









## AABB BACTERIAL RISK REFERENCE SHEETS | 24C-D3C-5

<b>Strategy</b>	2 Steps: Cultures		
<b>Intervention</b>	Primary ≥ 24 AND 2nd Culture ≥ Day 3	<b>Expiration</b>	5 days
<b>Technical notes</b>	<p><b>Step 1 is Primary culture ≥ 24:</b></p> <ul style="list-style-type: none"> <li>For apheresis: May test each component of the apheresis collection or original apheresis collection bag alone. For pre-storage pools: test pooled component only.</li> <li>Sample no sooner than 24 hours from time of collection with 16 mL evenly split into aerobic and anaerobic bottles</li> <li>Recommended minimum 12-hour incubation hold prior to release</li> </ul> <p><b>Secondary culture:</b></p> <ul style="list-style-type: none"> <li>Must test each component using 8 mL inoculum into at least aerobic bottle; Do not need to recalculate product yield after secondary testing</li> <li>Standard Operating Procedures must establish a minimum incubation period before issue</li> </ul>		
<b>Platelet type</b>	Apheresis platelets and pre-storage pools of WBD platelets		
<b>Solution</b>	Stored in plasma or platelet additive solution		
<b>Hospital Transfusion Service</b>	<p><b>Advantage:</b> Manage inventory for 5-day expiration.</p> <p><b>Disadvantages:</b> Need to liaise with microbiology lab; blood bank staff needs to be trained to perform sterile sampling and culture inoculation; additional staffing may be necessary to perform sampling; significant administrative/logistical burden to the HTS staff; product loss from additional testing.</p> <p><b>Regulatory perspectives:</b> Requires method validation; QC monitoring; instrument maintenance by vendor; Must establish the quarantine period and SOP.</p> <p><b>Quality/clinical considerations:</b> Expect efficacy to be equivalent to a non-pathogen reduced/primary culture/5-day expiration platelet.</p> <p><b>Cost:</b> Additional staff required for testing may add to cost. Secondary culture is relatively low cost.</p>		
<b>Blood Collection Center</b>	<p><b>Advantage:</b> Do not need to recalculate product yield after secondary testing; extends to 5 days.</p> <p><b>Disadvantages:</b> Additional disadvantages related to secondary culture, which may be done by BCC.</p> <p><b>Regulatory perspectives:</b> Must determine how to label as 3 and then 5-day product; Must determine quarantine period. Update COI.</p> <p><b>Quality considerations:</b> Lower product yield following secondary culture.</p> <p><b>Cost:</b> Additional cost for testing and staff time affecting the blood center and the hospital.</p>		
<b>Efficacy</b>	FDA has evaluated efficacy and includes this in the recommended strategies		
<b>Earliest day of receipt by hospital</b>	Early to middle of day 2		
<b>Shelf Life</b>	3-4-day shelf life; hold time determined by center; culture may be done at hospital or blood center		

WBD: whole blood derived; HTS: hospital transfusion service; QC: quality control; and BCC: blood collection center













# AABB BACTERIAL RISK REFERENCE SHEETS | 36C-R-7

<b>Strategy</b>	2 Steps: Culture and Rapid test		
<b>Intervention</b>	LVDS ≥ 36 hours AND Rapid testing	<b>Expiration</b>	7 days
<b>Technical notes</b>	<p><b>Primary culture:</b></p> <ul style="list-style-type: none"> <li>• Sampling taken no sooner than 36 hours from time of collection</li> <li>• 16 mL inoculum evenly split into aerobic and anaerobic bottles from each unit</li> <li>• When splitting apheresis collection into multiple units, must test each component</li> <li>• Recommended minimum 12-hour incubation hold prior to release</li> </ul> <p><b>Secondary culture:</b></p> <ul style="list-style-type: none"> <li>• Rapid testing of each apheresis component within 24 hours prior to platelet transfusion</li> </ul>		
<b>Platelet type</b>	Apheresis in bag approved by FDA for 7-day storage		
<b>Solution</b>	Plasma		
<b>Hospital Transfusion Service</b>	<p><b>Advantage:</b> Obtain final result relatively quickly (no incubation time required); potential for decreased platelet wastage due to increased shelf-life.</p> <p><b>Disadvantages:</b> Rapid test is good for 24 hours – if platelet used after 24 hours the unit must be re-tested; rapid test is somewhat labor intensive; possible increase in staffing needed.</p> <p><b>Regulatory perspectives:</b> Use of rapid testing to extend dating with a 6 or 7-day expiration date requires FDA registration or licensure to perform this manufacturing step; quality control monitoring needed; proficiency testing required. Update COI.</p> <p><b>Quality/clinical considerations:</b> Units need to be relabeled with new expiration time after each rapid test; facilities will need to decide which units to test and may need to reorganize inventory to know which units have been tested or are eligible for testing.</p> <p><b>Cost:</b> Expected similar overall cost when compared with secondary culture strategies.</p>		
<b>Blood Collection Center</b>	<p><b>Advantage:</b> Can extend shelf life of units. RT can extend shelf life of apheresis platelets stored in plasma to 7 days.</p> <p><b>Disadvantages:</b> Most disadvantages will be experienced by HTS unless BCC performs the secondary rapid test.</p> <p><b>Regulatory perspectives:</b> Applies only to Apheresis platelets stored in plasma based on FDA approval of storage bag for 7-day expiration; equipment validations; licensure for 7-day product for shipping across state lines; Update COI; new ISBT codes for 7-day products.</p> <p><b>Quality considerations:</b> Possibly lower product yield and rapid testing is usually performed by HTS.</p> <p><b>Cost:</b> 2 culture bottles required on every split bag; additional equipment and staff may be needed; changes to BECS system likely; increased number of culture bottles (2-6 bottles).</p>		
<b>Efficacy</b>	FDA has evaluated efficacy and includes this in the recommended strategies		
<b>Earliest day of receipt by hospital</b>	Middle to late day 2		
<b>Shelf life</b>	4-5 days; rapid testing may be done at hospital or blood center		

LVDS: large volume delayed sampling; HTS: hospital transfusion service; BCC: blood collection center; PAS: platelet additive solution; COI: Circular of Information; and BECS: Blood Establishment Computer Software









