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Bacterial Detection QC for Platelets

Vitalant performs bacterial detection testing on all Vitalant* platelet products supplied to our hospitals. Vitalant utilizes the Bac/T Alert microbial detection system (bioMérieux), a culture based system approved by the FDA. This is a quality control (QC) test and meets the FDA requirement to "adequately control" the risk of bacterial contamination of platelets. In the event a platelet is released due to transfusion need, either prior to completion of initial bacterial detection testing or testing cannot be performed, the platelet will be identified as untested with an appropriate tie tag. Should a positive test result be obtained subsequent to release of the platelet, the hospital will be notified.

*** Vitalant verifies imported platelet products are in compliance with regulatory requirements as stipulated below.**

This is in compliance with:

- **21 CFR § 606.145 Control of bacterial contamination of platelets.**
  - (a) Blood collection establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA.

- **AABB Standards for Blood Banks and Transfusion Services, 33rd edition**
  - **Standard 5.1.5.1:** The BB/TS shall have methods to limit introduction of bacteria into the collection. Standard 5.6.2 applies.
  - **Standard 5.1.5.2:** The BB/TS shall have methods to detect bacteria or use pathogen reduction technology in all platelet components stored at 20-24C.

- **College of American Pathologists (CAP) TRM. 44955 Bacterial Contamination in Platelets**
  - The laboratory (or its blood supplier) assures that the risk of bacterial contamination of platelets is adequately controlled using
    - 1) FDA-cleared/approved devices or an equivalent system for bacterial detection in platelets, and follow FDA recommended bacterial testing intervals and sampling volumes or
    - 2) other adequate and appropriate methods found acceptable by the FDA (eg, pathogen reduction).
  - Evidence of Compliance**:**
    - Records of use of individual units of whole blood derived (WBD) platelets or pools of up to six units of such platelets that have been tested by an FDA-cleared/approved method **OR**

- Records of use of pre-pooled WBD platelets tested with an FDA-cleared/approved culture-based QC test by the supplier **OR**
- Records of use of apheresis platelets tested with an FDA-cleared/approved culture-based QC test by the supplier **OR**
- Records of culture of aliquots from individual WBD platelet units destined for pooling **OR**
- Records of testing by methods that are not FDA-cleared/approved but have been validated to be of equivalent clinical sensitivity to an FDA-cleared/approved assay **OR**
- Records for use of other adequate/appropriate methods found acceptable by the FDA (eg, pathogen reduction)