K971512

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN - 8 1998

SUBMITTED BY: BECTON DICKINSON MICROBIOLOGY SYSTEMS
7 LOVETON CIRCLE
SPARKS, MD 21152

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PREPARED: December 23, 1997

DEVICE NAME: BACTEC MYCO/F LYTIC BLOOD CULTURE MEDIUM

DEVICE CLASSIFICATION: Monitor, Microbial Growth, Class I

PREDICATE DEVICE: BACTEC 13A MYCOBACTERIA CULTURE MEDIUM

INTENDED USE: BACTEC MYCO/F LYTIC when used with the BACTEC 9000MB instrument is a non-selelctive culture medium for the qualitative culture and recovery of mycobacteria from blood specimens.

DEVICE DESCRIPTION:

BACTEC MYCO/F LYTIC blood culture medium is a non-selective growth medium intended for the culture and recovery of mycobacteria and designed for blood volumes of one to five mL. BACTEC MYCO/F LYTIC culture medium is a Middlebrook 7H9 and Brain Heart Infusion broth formulation with specific formulation modifications made to enhance the growth of mycobacteria. It is used specifically with the BACTEC 9000MB instrument in the monitoring of clinical blood specimens for the presence of microorganisms. This medium contains the same fluorescence senor as the BACTEC MYCO/F Sputa culture medium and detection is based on changes in oxygen concentration in the vial resulting from metabolism and growth of microorganisms. The sensor is monitored by the BACTEC 9000MB System for increasing fluorescence which is proportinal to the decrease in oxygen. A positive determination indicates the presumptive presence of viable microorganisms in the vial.

SUBSTANTIAL EQUIVALENCE:

Table 1 summarizes the similarities and differences between the BACTEC MYCO/F LYTIC Culture medium and the BACTEC 13A Mycobacteria culture medium.

INTERNAL PERFORMANCE:

A study was conducted to evaluate the recovery and time to detection of a variety of mycobacteria species at different CFU levels with the BACTEC MYCO/F LYTIC Culture medium. The following isolates were detected as positive in the BACTEC 9000MB instrument using BACTEC MYCO/F Lytic medium: *M. tuberculosis, M. kansasii, M. fortuitum, M. avium, M. intracellulare, M bovis, M. terrae, M. simiae, M gordonae, M. celatum, M. abscessus, M. malmoense.* During internal studies, *M. xenopi* and *M. szulgai* exhibited unsatisfactory recovery with BACTEC MYCO/F LYTIC culture medium. TABLE 2 describes the results of this study.

CLINICAL PERFORMANCE:

The BACTEC MYCO/F Lytic culture medium was evaluated with the BACTEC 9000MB instrument at two clinical sites considered large tertiary care teaching hospitals in geographically diverse areas. The site populations included patients suspected of a mycobacterial infection, immunocompromised patients and transplant patients. The BACTEC MYCO/F Lytic culture medium was compared to the BACTEC 13A culture medium for the recovery and detection of mycobacteria from blood specimens. A total of 284 blood specimens were tested during the study. The total number of pathogenic mycobacterial isolates recovered in the study was 39 (See TABLE 1). Of these positives, five (13%) were recovered in the BACTEC MYCO/F Lytic culture medium only and two (5%) were recovered by BACTEC 13A culture medium only. A total of 28 BACTEC MYCO/F LYTIC vials were over filled with specimen (between 6 to 20 mL) during the clinical evaluation and were not included in this study since they were above the maximum fill volume. Of these 28 BACTEC MYCO/F LYTIC vials, 16 (57%) were identified as false positive.

Of the 284 blood specimens tested in the clinical study, one BACTEC MYCO/F LYTIC vial (0.4%) was determined to be false positive (instrument-positive, smear and/or subculture-negative). Of the 38 instrument positive MYCO/F LYTIC vials, 1 (2.6%) was determined to be false positive. The false negative rate (instrument-negative, smear and/or subculture-positive) was determined to be 0% based on terminal subcultures of 50% of negative vials. The contamination rate during this evaluation was determination to be 0.9%.

TABLE 1: SUMMARY OF MYCO/F LYTIC CULTURE MEDIUM ISOLATE RECOVERY DURING CLINICAL TRIALS

Organism	Total Isolates	Myco/F Lytic Medium Only	13A Medium Only	Both
All Pathogenic Mycobacteria:				
Mycobacterium avium	30	3	1	26
Mycobacterium tuberculosis	6	0	0	6
Mycobacterium kansasii	3	2	1	0
Total	**39**	**5**	**2**	**32**

Table 1. Substantial Equivalence of BACTEC MYCO/F LYTIC Culture Medium to BACTEC 13A

	BACTEC MYCO/F LYTIC	BACTEC 13A
Intended Use	Qualitative culture and recovery of mycobacteria	Qualitative culture and recovery of mycobacteria
Sample Type	Blood, unprocessed and other steile body fluids	Blood, unprocessed
Sample Volume	1 - 5 mL	1 - 5 mL
Blood to Broth Ratio	1 to 8	1 to 6
Growth Medium	Modified Middlebrook 7H9 and enriched brain heart infusion broth	Modified Middlebrook 7H9 broth
Reactive ingredients:		
• Process water	40mL	30mL
•Brain heart infusion	0.5%w/v	----
• Soybean-Casein Digest	0.10%w/v	----
• 7H9 Broth Base	0.12%w/v	0.47%w/v
• Inositol	0.05%w/v	----
• Casein Hydrolysate	0.10%w/v	0.10%w/v
• Ferric Ammonium Citrate	0.006%w/v	----
• Glycerol	0.10%w/v	----
•Sodium Polysulfonate(SPS)	0.025%w/v	0.025%w/v
•Tween 80(Polysorbate)	0.0025%w/v	0.02%w/v
•Saponin	0.24%w/v	----
• L-Asparagine[1]	0.10%w/v	----
• Catalase	----	1440 units
• Antifoam Agent	0.01%w/v	----
• Hemin	----	-----
• ^{14}C Substrate	----	5μCi
• Potassium Phosphate	0.024%w/v	----
• Pyridoxal HCL	0.0001%w/v	----
• Ammonium Sulfate	----	----
Supplement	None	BACTEC Enrichment
Instrument	BACTEC 9000MB	BACTEC 460TB
Growth Detection	O_2 metabolism	Palmitate Decarboxylation
Incubation T°/mixing	37°C ± 1.5°C; internal instrument agitation every 10 minutes	37° C ± 1.5°C; no agitation by instrument
Type of Monitoring	Non-invasive, fluorescent detection	Invasive vial headspace sampling
Antimicrobial Supplement	None	None

([1]noted as Supplement H)

Table 2

Detection of Mycobacteria in the Myco/F Lytic Medium.

			BACTEC 9000MB		
	strain	cfu/bottle	1 mL blood	3 mL blood	5 mL blood
M. tuberculosis	582	0, 0	20.7	18.7	17.3
Replicate			25.0	neg	neg
Average			22.9	18.7	17.3
M. avium	2638	49, 45	7.8	8.1	8.1
Replicate			8.1	8.1	8.1
Average			8.0	8.1	8.1
M. intracellulare	2792	80, 44	25.8	16.7	10.5
Replicate			24.3	22.5	15.0
Average			25.0	19.6	12.8
M. fortuitum	3072	5, 0	9.1	5.6	5.0
Replicate			6.8	6.0	5.2
Average			8.0	5.8	5.1
M. bovis	2003	12, 13	24.4	20.0	20.0
Replicate			24.7	21.0	20.4
Average			24.5	20.5	20.2
M. kansasii	2205	7,3	12.3	14.3	14.3
Replicate			13.0	13.3	neg
Average			12.7	13.8	14.3
M. terrae	3001	0, 0	15.3	11.6	16.6
Replicate			17.0	32.4	neg
Average			16.2	22.0	16.6
M. szulgai	2353	1,2	15.7	neg	neg
Replicate			neg	22.7	neg
Average			15.7	22.7	neg
M. simiae	2304	68, 58	7.2	7.4	7.7
Replicate			7.2	7.5	7.4
Average			7.2	7.5	7.6
M. gordonae	2454	2, 5	26.4	28.7	neg
Replicate			24.0	32.0	neg
Average			25.2	30.4	neg
M. celatum	3661	53, 31	18.3	12.0	12.3
Replicate			18.3	15.0	12.3
Average			18.3	13.5	12.3
M. abscessus	3370	1, 0	4.9	4.4	3.9
Replicate			9.3	4.3	neg
Average			7.1	4.4	3.9
M. malmoense	3472	16, 20	30.0	21.5	10.8
Replicate			32.0	21.1	18.6
Average			31.0	21.3	14.7
M. haemophilum	5121	1, 1	36.1	23.0	18.4
Replicate			39.3	23.4	24.4
Average			37.7	23.2	21.4
M. xenopi	3052	0, 0	neg	neg	neg
Replicate			neg	neg	neg
Average			neg	neg	neg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 8 1998

Mr. Dennis R. Mertz
Manager, Regulatory Affairs
Becton Dickinson Microbiology Systems
7 Loveton Circle
Sparks, Maryland 21152-0999

Re: K970512
Trade Name: BACTEC Myco/F Lytic Culture Vials
Regulatory Class: I
Product Code: MDB
Dated: October 20, 1997
Received: October 21, 1997

Dear Mr. Mertz:

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 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 requirement, 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.

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 Gutman

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

510(k) Number (if known): K970512

Device Name: Myco/F Lytic Culture Vials

Indications For Use:

The BACTEC ® MYCO/F LYTIC Culture vial when used with the BACTEC 9000MB System is a qualitative test for the culture and recovery of mycobacteria in human blood specimens from patients who are suspected of having septicemia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Tiebout MD 1/6/98

(Division Sign-Off) Interim Chief, Microbiology

Division of Clinical Laboratory Devices

510(k) Number K970512

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use____

(Optional Format 1-2-96)