

K 946268

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SUMMARY OF SAFETY & EFFICACY

Table 1: BACTEC® 9000MB versus BACTEC® 460TB

Intended Use	Detection of mycobacteria in clinical respiratory specimens	Detection of mycobacteria in clinical specimens
Sample type	Primary sample type - respiratory	Primary sample type - respiratory; other body fluids (including blood) acceptable
Sample volume	0.5 mL	0.5 to 1.0 mL
Growth medium	7H9 Middlebrook broth base with nutrient additives	7H12 Middlebrook broth base with nutrient additives
Detector	Fluorescence sensor in silicon rubber base	¹⁴ C labeled fatty acid present in the media
Antimicrobial supplement	Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin (PANTA)	Polymixin 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
Time to detection (TTD)	Eleven to fifteen days	Seven to twelve days
Incubation temp. 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.

SUMMARY OF SAFETY & EFFICACY

Table 2: BACTEC® 9000MB versus CONVENTIONAL MEDIA

Intended Use	Detection of mycobacteria in clinical respiratory specimens	Used for the cultivation of <i>Mycobacterium tuberculosis</i> and other mycobacterial species.
Sample type	Primary sample type - respiratory	Primary sample type - respiratory; other body fluids (including blood) acceptable
Sample volume	0.5 mL	0.1 to 0.5 mL
Growth medium	7H9 Middlebrook broth base with nutrient additives	Lowenstein-Jensen medium; Egg enriched agar base with nutrient additives
Detector	Fluorescence sensor in silicon rubber base	None
Antimicrobial supplement	Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin (PANTA)	None
Growth detection	Fluorescent detection of O ₂ consumption by mycobacterial growth	Macroscopic observance of growth on media surface
Time to detection (TTD)	Eleven to fifteen days	Twenty-one to forty-nine days
Incubation temp. Mixing	On-board incubation at 37° ± 1.5° C; internal instrument agitation every 10 minutes.	35° C to 38° C† Manual manipulation of media.

*CONVENTIONAL MEDIA -Lowenstein-Jensen agar slants

†CDC recommendations