HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Limiting and Detecting Bacterial Contamination in Platelet Concentrate		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 Developing a system for reduction and detection of bacterial contamination in platelet components to increase the safety of blood products and to minimize the possible risk of febrile transfusion reactions.

2. DEFINITONS:

N/A

3. POLICY:

3.1 Bacterial transmission by transfusion remains a significant problem in transfusion medicine. Platelet components present the greatest risk due to their storage at 20-24°C, which enhances the proliferation of bacterial species as well as the units may be pooled between many donors units.

3.2 The initial bacterial load, if present, may follow one of several growth models:

- 3.2.1 It may become non-viable and die.
- 3.2.2 After a short lag phase, viable bacteria enter a logarithmic growth phase.
- 3.2.3 Viable bacteria persist at low concentration in an extended lag phase before undergoing logarithmic growth; or
- 3.2.4 Viable bacteria may simply persist at low concentrations throughout the platelet storage period. As bacterial growth increases over time, the older platelet units carry a higher risk.

3.3 Sources of Bacterial Contamination:

- 3.3.1 Skin Surface Contamination.
  - 3.3.1.1 They are predominantly staphylococci that will grow profusely in platelet concentrates stored at 20-24 °C.
- 3.3.2 Phlebotomy Core.
- 3.3.3 Donor bacteraemia.
- 3.3.4 Containers and Disposables.
- 3.3.5 Environment.

3.4 The blood bank has a process to limit and detect bacterial contamination in platelet components.

3.5 Bacterial contamination screening is done after platelets collection.

3.6 Culture assays are the most widely used for the detection of bacteria.

3.7 There is a written agreement regarding platelet cultures between the blood bank and microbiology unit.

3.8 The clinicians should be aware of the problem of bacterial contamination of blood products, particularly platelets, and consider the possibility of bacterial contamination when investigating febrile transfusion reaction.

3.9 Release units of platelets, after the appearance of the negative results in the first day of the bacterial culture system (provided that the other serological markers are negative).

3.10 In case of the emergence of a positive result for the released platelets, communicate with treating physician about the test results to assess the patient's condition and give appropriate treatment if necessary.

4. PROCEDURE:

4.1 **Limitation of bacterial contamination:** This is done through the following measures;

4.1.1 Proper taking of donor medical history to screen for possible bacteraemia.

4.1.2 Proper skin disinfection during phlebotomy:

4.1.2.1 The venipuncture site must be prepared properly by aseptic technique to minimize the risk of bacterial contamination.

4.1.3 Diversion pouch:

4.1.3.1 The blood bags used in the blood bank must be sterile and pyrogen free, closed system and equipped with diversion pouch. Diversion pouch prevents small plug of skin "phlebotomy core" entering the unit as well as the initial 30-40 ml of blood , with higher possibility of contamination, will be delivered into a pouch.

4.1.4 Optimizing blood component processing, storage, and transport:

4.1.4.1 Appropriate processing, storage and transport conditions to maintain temperature specifications and to protect contents of container away from any cause of leakage.

4.2 **Bacterial detection options in platelet products:**

4.2.1 Visual Examination:

4.2.1.1 Inspect product prior to transfusion for discoloration, abnormal clumping, or loss of swirling.

4.2.1.2 Perform "swirl" procedure to detect morphologic changes in platelets:

4.2.1.2.1 It is not a specific marker for contamination.

4.2.1.2.2 Normal shaped platelets will align with fluid flow and "shimmer" when swirled.

4.2.1.2.3 Contaminated platelets, among others, lose discoid shape and do not "shimmer" when swirled.

4.2.2 Culture method using BacT/ALERT® (BioMérieux Inc.):

4.2.2.1 Principle:

4.2.2.1.1 It is an automated colorimetric blood culture method, based on the detection of carbon dioxide produced by proliferating microorganisms.

4.2.2.1.2 The bottom of the bottles contains a pH-sensitive liquid sensor which changes its color according to the amounts of CO_2 released.

4.2.2.1.3 Culture is performed for ≥ 24 hours after platelets collection. The CO_2 production is correlated with the alteration of the reflection of the light on the sensor.

4.2.2.2 Procedure:

4.2.2.2.1 Double long platelet-unit segments are made.

4.2.2.2.2 After ≥ 24 hours post-collection, a segment from each platelet unit is sent to microbiology lab for culture.by using special barcode and hematos system or Platelet culture forms 1 (Sending Form), 2 (Initial results), and 3 (Full results) should be filled and associated with segments in case of system failure .

4.2.2.2.3 The first reading of culture is taken after 24 hours of incubation (1st day culture system). The culture is continued for the shelf life of the unit (5 days).

4.2.2.2.4 Units can be released after the appearance of negative results of the 1st day of incubation (provided that the other serological markers are negative).

4.2.2.2.5 All platelet culture forms are kept in the specified file.

4.2.2.3 Limitations of Blood Culture Method:

4.2.2.3.1 Hold to end of culture to release.

4.2.2.3.2 Need to balance the risk of platelet shortages versus the risk of platelet contamination.

4.2.2.3.3 Probable negative impact on outdates.

4.2.3 Haemonetics eBDS system (Not available in MCH blood bank).

4.3 **Investigations of positive cases:**

4.3.1 The initial positive test result may be either true contamination introduced from the donor or during handling, or a false positive result.

4.3.2 When a positive signal was detected, another sample from platelet unit (if available) is sent to microbiology lab for culture. This is because approximately two-thirds of the initially positive signals are determined to be caused by either contamination of the bottle (and not the component) or false signals from the culture system.

4.3.3 If the 2nd culture is negative after 24 hours incubation, the units are released.

4.3.4 If the 2nd culture gives positive signal after 24 hours incubation; all blood components separated from such donor bag to be discarded.

4.3.5 Blood bank must notify donors of any medically significant abnormality discovered either during the interview or detected as a result of laboratory testing.

4.3.5.1 Call the donor, get another sample after complete sterilization of the skin.

4.3.5.2 Perform bacterial culture.

4.3.5.3 If negative, review the sterilization procedure of the blood donors.

4.3.5.4 If positive, refer the donor to the specified clinic through Preventive medicine department. Documentation is done through Bacterial Contamination Donor's notification form.

4.3.6 Notes:

4.3.6.1 True positive results may occur with a wide variety of organisms; while many may be of little or no clinical significance to the donor, others may be more significant.

4.3.6.2 A true positive result is most often the result of contamination of the platelet unit by skin flora (due to incomplete skin decontamination, or as a result of a skin plug).

4.3.6.3 However, a true positive result can also be the result of organisms that may be of clinical significance to the donor, including those that cause bacteraemia. Gram-negative organisms (e.g. E. *coli*) most often are due to occult bacteraemia.

4.3.6.4 All Gram-negative organisms should be considered potentially significant for the donor's health.

4.3.6.5 Gram-positive organisms (e.g. Staphylococcus epidermidis) are likely to be either skin commensals or environmental contaminants. However, some Gram-positive organisms (e.g., Staphylococcus *aureus*, Streptococcus *pneumoniae*) may be from endogenous bacteraemia in the donor. For example, an organism such as S. aureus may originate from a bacteraemia in a patient whose osteomyelitis was incompletely treated. Moreover, some organisms may have low pathogenicity, but may indicate a significant underlying disease (e.g., Streptococcus bovis bacteraemia associated with colon cancer).

4.4 **When platelet component recipient has signs or symptoms consistent with post-transfusion bacteraemia:** Refer to **"Investigation Of Suspected Cases Of Post-Transfusion Infection"** chapter

4.4.1 Because no test is 100% sensitive, false-negative results of platelet screening for bacterial contamination will occur.

4.4.2 Transfusing physicians should continue to evaluate all transfused patients with onset of signs or symptoms consistent with bacteraemia or sepsis for a transfusion reaction.

4.4.3 The minimal evaluation of a patient with suspected sepsis following platelet transfusion should include:

4.4.3.1 Culture of any residual component, it available;

4.4.3.2 Blood cultures of the patient.

4.4.3.3 Any isolates should be retained until the case investigation is completed.

4.4.4 Results of the patient workup should be communicated to the blood bank physician, these data will help determine the significance of the initially negative test result.

4.4.5 Signs and Symptoms of Transfusion-Associated Sepsis:

4.4.5.1 The transfusion of a contaminated cellular blood product unit may be associated with variable signs and symptoms. Not all contaminated blood products cause symptoms in the recipient; in fact, it appears that many do not.

4.4.5.2 The initial signs and symptoms, when they occur, include fever and chills, which usually begin shortly after (within 2 hours) the start of the transfusion. .

4.4.5.3 Subsequent signs may include hypotension, nausea, vomiting, diarrhoea, oliguria, and shock.

4.4.5.4 Other potential presenting symptoms include: respiratory symptoms (dyspnea, wheezing, and/or cough) and bleeding due to the consequence of endotoxin-induced disseminated intravascular coagulation.

4.4.5.5 It is important to note that a majority of septic transfusion reactions associated with contaminated platelets usually occur with units that have been stored for 3 days or more.

4.4.5.6 The clinical severity of a transfusion-associated septic reaction can vary considerably, depending on:

4.4.5.6.1 The species of bacteria present in the blood product unit with Gram-negative organisms tending to cause more severe reactions, due to the presence of endotoxin often elaborated by such organisms;

4.4.5.6.2 The total number of bacteria infused or present in the cellular blood product unit infused to a recipient;

4.4.5.6.3 The rate of propagation of the bacteria present; and

4.4.5.6.4 Recipient characteristics, such as underlying disease, leukocyte count, the status of the immune system, and whether the recipient is receiving concomitant antibiotic therapy.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Platelet culture form 1 (Sending Form)

5.1.2 Platelet culture form 2 (Initial results)

5.1.3 Platelet culture form 3 (Full results)

5.1.4 Bacterial Contamination Donor's notification form

5.2 **Equipment:**

5.2.1 Tube sealer.

5.2.2 barcode named sample laboratory QC printed from hematos system .

6. RESPONSIBILITIES:

6.1 Bank staff in separation area responsible for taking tube segments from platelet units and sending them to microbiology unit after 24 hours incubation.

6.2 Microbiology unit staff is responsible for receiving, processing, and registration of samples and their results following the policies and procedures of microbiology unit.

6.3 Blood bank specialist/technician is responsible for collection and retention of results.

6.4 Blood bank supervisor is responsible for collecting and discarding units with positive results after 48 hours.

6.5 Blood bank supervisor is responsible for notifying the donor for any medically significant abnormality detected as a result of laboratory testing.

7. APPENDICES:

N/A

8. REFERENCES:

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8.7 Association Bulletin # I0-05- suggested options for transfusion services and blood collectors to facilitate implementation of BB/TS interim standard 5.1.5.1.1. 19/8/2011.
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8.11 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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