

K954932

**BECTON
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510(k) SUMMARY

AUG 21 1996

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PREPARED: August 13, 1996

TRADE NAME: BBL® MGIT™ Products

COMMON NAME: Selective Culture Medium

**CLASSIFICATION
NAME:** Selective Culture Medium

PREDICATE DEVICES: BACTEC® 460TB System
BBL® SEPTI-CHEK® AFB Mycobacteria Culture System

INTENDED USE: The BBL® MGIT™ Mycobacteria Growth Indicator Tube supplemented with BBL® MGIT™ OADC and BBL® MGIT™ PANTA antibiotic, mixture, when appropriate, is intended for the detection and recovery of mycobacteria. Acceptable specimen types are digested and decontaminated clinical specimens (except urine) and sterile body fluids (except blood).

DEVICE DESCRIPTION:

The BBL[®] MGIT[™] Mycobacteria Growth Indicator Tube contains 4 mL of modified Middlebrook 7H9 Broth Base. The complete medium is supplemented with 0.5 mL OADC enrichment and 0.1 mL of PANTA antibiotic mixture, when necessary. The medium components are substances essential for the growth of mycobacteria. A fluorescent compound is embedded in the bottom of the BBL[®] MGIT[™] tube which is sensitive to the presence of oxygen dissolved in the broth.

Specimens are inoculated (0.5 mL) into the BBL[®] MGIT[™] tube and incubated at the appropriate temperature. Tubes are read daily from the second day of inoculation.

Actively respiring microorganisms consume the oxygen and allow the compound to fluoresce. Each inoculated BBL[®] MGIT[™] tube is compared to the fluorescence Positive Control and Negative Control tube to assist in the interpretation of a positive signal from the BBL[®] MGIT[™] tube.

A BBL[®] MGIT[™] tube which exhibits fluorescence comparable to the Positive Control tube is considered presumptively positive for growth.

DEVICE TECHNOLOGICAL CHARACTERISTICS:

Tables 1 & 2 summarize the similarities and differences between the BBL® MGIT™ tube and the predicate devices.

Table 1: Comparison of BBL® MGIT™ to the BACTEC® 460TB System

	BBL® MGIT™	BACTEC® 460TB
Intended Use	Growth and detection of mycobacteria from clinical specimens (excluding blood and urine).	Growth and detection of mycobacteria from clinical specimens.
Sample Type	Primary sample type - respiratory; other body fluids acceptable (excluding blood and urine).	Primary sample type - respiratory; other body fluids (excluding blood) acceptable.
Sample Volume	0.5 mL	0.5 - 1.0 mL
Reactive Ingredient Concentrations of Growth Medium	APPROX. COMPOSITION/1000 mL	APPROX. COMPOSITION/1000 mL
	Na ₂ HPO ₄ 2.5 g	Na ₂ HPO ₄ 2.5 g
	L-Asparagine 1.25	
	KH ₂ PO ₄ 1.0	KH ₂ PO ₄ 1.0
	Sodium glutamate 0.5	Sodium glutamate 0.5
	(NH ₄) ₂ SO ₄ 0.5	(NH ₄) ₂ SO ₄ 0.5
	Sodium citrate 0.1	Sodium citrate 0.1
	MgSO ₄ •7H ₂ O 0.5	MgSO ₄ •7H ₂ O 0.05
	Ferric ammonium citrate 0.04	Ferric ammonium citrate 0.04
	CuSO ₄ •5H ₂ O 1.0 mg	CuSO ₄ •5H ₂ O 1.0 mg
	Pyroxidine 1.0	Pyroxidine 1.0
	ZnSO ₄ •7H ₂ O 1.0	ZnSO ₄ •7H ₂ O 1.0
	Biotin 0.5	Biotin 0.5
	CaCl ₂ •2H ₂ O 0.5	CaCl ₂ •2H ₂ O 0.5
	Casein Peptone 1.25 g	
	Glycerol 3.1 mL	
		Casein Hydrolysate 0.1 g
Additional Medium Growth Factors	BBL® MGIT™ OADC enrichment: Oleic Acid, Albumin, Dextrose, Catalase	Albumin, Catalase
Detector	O ₂ sensitive fluorescent sensor in silicone rubber base.	¹⁴ C labeled fatty acid present in the medium.
Antimicrobial Supplement	BBL® MGIT™ PANTA™ antibiotic mixture: Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin.	BACTEC® PANTA™ PLUS: Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin.
Growth Detection	Manual observation of fluorescence via excitation with longwave UV light. Fluorescence results from O ₂ consumption by mycobacterial growth.	Radiometric detection of ¹⁴ CO ₂ liberated by mycobacterial growth.
Incubation Temperature	37° C ± 1° C	37° C ± 1° C

Table 2: Comparison of BBL® MGIT™ to BBL® SEPTI-CHEK® AFB

	BBL® MGIT™	BBL® SEPTI-CHEK® AFB
Intended Use	Growth and detection of mycobacteria from clinical specimens.	Growth and detection of mycobacteria from clinical specimens.
Sample Type	Primary sample type - respiratory; other body fluids acceptable (excluding blood and urine).	Primary sample type - respiratory; other body fluids acceptable (excluding blood).
Sample Volume	0.5 mL	0.5 - 1.0 mL
Reactive Ingredient Concentrations of Growth Medium	APPROX. COMPOSITION/1000 mL	APPROX. COMPOSITION/1000 mL
	Na ₂ HPO ₄ 2.5 g	Na ₂ HPO ₄ 1.579 g
	L-Asparagine 1.25	
	KH ₂ PO ₄ 1.0	KH ₂ PO ₄ 1.579
	Sodium glutamate 0.5	L-Glutamic acid 0.526
	(NH ₄) ₂ SO ₄ 0.5	(NH ₄) ₂ SO ₄ 0.526
	Sodium citrate 0.1	Sodium citrate 0.421
	MgSO ₄ ·7H ₂ O 0.5	MgSO ₄ ·7H ₂ O 0.053
	Ferric ammonium citrate 0.04	Ferric ammonium citrate 0.042
	CuSO ₄ ·5H ₂ O 1.0 mg	
	Pyroxidine 1.0	
	ZnSO ₄ ·7H ₂ O 1.0	
	Biotin 0.5	Biotin 5.0 mg
	CaCl ₂ ·2H ₂ O 0.5	CaCl ₂ ·2H ₂ O 0.5
	Casein Peptone 1.25 g	Casein hydrolysate 1.053 g
	Glycerol 3.1 mL	
		NaCl 0.895
		Malachite Green 1.0 mg
Additional Medium Growth Factors	BBL® MGIT™ OADC enrichment: Oleic Acid, Albumin, Dextrose, Catalase	BBL® SEPTI-CHEK® AFB Mycobacterial Culture Supplement: Oleic Acid, Albumin, Dextrose, Catalase
Other Growth Media as Part of System	None	BBL® SEPTI-CHEK® AFB Slide: Middlebrook 7H11 Agar Egg based agar medium Chocolate Agar
Detector	O ₂ sensitive fluorescent sensor in silicone rubber base.	None
Antimicrobial Supplement	BBL® MGIT™ PANTA™ antibiotic mixture: Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin.	BBL® SEPTI-CHEK® AFB Mycobacterial Culture Supplement: Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin.
Growth Detection	Manual observation of fluorescence via excitation with longwave UV light. Fluorescence results from O ₂ consumption by mycobacterial growth.	Macroscopic observance of growth on agar and/or in broth.
Incubation Temperature	37° C ± 1° C	37° C ± 1° C

SUMMARY OF DEVICE TESTING:

Internal testing of the BBL[®] MGIT[™] tubes demonstrated the ability to recover a wide variety of mycobacterial species. Additionally, internal testing showed comparable recovery between the BACTEC[®] 460TB System and the BBL[®] MGIT[™] tubes.

An external evaluation was performed at six (6) sites. Four (4) sites used the BACTEC[®] 460TB System and conventional solid agar media as reference methods for comparison to the BBL[®] MGIT[™] tubes. Two (2) sites used the BBL[®] SEPTI-CHEK[®] AFB Mycobacteria Culture System as the reference method for comparison to the BBL[®] MGIT[™] tubes. A combined total of 2801 specimens were evaluated. The distribution of specimens tested by source was respiratory (78%), gastric (0.4%), body fluid (9.8%), tissue (7.0%), stool (2.5%) and other (2.4%). A total of 318 specimens were positive which represented 330 isolates recovered during the study

Of these 330 isolates, 253 (77%) were recovered by the BBL[®] MGIT[™] tubes, 260 (79%) were recovered by the BACTEC[®] 460TB System and the BBL[®] SEPTI-CHEK[®] AFB and 219 (66%) were recovered by conventional solid media. The average time-to-detection for the BBL[®] MGIT[™] tubes for All mycobacteria was 14.1 days. The BBL[®] MGIT[™] tubes demonstrated a 0.5% false positive rate (MGIT fluorescent, no AFB present). The BBL[®] MGIT[™] tubes failed to recover 3.7% of the isolates which were recovered in one or more of the reference systems (BACTEC[®] 460TB, BBL[®] SEPTI-CHEK[®] AFB or conventional solid media). While this percentage represents a potential loss of recovery, it is not indicative of an actual false negative determination (refer to "Limitations of the Procedure" section). Use of a second medium, as recommended, will increase the probability of recovery of mycobacterial organisms. The average breakthrough contamination rate for the BBL[®] MGIT[™] tubes was 9.7%.

CONCLUSIONS

Based on the internal and external evaluation of the BBL[®] MGIT[™] tubes, the overall performance of the BBL[®] MGIT[™] tubes is comparable to the BACTEC[®] 460TB System and the BBL[®] SEPTI-CHEK[®] AFB Mycobacterial Culture System; therefore, we believe the BBL[®] MGIT[™] tube to be substantially equivalent to these devices.