

JAN 28 1998

K970333

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: BECTON DICKINSON MICROBIOLOGY SYSTEMS
7 LOVETON CIRCLE
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PREPARED: January 20, 1998

DEVICE NAME: BACTEC MYCO/F LYTIC BLOOD CULTURE MEDIUM

DEVICE

CLASSIFICATION: Monitor, Microbial Growth, Class I

PREDICATE

DEVICE: BACTEC 13A MYCOBACTERIA CULTURE MEDIUM, BACTEC NR FUNGAL CULTURE MEDIUM, AND ISOLATOR™ SYSTEM

INTENDED USE:

MYCO/F LYTIC culture medium when used with the BACTEC 9000 Blood Culture Series of instruments is a non-selective culture medium to be used as an adjunct to aerobic blood culture media for the recovery of mycobacteria, yeast and fungi. This media may also be used for the culture of sterile body fluids when yeast or fungi are suspected.

DEVICE

DESCRIPTION:

BACTEC MYCO/F LYTIC Culture medium is a Middlebrook 7H9 and Brain Heart Infusion broth formulation for the recovery of mycobacteria from blood specimens and yeast and fungi from blood and sterile body fluids. The range of specimen volume which can be cultured is one to five mL, with optimum recovery obtained at three to five mL. Specific modifications were made to enhance the growth and recovery of mycobacteria, yeast, and fungi. These modifications include ferric ammonium citrate to provide an iron source for specific strains of mycobacteria and fungi, the addition of saponin as a blood lysing agent and the addition of specific proteins and sugars to provide nutritional supplements. Each vial contains a sensor which can detect decreases in oxygen concentration in the vial resulting from microorganism metabolism and growth. The sensor is monitored by the BACTEC 9000 Blood Culture Systems for increasing fluorescence which is proportional 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 BACTEC 13A Mycobacteria culture medium and BACTEC NR FUNGAL culture medium. Internal and clinical studies demonstrated equivalent performance with all predicate devices.

INTERNAL PERFORMANCE

A study was conducted to evaluate the recovery and time to detection (TTD) of a variety of yeast and fungi species at different CFU levels and specimen volumes between BACTEC NR FUNGAL Culture medium and BACTEC MYCO/F LYTIC Culture medium. TABLE 2 shows the results of this study. The recovery of *Histoplasma capsulatum* and *Malessezia furfur* with BACTEC MYCO/F LYTIC culture medium demonstrated improved recovery compared to the BACTEC NR FUNGAL Culture medium. *Penicillium purpurescens* and *Blastomyces dermatitidis* were not detectable in the BACTEC MYCO/F LYTIC culture medium. *Hansenula anomala*, *Exophiala jeamselmei*, *Actinomyces bovis*, *Rhodotorula rubra*, and *Mucor ramosissimus* exhibited inconsistent results at low inoculum levels (<10 CFU/vial) during this evaluation. For yeast, the recovery of various *Candida* and *Cryptococcus* species in the BACTEC MYCO/F LYTIC Culture medium was equivalent to the BACTEC NR FUNGAL Culture medium.

A study was conducted to evaluate the recovery and time to detection of a variety of mycobacteria at different CFU levels and specimen volumes with BACTEC MYCO/F LYTIC Culture medium. TABLE 3 shows the results of this study. Recovery of a majority of the tested mycobacteria species at the various CFU levels and specimen volumes was acceptable with BACTEC MYCO/F LYTIC Culture medium, although with less than 3 mL of blood, *M. intracellulare*, *M. malmoense*, *M. haemophilum* and *M. xenopi* exhibited detection delays and/or compromised recovery.

CLINICAL PERFORMANCE:

The BACTEC MYCO/F Lytic medium was evaluated with the BACTEC 9240 instrument at two clinical sites considered large tertiary care teaching hospitals in geographically diverse areas. The site populations included patients infected with HIV, immunocompromised patients, transplant patients, and patients suspected of a mycobacterial infection. The BACTEC MYCO/F Lytic medium was compared to the BACTEC 13A medium for the recovery and detection of mycobacteria from blood. A total of 1,100 blood culture specimens were tested during the evaluation. The total number of pathogenic mycobacteria isolates recovered in the study was 111 (See TABLE 4). Of these positives, ten (9%) were recovered in the BACTEC MYCO/F Lytic medium only and three (3%) were recovered by BACTEC 13A medium only.

TABLE 4: SUMMARY OF MYCO/F LYTIC MEDIUM ISOLATE RECOVERY DURING CLINICAL TRIAL

Organism	Total Isolates	Myc/F Lytic Medium Only	13A Medium Only	Both
All Pathogenic Mycobacteria:				
<i>Mycobacterium avium</i>	108	10	3	95
<i>Mycobacterium tuberculosis</i>	2	0	0	2
<i>Mycobacterium celatum</i>	1	0	0	1
Total	111	10	3	98

The BACTEC MYCO/F LYTIC medium was evaluated with the BACTEC 9240 instrument at four clinical sites considered large tertiary care teaching hospitals. The site populations included patients infected with HIV, immunocompromised patients, transplant patients, and patients suspected of a fungal infection. The BACTEC MYCO/F LYTIC medium was compared to the ISOLATOR™ System (Wampole Laboratories, Cranbrook, NJ) for the recovery and detection of yeast and fungi from blood. MYCO/F LYTIC vials were inoculated with 1-5 mL of blood and ISOLATOR tubes were inoculated with 3-10 mL of blood. The ISOLATOR sediment was plated to Chocolate Agar, Brain Heart Infusion Agar with 5% sheep blood, and Sabaraud Dextrose Agar. A total of 748 specimens were tested during the evaluation. The total number of pathogenic yeast and fungal isolates recovered in the study was 32 (See TABLE 5). Of these positives, seven (22%) were recovered in the BACTEC MYCO/F LYTIC medium only and six (19%) were recovered in the ISOLATOR system only.

TABLE 5: SUMMARY OF MYCO/F LYTIC MEDIUM ISOLATE RECOVERY DURING CLINICAL TRIAL

Organism	Total Isolates	Myc/F Lytic Medium Only	Isolator Only	Both
All Pathogenic Fungi:				
<i>Candida albicans</i>	10	3	3	4
<i>Candida glabrata</i>	5	0	1	4
<i>Candida krusei</i>	2	2	0	0
<i>Candida parapsilosis</i>	1	1	0	0
<i>Candida tropicalis</i>	1	1	0	0
<i>Cryptococcus neoformans</i>	1	0	0	1
<i>Fusarium species</i>	1	0	1	0
<i>Histoplasma capsulatum</i>	11	0	1	10
Total	32	7	6	19

One thousand four hundred eighty-eight (1,488) blood cultures obtained from patients suspected of mycobacterial, yeast or fungal infections were evaluated in the BACTEC MYCO/F LYTIC culture vial with the BACTEC 9240 Blood Culture System. There were 315 positive cultures of which 243 had clinically significant organisms recovered, of which 131 (53.9%) were mycobacteria, 35 (14.4%) were yeast or fungi, and 77 (31.7%) were other bacteria. Of the 1,488 blood specimens tested in the clinical study, eleven BACTEC MYCO/F LYTIC culture vials (0.7%) were determined to be false positive (instrument-positive, smear and/or subculture-negative). Of the 315 instrument positive MYCO/F LYTIC vials, 11 (3.5%) were determined to be false positive. Of the 1,488 blood specimens tested in the clinical study, one (1) BACTEC MYCO/F LYTIC culture vial (0.07%) was determined to be false negative (instrument-negative, smear and/or subculture-positive). Of the 1,173 instrument negative BACTEC MYCO/F LYTIC culture vials, one (0.08%) was determined to be false negative. The contamination rate during this evaluation was 3.3%.

TABLE 1. Substantial Equivalence of BACTEC MYCO/F LYTIC Culture Medium to BACTEC 13A and BACTEC NR FUNGAL

	BACTEC MYCO/F LYTIC	BACTEC 13A	BACTEC NR FUNGAL
Intended Use	Qualitative culture and recovery of mycobacteria	Qualitative culture and recovery of mycobacteria	Qualitative culture and recovery of yeast and fungi
Sample Type	Blood, unprocessed and other sterile body fluids	Blood, unprocessed	Blood, unprocessed
Sample Volume	1 - 5 mL	1 - 5 mL	3 - 10 mL
Blood to Broth Ratio	1 to 8	1 to 6	1 to 2.5
Growth Medium	Modified Middlebrook 7H9 and enriched brain heart infusion broth	Modified Middlebrook 7H9 broth	Enriched brain heart infusion broth
Reactive ingredients:			
• Process water	40mL	30mL	25mL
• Brain heart infusion	0.5%w/v	----	1.0%w/v
• Soybean-Casein Digest	0.10%w/v	----	0.5%w/v
• 7H9 Broth Base	0.12%w/v	0.47%w/v	----
• Inositol	0.05%w/v	----	0.05%w/v
• Casein Hydrolysate	0.10%w/v	0.10%w/v	----
• Ferric Ammonium Citrate	0.006%w/v	----	0.0001%w/v
• Yeast Extract	----	----	0.035%w/v
• Glycerol	0.10%w/v	----	----
• Sodium Polysulfonate(SPS)	0.025%w/v	0.025%w/v	0.05%w/v
• Sucrose	----	----	0.6%w/v
• Tween 80(Polysorbate)	0.0025%w/v	0.02%w/v	----
• Saponin	0.24%w/v	----	0.24%w/v
• L-Asparagine ¹	0.10%w/v	----	----
• Catalase	----	1440 units	----
• Antifoam Agent	0.01%w/v	----	0.01%w/v
• Tobramycin	----	----	0.001w/v
• ¹⁴ C Substrate	----	5μCi	----
• Potassium Phosphate	0.024%w/v	----	----
• Pyridoxal HCL	0.0001%w/v	----	----
• Chloramphenicol	----	----	0.005%w/v
• Dextrose	0.10%w/v	----	0.10%w/v
Supplement	None	BACTEC Enrichment	None
Instrument	BACTEC 9000 Blood Culture Series Instruments	BACTEC 460TB	BACTEC NR Systems
Growth Detection	O ₂ metabolism	Palmitate Decarboxylation	CO ₂ production
Incubation T°/mixing	35°C ± 1.5°C; instrument agitation	37° C ± 1.5°C; no agitation	35° C ± 1.5°C; 48 hr agitation
Type of Monitoring	Non-invasive, fluorescent detection	Invasive vial headspace sampling	Invasive vial headspace sampling

(noted as Supplement H)

TABLE 2. Detection of fungi in Myco/F Lytic medium and NR Fungal medium. Each value is the average of all vials per test condition.

Organism	Strain	CFU/Vial	Time to Detection (days)					
			BACTEC 9000 Blood Culture			BACTEC NR Blood Culture		
			0 mL Blood	1 mL Blood	5 mL Blood	0 mL Blood	1 mL Blood	5 mL Blood
<i>Hansenula anomala</i>	580	TNTC	4.6	5.4	6.0	9.0	12.0	3.0
<i>Hansenula anomala</i>	580	170	8.4	7.0	6.7	3.0	6.5	3.5
<i>Hansenula anomala</i>	580	16	negative	negative	5.6	negative	negative	14.0
<i>Exophiala jeansemelei</i>	10224	TNTC	negative	11.1	12.1	12.0	12.0	12.0
<i>Exophiala jeansemelei</i>	10224	80	29.6	19.3	14.1	23.0	12.0	12.0
<i>Exophiala jeansemelei</i>	10224	6	negative	negative	25.9	29.0	14.0	16.0
<i>Penicillium purpurescens</i>	10485	35.5	4.1	negative	negative	negative	negative	negative
<i>Penicillium purpurescens</i>	10485	4.5	negative	negative	negative	negative	negative	negative
<i>Penicillium purpurescens</i>	10485	0	negative	negative	negative	negative	negative	negative
<i>Aspergillus fumigatus</i>	13073	TNTC	0.8	0.7	0.6	1.5	1.5	1.0
<i>Aspergillus fumigatus</i>	13073	63	1.2	0.7	0.7	1.5	2.3	1.0
<i>Aspergillus fumigatus</i>	13073	9.5	1.3	0.9	0.9	3.0	3.0	1.5
<i>Actinomyces bovis</i>	13683	14.5	2.4	1.6	1.6	2.0	1.5	1.5
<i>Actinomyces bovis</i>	13683	1.5	3.3	2.5	2.3	3.0	2.5	2.5
<i>Actinomyces bovis</i>	13683	0	negative	4.1	3.0	negative	negative	negative
<i>Histoplasma capsulatum</i>	16585	TNTC	0.9	1.0	0.9	negative	negative	negative
<i>Histoplasma capsulatum</i>	16585	61	1.0	1.0	0.9	negative	negative	negative
<i>Histoplasma capsulatum</i>	16585	6.5	1.1	1.1	0.9	negative	negative	negative
<i>Aspergillus flavus</i>	16883	TNTC	1.0	1.0	0.9	1.5	1.5	1.5
<i>Aspergillus flavus</i>	16883	145.5	2.0	1.2	1.6	3.0	1.5	1.5
<i>Aspergillus flavus</i>	16883	23.5	2.5	1.6	1.3	3.0	2.5	1.5
<i>Ajellomyces dermatitidis</i>	18187	42	1.1	0.9	0.9	3.0	3.0	1.5
<i>Ajellomyces dermatitidis</i>	18187	10.5	1.3	0.9	1.0	3.0	3.0	1.5
<i>Ajellomyces dermatitidis</i>	18187	0.5	1.3	1.3	1.1	3.5	3.0	3.0
<i>Nocardia asteroides</i>	18187	234	1.1	1.0	1.0	3.0	1.8	1.8
<i>Nocardia asteroides</i>	18187	28	2.9	2.1	1.5	3.0	3.0	2.0
<i>Nocardia asteroides</i>	18187	2.5	4.1	3.7	3.3	negative	negative	9.5
<i>Rhodotorula rubra</i>	18803	TNTC	7.8	5.9	4.2	3.0	3.0	3.0
<i>Rhodotorula rubra</i>	18803	100	23.4	11.9	15.8	5.5	4.0	4.0
<i>Rhodotorula rubra</i>	18803	8	negative	3.2	negative	12.0	9.5	5.0

TNTC: Too Numerous to Count
 negative: At least one vial negative at the end of protocol

TABLE 2 Detection of fungi in Myco/F Lytic medium and NR Fungal medium. Each value is the average of all vials per test condition.

Organism	Strain	CFU/Vial	Time to Detection (days)					
			BACTEC 9000 Blood Culture			BACTEC NR Blood Culture		
			0 mL Blood	1 mL Blood	5 mL Blood	0 mL Blood	1 mL Blood	5 mL Blood
<i>Trichophyton rubrum</i>	18803	131.5	9.6	4.0	3.9	13.0	4.0	4.0
<i>Trichophyton rubrum</i>	18803	10.5	12.5	4.5	4.3	13.0	4.0	4.0
<i>Trichophyton rubrum</i>	18803	0.5	10.9	6.6	6.2	19.0	5.0	5.0
<i>Mucor ramosissimus</i>	18803	85.5	18.7	4.8	3.1	6.0	4.0	3.0
<i>Mucor ramosissimus</i>	18803	13.5	11.3	5.4	4.3	negative	15.5	12.0
<i>Mucor ramosissimus</i>	18803	2	negative	negative	negative	negative	21.0	19.0
<i>Malesezia furfur</i>	19247	TNTC	0.6	0.6	0.6	13.0	negative	negative
<i>Malesezia furfur</i>	19247	231	2.0	0.6	0.6	3.0	negative	negative
<i>Malesezia furfur</i>	19247	22.5	0.7	0.6	0.7	negative	negative	negative
<i>Blastomyces dermatitidis</i>	19247	40.5	negative	24.1	24.1	negative	negative	23.0
<i>Blastomyces dermatitidis</i>	19247	3	negative	negative	negative	negative	negative	30.0
<i>Blastomyces dermatitidis</i>	19247	0	negative	negative	negative	negative	negative	negative
Average			6.8	4.6	4.5	7.4	6.0	7.7

TNTC: Too Numerous to Count

negative: At least one vial negative at the end of protocol

TABLE 3. Time to Detection of Mycobacteria in the Myco/F Lytic Medium.

	strain	cfu/bottle	BACTEC 9000 Blood Culture (Days)		
			1 mL blood	3 mL blood	5 mL blood
<i>M. tuberculosis</i>	582	0, 0	16.8	16.8	14.2
Replicate			neg	16.8	neg
Average			16.8	16.8	14.2
<i>M. avium</i>	2638	49, 45	8.1	8.1	8.1
Replicate			8.1	7.8	8.1
Average			8.1	8.0	8.1
<i>M. intracellulare</i>	2792	80, 44	21.5	10.8	10.1
Replicate			neg	10.5	9.8
Average			21.5	10.7	10.0
<i>M. fortuitum</i>	3072	5, 0	5.5	4.4	4.3
Replicate			5.8	4.4	3.9
Average			5.7	4.4	4.1
<i>M. bovis</i>	2003	12, 13	19.8	20.5	19.1
Replicate			20.8	19.5	19.5
Average			20.3	20.0	19.3
<i>M. kansasii</i>	2205	7, 3	13.1	12.5	15.8
Replicate			12.1	13.5	14.1
Average			12.6	13.0	15.0
<i>M. terrae</i>	3001	0, 0	13.8	18.5	9.5
Replicate			12.5	neg	12.7
Average			13.2	18.5	11.1
<i>M. szulgai</i>	2353	1, 2	25.5	22.8	19.1
Replicate			22.5	neg	neg
Average			24.0	22.8	19.1
<i>M. simiae</i>	2304	68, 58	7.0	7.4	7.4
Replicate			6.9	7.4	7.3
Average			7.0	7.4	7.4
<i>M. gordonae</i>	2454	2, 5	28.2	31.2	neg
Replicate			30.8	28.8	29.5
Average			29.5	30.0	29.5
<i>M. celatum</i>	3661	53, 31	13.1	10.8	10.8
Replicate			13.1	10.5	10.8
Average			13.1	10.7	10.8
<i>M. abscessus</i>	3370	1, 0	4.1	neg	neg
Replicate			4.3	4.0	3.6
Average			4.2	4.0	3.6
<i>M. malmoense</i>	3472	16, 20	24.8	10.8	10.4
Replicate			25.3	10.4	10.4
Average			25.1	10.6	10.4
<i>M. haemophilum</i>	5121	1, 1	neg	23.2	19.8
Replicate			35.9	23.5	17.2
Average			35.9	23.4	18.5
<i>M. xenopi</i>	3052	0, 0	neg	42.9	40.2
Replicate			neg	34.5	40.9
Average			neg	38.7	40.6
<i>C. neoformans</i>	13690	13, 31	2.8	2.5	2.8
Replicate			2.7	2.7	2.9
Average			2.8	2.6	2.9



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 28 1998

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

Re: K970333
Trade Name: BACTEC® Myco/F Lytic Culture Vials
Regulatory Class: I
Product Code: MDB
Dated: October 24, 1997
Received: October 27, 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.

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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 STATEMENT

510(k) Number K970333

Device Name: BACTEC® MYCO/F LYTIC Culture Vials

Indication for Use:

The BACTEC® MYCO/F Lytic culture vials when used with the 9000 Blood Culture series of instrumentation are intended as an adjunct to routine blood culture for patients suspected of having mycobacteria, yeast and fungi septicemia. Extended incubation times (7 days for yeast, 30 days for fungi, and 42 days for mycobacteria) will permit recovery of mycobacteria and fungi when more rapidly growing organisms are not present. This medium may also be used for the culture of sterile body fluids when yeast or fungi are suspected.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Ticehurst MD

(Division Sign-Off) *Interim Ch. of, Microbiol. Pr*
Division of Clinical Laboratory Devices

510(k) Number _____

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter Use _____