single-use Portrait GBS Assay Test Cartridges, and the Portrait data analysis software. The PA500 Portrait Analyzer System is designed to perform automated sample preparation, PCR, and optical chip-based detection with integrated data analysis in approximately 90 minutes. The Great Basin Portrait™ GBS Assay utilizes automated hot-start PCR technology to amplify target nucleic acid sequences that are detected using species-specific *S. agalactiae* DNA hybridization probes immobilized on a modified silicon chip surface. The PA500 Portrait Analyzer System was recently granted clearance for use with the Portrait™ Toxigenic *C. difficile* Assay (DEN120013).

G. Substantial Equivalence Information:

a. Predicate Device: *illumigene* ®Group B *Streptococcus* (GBS) DNA Amplification Assay
b. Predicate 510(k) number: K112125
c. Comparison with Predicate

Item	Portrait GBS Assay	Predicate (K112125)
Manufacturer	Great Basin Scientific, Inc.	illumigene
Trade Name	Portrait™ GBS Assay	*illumigene* ® Group B *Streptococcus* (GBS) DNA Amplification Assay
510(k) Number	K143312	K112125
Similarities		
Classification	Class I	same
Intended Use/Indications for Use	Detection of Group B *Streptococcus* (GBS) DNA from vaginal/rectal swabs from antepartum women following enrichment in LIM broth (18 - 29 hours)	Detection of Group B *Streptococcus* (GBS) DNA from vaginal/rectal swabs from antepartum women following enrichment in LIM broth or TransVag broth (18-24 hours)
Qualitative/ Quantitative	Qualitative	same
Single-Use Test Cartridge	Disposable, single-use, self-contained fluidic test cartridge	same
Automated	Yes	same
Test Principle	DNA Amplification Assay	same
Sample Types	Vaginal/rectal swabs enriched in LIM broth	same
Organism Detection	Group B *Streptococcus* (*S. agalactiae*)	same
Calibration	Not required	same
Differences		
Sample Type Enrichment Culture	LIM broth cultures only	LIM broth and TransVag broth cultures
DNA Amplification Technology	Polymerase chain reaction (PCR)	Loop-mediated isothermal DNA amplificatioin (LAMP)
Target Sequence Detected	Unique sequence region of the *S. agalactiae cfb* gene	213 base pair (bp) sequence residing in the 593-805 bp region of *S. agalactiae* genome Segment 3
Instrument	PA500 Portrait Analyzer	*illumipro*-10 Automated Isothermal Amplification and Detection System
Time to Result	90 minutes	60 minutes
Detection Method	Colorimetric target specific hybridization to probe on a chip surface, optical reader, automated software with built-in result interpretation	Visible light Transmission, automated software with built-in result interpretation
Clinical Sensitivity	97.9% [95% CI: 92.7% - 99.4%]	97.4% (95% CI: 91.9 - 99.0%)
Clinical Specificity	96.0% [95% CI: 93.5%- 97.6%]	92.3% (95% CI: 90.0 - 94.1%)

H. Performance Data – Analytical Studies

a. Analytical Sensitivity

The Limit of Detection (LoD) of the Portrait GBS Assay for Group B Streptococcus was assessed and confirmed by using strains of two different serotypes: ATCC strain BAA1177(serotype Ia) and ATCC strain 12403(serotype III). Each strain was spiked into negative LIM broth matrix and then serially diluted. Testing was performed on 20 replicates for each strain to establish the following LoDs in Table 1. For ATCC strain BAA1177, the LoD is reported as $5x10^3$ CFU/mL (2.4 CFU/PCR) and for ATCC strain 12403 the LoD is $8x10^3$ CFU/mL (3.9 CFU/PCR).

Table 1. Performance of the Portrait GBS Assay on 20 replicates of two Group B *Streptococcus* strains for establishing LoD.

GBS strains	Serotype	Tested Serial Dilutions (CFU/mL)	Estimated CFU in PCR	Group B Streptococcus POSITIVE
ATCC BAA1177	Ia	5000	2.4	20/20
ATCC 12403	III	8000	3.9	20/20

b. Analytical Reactivity (Inclusivity)

The analytical reactivity of the Portrait GBS Assay was tested in triplicate against an additional 14 GBS strains representing an additional 11 serotypes at approximately 2X LoD ($1.6x10^4$ CFU/mL) spiked in negative LIM broth matrix. All GBS strains were correctly identified as Positive by the Portrait GBS Assay (Table 2).

Table 2. Analytical Reactivity (Inclusivity) Panel.

GBS strains	Serotype	Group B Streptococcus POSITIVE
CDC 62587	Ia	3/3
ATCC 12401	Ib	3/3*
ATCC 27591	Ic	3/3
ATCC BAA1175	II	3/3
ATCC BAA22	III	3/3
ATCC 49446	IV	3/3
ATCC BAA611	V	3/3
CDC 49282	VI	3/3
CDC 61303	VII	3/3
CDC 43587	VIII	3/3
CDC 62706	IX	3/3
NCTC 9993	untyped	3/3
ATCC 13813	non-hemolytic	3/3
NCIMB 701348	untyped	3/3

* this set of runs also contained one 'Invalid' run

c. Analytical Specificity (Exclusivity)

Studies were performed to assess the potential cross-reactivity of the Portrait GBS Assay with human DNA and 60 non-target microflora (51 bacterial, 5 yeast, and 4 viral stock strains) spiked into a negative LIM broth matrix (Table 3). The non-target bacterial and yeast strains were spiked into the negative clinical LIM broth matrix at a minimum concentration of 10^6 CFU/mL. The human genomic DNA was tested at a concentration of $1.2x10^6$ copies/mL. The viral stocks were spiked into the negative LIM broth matrix at a target concentration close to 10^5 TCID50/mL. A minimum of 3 replicates was performed for each of the human DNA and bacterial, yeast, and viral strains evaluated and none of the tested DNA or strains interfered with the internal controls and all of the calls were 'Group B Streptococcus NEGATIVE,' indicating no cross-reactivity.

Table 3. Analytical Specificity (Exclusivity) Panel.

Bacteria		
Acinetobacter baumannii	*Klebsiella pneumonia*	*Pseudomonas fluorescens*
Aeromonas hydrophilia	*Lactobacillus acidophilus*	*Serratia marescens*
Bacillus cereus	*Lactobacillus casei*	*Shigella flexneri*
Bacteroides fragilis	*Lactobacillus delbrueckii lactis*	*Shigella sonnei*
Camphylobacter jejuni	*Lactobacillus fermentum*	*Staphylococcus aureus*
Citrobacter freundii	*Lactococcus lactis*	*Staphylococcus epidermidis*
Clostridium difficile	*Listeria monocytogenes*	*Staphylococcus haemolyticus*
Clostridium perfringins	*Micrococcus luteus*	*Staphylococcus lugdunensis*
Corynebacterium urealyticum	*Moraxella catarrhalis*	*Streptococcus anginosus*
Enterobacter aerogenes	*Morganella morganii*	*Streptococcus bovis*
Enterobacter cloacae	*Neisseria gonorrhoeae*	*Streptococcus dysgalactiae*
Enterococcus durans	*Peptostrepococcus anaerobius*	*Streptococcus equi subsp. equi*
Enterococcus faecalis	*Prevotella melaninogenica*	*Streptococcus mitis*
Enterococcus faecium	*Propinionibacterium acnes*	*Streptococcus oralis*
Escherichia coli	*Proteus mirabilis*	*Streptococcus pneumoniae*
Gardnerella vaginalis	*Proteus vulgaris*	*Streptococcus pyogenes*
Klebsiella oxytoca	*Pseudomonas aeruginosa*	*Yersinia enterocolitica*
Yeasts		
Candida albicans	*Candida krusei*	*Candida tropicalis*
Candida glabrata	*Candida parapsilosis*	
Viruses		
CMV	Norovirus	
HPV-16	VZV	
Human DNA		
Human genomic DNA		

d. Microbial Interference

The Portrait GBS Assay was further evaluated for interference by the same panel of human DNA and 60 non-target microflora (51 bacterial, 5 yeast, and 4 viral stock strains; Table 3). The same high concentrations of potentially interfering DNA and microorganisms were spiked into negative clinical LIM broth matrix containing Group B *Streptococcus* cells at low positive concentrations of approximately 2X LoD, $1x10^4$ CFU/mL for ATCC strain BAA1177 (serotype Ia) and $1.6x10^4$ CFU/mL for ATCC strain 12403 (serotype III). A minimum of three replicate Portrait GBS Assays were performed for each of the human DNA and bacterial, yeast, and viral strains tested. With the exception of *Enterococcus durans*, none of the potentially interfering DNA or microflora interfered with the detection of either of the Group B *Streptococcus* strains, resulting in 'Group B Streptococcus POSITIVE' calls as expected. Interference was observed for GBS strain ATCC 12403 at 2X LoD ($1.6x10^4$ CFU/mL) in the presence of 10^6 CFU/mL *E. durans*, but not when the GBS strain concentration was increased to 3X LoD ($2.4x10^4$ CFU/mL).

e. Interfering Substances (Chemical Interference)

The Portrait GBS Assay was evaluated for chemical interference by the following panel of 21 different substances (Table 4). Substances were spiked into a negative clinical LIM broth matrix containing Group B *Streptococcus* cells at low positive concentrations of approximately 2X LoD, $1x10^4$ CFU/mL for ATCC strain BAA1177 (serotype Ia) and $1.6x10^4$ CFU/mL for ATCC strain 12403 (serotype III).. A minimum of three replicate assays was performed with none of the chemical substances interfering with the detection of either Group B *Streptococcus* strain resulting in 'Group B Streptococcus POSITIVE' calls as expected.

Table 4. Interfering Substances Panel.

Interfering Substances	Commercial Product Name	Concentration in Sample Matrix
Exogenous Substances		
Anti-Diarrheal Medication	Immodium AD	2% v/v
Body Oil	Neutrogena Body Oil	2% v/v
Body Powder	Gold Bond Body Powder	1% w/v
Contraceptive Foam	VCF Contraceptive Foam	1 swab/5mL Broth
Contraceptive Gel	Options Gynol II Vaginal Contraceptive Gel	2% of swab
Deodarant Spray	Summer's Eve Island Splash	2% v/v
Enema Solution	Wallgreens Enema Saline Laxative	0.25% v/v
Hemorrhoid Cream	Preparation H Cream Max Strength	1 swab/5mL Broth
Lubricating Gel	KY Ultragel	1 swab/5mL Broth
Moisturizing Lotion	Jergens Body Lotion	1 swab/5mL Broth
Oral Laxative	Dulcolax Laxative Tablets	1% w/v
Stool Softener	Equate Stool Softener Pluse stimulant Laxative	0.0016% w/v
Vaginal Anti-fungal Med	Monstat 1 Tiococnazole Ointment 6.5%	1 swab/5mL Broth
Vaginal Anti-itch Cream	Vagisil Medicated Anti-Itch Crème	1 swab/5mL Broth
Endogenous Substances		
Human Amniotic Fluid	LEE Biosciences	2% v/v
Human DNA	Roche Human Genomic DNA	1.2x10^6 copies/mL
Human Feces	In-house	2% v/v
Human Meconium	LEE Biosciences	2% w/v
Human Urine	In-house	2% v/v
Human Whole Blood	In-house	2% v/v
Mucous	Mucin, Sigma M2378	0.05% w/v

f. Carry-over/Cross-Contamination Study

A study was performed to assess the carry-over/cross-contamination of the Portrait GBS Assay by alternatively testing high titered Group B *Streptococcus* samples (ATCC 12403) spiked into negative clinical LIM broth matrix at $5.6x10^7$ CFU/mL followed by true negative samples comprised of only negative clinical LIM broth matrix. By running a series of alternating runs of high titered and negative samples on multiple Portrait Analyzers, any possible carry-over/cross-contamination would be detected.

Table 5 lists the alternating pattern of high positives (HP) and true negatives (TN) performed on six different Portrait Analyzers. All of the 'calls' were in concordance with expected 'calls'. Therefore, there was no evidence of carry-over or cross-contamination in any of the tests.

Table 5. Carry-Over/Cross-Contamination Study.

		RESULTING CALL FOR GROUP B STREPTOCOCCUS					
	Sample	Portrait Analyzer 5.01	Portrait Analyzer 5.35	Portrait Analyzer 5.49	Portrait Analyzer 5.96	Portrait Analyzer 5.108	Portrait Analyzer 5.112
Run 1	High Positive	POSITIVE	POSITIVE	POSITIVE	POSITIVE	POSITIVE	POSITIVE
Run 2	True Negative	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE
Run 3	High Positive	POSITIVE	POSITIVE	POSITIVE	POSITIVE	POSITIVE	POSITIVE
Run 4	True Negative	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE
Run 5	High Positive	POSITIVE	POSITIVE	POSITIVE	POSITIVE	POSITIVE	POSITIVE
Run 6	True Negative	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE

g. Reproducibility

For the Reproducibility studies of the Portrait GBS Assay, a panel of five prepared samples was tested consisting of two Group B *Streptococcus* strains: ATCC strain BAA1177 (serotype Ia), and ATCC strain 12403 (serotype III) at a 'Moderate Positive' concentration (3X LoD; $1.5x10^4$ CFU/mL for ATCC strain BAA1177 and $2.4x10^4$ CFU/mL for ATCC strain 12403) and a 'Low Positive' concentration (1.5X LoD; $7.5x10^3$ CFU/mL for ATCC strain BAA1177 and $1.2x10^4$ CFU/mL for ATCC strain 12403). These samples were made by spiking in the respective cultures into a negative clinical LIM broth matrix. In addition, a True Negative sample consisting of only a negative clinical LIM broth matrix was tested.

The Reproducibility studies were performed in-house and at two external clinical sites using blind-coded panels and six different GBS Assay cartridge lots. At each site, these studies were performed over the course of 5 non-consecutive days. For each day, two runs were performed with three replicates of each sample per run on each day. A minimum of two operators performed the runs at each site.

Table 6 summarizes the cumulative data for the Portrait GBS Assay across all three sites for the Reproducibility studies. Results for the Reproducibility studies of the Portrait GBS Assay were within the expected percent agreement across all three sites. The only exception to this was at Site 1 where 4 out of the 30 True Negatives run resulted in Group B Streptococcus POSITIVE calls instead of NEGATIVE calls. By definition, the True Negative samples consist of only negative clinical LIM broth matrix and therefore should not result in a positive call. Due to the high sensitivity of molecular-based PCR assays, such as the Portrait GBS Assay, laboratory workspace contamination is a possibility. The other two sites did not experience any issues with the True Negative samples run during this study, resulting in 100% agreement, as expected.

Table 6. Results of the Reproducibility Studies

Sample Type (Panel)	% agreement*							
	In-house site		Site 1		Site 2		All Sites	
1. Moderate Positive ATCC 12403	30/30	100.0%	30/30	100%	30/30	100%	90/90	100.0%
2. Low Positive (C_{95}) ATCC 12403	27/30	90.0%	29/30	97.0%	30/30	100%	86/90	95.6%
3. Moderate Positive ATCC BAA1177	30/30	100.0%	30/30	100%	30/30	100%	90/90	100.0%
4. Low Positive (C_{95}) ATCC BAA1177	29/30	97.0%	30/30	100%	30/30	100%	89/90	98.9%
5. True Negative	30/30	100.0%	26/30	86.7%	29/29‡	97.0%	85/89	95.5%

* For Moderate Positive and Low Positive samples, % agreement = 'Group B Streptococcus POSITIVE' calls/total runs.
For True Negative samples, % agreement = 'Group B Streptococcus NEGATIVE' calls/total runs.

‡ This reflects 29 runs not 30 because an 'Invalid' run in this case was not re-run.

I. Performance Data – Prospective Clinical Studies

The clinical performance of the Portrait GBS Assay was determined in three sites in the United States. 448 compliant clinical samples (18-29 hr LIM broth enrichment) were run over the course of four months to evaluate the performance of the Portrait GBS Assay in comparison to the reference GBS clinical microbiology protocol. Samples were obtained according to the established guidelines for the collection of rectal/vaginal swabs from antepartum women (35 – 37 weeks) and enriched in LIM broth. Results from the studies of all three clinical sites combined are summarized in Table 7. The overall initial sample invalid rate was 2.01%. All invalids reported during the study were resolved upon repeated testing resulting in a final invalid rate of 0%. Overall assay performance vs. GBS culture testing is as follows: Overall assay performance vs. GBS culture testing is as follows: Sensitivity = 97.9%, Specificity = 96.0%, PPV = 86.9%, and NPV = 99.4%.

Table 7. Performance characteristics of Portrait GBS Assay vs. GBS culture testing

	Reference culture Positive	Reference culture Negative	
Test Positive	93	14	107
Test Negative	2	339	341
	95	353	448

		Lower CI_{95}	Upper CI_{95}
Sensitivity	**97.9%**	92.7%	99.4%
Specificity	**96.0%**	93.5%	97.6%
PPV	86.9%	79.2%	92.0%
NPV	99.4%	97.9%	99.8%

Prevalence	21.2%

J. Conclusion

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