

SEP 24 1998

K974572

10. 510(k) Summary

A. Name and Address of Submitter

Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121

Telephone: 619-410-8749

FAX: 619-410-8622

Contact Person: Gerald H. Schell, Director, Regulatory Affairs

Date 510(k) Summary was prepared: December 4, 1997

B. Device Names

Proprietary Name: Gen-Probe ACCUPROBE Group B Streptococcus Culture Identification Test

Common Name: cDNA probe test for the identification of Group B Streptococcus from culture

Classification Name: DNA-Probe, Reagents, Streptococcal

C. Legally Marketed Device

The ACCUPROBE Group B Streptococcus Culture Identification Test has been determined to be substantially equivalent to other commercially available products for the identification of Group B Streptococcus isolated from culture that were in commercial distribution prior to May 28, 1976.

D. Device Description

The ACCUPROBE Group B Streptococcus Culture Identification Test is a rapid DNA probe test which is based on the detection of ribosomal RNA sequences that are unique to *Streptococcus agalactiae*. Nucleic acid hybridization tests are based on the ability of complementary nucleic acid strands to specifically align and associate to form stable double-stranded complexes. The ACCUPROBE test uses a single-stranded DNA probe with a chemiluminescent label that is complementary to the ribosomal RNA of the target organism. After the ribosomal RNA is released from the organism, the labeled DNA probe combines with the target organism's ribosomal RNA to form a double-stranded DNA:RNA hybrid. The Selection reagent allows for the differentiation of non-hybridized and

hybridized probe. The labeled DNA:RNA hybrids are measured in the Gen-Probe luminometer. A positive result is a luminometer reading equal to or greater than the cut-off. A value below this result is a negative result.

E. Intended Use

As stated in the Package Insert, the ACCUPROBE Group B Streptococcus Culture Identification Test is a rapid DNA probe test which utilizes the technique of nucleic acid hybridization for the identification of Group B Streptococcus isolated from culture.

F. Comparison with Predicate Device

The ACCUPROBE Group B Streptococcus Culture Identification Test has been determined to be substantially equivalent to other commercially available products for the identification of Group B Streptococcus isolated from culture that were in commercial distribution prior to May 28, 1976 (reference: K894711/A, cleared for commercial distribution on November 14, 1989).

The purpose of this 510(k) Premarket Notification is to add a new indication for use for this product. The test kit reagents and procedures for hybridization, selection, detection, and interpretation of results, as well as the test specificity and recovery claims, remain unchanged. The product labeling has been modified to include the new indication for use in prenatal screening, appropriate instructions for collection and handling the vaginal and/or anorectal swab specimens, additional materials required to collect and culture the specimens, expected values, performance characteristics, clarification of current text, and an addition to the bibliography.

G. Performance Data

Non-Clinical Studies

Precision

The within run and between-run precision of the ACCUPROBE Group B Streptococcus test using mixtures of ribosomal RNA to mimic vaginal and anorectal swabs.

Within run precision was calculated by assaying a mixture of ribosomal RNA isolated from *Streptococcus agalactiae*, *Staphylococcus epidermidis*, *Escherichia coli*, and *Neisseria gonorrhoeae*, using 10 replicates in a single assay, with the following results:

Number of replicates	10
Mean Response	77,612
Standard Deviation	2,767
Coefficient of Variation	3.6%

Between-run precision was calculated by assaying the same mixture culture of ribosomal RNA using single determinations in 12 consecutive assays, with the following results:

Number of Replicates	12
Mean Response	78,676
Standard Deviation	2,966
Coefficient of Variation	3.8%

Clinical Studies

Sensitivity and Specificity

The diagnostic sensitivity and specificity of the ACCUPROBE Group B Streptococcus test as compared to the traditional culture methods are presented below, for each individual clinical site and for all sites combined.

**ACCUPROBE/CULTURE IDENTIFICATION
(CULTURED VAGINAL AND/OR ANORECTAL SWAB SPECIMENS)**

Results of Initial Determination:

ACCUPROBE Culture	Pos Pos	Pos Neg	Neg Pos	Neg Neg	Sensitivity/ Specificity	Percent Agreement
Site 1	84	7	6	401	93.3%/98.3%	97.4%
Site 2	26	0	1	151	96.3%/100%	99.4%
Site 3	81	6	16	315	83.5%/98.1%	94.7%
Site 4	109	5	2	423	98.2%/98.8%	98.7%
Total	300	18	25	1290	92.3%/98.6%	97.4%

ACCUPROBE assays with discrepant results were repeated, and culture was either repeated from the swab pledget or re-examined to determine whether correct identification of Group B colonies had been made. The results following resolution of the discrepant results are presented below.

Results Following Resolution of Discrepant:

ACCUPROBE Culture	Pos Pos	Pos Neg	Neg Pos	Neg Neg	Sensitivity/ Specificity	Percent Agreement
Site 1	90	2	2	405	97.8%/99.8%	99.2%
Site 2	26	0	1	151	96.3%/100%	99.4%
Site 3	86	1	3	328	96.6%/99.7%	99.0%
Site 4	114	0	2	423	98.3%/100%	99.6%
Total	316	2	8	1307	97.5/99.8%	99.4%

Conventional methods included culture on sheep blood agar and Lim broth (Todd-Hewitt with nalidixic acid and colistin) for 18 to 24 hours, followed by subculture from the Lim broth to another sheep blood agar plate. Colony identification methods included the CAMP test, the PathoDx test (Diagnostic Products Corp., Los Angeles, CA), and the ACCUPROBE Group B Streptococcus test.

The clinical protocol was developed to immerse swabs in Lim broth for at least one minute, and then express against the side of the tube. The tube was then vortexed, incubated at 35° to 37°C for 18 to 24 hours, and vortexed prior to use. The ACCUPROBE Group B Streptococcus test procedure was then performed exactly as recommended in the current Package Insert, using a 50 µl aliquot of the resulting broth culture. The results were interpreted according to the Package Insert recommendations.



SEP 24 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Rhonda A. Moe
Regulatory Affairs Specialist
Gen-Probe Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362

Re: K974572
Trade Name: Gen-Probe® Accuprobe Group B Streptococcus Culture
Identification Test
Regulatory Class: I
Product Code: MDK
Dated: August 14, 1998
Received: August 17, 1998

Dear Ms. Moe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

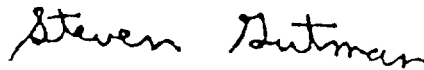
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K974572

Device Name: Gen-Probe AccuProbe Group B Streptococcus
Culture Identification Test

Indications For Use:

The AccuProbe Group B Streptococcus Culture Identification Test is a rapid DNA probe test which utilizes the technique of nucleic acid hybridization for the identification of Group B Streptococcus isolated from culture.

The new indication for use covered in this 510(k) is for culture identification of Group B Streptococcus from vaginal and/or anorectal swab specimens collected from pregnant women at 35 to 37 weeks gestation, and cultured in Lim broth for 18 to 24 hours.

(PLEASE DO NOT WRITE BELOW THIS LINE -
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K974572

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)