510(k) SUMMARY

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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name: **Platelet PGD® Test System**

Common or Usual Name: Bacterial Detection System

Classification Name: Bacterial Detection System for platelet transfusion products

Classification Code: **MZC**

Predicate Devices:

BacT/ALERT Culture Bottles (BK000042)

Description of the Device

The Platelet PGD Test system comprises the Platelet PGD Test and Platelet PGD Controls. The Platelet PGD Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive (GP) and Gram-negative (GN) bacteria in leukocyte reduced apheresis platelet (LRAP) units. The Platelet PGD Test consists of single-use PGD Test Devices, Reagents 1, 2 and 3, which are used to process LRAP unit samples for testing, and Disposable Pipettes and

Microfuge Tubes. There are two Platelet PGD Controls: the Platelet PGD Positive and Negative Controls. The PGD Controls are to be used only with the Platelet PGD Test as assay Quality Control Samples to verify the performance of the Platelet PGD Test. Platelet PGD Controls are provided with the Platelet PGD Test and are also available separately.

When processed platelet sample containing bacteria is added to the sample well of the Test Device, it flows into the sample pad and then enters the GP and GN conjugate pads. Here it re-solubilizes GP and GN conjugate/detector antibodies, which bind to bacterial antigens in the sample. The processed sample then carries the conjugate-labeled antigen through the nitrocellulose of the test strips to the capture lines (GP and GN antibodies). Any antigen present binds to the immobilized antibodies on the capture lines of either the GP or GN test strip (depending upon the bacterial species) forming a visible pink / red line(s) if they are present in the sample above the assay's detection limit. This line is visible in the Gram-Positive (GP) and/or Gram-Negative (GN) Test Result Window. The processed sample continues to flow into the terminal wicks of both strips. As the terminal wicks are wetted by the processed sample, dye coated on their surfaces changes color from yellow to blue/purple (visible through the Procedural Controls (PC) Windows). When both PC Windows have changed color to a blue/purple, the test has run to completion and is ready to be interpreted

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Statement of the Intended Use:

The Platelet PGD Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in leukocyte reduced apheresis platelets (LRAP) as an adjunct quality control test following testing with a bacterial detection device cleared by the FDA for quality control testing of LRAP.

Summary of the technological characteristics of the device compared to the predicate devices

The Platelet PGD Test System is substantially equivalent to BacT/ALERT Culture Bottles. Table 1 summarizes the technological characteristics of the Platelet PGD vs. the predicate device.

Table 1: Comparison of Platelet PGD and BacT/ALERT Culture Bottles

Features	Platelet PGD Test System	BacT/ALERT Culture Bottles (BK000042)
Similarities		
Intended Use	Bacterial (qualitative) detection for adjunct quality control testing of leukocyte-reduced apheresis platelets (LRAP) following testing with a bacterial detection device cleared by the FDA for quality control testing of LRAP,	Bacterial (qualitative) detection for quality control testing of LRAP
Device	In-vitro use	In-vitro use
Category	Pre-market Notification 510(k)	Pre-market Notification 510(k)
Sample Source	LRAP	LRAP
Bacteria detected	Aerobic and anaerobic Gram-positive and Gram-negative bacteria	Aerobic and anaerobic Gram-positive and Gram-negative bacteria
Differences		
Technology	Manual, rapid immunoassay detecting bacterial antigens	Growth of organisms in culture medium in automated detection instrument
Detection Used	Development of visible pinkish-red lines in the presence of bacterial contamination.	Color change based on CO2 production in the presence of bacteria growing in culture medium.
Assay Controls	Positive and Negative Controls	Certificate of Conformance

Summary of Performance Testing:

Testing established performance characteristics of the Platelet PGD Test system and included two growth model studies.

Study 1

The equivalence of the Platelet PGD Test to BacT/ALERT for detecting bacterial contamination in LRAP units was established by comparing the ability and time to detect 10 bacterial species. Three sites participated in the study, each site using three lots of Platelet PGD Test and three lots of Platelet PGD controls. With the exception of *Clostridium perfringens*, all bacteria were tested with each lot. In this study, LRAP units were inoculated with low levels of each bacterial species listed in the following table; the bacteria were then allowed to grow in the units. In addition, 28 LRAP units were inoculated with a PBS solution to serve as negative controls for the bacterial inoculation process.

For each bacterial species, both the bacterially contaminated and negative control units were sampled at 24 hours post-inoculation to inject BacT/ALERT BPA and BPN bottles. The units were again sampled at 48 hours post-inoculation to inject BacT/ALERT BPA and BPN bottles and to perform the Platelet PGD Test. For Platelet PGD testing, 12 blinded and coded samples were prepared (10 or 11 samples from the bacteria-inoculated unit and 1 or 2 samples from the negative control unit). If the Platelet PGD Test detected 100% of the bacteria-inoculated samples at 48 hours, testing was concluded. If any of the bacteria-inoculated samples were not detected by the Platelet PGD Test at 48 hours, the sampling and testing cycle described above was repeated every 24 hours until there was 100% detection by the Platelet PGD Test.

The following table shows the bacterial concentration in each LRAP unit at the time of inoculation and the time to detection (in total hours after that inoculation) for both BacT/ALERT and Platelet PGD. Results for BacT/ALERT samples taken at both 24 and 48 hours are based on the first bottle (BPA or BPN) to turn positive. Platelet PGD results reflect the first sampling interval (48 or 72 hours) at which 100% of PGD replicates were reactive.

Table 2: Study 1 Results

Bacteria	Site	Bacterial Concentration (CFU/mL) in LRAP at unit inoculation	BacT /ALERT (Hours after inoculation of LRAP unit for a positive result)		PGD (Hours after inoculation of LRAP unit tested and detected)
			24 hr Sample	48 hr Sample	
Bacillus cereus (ATCC 7064)	CC	2.8	28	52	48 (10/10)
	UH	1	28	52	48 (10/10)
	VB	1	28	52	48 (10/10)
Clostridium perfringens (ATCC 13124)	VB	0.4	35	69	48 (11/11)
	VB	0.6	36	59	48 (11/11)
Enterobacter aerogenes (Isolate)	CC	4	34	54	48 (10/10)
	UH	6.4	34	54	48 (10/10)
	VB	9.6	32	53	48 (10/10)
Escherichia coli (Isolate)	CC	35	28	52	48 (11/11)
	UH	89.4	31	55	48 (11/11)
	VB	3.4	32	57	48 (11/11)
Klebsiella pneumoniae (Isolate)	CC	3.2	33	56	72 (10/10)
	UH	7.6	31	54	48 (11/11)
	VB	8	Neg	53	48 (11/11)
Pseudomonas aeruginosa (Isolate)	CC	3.6	34	53	48 (10/10)
	UH	7.8	36	55	48 (10/10)
	VB	1.6	33	52	48 (10/10)
Serratia marcescens (ATCC 43862)	CC	4.4	33	52	48 (10/10)
	UH	2.4	30	52	48 (10/10)
	VB	10	31	52	48 (10/10)
Staphylococcus aureus (ATCC 27217)	CC	4	30	52	48 (10/10)
	UH	5	32	52	48 (10/10)
	VB	11.2	33	52	48 (10/10)
Staphylococcus epidermidis (ATCC 49134)	CC	32	35	55	72 (10/10)
	UH	10.6	34	54	72 (10/10)
	VB	10.8	35	55	72 (10/10)
Streptococcus agalactiae (ATCC 12927)	CC	2.8	30	52	48 (11/11)
	UH	5	31	52	48 (11/11)
	VB	2	32	52	48 (11/11)

Testing at 72 hours using the Platelet PGD Test System is substantially equivalent to sampling and testing by BacT/ALERT at 24 and 48 hours post-collection

Study 2

The objective of the second study was to demonstrate that the Platelet PGD Test, when used following a culture-based test, was able to detect bacteria missed by an early culture due to sampling errors. This study was performed using three lots of Platelet PGD and three bacterial species.

Three lots of PGD Test were used in the study. Three bacterial species were evaluated: a Gram-positive (*Bacillus cereus*), a Gram-negative (*Klebsiella pneumoniae*) and a slower growing organism (*Staphylococcus epidermidis*).

Because of the bactericidal properties of platelet-rich plasma, heat-inactivated plasma (HIP) was used as the medium for bacterial inoculation. Following heat treatment, 300 mL of HIP was placed into each LRAP bag. Bacteria were inoculated into the bags, allowed to mix on platelet rockers for 1 to 2 hours and then sampled for testing by culture. Ten 8 mL samples were removed; 2 mL of each 8 mL sample was added to four 150 mm Mueller-Hinton agar plates, 2 of which were incubated under anaerobic conditions. Plates were monitored for growth. An inoculated bag was excluded from further study if colonies were observed on 10 of the 10 samples. If colonies were observed on fewer than 10 of the 10 samples, PGD testing was performed.

For PGD testing, platelet pellets were processed and centrifuged and the plasma was decanted, leaving the pellets. Each platelet pellet was resuspended in 500 µL (inoculated) HIP and tested using Platelet PGD. Platelet PGD testing was repeated every 12 hours until reactive results were observed using all three PGD Test lots.

Bags were sampled for culture again when reactive PGD results were obtained or at 96 hours post-inoculation if PGD results were non-reactive. This culture sample was used to determine whether or not bacterial growth had occurred and to confirm the identity the study organism.

Table 3 shows bacterial inoculation and testing results for culture and Platelet PGD for Study 2.

Study 2 demonstrated that the Platelet PGD, when used following a culture-based test, was able to detect bacterial contamination when an early culture was unable to detect bacteria due to sampling errors.

Conclusions

Study data support the determination of substantial equivalence of the Platelet PGD Test system to BacT/ALERT Culture. In addition, data generated during the Study 2 demonstrate the value of the Platelet PGD Test system as an adjunct quality control test following testing by culture.

Table 3: Study 2 Results

Bacteria	Targeted Bacterial Concentration CFU / Bag	Observed Bacterial Concentration CFU / Bag	Initial Culture Samples Positive	PGD 24 hr	PGD 36 hr	PGD 48 hr	PGD 60 hr	PGD 72 hr	PGD 84 hr	PGD 96 hr	Second Culture	
											Sample Time	Result
Bacillus cereus												
Bag 1	190	45	5 of 10	NR	R	R					36 hrs	Pos
Bag 2	19	<4.5	0 of 10	NR	R	R					36 hrs	Pos
Bag 3	1.9	<0.45	0 of 10	NR	R	R					36 hrs	Pos
Klebsiella pneumoniae												
Bag 4	170	174	9 of 10	NR	NR	NR	NR	NR	NR	NR	96 hrs	Neg*
Bag 5	17	<17.4	0 of 10	R	R						24 hrs	Pos
Staphylococcus epidermidis												
Bag 6	76	26	5 of 10	NT	NT	NR	NR	R	R		72 hrs	Pos

*Culture sample taken at 96 hours was negative indicating no bacterial growth or auto-sterilization of the bag.

NR = Platelet PGD non-reactive
R = Platelet PGD reactive
POS = Bacterial growth confirmed; study organism confirmed
NT = Not tested