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510k Summary

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Proprietary Name: Scansystem™

Common Name: Bacterial detection system for the quality control testing of leukocyte reduced apheresis platelet units (LRAP)

Classification Name: MZC

Predicate Device: BacT/ALERT® 3D Microbial Detection System and BacT/ALERT® Culture Bottles

Description of the Device:

The Scansystem™ bacterial detection system is comprised of the Scansystem™ Sampling Device, the Scansystem™ Platelet Kit, the Scansystem™ Analyzer, including an epifluorescent microscope, and software to analyze results and facilitate visual confirmation of results by the operator. The Scansystem™ Sampling Device facilitates the pooling of samples from up to three LRAP units. The Scansystem™ Platelet Kit concentrates the bacteria in the LRAP pool, labels them using a fluorescent dye which is a double strand, DNA-specific marker, and deposits the residual bacteria onto a black membrane after filtering for analysis by the Scansystem™ Analyzer. The Analyzer is a solid phase cytometer which uses a laser to scan the entire membrane surface and analyzes the resulting data, differentiating between labeled bacteria and debris. The results are then transferred to a computer memory. The results are available as a scan map which shows the location of each detected bacterium. With the aid of a link to a motor-driven epifluorescent microscope stage, the operator visually confirms a random selection of fluorescent signals and the results are presented as "number of bacteria detected." The final interpretation is determined by the operator, after the ratio of confirmed positive signals to total number of fluorescent signals has been calculated and determined to be positive or negative.

Intended Use of the Device:

For *in vitro* diagnostic use; the Scansystem™ bacterial detection system is intended to be used to detect bacterial contamination in leukocyte reduced apheresis platelets (LRAP) for quality control testing. It is intended to be used by trained technicians.

Technical Characteristics:

The Scansystem™ Sampling Device is an empty sample transfer set with ports, sample pouches, breakable cannulae leading to a pooling/mixing chamber, and a port for connection to the Scansystem™ Platelet Kit. The Scansystem™ Platelet Kit contains ready-to-use reagents and chambers with breakable cannulae to allow the fluorescent labeling of bacteria, the aggregation of platelets, the permeabilization of bacteria cell membranes, and the plating of residual fluorescent bacteria in the LRAP sample onto a black filter.
The Scansystem™ Analyzer consists of an Argon Laser for scanning at 488 nm, computer with related keyboard, joy-stick module/mouse, monitor, and an epifluorescent microscope.

Substantial Equivalence to a Predicate Device:

The Scansystem™ bacterial detection system is substantially equivalent to the BacT/ALERT® 3D Microbial Detection System and BacT/ALERT® Culture Bottles for bacterial detection in LRAP units during quality control testing. The following table summarizes the technological characteristics of the Scansystem™ in comparison to those of the predicate device:

Table 1 - Comparison of Scansystem™ and BacT/ALERT®

Feature	Scansystem™	BacT/ALERT® Culture Bottle & 3D Microbial Detection System BK000042 & K981736
Intended Use	For the quantitative detection of bacteria in the quality control testing of LRAP units.	Qualitative test for the growth and detection of microorganisms in blood, including the quality control testing of LRAP units.
Platelet Sample volume used for actual test	3 mL single LRAP product or up to three LRAP samples may be pooled together for testing. 3 mL of the pool is then used for testing.	4 mL single LRAP product required; single sample testing only.
Means of bacterial detection	Direct bacterial detection based upon the ability of bacteria to fluorescence.	Culture medium promotes bacterial growth and the production of CO_2
How initial positive results are determined	Calculation of a ratio by the operator after fluorescent signals are detected by the device and confirmed visually by the operator.	Sufficient amount of acceleration of CO_2 production, sufficient amount of long-term growth, and sufficient change in the growth curve.
How positive results are confirmed	Gram stain and subculture.	Gram stain and subculture.
Bacteria which can be detected	Live or dead bacteria.	Live bacteria only; aerobic or anaerobic, depending upon culture environment.

Summary of Nonclinical and Clinical Tests:

Reproducibility - *Staphylococcus epidermidis* (ATCC #49134) or *Escherichia coli* (CIP #105901) was inoculated into aliquots of LRAP to give a final bacteria concentration of 10^3 CFU/mL. Six samples from each aliquot were processed sequentially with Scansystem™ Platelet Kit. All six tests were reported as positive by the Scansystem™ assay.

Detection of bacteria in LRAP - In a prospective comparative study performed at two different clinical sites, the ability of the Scansystem™ to detect bacteria in LRAP was evaluated for 10 bacteria species that are typical platelet contaminants (see Table 2).

LRAP were inoculated with bacteria at final concentrations ranging from 2 to 129 CFU/mL (mean 27 CFU/mL -low inoculum) and from 29 to 1370 CFU/mL (mean 284 CFU/mL - high inoculum). Inoculated LRAP units were maintained in a platelet agitator at 22°C for 30 hours. Following a 30-hour incubation, a 3 mL sample of each spiked LRAP unit was pooled with 3 mL samples from 2 uninoculated LRAP units and processed in the Scansystem™ Platelet Kit. 10 replicates were performed for each inoculated LRAP at each concentration in each site leading to a total of 40 tests per bacteria strain.

At the time of bacteria inoculation, the contaminated LRAP was diluted 1 to 4 with sterile LRAP and 4 mL of the diluted pool was inoculated into BacT/ALERT® aerobic and anaerobic bottles and incubated in the BacT/ALERT® 3D until positivity. Ten aerobic and ten anaerobic bottles were inoculated for each contaminated LRAP at each concentration in each site leading to a total of 80 bottles per bacteria strain.

All LRAP units included in the study were tested with both Scansystem™ and BacT/ALERT® prior to use for sterility control, leading to a total of 40 Scansystem™ controls. No false positives were detected in the 40 controls.

As illustrated in Table 2, 30 hours after inoculation for the 30 and the 300 CFU/mL bacterial inocula, 100% [98.2 – 100] of the Scansystem™ 3 unit LRAP pool tests were positive. For the same samples tested as single LRAP samples, 100% [98.2 – 100] of the BacT/ALERT® aerobic bottles and 95% [91.0 – 97.6] of the BacT/ALERT® anaerobic were positive. Depending upon the bacterial strain, time to achieve a positive BacT/ALERT® result ranged from 8 to 52 hours for the aerobic condition and 8.7 to 45 hours for the positive anaerobic bottles.

Table 2 : Recovery of Bacteria in LRAP tested with the Scansystem™ 30 Hours after Bacteria Inoculation.

		Low inoculum		High inoculum	
Bacteria	ATCC #	N*	%§	N*	%§
Staphylococcus aureus	49476	19	100	19	100
Bacillus cereus	7064	20	100	20	100
Escherichia coli	25922	20	100	20	100
Enterobacter cloacae	29005	20	100	20	100
Staphylococcus epidermidis	49134	20	100	20	100
Klebsiella oxytoca	13182	20	100	20	100
Pseudomonas aeruginosa	27853	20	100	20	100
Streptococcus pyogenes	12344	20	100	20	100
Salmonella choleraesuis	8326	20	100	20	100
Serratia marcescens	43862	20	100	20	100
Total		199	100	199	100
95% Confidence interval			98.2 - 100		98.2 - 100

N*, number of Scansystem™ tests.
%§, percentage of positive results.

Detection of Bacteria in LRAP Units in Routine Use - In two routine prospective studies, 429 clinical samples of (LRAP) were tested for bacterial detection from 30 hours to 2 days after platelet collection, depending upon product availability. The samples were simultaneously analyzed with the Scansystem™ and the BacT/ALERT® system (one aerobic and one anaerobic bottle per LRAP unit). For Scansystem™, each sample (3 mL) was tested as a pool of 3 LRAP units.

No confirmed positives were found with either test system. There were no false positives with the Scansystem™. Agreement between the systems was >99%.

Conclusion - The Scansystem™ performed as well as the BacT/ALERT® in detecting 10 bacterial species that were tested.