March 22, 2018

Hardy Diagnostics
Rianna Malherbe
Performance Studies Coordinator
1430 West McCoy Lane
Santa Maria, California 93455

Re: K173903
Trade/Device Name: Granada Medium
Regulation Number: 21 CFR 866.2360
Regulation Name: Selective culture medium
Regulatory Class: Class I
Product Code: PQZ
Dated: December 21, 2017
Received: December 26, 2017

Dear Rianna 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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K l 73903

Device Name
Granada Medium

Indications for Use *(Describe)*
Granada Medium is a selective and differential agar which is intended for the qualitative detection of Group B Streptococcus (GBS) from LIM Broth enrichment cultures of vaginal/rectal swabs from antepartum women following 18-24 hours of incubation.

Recovery of orange colored colonies on Granada Medium is a positive result for presence of β-hemolytic GBS. Results can be interpreted after18-24 hours of anaerobic incubation. Due to the properties of Granada Medium, white colonies recovered on Granada Medium must undergo additional testing to confirm absence of GBS. Subculture of GBS colonies must be performed for conducting susceptibility testing as recommended for penicillin- allergic women. A lack of growth or the absence of orange colonies on Granada Medium does not preclude the presence of GBS. Granada Medium is not intended to diagnose infection, or to guide or monitor treatment for infections.

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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510(k) Summary

I. SUBMITTER

Rianna Malherbe
Performance Studies Coordinator
Hardy Diagnostics
1430 W. McCoy Lane
Santa Maria, Ca. 93455
Phone: 805-346-2766 x5714
E-mail: MalherbeR@hardydiagnostics.com

II. DEVICE

Name of Device: Granada Medium
Classification Name: 21 CFR 866.2360
Selective Culture Medium
Regulatory Class: I
Product Code: PQZ

III. PREDICATE DEVICE

chromID Strepto B Agar, K163042

IV. DEVICE DESCRIPTION

Currently, Group B Streptococci (GBS) remains the primary cause of early-onset neonatal sepsis in the United States. Infection of the newborn baby is typically preceded by previous colonization of GBS in the maternal genitourinary or gastrointestinal tract. The Centers for Disease Control and Prevention (CDC), in their 11/19/2010 MMWR "Guidelines for the Prevention of Perinatal Group B Streptococcal Disease", recommends the screening of all pregnant women for vaginal and rectal GBS colonization between 35 and 37 weeks of gestation, using an enrichment broth, followed by additional testing to identify GBS.

Hardy Diagnostics Granada Medium agar utilizes the Granada reaction and contains the necessary components for pigment detection of beta-hemolytic GBS. The production of a light orange to dark orange pigmented colony is a unique characteristic of hemolytic GBS on Granada Medium due to a reaction with substrates such as starch, peptone, serum, and folate pathway inhibitors. Since the original description of starch serum agar by Islam in 1977, there have been many improvements to the original formula. GBS detection (orange colonies) with Granada Medium is only possible with beta-hemolytic GBS, which also provides evidence of a direct genetic linkage between pigment production on Granada Medium and hemolysin production. Beta-hemolytic, pigment producing GBS occurs with 95.3 to 99.5% of all GBS strains isolated from clinical specimens (Young, et. al. Korean J. Clin. Path, 1998; Merrit and Jacobs, J. Clin. Microbiol, 1978; Noble, Bent and West, J. Clin. Path. 1983).

V. INTENDED USE/INDICATIONS FOR USE

Granada Medium is a selective and differential agar which is intended for the qualitative detection of Group B Streptococcus (GBS) from LIM Broth enrichment cultures of vaginal/rectal swabs from antepartum women following 18-24 hours of incubation.

Recovery of orange colored colonies on Granada Medium is a positive result for presence of β-hemolytic GBS. Results can be interpreted after18-24 hours of anaerobic incubation. Due to the properties of Granada Medium, white colonies recovered on Granada Medium must undergo additional testing to confirm absence of GBS. Subculture of GBS colonies must be performed for conducting susceptibility testing as recommended for penicillin allergic women. A lack of growth or the absence of orange colonies on Granada Medium does not preclude the presence of GBS. Granada Medium is not intended to diagnose infection, or to guide or monitor treatment for infections.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attribute	Device	Comparator	Substantially Equivalent?
Name	Granada Medium	chromID Strepto B Agar	
510(k) Details	510(k) number K173903 Product Code PQZ 21 CFR 866.2360 GBS culture media, selective and differential Class I Panel 83 Microbiology	510(k) number K163042 Product Code PQZ 21 CFR 866.2360 GBS culture media, selective and differential Class I Panel 83 Microbiology	Yes
Intended Use	Granada Medium is a selective and differential agar which is intended for the qualitative detection of Group B Streptococcus (GBS) from LIM Broth enrichment cultures of vaginal/rectal swabs from antepartum women following 18-24 hours of incubation. Recovery of orange colored colonies on Granada Medium is a positive result for presence of β-hemolytic GBS. Results can be interpreted after18-24 hours of anaerobic incubation. Due to the properties of Granada Medium, white colonies recovered on Granada Medium must undergo additional testing to confirm absence of GBS. Subculture of GBS colonies must be performed for conducting susceptibility testing as recommended for penicillin allergic women. A lack of growth or the absence of orange colonies on Granada Medium does not preclude the presence of GBS. Granada Medium is not intended to diagnose infection, or to guide or monitor treatment for infections.	chromID® Strepto B agar is a selective chromogenic medium that is intended to aid in the qualitative determination of Group B Streptococcus (GBS) colonization in pregnant women. This medium supports the growth of, but does not differentiate between, hemolytic and non-hemolytic GBS strains. The test is performed on 18-24 hour LIM broth enrichments of vaginal/rectal swabs obtained from pregnant women. chromID® Strepto B agar results can be interpreted after 24 hours incubation with confirmation of characteristic GBS colonies from the media. chromID® Strepto B agar is not intended to diagnose infection nor to guide or monitor treatment for infections. chromID® Strepto B agar does not provide susceptibility results. Subculture to non-selective media should be performed as needed for susceptibility testing. chromID® Strepto B agar is intended for use by laboratory health practitioners in a clinical laboratory.	Yes
Methodology	Selective, Chromogenic	Selective, Chromogenic	Yes
Inoculation	LIM Broth Enrichment of Vaginal/Rectal Swabs	LIM Broth Enrichment of Vaginal/Rectal Swabs	Yes
Interpretation	Manual, Visual	Manual, Visual	Yes

VII. PERFORMANCE DATA

The performance of Granada Medium was evaluated at four geographically diverse hospitals with routine GBS specimen in the form of vaginal/rectal swabs. In Table 1, the detection of Group B Streptococci (β-hemolytic GBS and non-hemolytic GBS) by the reference method was compared to the recovery of orange colonies on Granada Medium. In Table 2, the detection of β-hemolytic GBS by the reference method was compared to the recovery of orange colonies on Granada Medium. The reference method was defined as the selective enrichment of specimen in LIM Broth followed by subculture to blood agar. Organisms that grew on Granada Medium or blood agar were confirmed to be Group B Streptococci by looking at hemolytic reaction on blood agar, gram-stain, catalase test, and StrepPRO™ latex agglutination. For the clinical study, vaginal/rectal swab specimens were collected in ESwab™ Liquid Amies, sponge based Liquid Amies and Sponge based Stuart's liquid.

All discrepant isolates were frozen in CryoSavers™ with Brucella Broth and returned to Hardy Diagnostics for testing. As part of discrepant analysis, the identity of each isolate was confirmed (β Group B Streptococci, non-hemolytic (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 $1.5x10^2$ CFU/mL in donated negative-vaginal/rectal matrix (equivalent to an inoculum of 4.5 CFU (1 - 9 CFU tested) and evaluated for their recovery from LIM Broth reference method and color development on Granada Medium.

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 154 specimens showed orange color development on Granada Medium after 18-24 hours of incubation at 35°C that were positive for Group B Streptococci by the LIM reference method. Results are shown in Table 1.

Table 1. LIM Reference Method vs. Granada Medium Color reaction

Site	TP	FP[1]	FN[2]	TN	Sensitivity	95% CI		Specificity	95% CI	
1	46	1	5	141	**90.2**	79.0	95.7	**99.3**	96.1	99.9
2	41	7	2	133	**95.3**	84.5	98.7	**95.0**	90.0	97.6
3	27	1	1	82	**96.4**	82.3	99.4	**98.8**	93.5	99.8
4	40	3	1	240	**97.6**	87.4	99.6	**98.8**	96.4	99.6
Overall	**154**	**12**	**9**	**596**	**94.5**	**89.8**	**97.1**	**98.0**	**96.6**	**98.9**

[1]There were 12 False Positives observed after 18 to 24 hours of incubation. All isolates were re-tested and confirmed by the discrepant analysis protocol above. Ten isolates recovered from Granada Medium were confirmed to be β-Group B Streptococci. Two isolates were recorded as pale orange on Granada Medium, but were not identified as Group B Strep. During discrepant analysis, both isolates were confirmed to be *Streptococcus salivarius* subsp. *salivarius*. One *Streptococcus salivarius* subs. *salivarious* isolate exhibited yellow colonies on Granada Medium and the other isolate grew as pale orange colonies.

[2]There were 9 False Negatives observed after 18 to 24 hours of incubation. All isolates were re-tested and confirmed by the discrepant analysis protocol above. Of these nine GBS isolates recovered by the reference method, three were β-hemolytic and six were non-hemolytic. For the β GBS isolates identified by the reference method and evaluated by discordant analysis, all three isolates grew as orange colonies on Granada Medium where originally the colony color was white. Samples where the six NH Group B Streptococci were identified by the reference method showed white colonies on Granada Medium as expected (no discordant analysis was performed for these isolates).

Because NH GBS cannot be detected by colony color, the performance of Granada Medium (orange color development) was compared to the recovery of only β-hemolytic GBS by the reference method. In Table 2, the overall sensitivity value increased to 98.1% (95% CI: 94.5-99.3%) while the overall specificity value, at 97.9% (95% CI: 96.4-98.8%), did not significantly change.

Table 2. LIM Reference Method (beta hemolytic Group B *Streptococcus*) vs. Granada Medium Color reaction

Site	TP	FP[1]	FN[2]	TN	Sensitivity	95% CI		Specificity	95% CI	
1	45	2	2	144	**95.7**	85.8	98.8	**98.6**	95.1	99.6
2	41	7	0	135	**100.0**	91.4	100.0	**95.1**	90.2	97.6
3	27	1	1	82	**96.4**	82.3	99.4	**98.8**	93.5	99.8
4	40	3	0	241	**100.0**	91.2	100.0	**98.8**	96.4	99.6
Overall	**153**	**13**	**3**	**602**	**98.1**	**94.5**	**99.3**	**97.9**	**96.4**	**98.8**

[1]12 of the 13 False Positives are identical to the False Positives listed in Table 1. The additional False Positive was originally recorded as non-hemolytic Group B Strep on blood agar and orange on Granada Medium. During discrepant analysis, the isolate was later confirmed as beta-hemolytic on blood agar.

[2]The 3 False Negatives are the 3 β-hemolytic GBS described in Table 1.

RECOVERY RATE

To determine the recovery [Limit of Detection (LoD)] of Granada Medium, the media was challenged with two beta-hemolytic ATCC® strains of Group B Streptococci at 10-fold decreasing concentrations and evaluated for color reaction. The lowest concentration at which a positive reaction was seen, indicated by orange colonies, was determined to be the LoD. The LoD was confirmed by testing Granada Medium with five replicate dilutions of the determined LoD concentration. Granada Medium, by direct inoculation, was able to recover both *S. agalactiae* ATCC® 12386 and *S. agalactiae* ATCC® 12403 at a LoD of $1.5x10^2$ CFU/mL, or 15 CFU (3-30 CFU) inoculated directly to Granada Medium. Blood agar plates were used to determine the concentrations of organisms present in each dilution.

To evaluate the performance of Granada Medium with a sample of overnight enriched culture, LIM Broth was challenged with two beta-hemolytic ATCC® strains of Group B Streptococci at 10-fold decreasing concentrations in GBS-negative specimen matrix. After overnight enrichment, LIM Broth culture was subcultured to Granada Medium and evaluated for color reaction. The lowest GBS concentration (previously spiked in LIM Broth and incubated overnight) yielding expected results on Granada Medium was then confirmed with five replicate dilutions of the lowest concentration. Following overnight enrichment in LIM Broth, Granada Medium was able to recover both *S. agalactiae* ATCC® 12386 and *S. agalactiae* ATCC® 12403 from a flocked vaginal/rectal swab specimen with $1.5x10^2$ CFU/mL, corresponding to an inoculum of 4.5 CFU (1 - 9 CFU). Blood agar plates were used to determine the concentrations of organisms present in each dilution.

ANALYTICAL REACTIVITY

Fifty-four selected ATCC, NCIMB, NCTC reference and clinical GBS strains representing seven of the nine different serotypes were directly inoculated to Granada Medium at the determined LoD of $1.5x10^2$ CFU/mL that corresponded to an inoculum of 15 CFU (3-30 CFU). Granada Medium was able to recover all GBS strains tested at the LoD with the expected color development. The GBS serotypes included in this study were serotypes Ia, Ib, II, III, IV, V, and VI. Serotypes VII and VIII are rare and were not available for testing. Four strains that were non-typable against the nine known serotypes were also included. Of the 54 GBS strains tested, 48 were beta-hemolytic strains (88.9%) and six were non-hemolytic strains (11.1%). All beta-hemolytic GBS strains produced the expected orange colony color reaction and all non-hemolytic GBS strains produced the expected white colony color reaction on Granada Medium after 24 hours of incubation.

ANALYTICAL SPECIFICITY

Eighty-four organisms that are phylogenetically-related to Group B Streptococci or potentially encountered in a vaginal-rectal swab were tested on Granada Medium following overnight enrichment in LIM Broth. A $1.5x10^8$ CFU/mL suspension of each organism was inoculated to a LIM Broth tube, corresponding to an inoculum of $1.5x10^6$ CFU. After incubation, each LIM broth tube was subcultured to a Granada Medium plate and evaluated for growth and color reaction after 24 hours of anaerobic incubation. Organisms tested either produced a negative color reaction (39/84, 46.4%) or were not recovered (45/84, 53.6%) on Granada Medium after LIM Broth enrichment.

Non-target Organisms Tested in Analytical Specificity		
Acinetobacter baumannii	*Enterococcus hirae*	*Providencia alcalifaciens*
Aeromonas hydrophila	*Enterococcus malordoratus*	*Pseudomonas aeruginosa*
Bacillus cereus	*Enterococcus mundtii*	*Pseudomonas fluorescens*
Bacillus subtilis	*Enterococcus pseudoavium*	*Salmonella enterica (typhii)*
Bacteroides fragilis	*Enterococcus raffinosus*	*Salmonella enterica arizonae*
Bifidobacterium breve	*Enterococcus saccharolyticus*	*Serratia marcescens*
Campylobacter jejuni	*Enterococcus sulfureus*	*Shigella boydii*
Candida albicans	*Escherichia coli*	*Shigella flexneri*
Candida glabrata	*Gardnerella vaginalis*	*Shigella sonnei*
Candida parapsilosis	*Geotrichum candidum*	*Staphyloccocus aureus*
Candida tropicalis	*Klebsiella oxytoca*	*Staphylococcus epidermidis*
Citrobacter freundii	*Klebsiella pneumoniae*	*Staphylococcus saprophyticus*
Clostridium difficile	*Lactobacillus acidophilus*	*Stenotrophomonas maltophilia*
Clostridium novyi	*Lactobacillus fermentum*	*Streptococcus anginosus*
Clostridium perfringens	*Lactobacillus gasseri*	*Streptococcus bovis*
Clostridium sporogenes	*Lactobacillus leichmannii*	*Streptococcus dysgalactiae*
Enterobacter aerogenes	*Lactococcus lactis*	*Streptococcus equi subsp. zooepidemicus*
Enterobacter cloacae	*Leuconostoc mesenteroides*	*Streptococcus gallolyticus*
Enterococcus avium	*Listeria monocytogenes*	*Streptococcus mitis*
Enterococcus casseliflavus	*Moraxella cartarrhalis*	*Streptococcus mutans*
Enterococcus cecorum	*Morganella morganii*	*Streptococcus pneumoniae*
Enterococcus columbae	*Neisseria gonorrhoeae*	*Streptococcus pyogenes*
Enterococcus dispar	*Pediococcus acidilacti*	*Streptococcus salivarius subsp. salivarius*
Enterococcus durans	*Pediococcus damnosus*	*Streptococcus salivarius subsp. thermophilus*
Enterococcus faecalis	*Peptostreptococcus anaerobius*	*Streptococcus uberis*
Enterococcus faecium	*Plesiomonas shigelloides*	*Vibrio parahaemolyticus*
Enterococcus flavescens	*Proteus mirabilis*	*Yersinia enterocolitica*
Enterococcus gallinarum		

MICROBIAL INTERFERENCE

Granada Medium was challenged to determine if target organism at low concentration could be recovered in the presence of non-target organisms at a high concentration. All organisms that were recovered on Granada Medium in the Analytical Specificity study were tested in the Microbial Interference study. Non-target organisms at a high concentration ($1.5x10^8$ CFU/mL) were mixed 1:1 with each target organism ($1.5x10^4$ CFU/mL) and inoculated directly to Granada Medium with a 10µL loop. If the target organism was not recovered on Granada Medium, the concentration of the non-target organism was lowered 10-fold until the target organism was recovered.

Granada Medium was able to produce the expected orange color reaction and recover target organisms when in the presence of high concentrations of all but one of the non-target organisms used in this study. The only organism found to affect recovery of GBS was *Enterococcus faecalis* (ATCC 29212). At $1.5x10^8$ CFU/mL, this organism inhibited recovery of GBS on Granada Medium; however when reduced to $1.5x10^6$ CFU/mL, target GBS was recovered.

Several organisms did not affect recovery, but did affect colony size of target organisms when inoculated to Granada Medium at $1.5x10^8$ CFU/mL: *E. faecalis* (ATCC 51299), *E. avium* (ATCC 14025), *E. gallinarum* (ATCC 49573), *E. saccharolyticus* (ATCC 43076), *Lactococcus lactis* (ATCC 19435), *Morganella Morganii* (ATCC 25830), *Proteus mirabilis* (ATCC 43071), and *Serratia marcescens* (ATCC 13880). However, when these non-target organisms were reduced to $1.5x10^7$ CFU/mL, GBS colony size was larger and more clearly visible on Granada Medium. Colony size and color, but not recovery, of GBS was affected by *Vibrio parahaemolyticus* (ATCC 17802) when present at a high concentration ($1.5x10^8$ CFU/mL). When *V. parahaemolyticus* concentration was reduced to $1.5x10^7$ CFU/mL, the colony morphology of target GBS was as expected.

INTERFERENCE

Commonly used or encountered endogenous and exogenous substances that may be present in vaginal/rectal specimens were evaluated for potential interference of growth or color reaction on Granada Medium. 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 vaginal/rectal 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, Granada Medium was evaluated using nine beta-hemolytic strains of GBS by direct inoculation from a $1.5x10^2$ CFU/mL suspension, corresponding to an inoculum of 15 CFU (3-30 CFU). Growth and color reaction were recorded every 2 hours from 18 to 24 hours. All organisms tested grew with visible orange colonies by 18 hours. The incubation range for Granada Medium was set from 18-24 hours.

SPECIMEN STABILITY

Various types of specimen transport swabs were evaluated to determine the storage conditions that allowed for recovery of GBS on Granada Medium after LIM Broth enrichment. Swabs were spiked with beta-hemolytic Group B Streptococci strains in vaginal/rectal matrix and were kept under both room temperature and refrigerated conditions. The swabs were inoculated to LIM Broth at 0, 24, 48, 72, 96, and 120 hours. TransPRO™ swabs with Liquid Amies (liquid-based transport system) and five types of Healthlink swabs were used in this study: Liquid Amies, Amies Gel, Liquid Stuart's, Stuart's Gel, and Amies Charcoal. After an overnight incubation at 35°C, LIM Broth cultures were subcultured to Granada Medium.

Granada Medium was able to recover 2/2 (100%) of GBS strains after LIM Broth enrichment from TransPRO™ Liquid Amies and Healthlink swabs in Liquid Amies, Amies Gel, Liquid Stuart's, Stuart's Gel, and Amies Charcoal when stored at room temperature up to 24 hours and at 2-8°C for up to 120 hours. GBS was recovered from Granada Medium for all time points and storage conditions tested.

REPRODUCIBILITY

Prior to initiating the study, a panel of 22 blinded isolates (set of 11 organisms tested in duplicate) provided by Hardy Diagnostics was tested at three distinct study sites 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 Granada Medium $\geq$ 95% of the time after 24 hours. All beta-hemolytic GBS isolates tested (100%) were recovered by Granada Medium with the expected orange color reaction for isolated colonies on all days of the reproducibility study.

CONCLUSIONS

The clinical and analytical data summarized above demonstrate that Granada Medium is substantially equivalent to the predicate device.