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 Gram-positive 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.
VERAX Tested Platelet Product Codes

LEUKOREDUCTED/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

LEUKOREDUCTED 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

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