

AUG - 8 1997

June 13, 1997

SUMMARY OF SAFETY AND EFFECTIVENESS**SUBMITTED BY:**

Colleen A. Rohrbeck
Becton Dickinson Microbiology Systems
250 Schilling Circle
Cockeysville, MD 21030-0243

NAME OF DEVICE:

Trade Name: BACTEC® MYCO/F-Sputa Culture Vials

Common Name: Microbial Growth Monitor

PREDICATE DEVICES:

BACTEC® 460TB System
Conventional Media

INTENDED USE:

MYCO/F-Sputa culture media BACTEC Supplement /F when used with the BACTEC Brand 9000MB fluorescent series instrument is a qualitative procedure for the *in vitro* culture and recovery of mycobacteria from digested decontaminated clinical specimens and sterile body fluids other than blood.

DEVICE COMPARISON:

The BACTEC® MYCO/F-Sputa culture vials will be compared to the BACTEC 12B culture vials and conventional medium (Lowenstein-Jensen agar slants) for purposes of evaluating equivalence of mycobacterial growth detection methods in non-respiratory specimens.

Table 1: BACTEC MYCO/F-Sputa Culture Vials versus BACTEC 12B Culture Vials

	BACTEC MYCO/F-Sputa Culture Vials	BACTEC 12 B Culture Vials
Intended Use	Qualitative culture and recovery of mycobacteria from clinical specimens	Qualitative culture and recovery of mycobacteria from clinical specimens
Sample type	Sterile body fluids other than blood and digested decontaminated clinical specimens	Clinical specimens, sputum, gastric, urine, tissue, mucopurulent specimens, other body fluids and other respiratory secretions
Sample volume	0.5mL	0.5 - 1.0 mL
Growth medium	7H9 Middlebrook broth base with nutrient additives	Enriched 7H9 Middlebrook broth base
Reactive Ingredient Concentration		
Processed Water	40 ml	4 ml
7H9 Broth Base	0.47% w/v	4.7 g/L
Casein Hydrolysate	0.10% w/v	1.0g/L
Supplement H*	0.30% w/v	---
Glycerol	0.10% w/v	---
Ammonium Sulfate	0.05% w/v	---
Ferric Ammonium Citrate	0.006% w/v	---
Polysorbate 80	0.0025% w/v	---
Hemin	0.0005% w/v	---
Bovine Serum Albumin	---	5.0g/L
Catalase	---	48,000 units/L
¹⁴ C-substrate	---	1,000 μCi/L

	BACTEC MYCO/F-Sputa Culture Vials	BACTEC 12 B Culture Vials
Antimicrobial Supplement	Polymyxin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin (PANTA)	Polymyxin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin (PANTA)
Growth Detection	Fluorescent detection of O ₂ consumption by mycobacterial growth	Radiometric detection of CO ₂ liberated by mycobacterial growth
Incubation temperature/ mixing	On-board incubation at 37°C ±1.5°C; internal instrument agitation every 10 minutes	External incubation at 37°C ± 1.0°C. No agitation in instrument
Automated System Used for Detection	BACTEC® 9000MB	BACTEC® 460TB

* L-asparagine

Device Comparison (cont.)

Table 2: BACTEC® MYCO/F-Sputa Culture Vials versus CONVENTIONAL MEDIUM

	BACTEC MYCO/F-Sputa Culture Media	CONVENTIONAL MEDIUM¹
Intended Use	Qualitative culture and recovery of mycobacteria from clinical specimens	Qualitative culture and recovery of mycobacteria from clinical specimens
Sample type	Sterile body fluids other than blood and digested decontaminated clinical specimens	Primary specimens type - respiratory; other body fluids (including blood) acceptable
Sample volume	0.5mL	0.1 - 0.5 mL
Growth medium	7H9 Middlebrook broth base with nutrient additives	Lowenstein-Jensen medium; Egg enriched agar base with nutrient additives
Reactive Ingredient Concentration		
Processed Water	40 ml	8 ml
7H9 Broth Base	0.47% w/v	---
Casein Hydrolysate	0.10% w/v	---
Supplement H*	0.30% w/v	0.22% w/v
Glycerol	0.10% w/v	0.74% v/v
Ammonium Sulfate	0.05% w/v	---
Ferric Ammonium Citrate	0.006% w/v	---
Polysorbate 80	0.0025% w/v	---
Hemin	0.0005% w/v	---
Monopotassium Phosphate	---	0.15% w/v
Magnesium Sulfate	---	0.014% w/v
Sodium Citrate	---	0.037% w/v
Potato Flour	---	1.86 % w/v
Whole Egg	---	62 % v/v
Malachite Green	---	0.024% w/v
Antimicrobial Supplement	Polymyxin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin (PANTA)	None

	BACTEC MYCO/F-Sputa Culture Media	CONVENTIONAL MEDIUM¹
Growth Detection	Fluorescent detection of O ₂ consumption by mycobacterial growth	Macroscopic observance of growth of media surface
Incubation temperature mixing	On-board incubation at 37°C ±1.5°C; internal instrument agitation every 10 minutes	35°C to 38°C ² Manual manipulation of media
Automated System Used for Detection	BACTEC® 9000MB	None Required

1- CONVENTIONAL MEDIA - Lowenstein-Jensen agar slants

2- CDC recommendations

* L-asparagine

TIME TO DETECTION:

Table 3 shows the overall average times to detection of positive mycobacterial cultures for the BACTEC® MYCO/F-Sputa culture vials, BACTEC 12B culture vials, and conventional media.

Table 3: Overall Average Times to Detection for Non-Respiratory Specimens

ISOLATE GROUP	BACTEC 9000MB	BACTEC 460TB	CONVENTIONAL LJ
ALL MYCOBACTERIAL ISOLATES	12.2 days	13.3 days	24.3 days
MTB COMPLEX	18.4 days	17.2 days	22.1 days
M AVIUM COMPLEX	7.9 days	10.2 days	28.3 days

Paired t-tests were performed to compare time to detection in the BACTEC MYCO/F-Sputa culture vials to each of the reference systems, BACTEC 460TB and conventional media (Lowenstein-Jensen), for digested decontaminated clinical specimens and sterile body fluids other than blood. Both tests were performed at the 5% significance level.

No significant difference in time to detection was seen between the BACTEC MYCO/F-Sputa culture vials and the BACTEC 460TB system. A statistically significant difference in time to detection was seen between the BACTEC MYCO/F-Sputa culture vials and conventional media.

RECOVERY PERFORMANCE:

In a separate study at a large tertiary care teaching hospital, 803 non-respiratory specimens were tested with the BACTEC MYCO/F-Sputa culture medium, BACTEC 12B culture medium, and conventional medium (Lowenstein-Jensen). The total number of pathogenic mycobacteria positive isolates recovered in the study was 38. Of these positive isolates, the BACTEC 9000MB system recovered 29 (76.3%), 30 (78.9%) were recovered in the BACTEC 460TB system, and 24 (63.2%) were recovered by conventional medium (Lowenstein-Jensen). The BACTEC 9000MB system and solid media combined recovered 89.5% of the total pathogenic isolates. Total positive specimens (pathogenic and non-pathogenic mycobacteria) were distributed among the following sources: gastric (5.1%), sterile body fluids other than blood (17.9%), stool (10.3%), superficial skin/wound drainage (5.1%), tissue (53.8%), and urine (7.7%). The following isolates were detected as positive in the BACTEC 9000MB system using MYCO/F-Sputa during this clinical trial: *M. tuberculosis*, *M. avium complex*, *M. chelonae*, *M. fortuitum*, and *M. bovis*.

A McNemar's paired comparison (modified chi-square test) was conducted to determine the significance of differences in total recovery between BACTEC MYCO/F-Sputa culture vials and the BACTEC 460TB system, as well as between the BACTEC MYCO/F-Sputa culture vials and conventional (Lowenstein Jensen) media. Both tests were performed at the 5% significance level.

No statistical difference in recovery was seen between the BACTEC MYCO/F-Sputa culture vials and the BACTEC 460TB system. No statistical difference in recovery was seen between the BACTEC MYCO/F-Sputa culture vials and conventional media. Therefore, recovery of mycobacteria from digested decontaminated clinical specimens and sterile body fluids other than blood was not found to be different in the BACTEC MYCO/F-Sputa culture vials when compared to either the BACTEC 460TB system or conventional media.

The overall false positive rate (instrument-positive, smear and/or subculture negative) was 5.0%. Due to the variety of specimens collected and tested, the false positive rate varied significantly from the rate previously reported for respiratory specimens.

The breakthrough contamination rate for normally sterile specimens (i.e. tissue and sterile body fluids other than blood) ranged from 4.7% - 18.9%; non-sterile specimens (i.e. gastric, stool, urine, superficial skin/wound drainage) ranged from 8.2% - 73.9%. The overall breakthrough contamination rate was 14.9%.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Colleen Rohrbeck
Regulatory Affairs Associate
Becton Dickinson Microbiology Systems
250 Schilling Circle
Cockeysville, Maryland 21030-0243

AUG - 8 1997

Re: K972758
Trade Name: BACTEC® MYCO/F-Sputa Culture Vials
Regulatory Class: I
Product Code: MDB
Dated: June 13, 1997
Received: June 16, 1997

Dear Ms. Rohrbeck:

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.

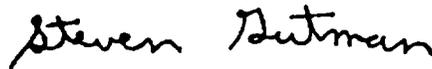
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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 (if known): ~~K940268~~ K972758

Device Name: BACTEC® MYCO/F - Sputa Culture Vials

Indications for Use:

MYCO/F-Sputa culture media with the addition of BACTEC Supplement/F when used with the BACTEC Brand 9000MB fluorescent series instrument is a qualitative test for the *in-vitro* culture and recovery of mycobacteria from digested decontaminated clinical specimens and sterile body fluids other than blood from patients suspected of pulmonary or disseminated mycobacterial infection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number ~~K940268~~
K972758

Prescription Use
(Per 21CFR 801.109)

OR

Over-the-Counter-Use