

Platelet Sterility Testing Policy

Purpose

To describe the Indiana blood Center's policies for performing **Sterility Testing for apheresis platelets (SDPs)** manufactured by the Indiana Blood Center

All platelets manufactured by the Indiana Blood Center are tested before distribution.

Policies

- IBC only manufactures platelet products by apheresis. Testing on whole blood derived platelets or a pool of whole blood derived platelets is not performed.
- IBC uses the BacT/ALERT 3D system for bacterial testing.
- According to the manufacturer's package insert, all products must be leukocyte reduced before testing. Any product that contains excessive WBCs will be leukocyte reduced by filtration prior to testing.
- To ensure maximum detectability (and maximum patient safety), products are incubated at room temperature for 24 hours before testing. The test must incubate for a minimum of 12 hours and indicate no growth detected before products are acceptable for distribution.
- Bacterial cultures are monitored for at least 5 days, **or until a positive culture result is obtained.**
- **When a positive result is obtained, additional testing will be performed to identify the organism. See Process CP101.**
- If bacterial growth is detected after product release, the product will be immediately recalled from the facility by a Distribution associate.
- If bacterial growth is detected after a product has been transfused, the IBC physician (in-house or on-call) will be notified for further evaluation if the patient. A copy of all culture results from the reference microbiology laboratory is given to the IBC physician for further review.
- If the product integrity is compromised before the bacterial detection sample is obtained, then testing will not be performed.
- If a product is contaminated during the sampling process after the bacterial detection sample is obtained, then testing will be discontinued.
- Negative bottles should be unloaded promptly from the system.
- Individuals who perform platelet bacterial detection are subject to competency assessment and proficiency testing.
- Evidence of compliance with these policies can be made available to a customer's inspector, investigator, or assessor upon request.

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