



AABB BACTERIAL RISK REFERENCE SHEETS

I. The Bacterial Risk Reference Sheets for options in the December 2020 Platelet Bacterial Risk Control Guidance are intended to:

- Assist blood collection centers and hospital transfusion services with operational and clinical considerations for:
 - » Manufacturing and labeling/expiration,
 - » Inventory management, and
 - » Challenges facing the transfusion medicine/clinical community.
- Supplement but not replace your review of the recommendations in FDA's [December 2020 Guidance](#).

II. Resources for Implementation of Risk Control Strategies:

- Flowchart: Provides overview of [Timelines for Testing Strategies for Apheresis Platelets](#)
- ICCBBA's [TB-015 Bacterial testing strategies for Platelets - US Guidance](#) v1.0.0 – PDF for “use of labeling to communicate bacterial testing strategy and additional relevant information”

III. Key Regulatory Requirements to Consider:

A. Sampling and Expiration [[*Section III.A.4, pages 3-4](#)] - **Section, page number from the [December 2020 FDA Guidance](#) are linked for your reference.*

- Sample based on the collection time
- The expiration date is based on the collection date as Day 0 and product expires at 23:59 on Day 5. Example:
If collected on Jan 1 (day 0), component expires at 23:59 on Jan 6 (Day 5).
- Sampling on specified day - sample any time on day prior to midnight on Day 3, 4, 5, etc. to extend expiration. Example:
If sampled on May 20 (day 4) at 10:00 am, component expires May 21 at 10:00 am.
- Must have SOPs for traceability of the bacterial testing status of platelet components in inventory. [[*Section III.A.8, page 4](#)]

B. Testing to Extend Expiration beyond Day 5 and up to Day 7 requires: [[*Appendix B, footnote 4, page 17](#)]

- The use of devices labeled as a “safety measure” and
- Storage containers cleared or approved by FDA for 7-day storage.
- FDA Registration for this manufacturing step as described in the next section.

C. Transfusion Services-Registration and Blood Product Listing [[*Section V, page 13](#)]

- A transfusion service, currently exempt from registration [under [21 CFR 607.65\(f\)](#)], implementing bacterial detection strategy to extend the expiration of platelets to **Day 6 or Day 7** is:
 - “engaging in blood product manufacturing under [21 CFR 607.3\(d\)](#),”

- is no longer exempt under [21 CFR 607.65\(f\)](#), and
- **must register** with FDA.

D. Licensed Blood Establishments

- Prior Approval Supplement (PAS) [[*Section IV.A, pages 11-13](#)]
 - » Must submit a PAS or consider submitting a Comparability Protocol as a PAS under [21 CFR 601.12\(e\)](#):
 - ◊ Because implementation of these new/changed manufacturing processes strategies is a major change under [21 CFR 601.12\(b\)](#).
 - ◊ Approved PAS is required before distribution in interstate commerce (21 CFR 601.12(b), including when:
 - Currently licensed for 5-day apheresis platelets and
 - Extending the storage to a 6- or 7- day expiration date.
- Annual Report [[*Section IV.B, page 13](#)]
 - » Reporting requirements of [21 CFR 601.12\(d\)](#) apply.

IV. Reference Sheets - Risk Control Strategies for Platelet Components:

Refer to **Flowchart** for an overview of [Timelines for Testing Strategies for Apheresis Platelets](#)

1 Step: Culture

- Primary culture ≥ 24 hours, Exp: 3 days – see [Reference Sheet 24C-3](#), p 3
- LVDS ≥ 36 hours, Exp: 5 days – see [Reference Sheet 36C-5](#), p 7
- LVDS ≥ 48 hours, Exp: 7 days – see [Reference Sheet 48C-7](#), p 10

2 Steps: Cultures

- Primary ≥ 24 hours AND 2nd Culture ≥ Day 3, Exp: 5 days – see [Reference Sheet 24C-D3C-5](#), p 4
- Primary ≥ 24 hours AND 2nd Culture ≥ Day 4, Exp: 7 days – see [Reference Sheet 24C-D4C-7](#), p 5
- LVDS ≥ 36 hours AND 2nd Culture ≥ Day 4, Exp: 7 days – see [Reference Sheet 36C-D4C-7](#), p 8

2 Steps: Culture and Rapid Bacterial Test

- Primary ≥ 24 hours AND Rapid Test, Exp: 5 days – see [Reference Sheet 24C-R-5](#), p 6
- LVDS ≥ 36 hours AND Rapid Test, Exp: 7 days – see [Reference Sheet 36C-R-7](#), p 9

Pathogen Reduction Technology

- Pathogen reduction technology using amotosalen and UVA irradiation or apheresis platelets, Exp: 5 days, see [Reference Sheet PRT](#), p 11

Strategies limited to single Whole Blood Derived (WBD) platelets and post-storage pools of WBD platelets

- Single Step Culture ≥ 24 hours, Exp: 5 days – see [WBD option Reference Sheet](#), p 12
- Single Step Culture ≥ 36 hours, Exp: 5 days – see [WBD option Reference Sheet](#), p 13
- Single Step Rapid testing for single units of WBD platelets and post-storage pools of WBD platelets, Expiration: per device instructions for use – see [WBD option Reference Sheet](#), p 14



AABB BACTERIAL RISK REFERENCE SHEETS | 24C-3

Strategy	1 Step: Culture		
Intervention	Primary ≥ 24	Expiration	3 days
Technical notes	<p>No sooner than 24 hours from time of collection:</p> <ul style="list-style-type: none"> • Sample pre-storage pool of WBD platelets, each platelet component prepared from the apheresis collection or original apheresis collection bag alone with 16 mL evenly split into aerobic and anaerobic bottles • Recommended minimum 12-hour incubation hold prior to release • Transfuse by 23:59 on day 3 without secondary testing. Requires secondary testing before transfusion on day 4 or day 5 – refer to Two Step Strategies • Requires inventory controls to prevent transfusion after day 3 		
Platelet type	Apheresis platelets and pre-storage pools of WBD platelets		
Solution	Stored in plasma or platelet additive solution		
Hospital Transfusion Service	<p>Advantages: No quarantine period within the HTS; no additional testing after receipt of product from the BCC if transfused by end of day 3.</p> <p>Disadvantages: 3-day expiration unless secondary testing is performed; requires inventory controls to ensure secondary testing is completed if transfused on day 4 or day 5</p> <p>Regulatory perspectives: Inventory controls required to ensure secondary testing is completed if transfused on day 4 or day 5</p> <p>Quality/clinical considerations: Possible increased CCIs due to shift to fresher platelets.</p> <p>Cost: Low with inventory management to prevent increased expiration of platelet.</p>		
Blood Collection Center	<p>Advantage: Lowest sampling volume if using option to test original apheresis collection bag only; no additional testing required if transfused by day 3.</p> <p>Disadvantages: 3-day product that requires inventory controls for transfusion after day 3.</p> <p>Regulatory perspectives: New 3-day product label is required – if 3-day label is not available this will create confusion as the product may only be used to day 3 despite being labeled as good to day 5 (new ICCBBA label available); equipment validations; update COI.</p> <p>Cost: Both aerobic and anaerobic culture bottles; Possible BECS changes; Lowest cost if inventory management prevents loss due to expiration on day 3.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 2		
Shelf life	2-3 days		

CCI: corrected count increment; BECS: blood establishment computer software; COI: circular of Information; HTS: hospital transfusion service; and BCC: blood collection center



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

Strategy	2 Steps: Cultures		
Intervention	Primary ≥ 24 AND 2nd Culture ≥ Day 3	Expiration	5 days
Technical notes	<p>Step 1 is Primary culture ≥ 24:</p> <ul style="list-style-type: none"> For apheresis: May test each component of the apheresis collection or original apheresis collection bag alone. For pre-storage pools: test pooled component only. Sample no sooner than 24 hours from time of collection with 16 mL evenly split into aerobic and anaerobic bottles Recommended minimum 12-hour incubation hold prior to release <p>Secondary culture:</p> <ul style="list-style-type: none"> Must test each component using 8 mL inoculum into at least aerobic bottle; Do not need to recalculate product yield after secondary testing Standard Operating Procedures must establish a minimum incubation period before issue 		
Platelet type	Apheresis platelets and pre-storage pools of WBD platelets		
Solution	Stored in plasma or platelet additive solution		
Hospital Transfusion Service	<p>Advantage: Manage inventory for 5-day expiration.</p> <p>Disadvantages: 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>Regulatory perspectives: Requires method validation; QC monitoring; instrument maintenance by vendor; Must establish the quarantine period and SOP.</p> <p>Quality/clinical considerations: Expect efficacy to be equivalent to a non-pathogen reduced/primary culture/5-day expiration platelet.</p> <p>Cost: Additional staff required for testing may add to cost. Secondary culture is relatively low cost.</p>		
Blood Collection Center	<p>Advantage: Do not need to recalculate product yield after secondary testing; extends to 5 days.</p> <p>Disadvantages: Additional disadvantages related to secondary culture, which may be done by BCC.</p> <p>Regulatory perspectives: Must determine how to label as 3 and then 5-day product; Must determine quarantine period. Update COI.</p> <p>Quality considerations: Lower product yield following secondary culture.</p> <p>Cost: Additional cost for testing and staff time affecting the blood center and the hospital.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 2		
Shelf Life	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 | 24C-D4C-7

Strategy	2 Steps: Cultures		
Intervention	Primary ≥ 24 AND 2nd Culture ≥ Day 4	Expiration	7 days
Technical notes	<p>Step 1: Primary culture:</p> <ul style="list-style-type: none"> • May test each component from the apheresis collection or original collection bag alone. • Sample no sooner than 24 hours from time of collection with 16 mL evenly split into aerobic and anaerobic bottles • Recommended minimum 12-hour incubation hold prior to release <p>Step 2: Secondary culture:</p> <ul style="list-style-type: none"> • Each component of the apheresis collection must be tested on or after day 4 using 16 mL inoculum evenly split into aerobic and anaerobic bottles • Recommended minimum 12-hour incubation period prior to release and products • During secondary culture incubation, product remains in-date through their labeled storage period which means there is no requirement to remove it from inventory during any portion of the labeled storage if following SOPs to 1) identify when secondary testing has been completed, and 2) maintain product control during the incubation period 		
Platelet type	Apheresis platelets in bag approved by FDA for 7-day storage		
Solution	Stored in plasma		
Hospital Transfusion Service	<p>Advantage: Potential for decreased platelet wastage due to increased shelf-life.</p> <p>Disadvantages: Applies only to apheresis platelets stored in plasma; quarantine period necessary for secondary culture; need to liaise with microbiology lab; train staff on sterile sampling and culture inoculation; additional staffing may be necessary to perform sampling; significant administrative/logistical/regulatory burden to the HTS; significant product loss from additional testing.</p> <p>Regulatory perspectives: Requires FDA registration or licensure to extend dating, method validation, QC monitoring, instrument maintenance by vendor, and proficiency testing; need to establish a quarantine period in SOP</p> <p>Quality/clinical considerations: Possible increased platelet storage lesion beyond day 5, however no clear evidence of differential in vivo efficacy between day 5 and day 7.</p> <p>Cost: Additional staff required for testing may add to cost. Secondary culture is relatively low cost.</p>		
Blood Collection Center	<p>Advantage: Not required to recalculate product yield after secondary testing.</p> <p>Disadvantages: Applies only to apheresis platelets stored in plasma based on FDA approval of storage bag for 7-day storage.</p> <p>Regulatory perspectives: Labeling changes after second step to update expiration date; new ISBT codes; must determine quarantine period. Update COI.</p> <p>Quality considerations: Lower product yield following secondary culture.</p> <p>Cost: Additional cost for testing and staff time affecting the BCC and HTS.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 2 or blood center releases late day 4		
Shelf life	4-5 days blood center; culture may be done at hospital or blood center		

QC: quality control; PRT: pathogen reduction technology; PAS: platelet additive solution; BCC: blood collection center; and HTS: hospital transfusion service



AABB BACTERIAL RISK REFERENCE SHEETS | 24C-R-5

Strategy	2 Steps: Culture and Rapid test		
Intervention	Primary ≥ 24 AND Rapid testing	Expiration	5 days*/7 days **
Technical notes	<p>Step 1: Primary culture:</p> <ul style="list-style-type: none"> • May test each component from the apheresis collection <u>OR</u> original collection bag alone. • Sample no sooner than 24 hours from time of collection with 16 mL evenly split into aerobic and anaerobic bottles • Recommended minimum 12-hour incubation hold prior to release <p>Step 2: Rapid bacterial testing (RT) :</p> <ul style="list-style-type: none"> • Rapid test each platelet component within 24 hours prior to transfusion per instructions 		
Platelet type	*5 day: Apheresis or pre-storage pools of WBD platelets; **7 day: apheresis platelets in bag approved by FDA for 7-day storage		
Solution	*5 day: Apheresis or pre-storage pools of WBD platelets; **7 day: apheresis in plasma		
Hospital Transfusion Service	<p>Advantage: Complete required secondary test relatively quickly (no incubation time required). Disadvantages: RT is good for 24 hours – after 24 hours, the platelets must be re-tested prior to use; possible increase in staffing needed. Regulatory perspectives: Use of RT to extend expiration to day 6 or 7 requires storage bag FDA-approved for 7-day storage, FDA registration or licensure to perform the re-labeling/manufacturing step; quality control monitoring needed; proficiency testing required. Quality/clinical considerations: Must relabel with new expiration time after each RT; facilities will need an inventory management process to determine which units have been tested and which require testing prior to release for transfusion. Update COI. Cost: Expected similar overall cost when compared with secondary culture strategies.</p>		
Blood Collection Center	<p>Advantage: Can extend shelf life of pre-storage pools of WBD platelets and apheresis platelets stored in plasma or PAS up to 5 days*. RT is an approved safety measure to extend expiration of apheresis platelets stored in plasma through day 7.** Disadvantages: Most disadvantages will be experienced by HTS unless BCC performs the secondary rapid test. Regulatory perspectives: Additional regulatory considerations are otherwise the responsibility of the HTS. Update COI. Quality considerations: Rapid testing is usually performed by HTS. Cost: Low cost for BCC with additional testing performed by HTS.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 2		
Notes	Rapid test may be performed at BCC of HTS.		

PRT: pathogen reduction technology RT: rapid bacterial test; PAS: platelet additive solution; HTS: hospital transfusion service; and BCC: blood collection center



AABB BACTERIAL RISK REFERENCE SHEETS | 36C-5

Strategy	1 Step: Culture		
Intervention	LVDS ≥ 36	Expiration	5 days
Technical notes	<ul style="list-style-type: none"> Sample each pre-storage pool of WBD platelets and each apheresis component no sooner than 36 hours from time of collection with 16 mL evenly split into aerobic and anaerobic bottles Recommended minimum 12-hour incubation hold prior to release 		
Platelet type	Apheresis platelets and pre-storage pools of WBD Platelets		
Solution	Plasma, platelet additive solution		
Hospital Transfusion Service	<p>Advantage: No quarantine period within the HTS; no additional testing after receipt of product from the BCC; no HTS validation of additional assays.</p> <p>Disadvantages: Increased time from collection to BCC issuing the product.</p> <p>Regulatory perspectives: No additional regulatory requirements for the HTS.</p> <p>Quality/clinical considerations: Expect efficacy to be equivalent to a non-pathogen reduced/primary culture/5-day expiration platelet.</p> <p>Cost: Low/minimal change from practice prior to new guidelines.</p>		
Blood Collection Center	<p>Advantage: 5-day product with no additional testing; No label changes needed.</p> <p>Disadvantages: Hospital might get product middle to late day 2, which is later than other options that have 5-day shelf-life; might reduce split rate due to additional testing required for each platelet component; additional instrumentation needed for testing.</p> <p>Regulatory perspectives: Equipment validations. Update COI.</p> <p>Quality considerations: May serve as step 1 in a 2-step process to extend up to day 7.</p> <p>Cost: 2 bottles required to culture every platelet component; additional equipment and staff may be needed; changes to BECS system likely; increased number of culture bottles (2-6 bottles) for results.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Middle to late day 2		
Shelf life	2-3 days		

LVDS: large volume delayed sampling; COI: circular of Information; BECS: blood establishment computer software; HTS: hospital transfusion service; and BCC: blood collection center



AABB BACTERIAL RISK REFERENCE SHEETS | 36C-D4C-7

Strategy	2 Steps: Cultures		
Intervention	LVDS ≥ 36 AND 2nd Culture ≥ Day 4	Expiration	7 days
Technical notes	<p>LVDS at 36:</p> <ul style="list-style-type: none"> Sample each apheresis platelet component no sooner than 36 hours from time of collection with 16 mL evenly split into aerobic and anaerobic bottles <p>Secondary culture:</p> <ul style="list-style-type: none"> 16 mL sample evenly split into aerobic and anaerobic bottles from each component. When splitting apheresis collection into multiple units, must test each component Recommended minimum 12-hour incubation hold prior to release – applies to primary and secondary culture 		
Platelet type	Apheresis in bag approved by FDA for 7-day storage		
Solution	Plasma		
Hospital Transfusion Service	<p>Advantage: Potential for decreased platelet wastage due to increased shelf-life.</p> <p>Disadvantages: Cannot be used on pre-storage pooled units; required quarantine period; 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/regulatory burden to the HTS; significant product loss from additional testing.</p> <p>Regulatory perspectives: Requires method validation; QC monitoring; instrument maintenance by vendor; need to establish a quarantine period; requires FDA registration or licensure to extend dating beyond 5 days; proficiency testing required.</p> <p>Quality/clinical considerations: Possible increased platelet storage lesion beyond day 5, however no clear evidence of differential in vivo efficacy between day 5 and day 7.</p> <p>Cost: Additional staff required for testing may add to cost.</p>		
Blood Collection Center	<p>Advantage: No additional advantages specific to BCC</p> <p>Disadvantages: Can only be used with platelets stored in plasma, as FDA-approved storage bags are not available for extended 7-day storage with PAS platelets.</p> <p>Regulatory perspectives: Labeling changes to extend expiration is manufacturing step; new ISBT codes; must determine quarantine period. Update COI.</p> <p>Quality considerations: Lower product yield following sampling for secondary culture.</p> <p>Cost: Additional cost for testing and staff time affecting the BCC and HTS.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Middle to late day 2		
Shelf life	Culture may be done at hospital or blood center; shelf life 3-4 days		

LVDS: large volume delayed sampling; HTS: hospital transfusion service; QC: quality control; PRT: pathogen reduction technology; BCC: blood collection center; and PAS: platelet additive solution



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

Strategy	2 Steps: Culture and Rapid test		
Intervention	LVDS ≥ 36 hours AND Rapid testing	Expiration	7 days
Technical notes	<p>Primary culture:</p> <ul style="list-style-type: none"> • Sampling taken no sooner than 36 hours from time of collection • 16 mL inoculum evenly split into aerobic and anaerobic bottles from each unit • When splitting apheresis collection into multiple units, must test each component • Recommended minimum 12-hour incubation hold prior to release <p>Secondary culture:</p> <ul style="list-style-type: none"> • Rapid testing of each apheresis component within 24 hours prior to platelet transfusion 		
Platelet type	Apheresis in bag approved by FDA for 7-day storage		
Solution	Plasma		
Hospital Transfusion Service	<p>Advantage: Obtain final result relatively quickly (no incubation time required); potential for decreased platelet wastage due to increased shelf-life.</p> <p>Disadvantages: 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>Regulatory perspectives: 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>Quality/clinical considerations: 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>Cost: Expected similar overall cost when compared with secondary culture strategies.</p>		
Blood Collection Center	<p>Advantage: Can extend shelf life of units. RT can extend shelf life of apheresis platelets stored in plasma to 7 days.</p> <p>Disadvantages: Most disadvantages will be experienced by HTS unless BCC performs the secondary rapid test.</p> <p>Regulatory perspectives: 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>Quality considerations: Possibly lower product yield and rapid testing is usually performed by HTS.</p> <p>Cost: 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>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Middle to late day 2		
Shelf life	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



AABB BACTERIAL RISK REFERENCE SHEETS | 48C-7

Strategy	1 Step: Culture		
Intervention	LVDS ≥ 48 hours	Expiration	7 days
Technical notes	<ul style="list-style-type: none"> • Sampling taken no sooner than 48 hours from time of collection • 16 mL inoculum evenly split into aerobic and anaerobic bottles from each component • When apheresis collections are split into multiple units, each component must be tested • Recommended minimum 12-hour incubation hold prior to release 		
Platelet type	Apheresis in bag approved by FDA for 7-day storage		
Solution	Plasma		
Hospital Transfusion Service	<p>Advantage: No quarantine period within the HTS; no additional testing after receipt of product from the BCC; no HTS validation of additional assays; potential for decreased platelet wastage due to increased shelf-life.</p> <p>Disadvantages: Increased time from collection to BCC issuing the product.</p> <p>Regulatory perspectives: No additional regulatory requirements for the HTS. Update COI.</p> <p>Quality/clinical considerations: Possible increased platelet storage lesion beyond day 5, however no clear evidence of differential in vivo efficacy between day 5 and day 7.</p> <p>Cost: Low to negative, due to potential decreased total expense on platelet products if expiration rate decreases.</p>		
Blood Collection Center	<p>Advantage: No additional advantage in terms of manufacturing for BCC</p> <p>Disadvantages: HTS might get product later than current state; might reduce split rate due to additional testing requirements (split units); additional instrumentation needed for testing; can only use platelets stored in plasma.</p> <p>Regulatory perspectives: Can only be used with platelets stored in plasma as unit bags are not available for extended storage with PAS platelet; equipment validations; licensure for 7-day product for shipping across state lines; Update COI; New ISBT codes for 7-day products.</p> <p>Quality considerations: Possibly lower product yield; hospital receives older products.</p> <p>Cost: 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) for results.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 3		
Shelf life	4-5-day		

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 software system



AABB BACTERIAL RISK REFERENCE SHEETS | PRT

Strategy	Pathogen Reduction Technology (PRT)		
Intervention	Pathogen Reduction	Expiration	5 days
Technical notes	Pathogen reduction technology using amotosalen and UVA irradiation		
Platelet type	Apheresis		
Solution	Plasma and Platelet Additive Solution (PAS)		
Hospital Transfusion Service	<p>Advantage: Early release from blood center (day 1-2); no irradiation needed to prevent TA-GVHD; provides protection against bacterial, viral and protozoal contamination; may provide protection for new emerging infectious diseases.</p> <p>Disadvantages: Lower CCI compared to plasma platelets; some BCC will only provide PRT platelets stored in platelet additive solution; must take steps to avoid irradiation.</p> <p>Regulatory perspectives: No additional regulatory requirements for the HTS.</p> <p>Quality/clinical considerations: Cannot be irradiated - this may require changes to workflow if using a mixed inventory; Lower CCI when compared to non-pathogen reduced stored in plasma, primary culture, 5-day expiration.</p> <p>Cost: Cost may be partially offset by better cost recovery in out- patient setting and no fee for irradiation.</p>		
Blood Collection Center	<p>Advantage: No additional testing required; early release of units to hospitals.</p> <p>Disadvantages: Currently requires two kits for triples; guard bands reduce the split rate for triples.</p> <p>Regulatory perspectives: Licensure for shipping across state lines. Update COI.</p> <p>Quality considerations: Platelets may be released earlier after collection.</p> <p>Cost: More personnel needed with training.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Middle to late day 1		
Shelf life	3-4 days		

PRT: pathogen reduction technology; PAS: platelet additive solution; TA-GVHD: transfusion associated graft versus host disease; CCI: corrected count increment; BCC: blood collection center; and HTS: hospital transfusion service.



AABB BACTERIAL RISK REFERENCE SHEETS | WBD

Strategy	Single Step Culture		
Intervention	Single Culture ≥ 24 hours	Expiration	5 days*
Technical notes	<ul style="list-style-type: none"> • Sampling taken no sooner than 24 hours from time of collection • Inoculate the largest practical volume within the range permitted by the device instructions for use • Inoculate into aerobic culture media • Minimum 12-hour incubation prior to release for transfusion • *If the unit is transfused after day 3 of storage, secondary rapid testing may be considered 		
Platelet type	Single units of WBD platelets		
Solution	Plasma		
Hospital Transfusion Service	<p>Advantage: No quarantine period within HTS; no HTS validation of additional assays unless secondary rapid testing is considered after day 3 of storage.</p> <p>Disadvantages: Short shelf-life of product; Sampling represents a large volume loss in a small volume component.</p> <p>Regulatory perspectives: No additional regulatory requirements other than FDA states “Blood collection establishments and transfusion services should establish procedures to assure traceability of the bacterial testing status of platelet products in their inventory.”</p> <p>*Single units of WBD platelets “should be labeled with a 5-day expiration” and if the unit is transfused after day 3, secondary rapid testing may be considered up to day 5 of storage.</p> <p>Quality/clinical considerations: Lower yield product based on sample volume loss; lack of anaerobic culture; possible increased CCIs due to shift to fresher platelets. Additional testing after receipt of product from the BCC may considered.</p> <p>Cost: Low with inventory management to prevent increased expiration.</p>		
Blood Collection Center	<p>Advantage: Inventory management</p> <p>Disadvantages: Sampling represents a large volume loss in a small volume component;</p> <p>Regulatory perspectives: Update COI.</p> <p>Quality considerations: Lower yield product based on sample volume loss; lack of anaerobic culture.</p> <p>Cost: Could be high for a single WBD platelet product.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 2		
Shelf life	*Following primary culture performed no sooner than 24 hours after collection, secondary rapid testing may be considered for transfusion after day 3 of storage.		

CCI: corrected count increment; BECS: blood establishment computer software; COI: circular of Information HTS: hospital transfusion service; and BCC: blood collection center, WBD: Whole Blood Derived



AABB BACTERIAL RISK REFERENCE SHEETS | WBD

Strategy	Single Step Culture ≥ 36 hours		
Intervention	Single Culture ≥ 36 hours	Expiration	5 days
Technical notes	<ul style="list-style-type: none"> • Sampling taken no sooner than 36 hours from time of collection • Inoculate the largest practical volume within the range permitted by the device instructions for use • Inoculate into aerobic culture media • Minimum 12-hour incubation prior to release for transfusion 		
Platelet type	Single units of WBD platelets		
Solution	Plasma		
Hospital Transfusion Service	<p>Advantage: No quarantine period within the HTS; no additional testing after receipt of product from the BCC; no HTS validation of additional assays. Low/minimal change from practice prior to new guidelines.</p> <p>Disadvantages: Increased time from collection to BCC issuing the product. HTS might get product middle to late day 2, which is later than other options that have 5-day shelf-life.</p> <p>Regulatory perspectives: No additional regulatory requirements for the HTS.</p> <p>Quality/clinical considerations: Lower yield product based on sample volume loss; lack of anaerobic culture</p> <p>Cost: Relatively low cost.</p>		
Blood Collection Center	<p>Advantage: 5-day product with no additional testing; no label change needed.</p> <p>Disadvantages: Sampling represents a large volume loss in a small volume component.</p> <p>Regulatory perspectives: Equipment validations; Update COI.</p> <p>Quality considerations: Lower yield product based on sample volume loss; lack of anaerobic culture.</p> <p>Cost: Could be high for a single WBD platelet product.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Middle to late day 2		
Shelf life	2-3 days		

CCI: corrected count increment; BECS: blood establishment computer software; COI: circular of Information HTS: hospital transfusion service; and BCC: blood collection center, WBD: Whole Blood Derived



AABB BACTERIAL RISK REFERENCE SHEETS | WBD

Strategy	Single Step Rapid Testing (single units of WBD platelets and post-storage pools)		
Intervention	Rapid test performed in accordance with the device labeling	Expiration	Per device instructions for use, max of 5-day exp
Technical notes	FDA guidance does not specifically address sample volume but refers to sampling per the device instructions for use.		
Platelet type	Single units of WBD platelets and post-storage pools of previously untested WBD platelets		
Solution	Plasma		
Hospital Transfusion Service	<p>Advantage: Small sample volume per device instructions for use. Obtain final result relatively quickly (no incubation time required).</p> <p>Disadvantages: Short shelf-life of product which requires rapid testing within a specified time frame prior to transfusion (per device instructions for use). Currently, rapid testing is approved for 24-hour labeling – if platelet is to be transfused after 24 hours, the unit must be re-tested; rapid test is somewhat labor intensive; possible increase in staffing needed.</p> <p>Regulatory perspectives: FDA states “Blood collection establishments and transfusion services should establish procedures to assure traceability of the bacterial testing status of platelet products in their inventory” to identify platelet products which require rapid testing prior to transfusion to support labeling up to day 5:</p> <ul style="list-style-type: none"> • Single units of WBD platelets “should be labeled with a 5-day expiration” and require rapid testing performed prior to transfusion. • Post-storage pools of WBD platelets expire 4 hours after pooling and require rapid testing performed prior to transfusion. <p>Quality control monitoring needed; proficiency testing required.</p> <p>Quality/clinical considerations: 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>Cost: Expected similar overall cost when compared with secondary culture strategies.</p>		
Blood Collection Center	<p>Advantage: Small sample volume; Can extend shelf life of single units of WBD platelets up to day 5.</p> <p>Disadvantages: Are few because the HTS must perform rapid test unless BCC performs the rapid test.</p> <p>Regulatory perspectives: Additional regulatory considerations are otherwise the responsibility of the HTS. Update COI.</p> <p>Quality considerations: Rapid testing is usually performed by HTS.</p> <p>Cost: Low cost for BCC with additional testing performed by HTS.</p>		
Efficacy	FDA has evaluated efficacy and includes this in the recommended strategies		
Earliest day of receipt by hospital	Early to middle of day 2 - Per device instructions for use.		
Shelf life	Single unit WBD platelets: Up to day 5 with testing performed per device instructions for use. Post-storage pools of WBD platelets: expire 4 hours after pooling		

CCI: corrected count increment; BECS: blood establishment computer software; COI: circular of Information HTS: hospital transfusion service; and BCC: blood collection center, WBD: Whole Blood Derived