

K 954924

510(k) SUMMARY

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TRADE NAME: BACTEC® PEDS PLUS™ Culture Vials

COMMON NAME: Blood Culture Medium

**CLASSIFICATION
NAME:** Monitor, Microbial Growth

**PREDICATE
DEVICE:** BACTEC® NR6A Culture Vials

INTENDED USE: A qualitative procedure for the culture and recovery of aerobic microorganisms (mainly bacteria and fungi) from pediatric and other blood specimens which are generally less than 3 mL in volume.

DESCRIPTION: BACTEC PEDS PLUS medium is a bacterial growth medium providing an aerobic environment for the detection of bacteria and fungi. It has been designed for the recovery of microorganisms from pediatric and other blood specimens which are generally less than 3 mL in volume and is used specifically with the BACTEC NR (non-radiometric) blood culture series instruments. Each glass vial of medium contains 20 mL of enriched Soybean-Casein Digest Broth with resins and CO₂. If microorganisms are present in the test sample inoculated into the BACTEC vial, CO₂ will be produced and liberated into the atmosphere when the organisms metabolize the substrates present in the vial. The instrument analyzes the vial head space gas for CO₂ and, if a threshold level is exceeded, indicates that the vial is positive, i.e., that the test sample contains viable organisms.

**SUBSTANTIAL
EQUIVALENCE:**

Table 1 summarizes the similarities and differences between BACTEC® PEDS PLUS™ Culture Vials and BACTEC® NR6A Culture Vials.

Table 1. Substantial Equivalence of BACTEC® PEDS PLUS™ Culture Vials to BACTEC® NR6A Culture Vials

	BACTEC NR 6	BACTEC PEDS PLUS
Basic Medium Formulation	* See below	* See below
Sodium Polyanetholesulfonate(SPS)	0.035% w/v	0.025% w/v
Antifoaming Agent	0.01% w/v	None
Yeast Extract	None	0.25% w/v
Nonionic Adsorbing Resin	None	20.0% w/v
Cationic Exchange Resin	None	1.2% w/v
Processed Water	30 mL	20 mL
Optimum Blood-to-Broth Ratio	1:6	1:6.7
Recommended Specimen Volume (maximum)	5 mL	5 mL
Recommended Specimen Volume (optimum range)	3 - 5 mL	1 - 3 mL
Instrument	BACTEC NR Series	BACTEC NR Series
Metabolite Detected	CO ₂	CO ₂
CO ₂ Detector	I.R. Analyzer	I.R. Analyzer
CO ₂ Monitoring	Invasive Vial Headspace Sampling	Invasive Vial Headspace Sampling
Agitation	Orbital Rotator	Orbital Rotator
Vial Type	Type III Soda Lime Glass with Notched Base	Type III Soda Lime Glass with Notched Base

* Ingredients list (% is w/v): Soybean-Casein Digest Broth 2.75%, Hemin 0.0005%, Dextrose 0.06%, Sucrose .08%, Pyridoxal HCL (Vitamin B₆) 0.001%, Menadione 0.00005% w/v

CLINICAL PERFORMANCE:

Clinical studies were conducted comparing BACTEC® PEDS PLUS™ Culture Vials and BACTEC® NR6A Culture Vials at three tertiary care pediatric hospitals. A total of 4,581 paired vials were evaluated. From those sets a total of 289 clinically significant organisms were isolated from 452 positives. Of the 289 clinically significant organisms isolated, 181 (63%) were from both media, 75 (26%) from the BACTEC PEDS PLUS medium and 33 (11%) from the BACTEC NR6A medium. The difference in recovery between the two media was statistically significant ($X^2 = 16.3$, $p < 0.001$). In regards to time to detection, 129 (71%) organisms were detected from both media at the same time, 39 (22%) were detected earlier in the BACTEC PEDS PLUS medium and 13 (7%) were detected earlier in BACTEC NR6A medium. The time to detection between the two media was statistically significant for the BACTEC PEDS PLUS medium ($X^2 = 13.0$, $p < 0.001$). Additionally, of the 143 patients receiving therapy, 82 (58%) organisms were recovered from both media, 45 (31%) organisms were recovered from the BACTEC PEDS PLUS medium only which contains antimicrobial resins and 16 (11%) from the BACTEC NR6A medium only. The BACTEC PEDS PLUS medium detected significantly more organisms than the BACTEC NR6A ($X^2 = 13.8$, $p < 0.001$). Thus, the performance of BACTEC PEDS PLUS medium was as good as the BACTEC NR6A medium.