TECHNICAL SERVICES BULLETIN

1099 Bracken Road, Piedmont, SC 29673 | Phone 864.255.5000 | Fax 864.242.4842 | www.thebloodconnection.org *Not-for-profit community service.*

Dr. Robert Rainer, MD Medical Director

Brian Madden Executive VP, Operations and COO

Tracy Bridges VP, Business Development and Chief Technical Officer

BACTERIAL CONTAMINATION TESTING/EXTENDED DATING FOR PLATELETS (APHERESIS)

BACKGROUND:

In 2016, the 30th edition of the AABB Standards for Blood Banks and Transfusion Services incorporated permissibility for extending platelet storage beyond five days. Standard 5.1.8A permits Apheresis Platelets Leukocytes Reduced to have a seven-day expiration "only if 1) storage containers are cleared or approved by the FDA for 7-day platelet storage, and 2) labeled with requirement to test every product stored beyond 5 days with a bacteria detection device cleared by the FDA and labeled as a 'safety measure.'

Two recent FDA clearances of seven-day storage containers from the largest suppliers of platelet collection systems in the United States – Fresenius Kabi and Terumo BCT – allow for seven-day platelet dating in the U.S. when used in conjunction with the Verax Platelet PGD Test.

The Verax Biomedical Platelet Pan Genera Detection (PGD®) Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Grampositive and Gram-negative bacteria in platelet components. An apheresis platelet may be transfused for up to 24 hours after a non-reactive PGD test result.

The efficacy of platelets stored for seven days has been shown to not be different than a platelet stored for five days.

ACTION ITEMS:

Beginning on or after November 12, 2018, The Blood Connection will implement Verax testing on selected apheresis platelet products. These products will be labeled according to AABB Standards. Please reference the ISBT product codes below and make any changes necessary within your facility to enable receipt of these products.

NOTE: Products tested on Day 6 expire 24 hours after testing. Products tested on Day 7 expire at midnight on Day 7.



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VP, Business Development and Chief Technical Officer VERAX Tested Platelet Product Codes

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LEUKOREDUCED/NON-IRRADIATED PLATELETS:

Tested Day 6:

E9232 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial test D6 E9233 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Bacterial test D6 E9234 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Bacterial test D6 E9235 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|Bacterial test D6

Tested Day 7:

E9236 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial test D7 E9237 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Bacterial test D7 E9238 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Bacterial test D7 E9239 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|Bacterial test D7

LEUKOREDUCED IRRADIATED PLATELETS:

Tested Day 6:

E9256 Apheresis PLATELETS ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | Bacterial test D6 E9257 Apheresis PLATELETS ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | 1st container | Bacterial test D6 E9258 Apheresis PLATELETS ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | 2nd container | Bacterial test D6 E9259 Apheresis PLATELETS | ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | 3rd container | Bacterial test D6

Tested Day 7:

E9260 Apheresis PLATELETS ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | Bacterial test D7 E9261 Apheresis PLATELETS | ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | 1st container | Bacterial test D7 E9262 Apheresis PLATELETS | ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | 2nd container | Bacterial test D7 E9263 Apheresis PLATELETS | ACD-A/XX/20-24C | Irradiated | ResLeu:<5E6 | 3rd container | Bacterial test D7

For any questions or concerns contact: Melanie Porter **mporter@thebloodconnection.org** 864-751-3047

> TBC-lssue 25 October 2018



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