Section 5: 510(k) Summary

1 Submitter Name:

Immunetics, Inc.
27 Drydock Ave., 6th Floor
Boston, MA 02210

Contact: Ginger-Abraham-Freel
Telephone: (781) 248-8180

2 Correspondent/Contact

Ginger-Abraham-Freel
Director, QA/QC
Immunetics, Inc.
27 Drydock Ave.
Boston, MA 02210
Phone: (781) 248-8180 (cell)
Fax: 617-896-9110
E-mail: gafreel@oxfordimmunotec.com

3 Date Prepared: November 29, 2017

4 Device Name:

Device Trade Name:	BacTx® Bacterial Detection Kit
Regulatory Name:	Bacterial detection kit for platelet transfusion products
Review Panel:	CBER Immunology Devices
Classification Name:	Class I (Reserved)
Classification Code:	MZC: System, Detection, Bacterial, For Platelet Transfusion Products

5 Predicate Devices: BacTx® Bacterial Detection Kit, BK130017
BacTx® Bacterial Detection Kit, BK110054
Classification Code: MZC, Class I (Reserved)

6 Device Description:

The BacTx® Assay System for detection of bacteria in platelets consists of the BacTx® Bacterial Detection Kit, BacTx® Assay Software provided on a laptop computer, and a BacTx® Reader. The BacTx® Reader is connected to the laptop computer by a USB connection.

The BacTx® Assay System detects the presence of peptidoglycan, which is a component of bacterial cell walls in both Gram-positive and Gram-negative bacteria. To carry out the assay, a processed platelet sample is added to a Reaction Tube, which contains lyophilized detection reagent, and the tube is then placed in the BacTx® Reader. If peptidoglycan is present in the sample, an enzymatic reaction is activated and produces a red-colored product. The BacTx® Reader is a photometer which monitors the detection reaction for 30 minutes and is controlled by the BacTx® Assay Software on the laptop computer. Using the provided BacTx® Assay Software, if bacteria are detected within the 30-minute reading time, a “Fail” result appears on the computer screen and is accompanied by an audible alarm; otherwise, a “Pass” result will be displayed.

7 Intended Use:

The Immunetics BacTx Bacterial Detection Kit is a qualitative colorimetric assay that detects the presence of bacteria in platelets for transfusion.

8 Indications For Use:

The Immunetics BacTx® Bacterial Detection Kit for detection of bacteria in platelets is a rapid, qualitative, colorimetric, quality control test for the detection of aerobic and anaerobic, Gram-positive and Gram-negative bacteria in:

-Leukocyte Reduced Apheresis Platelet units (LRAP) (Apheresis Platelets Leukocytes Reduced) as a quality control test following testing with a growth based bacterial detection device cleared by the FDA for quality control testing of leukocyte reduced apheresis platelets and;

-Pools of up to six (6) units of Leukocyte Reduced Whole Blood-Derived Platelets (Platelets, Leukocytes Reduced) that are pooled within four (4) hours of transfusion.

-Pre-storage pools of up to six (6) units of Leukocyte Reduced Whole Blood Derived Platelets (LR-WBDP) as a quality control test.

9 Summary of Technological Characteristics Compared to the Predicate Device:

There are no differences in the technological characteristics of the predicate device BacTx® Bacterial Detection Kit, 510(k) Number BK110054 and BK130017 and the device subject of this premarket notification BacTx® Bacterial Detection Kit for Detection of Bacteria in Platelets since they are the same device. This notification is to modify the intended use of the current device to add pre-storage pools of leukocyte reduced whole blood derived platelets as an additional platelet product for testing. There are no changes to any component of the test system that includes the reagent kit, the reader, and software.

In principle, BacTx® can detect both viable and nonviable bacteria. BacTx® detection time is up to 30 minutes.

The BacTx® Bacterial Detection Kit is for in vitro use for the detection of aerobic and anaerobic, Gram-positive and Gram-negative bacteria. The assay is a rapid test that detects components of bacterial cell walls. The BacTx® Test is an enzyme-based colorimetric assay that utilizes the prophenoloxidase cascade present in insect larval plasma to detect peptidoglycan in prepared platelet samples.

The predicate comparison table and performance testing provided in this 510(k) are sufficient to demonstrate that the modification of the intended use of the BacTx® Bacterial Detection Kit for Detection of Bacteria in Platelets to include pre-storage pools of leukocyte reduced whole blood derived platelets is substantially equivalent to the legally marketed predicate device, BacTx® Bacterial Detection Kit, BK110054 and BK130017.

10 Summary of Non-clinical Performance Testing as Basis for Substantial Equivalence

Because there were no design changes to any component of the BacTx® Bacterial Detection System, non-clinical testing was not performed. Platelets stored in pre-storage pool bags are identical to the Leukoreduced Whole Blood Derived platelets that were studied in 510(k) submission BK110054.

11 Summary of Clinical Testing as Basis for Substantial Equivalence

Clinical testing performed demonstrates that pre-storage pools of leukocyte reduced whole blood derived platelets (LR-WBDP) perform substantially equivalently to pools up to six (6) units of leukocyte reduced whole blood-derived platelets (LR-WBDP), and Apheresis Platelets Leukocytes Reduced (LRAP) when tested with BacTx® Bacterial Detection Kit. Clinical testing to assess the optimal time-to-detection was performed at two external sites, and Immunetics. Bacteria tested are listed in the Table 1.

Table 1 - Bacteria utilized for analytical performance

Strain	ATCC #	Aerobe Anaerobe	Gram Positive (GP) Gram negative (GN)
Staphylococcus aureus	27217	Aerobe	GP
Staphylococcus epidermidis	49134	Aerobe	GP
Bacillus cereus	11778	Aerobe	GP
Streptococcus agalactiae / Streptococcus pyogenes	12386 / PEI-B-P-20	Aerobe	GP
Serratia marcescens	43862	Aerobe	GN
Pseudomonas aeruginosa	27853	Aerobe	GN
Escherichia coli	25955	Aerobe	GN
Klebsiella oxytoca	43863	Aerobe	GN
Clostridium perfringens	3629	Anaerobe	GP
Propionibacterium acnes	11827	Anaerobe	GP

Time-to-Detection – Pre-Storage Pool Study Description:

To determine the time to detection of bacteria growing in Leukocyte-Reduced Whole Blood Derived Platelets Pre-Pooled Using the Acrodose PL System, a bacterial growth study was performed to determine the earliest sampling time that the BacTx® Assay could successfully detect bacteria that were inoculated at low titers (2 – 5 CFU/mL). The same bacterial strains used in the analytical sensitivity study above (See Table 1) were used for the Time to Detection Study, with the addition of an eleventh strain, Streptococcus pyogenes. Individual LRWBDP were spiked with bacteria (or PBS as a negative control) on Day 0, and after 24 hours, the individual LRWBDP unit was pooled with a five-unit Acrodose pool. All pooling was performed with ABO blood type matched platelet units.

At approximately 48 hours after inoculation, a small volume of platelets was withdrawn from the contaminated and uncontaminated unit Acrodose pools. Ten samples from the contaminated Acrodose pool and three samples from the uncontaminated Acrodose pool were blinded and tested with the BacTx® Assay. If less than 10 of the contaminated samples were detected at the 48 hour time point, this testing was repeated at approximately 72 hours after inoculation. All Acrodose pools were also tested at approximately 7 days after inoculation. When BacTx® testing was performed, quantitative plate culture (QPC) was carried out to determine the bacterial titer in the contaminated unit at that time point. Culture plates made at 24 hours and 7 days after inoculation from the spiked units were submitted for bacterial identification to confirm the strain that proliferated in the unit was the same as the strain that was inoculated. BacT/ALERT® testing was performed at day 0 to confirm sterility of the unit. Testing was conducted at three sites with multiple lots of BacTx® Assay Kits

Pre-Storage Pool Study Results:

A summary of the BacTx® Assays, BacT/ALERT, and quantitative plate culture results for the Time to Detection study performed at 2 sites is shown in Table 2. For each bacterial strain tested at each site, the earliest time point at which 10 out of 10 BacTx® Assays were positive is shaded in grey. Of the 8 aerobic species tested, six species were detected at 48 hours at both sites. S. epidermidis was detected at 48 hours at one site and at 72 hours at the second site. Streptococcal strains (Streptococcus agalactiae or Streptococcus pyogenes) were detected at 72 hours at both sites. As anticipated, the presence of colonies on quantitative plate cultures in Acrodose Pools inoculated with anaerobes could not be detected, and BacTx® Assays were negative for Acrodose Pools inoculated with the anaerobic species.

Pre-storage Pool Study Conclusion:

Based on these results, the optimal time for detection of all of the bacterial strains that proliferate in pre-storage pools is 72 hours. For each bacterial strain tested at each sites, the ability of the BacTx® Assay to detect bacteria in 10 out of 10 samples is supported by the plate culture results. At each time point that 10 out of 10 samples were detected in the BacTx® Assay, the results of BacT/ALERT culture testing were also positive for one or both types of bottles..