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510(k) SUMMARY

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DEVICE NAME: BACTEC® Fungal Medium

PREDICATE DEVICE: BACTEC® PLUS 26 Culture Vials

INTENDED USE: Qualitative culture and recovery of yeasts and fungi from blood

DEVICE DESCRIPTION:

BACTEC Fungal Medium is a growth medium providing an aerobic environment for the detection of yeast and fungi. It has been designed for blood volumes of four to 10 mL, and is used specifically with BACTEC non-radiometric (NR) series instruments in the monitoring of clinical blood specimens for the presence of yeasts and fungi. BACTEC Fungal medium has a higher weight/volume concentration of dextrose and sucrose then the predicate device to enhance the recovery and CO_2 production of yeast. Saponin was added to the BACTEC Fungal Medium as a lysing agent, and ferric ammonium citrate was added as a source of iron to stimulate recovery of fungi other than yeast. Resin was removed from this medium. Principles for detection of CO_2 produced by microorganisms metabolizing blood culture medium nutrients are identical to the predicate device.

SUBSTANTIAL EQUIVALENCE:

Table 1 summarizes the similarities and differences between BACTEC® Fungal Medium and BACTEC® PLUS 26 Culture Vials.

Table 1. Substantial Equivalence of BACTEC® Fungal Medium to BACTEC® PLUS 26 Culture Vials

	BACTEC®Fungal Medium	BACTEC® PLUS 26
Intended use	Qualitative culture and recovery of yeasts and fungi	Qualitative culture and recovery of aerobic microorganisms (mainly bacteria and fungi)
Sample type	Blood	Blood
Sample volume	4 - 10 mL	5 - 10 mL
Blood to broth ratio	1 to 2.5	1 to 2.5
Growth medium	Enriched brain heart infusion broth with CO_2	Enriched soybean-casein digest broth with CO_2
Lysing Agent	Saponin (0.24% w/v)	None
Reactive ingredient concentrations		
• Processed water	25 mL	25 mL
• Brain heart infusion broth	1.0% w/v	---
• Soybean-casein digest broth	0.035% w/v	2.75% w/v
• Yeast extract	0.035% w/v	0.25% w/v
• Dextrose	0.1% w/v	0.06% w/v
• Sucrose	0.6% w/v	0.084% w/v
• m-Inositol	0.05% w/v	---
• Hemin	---	0.0005% w/v
• Menadione	---	0.00005% w/v
• Ferric ammonium citrate	0.0001% w/v	---
• Pyridoxal HCl	---	0.001% w/v
• Saponin	0.24% w/v	---
• Anti-foaming agent	0.01% w/v	---
• SPS	0.05% w/v	0.05% w/v
• Chloramphenicol	0.005% w/v	---
• Tobramycin	0.001% w/v	---
• Nonionic adsorbing resin	---	16.0% w/v
• Cationic exchange resin	---	1.0% w/v
Resins	None	Yes (see above)
Instrument	BACTEC® NR instruments	BACTEC® NR instruments
Growth detection	Infrared spectrophotometric measurement of CO_2 produced by microorganisms metabolizing culture medium nutrients	Infrared spectrophotometric measurement of CO_2 produced by microorganisms metabolizing culture medium nutrients
Incubation temperature	35°C ± 1.5°C	35°C ± 1.5°C
Agitation	Orbital agitation for the first 24 hours recommended	Orbital agitation for the first 24 hours recommended
Vial glass	Type III, soda lime	Type III, soda lime
Closure	Rubber	Rubber
CO_2 Monitoring	Invasive vial headspace sampling	Invasive vial headspace sampling

CLINICAL PERFORMANCE:

A multi-center clinical study comparing BACTEC® Fungal Medium, BACTEC® PLUS 26 blood culture medium, and the ISOLATOR™ Microbial Tubes/ISOSTAT® Microbial System (IS System) was conducted at four university-affiliated hospitals. There were a total of 4886 adequately filled paired vials in the comparison of BACTEC® Fungal Medium to BACTEC® PLUS 26 blood culture medium, and 4907 adequately filled paired vials and tubes in the comparison of BACTEC® Fungal Medium to the IS System. Of the 229 clinically significant isolates recovered in the comparison of BACTEC® Fungal Medium to BACTEC® PLUS 26 blood culture medium, 161 were bacteria and 68 were fungi. Of the 68 fungi, 31 isolates (45.6%) were recovered in both media, 11 (16.2%) were recovered in BACTEC® PLUS 26 blood culture medium only, and 26 (38.2%) were recovered in BACTEC® Fungal Medium only. Recovery of all fungi combined and of *Torulopsis glabrata* was statistically significantly better ($p < 0.025$) in BACTEC® Fungal Medium. There was no statistically significant difference in the speed of detection of any of the fungi in the two media, nor of all fungi combined.

Of the 218 clinically significant isolates recovered in the comparison of BACTEC® Fungal Medium to the IS System, 125 were bacteria and 93 were fungi. Of the 93 fungi, 42 isolates (45.2%) were recovered in both media, 34 (36.6%) were recovered in the IS System only, and 17 (18.3%) were recovered in BACTEC® Fungal Medium only. Of the 34 isolates recovered only in the IS System, 25 were *Histoplasma capsulatum*; recovery of *H. capsulatum* was statistically significantly better ($p < 0.001$) in the IS System. Excluding the *H. capsulatum* isolates, 17 fungi were isolated only in BACTEC® Fungal Medium and nine fungi were isolated only in the IS System; this difference is not statistically significant. *T. glabrata* was detected significantly earlier in BACTEC® Fungal Medium ($p < 0.05$). The difference in speed of detection of all fungi in each of the two media was not significantly significant. Thus, the performance of BACTEC® Fungal Medium in detecting growth of fungi in blood was as good or better than that of BACTEC® PLUS 26 blood culture medium, and, with the exception of *H. capsulatum*, equivalent to that of the IS System.