DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 16, 2017

HARDY DIAGNOSTICS
RIANNA MALHERBE
LEAD PERFORMANCE STUDIES MICROBIOLOGIST
1430 WEST MCCOY LANE
SANTA MARIA CA 93455

Re: K170481
Trade/Device Name: Strep B Carrot Broth Kit
Regulation Number: 21 CFR 866.2360
Regulation Name: Selective culture medium
Regulatory Class: I
Product Code: PQZ
Dated: January 20, 2017
Received: February 16, 2017

Dear Ms. Malherbe:

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)*
K170481

Device Name
Strep B Carrot Broth™ Kit

Indications for Use *(Describe)*
Strep B Carrot Broth™ Kit is a selective and differential medium which is intended for the detection of Group B Streptococcus (GBS) from anovaginal specimens collected from pregnant women. The medium is used as an aid in the qualitative determination of GBS colonization in pregnant women. The color change reaction from white to orange is representative of a positive result for presence of GBS. The medium requires 24 hours of incubation but positive results can be interpreted and reported as early as 16 hours. Due to the properties of Strep B Carrot Broth™ Kit, non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification. Any presumptive negative indicated by lack of color change at the end of the incubation period must be subcultured to a non-selective medium (e.g., Tryptic Soy Agar with 5% Sheep Blood) to confirm absence of GBS. Subculture must also be performed to recover isolates for conducting 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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Appendix D – 510(k) Summary

I. SUBMITTER

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II. DEVICE

Name of Device: Strep B Carrot Broth™ Kit
Classification Name: Selective Culture Medium
Regulatory Class: I
Product Code: PQZ

III. PREDICATE DEVICE

LIM Broth, K871447

IV. DEVICE DESCRIPTION

Approximately 10-35% of women are asymptomatic carriers of group B streptococci (GBS) in the genital and gastrointestinal tracts. Group B Streptococci (GBS) remains a leading cause of serious illness and death in newborn populations and, therefore, the detection of Group B Streptococci in the vaginal-anorectal area is critical to the prevention of neonatal GBS disease. The Centers for Disease Control and Prevention (CDC) recommends the screening of all pregnant women for vaginal and rectal Group B Streptococci colonization between 35 and 37 weeks of gestation using an enrichment broth followed by subculture.

Strep B Carrot Broth™ is a selective and differential medium with selective components designed to enrich for Group B Streptococci. The production of a light orange, orange, or red-orange pigment is a unique characteristic of β-hemolytic GBS due to reaction with substrates such as starch, peptone, serum, and folate pathway inhibitors. GBS detection by color with Strep B Carrot Broth™ is only possible with β-hemolytic Group B Streptococci colonies, which provides evidence of a direct genetic linkage between pigment production in this media and hemolysin production. Non-hemolytic GBS can be recovered Strep B Carrot Broth™ upon subculture to 5% sheep blood agar plates.

V. INDICATIONS FOR USE

Strep B Carrot Broth™ Kit is a selective and differential medium which is intended for the detection of Group B *Streptococcus* (GBS) from anovaginal specimens collected from pregnant women. The medium is used as an aid in the qualitative determination of GBS colonization in pregnant women. The color change reaction from white to orange is representative of a positive result for presence of GBS. The medium requires 24 hours of incubation but positive results can be interpreted and reported as early as 16 hours. Due to the properties of Strep B Carrot Broth™ Kit, non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification. Any presumptive negative indicated by lack of color change at the end of the incubation period must be subcultured to a non-selective medium (e.g., Tryptic Soy Agar with 5% Sheep Blood) to confirm absence of GBS. Subculture must also be performed to recover isolates for conducting susceptibility testing as recommended for penicillin-allergic women.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attribute	Device	Comparator	Substantially Equivalent?
Name	Strep B Carrot Broth™ Kit	LIM Broth	
510(k) Details	510(k) number K170481 Product Code PQZ 21 CFR 866.2360 "Culture media, selective and differential" Class I Panel 83 Microbiology	510(k) number K871447 Product Code JSD 21 CFR 866.2360 "Culture Media, Selective Broth" Class I Panel 83 Microbiology	Yes
Intended Use	Strep B Carrot Broth™ Kit is a selective and differential medium which is intended for the detection of Group B *Streptococcus* (GBS) from anovaginal specimens collected from pregnant women. The medium is used as an aid in the qualitative determination of GBS colonization in pregnant women. The color change reaction from white to orange is representative of a positive result for presence of GBS. The medium requires 24 hours of incubation but positive results can be interpreted and reported as early as 16 hours. Due to the properties of Strep B Carrot Broth™ Kit, non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification. Any presumptive negative indicated by lack of color change at the end of the incubation period must be subcultured to a non-selective medium (e.g., Tryptic Soy Agar with 5% Sheep Blood) to confirm absence of GBS. Subculture must also be performed to recover isolates for conducting susceptibility testing as recommended for penicillin-allergic women.	Remel Todd Hewitt Broth w/ CNA (Lim Broth) is a liquid medium recommended for use in qualitative procedures for the isolation of Group B Streptococcus (GBS) from clinical specimens containing mixed bacterial flora.	Yes
Methodology	Enrichment Broth, Chromogenic	Enrichment Broth	Yes
Inoculation	Direct	Direct	Yes
Sample Type	Vaginal/rectal swab	Vaginal/rectal swab	Yes
Interpretation	Manual/visual and subculture negatives	Manual/visual and subculture	Yes

VII. PERFORMANCE DATA

Performance of Strep B Carrot Broth™ was evaluated at four geographically diverse hospitals with routine GBS specimen in the form of an anovaginal swab. The detection of Group B Streptococci by orange color development in Strep B Carrot Broth™ Kit was compared to routine culture, defined as the selective enrichment of specimen in LIM Broth, followed by subculture to Blood Agar and confirmed by biochemical testing. Additionally, the recovery of Group B Streptococci from Strep B Carrot Broth™ that had been subsequently subcultured to Blood Agar was also compared to LIM broth routine culture. Organisms that grew on Blood Agar were confirmed to be Group B Streptococci using gram-stain, catalase test, and latex agglutination.

A total of 884 specimens were tested against routine culture, 113 specimens did not meet enrollment criteria, and were therefore excluded from the analysis. Of the remaining 771 valid samples tested, a total of 143 specimens were positive for Group B Streptococci by orange color development in Strep B Carrot Broth™ after 24 hours of incubation at 35-37ºC with concordant results obtained from the LIM reference method. Those results are shown in Table 1.

All discrepant isolates were frozen in CryoSavers™ with Brucella Broth and returned to Hardy Diagnostics for testing. The identity of each isolate was confirmed (β Group B Streptococci, NH Group B Streptococci, or non-Group B Streptococci). Once the identity was confirmed, positive organisms (β Group B Streptococci or NH Group B Streptococci) were tested at LoD (10^3 CFU/mL) in donated negative-vaginal rectal matrix for their recovery from the LIM reference method, color development in Carrot Broth™ Kit, and recovery from the Carrot Broth™ Kit to Blood Agar System.

Table 1. LIM Reference Method vs. Strep B Carrot Broth™ Kit Color reaction

Site	TP	FP[1]	FN[2]	TN	Sensitivity	95% CI		Specificity	95% CI	
CCP	47	1	4	141	**92.2**	81.5	96.9	**99.3**	96.1	99.9
NY	34	3	9	137	**79.1**	64.8	88.6	**97.9**	93.9	99.3
CC	26	0	2	83	**92.9**	77.4	98.0	**100.0**	95.6	100.0
MCW	36	3	5	240	**87.8**	74.5	94.7	**98.8**	96.4	99.6
Overall	**143**	**7**	**20**	**601**	**87.7[3]**	81.8	91.9	**98.8[3]**	97.6	99.4

[1] There were 7 False Positives observed. All isolates were re-tested and confirmed at Hardy Diagnostics using the discrepant analysis protocol described above. Three isolates were originally negative by LIM reference method, showed a positive color reaction in Carrot Broth, but no β-hemolytic colonies were recovered upon subculture to Blood Agar. Of these three, both Blood Agar plates from one sample (from LIM and CB subcultured plates) were swarmed with Proteus and no β-hemolytic colonies could be isolated for confirmation. No β-hemolytic colonies were recovered from the frozen samples of the other two isolates, and therefore could not be confirmed. The remaining four discrepant isolates were confirmed to be β Group B Streptococci.

[2] There were 20 False Negatives observed. All isolates were re-tested and confirmed at Hardy Diagnostics using the discrepant analysis protocol described above. Fourteen of the β Group B Streptococci isolates recovered from LIM, but originally gave a negative Carrot Broth color reaction, were confirmed as β Group B Streptococci and subsequently confirmed to have a positive Strep B Carrot Broth™ Kit color reaction at LoD. Two isolates were identified as a very weak β Group B Streptococci and did not produce the expected color reaction in Strep B Carrot Broth™ Kit. Four isolates were confirmed as non-hemolytic Group B Streptococci with a negative color reaction in Strep B Carrot Broth™.

[3] Considering that non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification, there were seven specimens that were found to be non-hemolytic upon subculture and identification by the reference method. If these specimens are included as negatives, then the overall sensitivity and specificity values observed when comparing the recovery of β-hemolytic GBS by the LIM reference method to the Strep B Carrot Broth™ Kit color reaction were 90.4% (141/156) [95% CI: 84.7-94.1] and 98.5% (606/615) [95% CI: 97.2-99.2], respectively.

When comparing the number of Group B Streptococci positive specimens recovered by the LIM reference method to the number identified by Strep B Carrot Broth™ color change in conjunction with the subculture of presumptive negatives to the Blood Agar, an additional 18 specimens showed concordant positive results for a total of 161 true positive results. The Lim reference method included the identification of both β-hemolytic and non-hemolytic GBS from samples by culture. Those results are shown in Table 2.

Table 2. LIM Reference Method vs. Strep B Carrot Broth™ Kit (color), plus Subculture of Presumptive Negatives to Blood Agar with Biochemical Testing

Site	TP	FP[1]	FN[2]	TN	Sensitivity	95% CI		Specificity	95% CI	
CCP	50	1	1	141	**98.0**	89.7	99.7	**99.3**	96.1	99.9
NY	43	7	0	133	**100.0**	91.8	100.0	**95.0**	90.0	97.6
CC	28	0	0	83	**100.0**	87.9	100.0	**100.0**	95.6	100.0
MCW	40	5	1	238	**97.6**	87.4	99.6	**97.9**	95.3	99.1
Overall	**161**	**13**	**2**	**595**	**98.8**	95.6	99.7	**97.9**	96.4	98.7

[1] There were thirteen False Positives observed. All isolates were re-tested and confirmed at Hardy Diagnostics using the discrepant analysis protocol described above. All isolates recovered from the Strep B Carrot Broth to Blood Agar system were confirmed to be β Group B Streptococci.

[2] There were two False Negatives observed. Both isolates were re-tested and confirmed at Hardy Diagnostics using the discrepant analysis protocol described above. Both of the β Group B Streptococci isolates recovered from LIM were confirmed as β Group B Streptococci.

RECOVERY RATE

To determine the recovery (Limit of Detection (LoD)) of Strep B Carrot Broth™, the media was challenged with two beta-hemolytic ATCC® strains of Group B Streptococci at 10-fold decreasing concentrations and evaluated for color change. The lowest concentration at which a positive reaction was seen, indicated by an orange color, was determined to be the LoD. The determined LoD was confirmed by testing Strep B Carrot Broth™ with 20 replicate dilutions of the determined LoD concentrations. Strep B Carrot Broth™ was able to recover both *S. agalactiae* ATCC® 12386 and *S. agalactiae* ATCC® 12403 at a LoD of 10^3 CFU/mL of the fluid from a flocked anovaginal swab specimen (30 CFU/tube when using a 30µL inoculum). Variable recovery was seen at lower concentrations. Blood Agar plates were used to determine the concentration of organisms present in each dilution.

ANALYTICAL REACTIVITY

Fifty-four ATCC reference and clinical Group B Streptococci strains representing seven of the nine known serotypes were recovered in Strep B Carrot Broth™ when inoculated at the limit of detection concentration of 10^3 CFU/mL. The GBS serotypes included in this study were serotypes Ia, Ib, II, III, IV, V, and VI. Four strains that were non-typable against the nine known serotypes were also included. All the beta-hemolytic strains of Group B Streptococci produced the expected orange color in Strep B Carrot Broth™. The non-hemolytic strains showed no orange color in Strep B Carrot Broth™ but were successfully recovered upon subculture to Blood Agar.

ANALYTICAL SPECIFICITY

Seventy-eight non-target organisms that are phylogenetically-related to Group B Streptococci or potentially encountered in an anovaginal swab were tested in Strep B Carrot Broth™ at a concentration of 10^8 CFU/mL. All

organisms tested are listed in Table 3 below. After 24 hours of incubation, all Carrot Broth tubes were evaluated for color reaction. In order to determine if Strep B Carrot Broth™ supported the growth of non-target organisms in the absence of a color reaction, all negative tubes were subcultured to an appropriate medium for the non-target organism. All organisms tested produced a negative color reaction in Strep B Carrot Broth™ and 48/78 (61.5%) of the organisms were recoverable when subcultured after enrichment.

Table 3. List of non-target organisms tested in Analytical Specificity

Organism		
Acinetobacter baumannii	*Enterococcus durans*	*Proteus mirabilis*
Aeromonas hydrophila	*Enterococcus faecalis*	*Providencia alcalifaciens*
Aspergillus brasiliensis	*Enterococcus faecium*	*Pseudomonas aeruginosa*
Bacillus cereus	*Enterococcus flavescens*	*Pseudomonas fluorescens*
Bacillus subtilis	*Enterococcus hirae*	*Saccharomyces cerevisiae*
Bacteroides fragilis	*Enterococcus raffinosus*	*Salmonella enterica (typhii)*
Bifidobacterium breve	*Enterococcus saccharolyticus*	*Salmonella enterica arizonae*
Campylobacter coli	*Escherichia coli*	*Serratia marcescens*
Campylobacter jejuni	*Gardnerella vaginalis*	*Shigella boydii*
Candida albicans	*Geotrichum candidum*	*Shigella flexneri*
Candida glabrata	*Hafnia alvei*	*Shigella sonnei*
Candida parapsilosis	*Klebsiella oxytoca*	*Staphyloccocus aureus*
Candida tropicalis	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Citrobacter brakkii	*Lactobacillus acidophilus*	*Staphylococcus saprophyticus*
Citrobacter freundii	*Lactobacillus gasseri*	*Stenotroph. maltophilia*
Citrobacter koseri	*Lactobacillus leichmannii*	*Streptoccocus mutans*
Clostridium difficile	*Lactococcus lactis*	*Streptococcus anginosus*
Clostridium novyi	*Legionella pneumophila*	*Streptococcus bovis*
Clostridium perfringens	*Listeria monocytogenes*	*Streptococcus dysgalactiae*
Clostridium sporogenes	*Micrococcus luteus*	*Streptococcus mitis*
Corynebacterium jekeium	*Moraxella cartarrhalis*	*Streptococcus pneumoniae*
Enterobacter aerogenes	*Morganella morganii*	*Streptococcus pyogenes*
Enterobacter cloacae	*Neisseria gonorrhoeae*	*Streptococcus salivarius*
Enterococcus casseliflavus	*Pediococcus acidilacti*	*Streptococcus uberis*
Enterococcus cecorum	*Peptostreptococcus anaerobius*	*Vibrio parahaemolyticus*
Enterococcus dispar	*Plesiomonas shigelloides*	*Yersinia enterocolitica*

MICROBIAL INTERFERENCE

Strep B Carrot Broth™ was challenged to determine if target organisms at low concentration could be recovered in the presence of non-target organisms at a high concentration. All organisms that were recovered upon subculture from Strep B Carrot Broth™ in the Analytical Specificity study were used in this Microbial Interference study. Non-target organisms at a high concentration (1.5×10^8 CFU/mL) were mixed with each target organism at the LoD and

inoculated into Strep B Carrot Broth™. If the target organism was not recovered, the concentration of the non-target organism was lowered 10-fold until the target organism was recovered.

Strep B Carrot Broth™ was able to produce the expected color reaction with target organisms and allowed the recovery of both GBS strains in the presence of high concentrations (1.5 x 10^8 CFU/mL) of all but one of the non-target organisms used in this study. The only organism found to affect recovery of Group B Streptococci was *E. faecalis* ATCC 29212. *S. agalactiae* ATCC 12386 produced the expected color reaction when the concentration of *E. faecalis* ATCC 29212 was 10^5 CFU/mL or lower. *S. agalactiae* ATCC 13813, a non-hemolytic strain, was recovered upon subculture when the concentration of *E. faecalis* ATCC 29212 was 10^6 CFU/mL or lower.

INTERFERENCE

Commonly used or encountered endogenous and exogenous substances that may be present in anovaginal swabs were evaluated for potential interference of growth or chromogenic reaction in Strep B Carrot Broth™. The substances tested are listed in the table below. No interference was observed with any substance at the highest clinically relevant concentration in the GBS-negative specimen matrix.

Interfering Substances		
Category	**Substance/Supplier**	**Concentration in Sample Matrix[1]**
Anti-diarrheal Medication	Pepto-Bismol® (Bismuth subsalicylate solution)	1% v/v
	Imodium A-D® (Loperamide HCl)	2% w/v
Body Oil	Neutrogena Body Oil	2% v/v
Body Powder	Gold Bond Body Powder	1% w/v
Contraceptive Gel	Options Gynol II® (Nonoxynol-9)	0.59% w/v
Enema Solution	Physiological saline	0.25% v/v
Lubricating Gel	K-Y® Jelly	0.57% w/v
Oral Laxative	Milk of Magnesia	1.78% v/v
	Dulcolax® (Sodium picosulfate solution)	1% w/v
Polysorbate 80	Tween®80	10% v/v
Rectal Laxative	Fleet® Glycerin Suppositories	10% v/v
Topical Hemorrhoid Ointment	Preparation-H®	0.26% w/v
Vaginal Anti-Itch Medication	Vagisil® Cream	0.41% w/v
Vaginal Anti-Fungal Medication	Monistat® (Miconazole nitrate)	0.29% w/v
	Lotrimin® (Clotrimazole)	0.29% w/v
Endogenous Substances		
Human Amniotic Fluid	Medfusion	2% v/v
Human Feces	Central Coast Pathology	2% v/v
Human Meconium	LEE Biosolutions	2% v/v
Human Urine	Central Coast Pathology	2% v/v
Human Whole Blood	In-house	2% v/v
Mucin	Sigma, M2378	0.05% w/v

[1]Specific amounts of substance added to anovaginal specimen matrix calculated using $C_1V_1=C_2V_2$ with the assumption that 1g=1mL.

INCUBATION STUDY

In order to determine a recommended incubation time range, the performance of Strep B Carrot Broth™ was evaluated using nine beta-hemolytic strains of GBS and one non-hemolytic strain of GBS at the LoD from 12 to 24

hours at 35°C. The enrichment broth was subcultured to a Tryptic Soy Agar plate with 5% sheep blood every two hours to confirm the presence of GBS. All hemolytic organisms tested produced some kind of orange color reaction by 12 hours. All organisms, including the non-hemolytic strain tested, were recovered upon subculture of Strep B Carrot Broth™ at 12 hours. The incubation range for Strep B Carrot Broth™ was set from 16-24 hours.

SPECIMEN STABILITY

Various types of specimen transport swabs were evaluated to determine the acceptable storage conditions required to recover GBS from Strep B Carrot Broth™. Swabs were spiked with Group B Streptococci and a contrived matrix consisting of organisms commonly found in vaginal flora, kept at both room temperature and refrigerated conditions, and were inoculated to Carrot Broth at 0, 24, 48, 72, 96, and 120 hours. Eight different GBS strains were used in this study and were spiked into the contrived matrix near LoD. The contrived matrix containing non-target organisms consisted of *E. faecalis*, *E. coli*, *C. albicans*, and *L. acidophilus*. TransPRO™ swabs with Liquid Amies (flocked swab liquid-based transport system) and four types of Healthlink transport systems: Sponge-based Liquid Amies and Liquid Stuart's, and Gel-based: Amies Gel and Stuart's Gel were used in this study.

Strep B Carrot Broth™ was able to recover 8/8 (100%) of GBS strains and produce orange coloration from Healthlink swabs in Liquid Amies, Stuart's liquid, Amies Gel, and Stuart's Gel when stored at 2-8°C for up to 96 hours. 100% of GBS strains also produced the expected orange color reaction from the flocked swab TransPRO™ Liquid Amies stored at 2-8°C for up to 120 hours. All transport systems tested saw a decline in recovery of GBS after 24 hours of room temperature storage.

REPRODUCIBILITY

Prior to initiating the study, a panel of 12 blinded isolates provided by Hardy Diagnostics was tested at three distinct study sites in triplicate on five work days to demonstrate reproducibility and to document proficiency in the performance of the test. Agreement of >95% with known test results was required before proceeding with the study. The testing was done with at least one operator and two readers, blinded to each other's results, per site. Strains in the reproducibility panel produced the expected color results with Strep B Carrot Broth™ $\geq$ 95% of the time at 24 hours. All non-hemolytic GBS isolates tested (100%) were recovered upon subculture to TSA with 5% Sheep's Blood.

CONCLUSIONS

The clinical and performance studies summarized above demonstrate the substantial equivalence of Strep B Carrot Broth™ Kit to the predicate device.