DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 25, 2017

GENEPOC INC.
GUY SEVIGNY
SENIOR REGULATORY AFFAIRS SPECIALIST
360 RUE FRANQUET
QUEBEC G1P 4N3
CA

Re: K170557
Trade/Device Name: GenePOC GBS LB
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus spp. serological reagents
Regulatory Class: I
Product Code: NJR, OOI
Dated: February 23, 2017
Received: February 24, 2017

Dear Mr. Sevigny:

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)*
K170557

Device Name
GenePOC GBS LB

Indications for Use *(Describe)*

The GenePOC™ GBS LB assay performed on the revogene™ instrument is a qualitative in vitro diagnostic test designed to detect Group B Streptococcus (GBS) DNA from 18-24 hour LIM broth enrichments of vaginal/rectal specimen swabs obtained from pregnant women. The GenePOC GBS LB assay utilizes automated sample processing and real-time polymerase chain reaction (PCR) to detect a cfb gene sequence specific to the Streptococcus agalactiae genome.

The GenePOC GBS LB assay is indicated for the identification of antepartum GBS colonization and does not provide susceptibility results. It is not intended to diagnose or monitor treatment of GBS infection. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

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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510K SUMMARY

A. GENERAL INFORMATION

Submission Date: February 23, 2017

Submitter Information:

Submitted By: GenePOC Inc.
360 rue Franquet, Suite 100 Porte 3
Québec (Québec) G1P 4N3

Contact Person: Guy Sevigny
Sr. Regulatory Affairs Specialist
GenePOC Inc.
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B. PURPOSE FOR SUBMISSION:

To obtain a substantial equivalence determination for the GenePOC Group B Step (GBS) LB test

C. MEASURAND:

cfb gene of *Streptococcus agalactiae* (Group B *Streptococcus*, GBS)

D. TYPE OF TEST:

Real-time Polymerase chain reaction (rtPCR)

E. DEVICE INFORMATION:

1. *Trade Name:*
   GenePOC GBS LB

2. *Regulation:*
   21 CFR 866.3740 - Streptococcal spp. serological reagents

3. *Classification:*
   Class I

4. *Product Code:*
   NJR – Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen

OOI – Real-time nucleic acid amplification

5. *Panel:*
   83, Microbiology

F. INTENDED USE:

1. Intended Use and Indications for Use:

The GenePOC™ GBS LB assay performed on the revogene™ instrument is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from 18-24 hour LIM broth enrichments of vaginal/rectal specimen swabs obtained from pregnant women. The GenePOC GBS LB assay utilizes automated sample processing and real-time polymerase chain reaction (PCR) to detect a *cfb* gene sequence specific to the *Streptococcus agalactiae* genome.

The GenePOC GBS LB assay is indicated for the identification of antepartum GBS colonization and does not provide susceptibility results. It is not intended to diagnose or monitor treatment of GBS infection. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

2. Special conditions for use statement(s):
   Prescription Use Only

3. Special instrument requirements:
   revogene™

G. DEVICE DESCRIPTION:

The GenePOC GBS LB assay is a single-use test for the qualitative detection of Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens using real-time Polymerase Chain Reaction (PCR) technology with fluorogenic detection of the amplified DNA. The GenePOC GBS LB assay utilizes the GBS LB microfluidic cartridge for the simultaneous detection of the target GBS DNA and the internal process control (PrC) DNA (to monitor processing, amplification, and the absence of reaction inhibitors). The GenePOC GBS LB assay is an automated assay performed on the revogene™ including sample processing.

The GenePOC Group B Strep (GBS) LB is composed of a GBS specific disposable microfluidic cartridges, Sample Buffer Tube (SBT) and Disposable Transfer Tool (DTT). These components are used to lyse and dilute the sample, amplify, and detect GBS nucleic acid from vaginal/rectal swabs following LIM broth enrichment. User intervention is required for sample preparation, discharging the LIM broth enriched sample into the SBT, transferring the sample into the cartridge and loading/unloading the cartridge into the revogene instrument. Once the sample is added into the cartridge, the process is then fully automated.

Each GenePOC GBS LB Test kit contains 24 individual pouches, and each pouch has components for 1 test including 1 cartridge, 1 SBT, and 1 DTT. The GBS LB Test is run on the revogene instrument which can process from one up to a maximum of 8 samples simultaneously in the same run. On completion of a run, the results are interpolated by the revogene™ from measured fluorescent signals and embedded calculation algorithms. For the GBS application, two spectral signals are processed: GBS target and Internal Process Control. The output results include positive, negative, indeterminate, and unresolved. On completion of a run, the user removes the used cartridges and disposes of them in normal biological waste. Results may be viewed, printed, transferred, and/or stored by the user.

H. SUBSTANTIAL EQUIVALENCE INFORMATION:

1. Predicate Device Name:
   BD MAX™ GBS Assay

2. Predicate 510(k) Number:
   K111860

3. Comparison with Predicate:

Item	GenePOC GBS LB (Subject Device)	BD MAX GBS Assay (Predicate Device)
K Number	K170557	K111860
SIMILARITIES		
Classification	Class I	Same
Intended Use	Intended Use for detection of GBS	Same
Specimen type	Vaginal-Rectal Swab (Enriched Lim Broth)	Same
Collection and Transport Media	Liquid Amies or Stuart	Same
Sample Preparation Method	Manual; swab enriched overnight in Lim Broth	Same
DNA Extraction	Automated by instrument	Same
Assay Format	• Amplification: Real Time PCR • Detection: Fluorogenic	Same
Automatic Assay	Yes-result interpretation	Same
Internal Process Control	Extraction and PCR internal control is a process monitor	Same
External Control	Materials available commercially but not required to run the test	Same
DIFFERENCES		
DNA Target	190 bp region of the *cfb* gene	124 bp region of *cfb* gene
Probe Design	TaqMan®	Scorpion

Item	GenePOC GBS LB (Subject Device)	BD MAX GBS Assay (Predicate Device)
GBS Assay Format	Fully integrated sample processing and PCR reaction/detection in a cartridge	Requires combination of a reagent strip and a PCR cartridge
Single Use	Cartridge can be used once	Cartridge can be used twice
Time to Result	~70 min	2-3 hours
Instrument Optical Channels	revogene™ contains 4 channels	BD MAX Instrument contains 6 optical channels

I. STANDARDS/GUIDANCE DOCUMENTS REFERENCED:

- CLSI Guideline EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.

J. TEST PRINICIPLE:

Vaginal-rectal specimen are collected and used to inoculate selective LIM broth. After incubation at 35-37°C for 18-24 hours in ambient, 15 µL of the inoculated broth is transferred to the Sample Buffer Tube (SBT). After vortexing the SBT for 15 seconds, approximately 150 µL of the inoculated sample buffer is transferred into the GenePOC microfluidic cartridge using the Disposable Transfer Tool (DTT). The loaded GBS LB cartridge is placed into the revogene for further sample processing. No operator intervention is necessary once the clinical sample is loaded onto the revogene.

Each GBS LB microfluidic cartridge is a completely integrated and self-contained device. Each sample is transferred by centrifugation from one microfluidic chamber to the next in sequence, and all reagents specific for the PCR reaction are incorporated and dried within the PCR wells. The stepwise process includes sample homogenization, lysis of cells, and specimen dilution followed by the subsequent real-time PCR steps within 1 PCR well in the cartridge. An internal Process Control (PrC) is contained in the homogenization chamber and is therefore present in every test to monitor critical steps of the analytical process (including sample lysis, dilution and nucleic acid amplification and detection) for the presence of potential inhibitory substances as well as system or reagent failures. The amplified products are detected in real time using target-specific TaqMan® chemistry-based probes. The GBS LB specific designed primers and probe detect a target region of 190 base pairs of the *cfb* gene specific to the *Streptococcus agalactiae* genome. The results are interpolated by the revogene from measured fluorescent signals and embedded calculation algorithms.

K. PERFORMANCE CHARACTERISTICS:

1. Analytical Performance

a. Precision/Reproducibility

The reproducibility study was conducted at three sites (two external sites and GenePOC laboratories) to evaluate the within-run, between-run (three runs per

day) and between-day (five days, consecutive or not) reproducibility and variance with multiple operators (n=6; two operators per site). Precision was evaluated based on the within-site variability over 5 days. Three revogene instruments (one per site) and a single lot of the GenePOC GBS LB assay were used by each site (total of three reagent lots).

Three GBS strains were tested at two different concentrations in each run: low positive (LP; 735 CFU/mL SB) and moderate positive (MP; 1,125 CFU/mL SB). The GBS strains used in the panels were the hemolytic serotype Ia S. agalactiae strain ATCC 12400, the hemolytic serotype III S. agalactiae strain ATCC 12403 and the non-hemolytic S. agalactiae strain ATCC 13813. Two true negative (TN) samples were included in each run.

After the testing of 720 replicates (270 low positive, 270 moderate positive, and 180 true negative samples) with the GenePOC GBS LB assay, the overall analysis showed 100% agreement for negative samples, 98.9% agreement for low positive samples, and 98.5% agreement for moderate positive samples as summarized in the table below.

Summary of the Percent Agreement Analysis across all Sites

Sample	Strain	Site 1	Site 2	Site 3	Overall Assay Results/Total	% Agreement
		Assay Results/Total				
Low Positive (735 CFU/mL of SB)	ATCC 13813	29/30	30/30	30/30	89/90	98.9%
	ATCC 12403	28/30	30/30	30/30	88/90	97.8%
	ATCC 12400	30/30	30/30	30/30	90/90	100%
	Overall Results/Total (% Agreement)	87/90 (96.7%)	90/90 (100%)	90/90 (100%)	267/270	98.9%
Moderate Positive (1,125 CFU/mL of SB)	ATCC 13813	28/30	29/30	30/30	87/90	96.7%
	ATCC 12403	29/30	30/30	30/30	89/90	98.9%
	ATCC 12400	30/30	30/30	30/30	90/90	100%
	Overall Results/Total (% Agreement)	87/90 (96.7%)	89/90 (98.9%)	90/90 (100%)	266/270	98.5%
True Negative	NA Overall Results/Total (% Agreement)	60/60 (100%)	60/60 (100%)	60/60 (100%)	180/180	100%

The quantitative results for the between strain, between-site, between-operator and between-day reproducibility for Ct values are summarized below:

Summary of the Overall SD and % CV for the Ct values for the Reproducibility Study

GBS Ct; Low Positive (735 CFU/mL)						
Variance component	**N***	**Variance**	**%**	**Mean**	**SD**	**rSD (%CV)**
Residual	267	2.57	68.5%	36.4	1.6	4.4%
Strain		0.32	8.5%		0.6	1.6%
Site		0.73	19.4%		0.9	2.3%
Operator (Site)		0.14	3.6%		0.4	1.0%
Day (Site x Op)		0.00	0.0%		0.0	0.0%
All components		1.18	31.5%		1.1	3.0%
GBS Ct; Moderate Positive (1,125 CFU/mL)						
Variance component	**N***	**Variance**	**%**	**Mean**	**SD**	**rSD (%CV)**
Residual	266	2.33	72.4%	35.7	1.5	4.3%
Strain		0.11	3.6%		0.3	1.0%
Site		0.65	20.1%		0.8	2.3%
Operator (Site)		0.11	3.4%		0.3	0.9%
Day (Site x Op)		0.02	0.5%		0.1	0.4%
All components		0.89	27.6%		0.9	2.6%
PrC Ct; All specimens						
Variance component	**N***	**Variance**	**%**	**Mean**	**SD**	**rSD (%CV)**
Residual	718	1.22	65.8%	31.9	1.1	3.5%
Strain/NEG		0.01	0.7%		0.1	0.4%
Site		0.56	29.9%		0.7	2.3%
Operator (Site)		0.05	2.5%		0.2	0.7%
Day (Site x Op)		0.02	1.1%		0.1	0.4%
All components		0.64	34.2%		0.8	2.5%

		Ct GBS		Inter-site		Inter-operator		Inter-day		Overall	
Load	**Strain**	**N**	**Mean Ct**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
Low Positive (1-2xLoD)	ATCC 13813	89	36.4	2.6	7.1	2.4	6.6	3.9	10.6	**5.2**	14.4
	ATCC 12403	88	36.9	3.2	8.5	2.7	7.3	4.3	11.5	**5.9**	16.1
	ATCC 12400	90	35.8	2.6	7.4	2.2	6.2	3.8	10.5	**5.1**	14.3
Overall Low Positive		267	36.4	2.9	8.0	2.6	7.0	4.1	11.2	**5.6**	15.5
Moderate Positive (3xLoD)	ATCC 13813	87	35.9	2.5	7.1	2.5	7.0	4.0	11.2	**5.4**	15.0
	ATCC 12403	89	35.9	2.8	7.8	2.4	6.7	3.9	10.7	**5.3**	14.9
	ATCC 12400	90	35.3	2.7	7.6	2.2	6.4	3.7	10.4	**5.1**	14.4
Overall Moderate Positive		266	35.7	2.7	7.6	2.4	6.8	3.9	10.8	**5.3**	14.9
		Ct PrC		**Inter-site**		**Inter-operator**		**Inter-day**		**Overall**	
Load	**Strain**	**N**	**Mean**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**	**SD**	**% CV**
True Negative	N/A	180	31.9	1.7	5.5	1.8	5.7	2.9	9.2	3.9	12.1

A summary of the SD and % CV for the Ct values for the quantitative within-site analysis are presented below.

Summary of the SD and % CV for the Ct values for the Within-Site Precision Study

		Site 1				Site 2				Site 3			
Target Load	**Strain**	**Mean Ct, SD and %CV GBS**											
		N	Mean	SD	% CV	N	Mean	SD	% CV	N	Mean	SD	% CV
True Negative	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Low Positive (735 CFU/mL)	ATCC 13813	29	37.6	1.8	4.9	30	36.3	1.0	2.8	30	35.4	1.5	4.3
	ATCC 12403	28	37.7	2.4	6.4	30	37.0	1.6	4.3	30	36.1	1.3	3.5
	ATCC 12400	30	36.7	1.6	4.4	30	35.4	1.5	4.1	30	35.2	1.5	4.2
Overall (Low positive sample only) Result/expected result		87	37.3	2.0	5.4	90	36.3	1.5	4.2	90	35.5	1.5	4.1
Moderate Positive (1125 CFU/mL)	ATCC 13813	28	37.2	1.9	5.2	29	36.0	1.1	3.2	30	34.7	1.2	3.3
	ATCC 12403	29	36.6	2.1	5.7	30	35.9	1.5	4.1	30	35.2	1.2	3.4
	ATCC 12400	30	36.0	1.2	3.5	30	35.1	1.3	3.6	30	34.7	2.0	5.8
Overall (Moderate positive sample only) Result/expected result		87	36.6	1.8	5.0	89	35.7	1.4	3.8	90	34.9	1.5	4.3
Target Load	**Strain**	**Mean Ct, SD and %CV PrC**											
		N	Mean	SD	% CV	N	Mean	SD	% CV	N	Mean	SD	% CV
True Negative	NA	60	32.1	1.2	3.7	60	32.7	0.7	3.2	60	30.8	1.1	2.4
Low Positive (735 CFU/mL)	ATCC 13813	30	32.5	1.0	3.0	30	32.4	0.9	2.6	30	31.2	1.0	3.1
	ATCC 12403	30	32.5	2.2	6.9	30	32.2	0.9	2.7	30	31.2	1.6	5.0
	ATCC 12400	30	32.4	1.5	4.7	30	31.9	0.9	2.8	30	31.1	0.7	2.4
Overall (Low positive sample only) Result/expected result		90	32.5	1.6	5.1	90	32.2	0.9	2.7	90	31.2	1.1	3.7
Moderate Positive (1125 CFU/mL)	ATCC 13813	30	32.7	1.2	3.8	30	32.9	1.2	3.5	30	31.0	0.9	3.1
	ATCC 12403	30	31.6	0.9	2.9	30	32.5	1.1	3.5	30	30.8	0.8	2.6
	ATCC 12400	29	32.1	0.8	2.5	30	32.1	0.8	2.4	29	31.3	1.0	3.3
Overall (Moderate positive sample only) Result/expected result		89	32.1	1.1	3.4	90	32.5	1.1	3.3	89	31.0	0.9	3.0

b. Linearity/Assay Reportable Range

Not applicable. The GenePOC GBS LB Test is a qualitative assay.

c. Traceability, Stability, Expected Values (controls, calibrators, or methods)

Commercial control material (e.g. *Streptococcus agalactiae* ATCC® 13813) can be used as a Positive External Control. It is recommended that bacterial strains be freshly prepared in LIM broth. Transfer a 15 µL aliquot of a 18-24 hours culture in LIM broth into a SBT. Pure LIM broth is recommended for use as a Negative External Control.

An Internal Process Control (PrC) is provided in each GenePOC GBS LB test. The PrC is extracted, amplified, and detected along with each specimen tested and monitors the efficacy of the cell lysis, dilution and PCR amplification and detection processes.

d. Detection Limit

The analytical sensitivity (Limit of Detection or LoD) of the GBS LB assay was determined using clinical LIM broth matrix previously tested negative for GBS and spiked with different concentrations of GBS bacterial suspensions. Two

strains of GBS (ATCC 12403 and ATCC 13813) were tested in 24 replicates per concentration by 2 operators using 3 different lots of GBS LB kits. The LoD is defined as the lowest concentration at which 95% of all replicates tested positive. The LoD of the GBS LB assay ranged from 200 to 375 CFU/mL of SB (200 CFU/mL for ATCC 13813 and 375 CFU/mL for ATCC 12403).

e. Analytical Inclusivity

The analytical reactivity was determined with 12 strains of *S. agalactiae* representing 11 known serotypes and one non-haemolytic strain. Each strain was tested in 8 replicates per dilution per lot of material. All strains were detected at concentrations ranging from 1x to 15x LoD.

Strain[1]	Serotype	Concentration at which replicates are 100% positive
		CFU/mL of SB
ATCC 12400	Ia	735
ATCC 51487	Ib	5,625
ATCC 27591	Ic	1,875
ATCC 12973	II	735
ATCC 12403	III	375
ATCC 49446	IV	2,625
ATCC BAA-611	V	1,875
ATCC BAA-2671	VI	1,125
ATCC BAA-2670	VII	2,625
ATCC BAA-2669	VIII	3,750
ATCC BAA-2668	IX	1,125
ATCC 13813	Non-hemolytic	500

f. Analytical Specificity

Cross Reactivity:

A total of 75 non-specific analytes were tested in this study and listed in the table below. The various analytes selected are found in clinical vaginal-rectal specimens (different from *Streptococcus agalactiae*) including commensal and pathogenic microorganisms (yeasts, viruses, parasites and bacteria) from urogenital and intestinal tracts; species phylogenetically similar to *S. agalactiae*; and human DNA. Bacteria and yeasts were diluted at a concentration of $\geq 10^6$ CFU/mL SB whereas viruses, parasites and human DNA were prepared at $\geq 10^5$ DNA or RNA cp/mL SB.

Assays were carried with 3 reagent kit lots on 2 revogene instruments. All samples were tested in triplicate (4 yeasts, 4 viruses, 2 parasites, human DNA and 64 bacteria). The total reactivity rate of the GenePOC GBS LB test with the selected non-specific analytes is 0%.

Name	
Bacteria (strain or gDNA)	
Acinetobacter baumannii	*Mycoplasma genitalium* gDNA
Aerococcus viridans	*Mycoplasma hominis* gDNA
Aeromonas hydrophila	*Neisseria gonorrhoeae*
Bacillus cereus	*Peptostreptococcus anaerobius*
Bacillus subtilis	*Porphyromonas asaccharolytica*
Bacteroides fragilis	*Prevotella melaninogenica*
Bifidobacterium adolescentis	*Propionibacterium acnes*
Bifidobacterium breve	*Proteus mirabilis*
Brevibacterium linens	*Pseudomonas aeruginosa*
Campylobacter jejuni	*Salmonella enterica subsp. enterica serovar Dublin*
Chlamydia trachomatis gDNA	*Salmonella enterica subsp. enterica serovar Minneapolis*
Citrobacter freundii	*Salmonella enterica subsp. enterica serovar typhimurium*
Clostridium difficile	*Salmonella enterica subsp. enterica serovar Newport*
Clostridium perfringens	*Serratia marcescens*
Corynebacterium genitalium	*Shigella sonnei*
Enterobacter aerogenes	*Staphylococcus aureus*
Enterobacter cloacae	*Staphylococcus aureus (Cowan)*
Enterococcus avium	*Staphylococcus epidermidis*
Enterococcus dispar	*Staphylococcus saprophyticus*
Enterococcus durans	*Streptococcus anginosus*
Enterococcus faecalis	*Streptococcus bovis*
Enterococcus faecium	*Streptococcus dysgalactiae subsp. disgalactiae*
Escherichia coli	*Streptococcus dysgalactiae equisimilis*
Escherichia fergusonii	*Streptococcus intermedius*
Gardnerella vaginalis	*Streptococcus oralis*
Klebsiella oxytoca	*Streptococcus pneumoniae*
Klebsiella pneumoniae	*Streptococcus pyogenes*
Lactobacillus acidophilus	*Streptococcus salivarius*

Name	
Lactobacillus brevis	*Streptococcus sanguinis*
Lactobacillus casei	*Streptococcus uberis*
Lactobacillus delbreuckii	*Ureaplasma urealyticum* gDNA
Lactobacillus jensenii	*Yersinia enterocolitica*
Yeasts	
Candida albicans	*Candida parapsilosis*
Candida glabrata	*Candida tropicalis*
Viruses (gDNA or RNA)	
HerpesSimplexVirus-1 gDNA	*Norovirus* GII RNA
HerpesSimplexVirus-2 gDNA	Human Papillomavirus (HPV) gDNA
Parasites (gDNA)	
Blastocystis hominis gDNA	*Trichomonas vaginalis* gDNA

g. Interference with Non-Target Organisms

Microbial interference on the GenePOC GBS LB assay was evaluated with 29 potentially interfering microorganisms in absence and in presence of 2 GBS strains tested at 735 CFU/mL of SB. Samples were grouped together into 7 pools of interferences. Each of the 7 pools were tested in triplicate across 3 reagent lots for a total of 9 replicates by pool were analyzed to determine the presence or absence of interference. Results of the study showed no interference against the GBS target (735 CFU/mL of SB) was detected for 26 out of 29 microorganisms when present in high loads (10^5 or 10^6 CFU/mL of SB). However, strains *Enterococcus faecalis* ATCC 19433, *Enterococcus faecium* ATCC 19434 and *Lactobacillus acidophilus* ATCC 4356 showed interference against the GBS target (735 CFU/mL of SB) when they were present at $>10^4$ CFU/mL of SB. No interference on the Process Control was observed when microorganisms were present in high loads (10^5 or 10^6 CFU/mL of SB).

h. Interference with Exogenous and Endogenous Substances

Interference on the GenePOC GBS LB assay was evaluated with 31 potentially interfering exogenous and endogenous substances in absence and in presence of 2 GBS strains tested at 735 CFU/mL SB across 3 reagent lots. The interferences tested included the following: whole blood, leukocytes, amniotic fluid, mucous, seminal fluid, urine, feces, meconium, human DNA, Fungicide, Hemorrhoid cooling gel, Lubricating gel, Body powder, moisturizing lotion, body oil, Deodorant spray, enemas, Antimicrobials, Radiology oral compounds, gastritis medications, Non-Steroidal Anti-Inflammatory, Medications, gastritis medications, anti-Diarrheal medication, Laxatives, Spermicidal, and Moist Towelettes. Results demonstrated no reportable interference on PrC. Only the combination of loperamide hydrochloride (e.g. Imodium®), bismuth

subsalicylate (e.g. Pepto-Bismol™) and sennosides (e.g. Senokot®) at concentrations of 0.023 µg/mL, 0.675 µg/mL and 0.011 µg/mL SB, respectively, showed a potentially inhibitory effect on detection of GBS. When tested individually, these substances showed no reportable interference with the GBS LB assay.

i. Carryover and Cross Contamination Studies

The carry-over and cross-contamination study showed that there is no evidence of amplicon carry-over or sample contamination when using the revogene with the GenePOC GBS LB assay. A total of 80 samples in the within-run study and 80 samples in the between run study were tested and none gave a false positive result. For each study various combinations of high positive and GBS negative samples were run for each of the 10 runs per study across 3 reagent lots. For each sample, quantitated culture of the organism was diluted in negative matrix. The high positive (>$1x10^6$ CFU/mL of SBT) suspension tested in this study was prepared with the *S. agalactiae* strain Serotype III ATCC 12403.

2. Comparison Studies

a. Method Comparison with predicate device

Not applicable.

b. Matrix Comparison

Not applicable.

3. Clinical Studies

GenePOC conducted a prospective multicenter trial at 4 geographically diverse clinical trial sites; specifically, two Canadian and two US clinical sites. A vaginal/rectal swab specimen was collected from n=839 pregnant women at 35-37 weeks of gestation for whom GBS diagnostic procedures were ordered. For each patient, the swab was used for the composite reference method consisting of LIM Broth enrichment of the vaginal/rectal swab followed by a subculture on blood agar plate and biochemical identification of GBS. All specimens with a negative bacterial culture result were re-tested using the same standard operating procedures required for bacterial culture. Residual de-identified LIM Broth samples were used for testing with the GenePOC GBS LB assay. Of those, 63 specimens were regarded as noncompliant per the composite reference method and/or GBS LB assay protocol criteria, 1 specimen was regarded as noncompliant in terms of transport and storage conditions and 4 specimens were regarded as noncompliant due to missing test results. Two (2) fully compliant specimens gave final non-reportable PCR results. A total of 771 specimen results were used to determine the clinical performance of the GBS LB assay in comparison to the composite reference method. A total of 170 GBS positive and 601 GBS negative samples were collected across the four sites.

Overall performance characteristics of the GBS LB assay in comparison to the composite reference method.

Overall performance		Composite Reference Method		
		Positive	**Negative**	**Total**
GBS LB assay	**Positive**	163	27[B]	190
	Negative	7[A]	574	581
	Total	170	601	771
Sensitivity: 95.9% (95%CI: 91.7 - 98.0 %) Specificity: 95.5% (95%CI: 93.5 – 96.9 %)				

[A] 5 out of 7 false negative GenePOC GBS LB results were tested on a FDA-cleared molecular device and yielded negative results.

[B] 10 out 27 false positive GenePOC GBS LB results were tested on a FDA-cleared molecular device and yielded positive results.

Summary of performance characteristics of the GBS LB assay per site

Site	**Sensitivity**	**Specificity**	**Prevalence[1]**
1	87.8% (36/41)	92.8% (142/153)	21.1% (41/194)
2	98.0% (48/49)	97.5% (194/199)	19.8% (49/248)
3	100% (43/43)	97.0% (164/169)	20.3% (43/212)
4	97.3% (36/37)	92.5% (74/80)	31.6% (37/117)
Total	95.9% (163/170)	95.5% (574/601)	22.0% (170/771)

[1] Prevalence was calculated with samples compliant at culture composite reference method and GenePOC™ GBS LB assay levels.

4. Clinical Cut-off

Not applicable.

5. Expected Values/Reference Range

In the investigational study for the GenePOC GBS LB assay, a total of 771 reportable results from specimens compliant at the culture and PCR levels were obtained from 4 geographically diverse regions. Overall, GBS prevalence rate was 22.0 % (170/771) with a 95 % CI of 19.3 – 25.1 %.

L. INSTRUMENT NAME:

revogene™

M. SYSTEM DESCRIPTIONS:

1. Modes of Operation:
   Real-time Polymerase chain reaction with fluorogenic detection of amplified DNA.

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:
   Barcodes are used to identify patient specimens. The GenePOC GBS LB assay's Sample Buffer Tube (SBT) and microfluidic cartridge (PIE) both are pre-labeled with a unique barcode to identify both specimen and assay. The instrument has two barcode readers to identify reagents and patient specimens. It provides traceability of the sample ID to the PIE ID, SBT ID, and assay ID.

4. Specimen Sampling and Handling:
   User intervention is required for discharging the patient sample into the SBT, transferring a 150 µL aliquot of the sample into the microfluidic cartridge and for loading the microfluidic cartridge into the revogene. All further specimen handling is automated.

5. Calibration:
   The system is factory calibrated by the manufacturer as well as during annual preventive maintenance.

6. Quality Control:
   An Internal Process Control (PrC) provided in each microfluidic cartridge of the GenePOC GBS LB assay. The PrC is lysed, amplified, and detected along with each specimen tested and monitors the efficacy of the DNA extraction and PCR amplification processes.

   Commercial control material (e.g. *Streptococcus agalactiae* ATCC® 13813) can be used as a Positive External Control. It is recommended that bacterial strains be freshly prepared in LIM broth. Transfer a 15 µL aliquot of a 18-24 hours culture in LIM broth into a SBT. Pure LIM broth is recommended for use as a Negative External Control.

N. OTHER SUPPORTIVE INSTRUMENT PERFORMANCE CHARACTERISTICS DATA NOT COVERED IN THE "PERFORMANCE CHARACTERISTICS" SECTION:

Not applicable.

O. PROPOSED LABELING:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

P. CONCLUSION:

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