Advancing Transfusion and Cellular Therapies Worldwide

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To: AABB Members

From: David Green, MSA - President
Debra BenAvram - Chief Executive Officer

Re: Impact of the FDA Guidance "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion"

Association Bulletins provide a mechanism for publication of documents that have been approved by the Board of Directors for distribution to individual and institutional members, such as:

- Standards that were adopted after publication of the most recent edition of *Standards*
- Statements of AABB policy intended for distribution to members
- Guidance, recommendations, and reports that have been developed AABB committees or National Office staff for distribution to members.

This Bulletin contains guidance and considerations to support the October 1, 2021 implementation of the December 2020 FDA Guidance titled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion."

Given the differences in benefits and limitations among options, a universal risk mitigation strategy is unlikely to meet the requirements of all blood centers and transfusion services. This Association Bulletin is intended to provide information that can help blood centers and transfusion services communicate and discuss which mitigation strategy(ies) will support the continued availability of platelets for transfusion. The considerations in this Association Bulletin are intended to supplement but not replace your review of the 2020 Guidance.

The following attachment provides key points for the AABB membership to consider: those points are:

1. Mitigation strategies must be in place by October 1, 2021
2. All mitigation strategies improve the safety of platelet transfusions
3. All mitigation strategies are approved by the FDA and are deemed therapeutically equivalent
4. Hospitals should be prepared to accept a range of products to maximize platelet availability
5. Hospitals should be prepared to perform secondary testing to maximize platelet availability

Introduction: In the 2020 Guidance, the Food and Drug Administration (FDA) updated recommendations first issued in September 2019. FDA's 2020 Guidance recommends that blood centers and transfusion services implement "bacterial risk control strategies" to mitigate the risk of septic

transfusion reactions caused by bacterial contamination of platelets stored at room temperature.[1] FDA extended the timeframe for implementation of these recommendations to October 1, 2021 using various multiple single-step and two-step mitigation strategies to achieve expiration on day 5, 6 and 7 that include

- Large-volume delayed sampling (LVDS) at ≥36 (5-day expiration) OR LVDS at ≥48 hours (7-Day expiration) OR Primary Culture at ≥24 (to support transfusion through day 3).
- Primary Culture at ≥24 + Secondary testing with culture or Rapid Bacterial Testing (RT) (5-, 6-, and 7-day expiration)
- LVDS at ≥36 + Secondary testing with culture or RT (6-, and 7-day expiration)
- Pathogen reduction technology (PRT) (5-day expiration)

General Considerations: When considering which bacterial risk control strategies to implement, it is important to understand the FDA regulations and recommendations that will apply to transfusion services and blood centers implementing bacterial testing strategies to extend the platelet expiration beyond day 5 to day 6 or day 7. The following should be considered:

- In addition to requirements to support a 5-day expiration, extending the expiration from day 5 to day 7:
    - Requires culture followed by secondary testing using a culture method or rapid test that is an FDA approved "safety measure" and
    - Requires a platelet storage container cleared or approved by FDA for 7-day storage.
    - Could apply to other platelet products in the future if FDA approved or cleared devices and storage containers become available.
- The blood center or transfusion service that performs the secondary testing must update the container label to reflect the new expiration date as required by 21 CFR 606.121(c)(4)(i).
- Extending expiration beyond 5 days is a manufacturing procedure requiring FDA registration and blood product listing, as defined in 21 CFR 607.3(d).
- If you are a transfusion service that is currently exempt from FDA registration and blood product listing under 21 CFR 607.65(f) because you are "engaged in the compatibility testing and transfusion of blood and blood components" but do not routinely manufacture other blood components, you are no longer exempt if you extend the expiration to day 6 or 7.

Mitigation Strategies: This section provides a brief description of each mitigation strategy that may be used with single donor platelets (SDP) and whole blood derived (WBD) platelets.

An SDP is an apheresis collection of platelets from a single donor that is prepared as 1-3 SDP platelet components based on the total yield of the original collection. WBD platelets are from a single whole blood donation that is prepared as a single WBD platelet component or as a pre-storage pool or post-storage pool of multiple WBD platelets. Some strategies are limited to specific types of platelet components, as described in each strategy. For details of each strategy, please refer to the reference sheet for each strategy, tables 1-5 in the appendix, or the FDA Guidance. The Reference Sheets also link to ICCBBA's Labeling Guidance.

Given the many possible options and combination of strategies, a flowchart presenting a visual guide to these options is also available here.

- **Pathogen Reduction Technology:**
  PRT uses amotosalen (a psoralen) and UVA light to cross-link nucleic acids irreversibly, thereby inactivating a broad spectrum of viruses, bacteria, and parasites, as well as white blood cells that can cause transfusion-associated graft-vs-host disease (TA-GVHD).
  1) Applies to SDPs stored in plasma and Platelet Additive Solution (PAS).
  2) Approved for 5-day expiration.
  3) Refer to Reference Sheet PRT, p 11, for additional details.

- **One-Step Culture Strategies at ≥ 36, 48, or 24 hours:**
  This section describes options for use of a single culture.

  1) **Large-Volume Delayed Sampling (LVDS) at ≥36 hours as a single step for 5-day expiration**: This is a single culture with sampling performed no sooner than 36 hours after collection, using a sampling volume of at least 16 mL per component inoculated evenly into both aerobic and anaerobic culture media.
     a) Minimum 12-hour incubation period prior to release for transfusion.
     b) Applies to SDPs stored in plasma or PAS and pre-storage pools of WBD platelets.
     c) Supports 5-day expiration *without* secondary testing.
     d) Refer to Reference Sheet 36C-5, p 7, for additional details.
     e) May serve as step 1 in a Two-Step Strategy to extend to 7-day expiration as described below.

  2) **Large-Volume Delayed Sampling (LVDS) at ≥48 hours as a single step for 7-day expiration:** This is a single culture with sampling performed no sooner than 48 hours after collection, using a sampling volume of at least 16 mL per component inoculated evenly into both aerobic and anaerobic culture media.
     a) Minimum 12-hour incubation prior to release for transfusion.
     b) Applies to SDPs stored in plasma only.
     c) Supports 7-day expiration *without* secondary testing in a Two-Step Strategy.
     d) Requires FDA approved 7-day storage container.
     e) Refer to Reference Sheet 48C-7, p 10.

  3) **Primary Culture at ≥24 hours as a single culture to support transfusion before the end of day 3:**
     Primary Culture is performed no sooner than 24 hours after collection with a sampling volume of at least 16 mL, inoculated evenly into both aerobic and anaerobic culture media.
     a) Minimum 12-hour incubation prior to release for transfusion.
     b) Applies to SDPs stored in plasma or PAS and pre-storage pools of WBD platelets
     c) Permits sampling of the original collection bag (Sometimes referred to as "mother bag"), **or** each SDP component if original collection is split into multiple components, **or** pre-storage pool of WBD platelets.
     d) Labeled with 5-day expiration but **must be transfused before the end of day 3**.
     e) If transfused after day 3, this Primary Culture at ≥24 must be followed with secondary testing as a two-step strategy to support the 5-day expiration, as described in the next section.

f) Requires additional controls to ensure secondary testing has been completed if transfused on day 4 or day 5.
g) Refer to Reference Sheet 24C-3, p 3.
h) *May also serve as Step 1 in other Two-Step Strategies using either Secondary Culture or RT, described in sections below, to extend expiration to day 6 or day 7*.

- **Two-Step Strategies with Secondary Culture:**

This section describes options for use of secondary culture:
- Step 1 is either Primary Culture at ≥24 hours **OR** LVDS at ≥36 hours
- Step 2 is Secondary Culture to support 5-day or 7-day expiration.
- Following this section, Two-Step Strategies with Rapid Bacterial Testing are described.

1) ***If step 1 is Primary Culture at ≥24 hours*, then Secondary Culture for 5-day expiration is performed no sooner than day 3** of storage using at least an 8 mL sampling volume inoculated into at least an aerobic medium media.
   a) No minimum incubation period before component release which allows each facility to establish a minimum incubation in standard operation procedures (SOPs).
   b) Applies to SDPs in plasma or PAS (sample each SDP component if original collection is split into multiple components), and pre-storage pools of WBD platelets.
   c) Refer to Reference Sheet 24C-D3C-5, p 4.

2) ***If step 1 is Primary Culture at ≥24 hours OR LVDS at ≥36 hours*, then Secondary Culture for 7-day expiration is performed no sooner than day 4** of storage with at least 16 mL total sample volume, inoculated evenly into both aerobic and anaerobic culture media.
   a) Minimum 12-hour incubation prior to release for transfusion.
   b) Applies to SDPs in plasma.
   c) Requires both FDA approved safety measure and 7-day storage container.
   d) Refer to Reference Sheet 24C-D4C-7, p 5, if used after Primary Culture ≥24 hours, or Reference Sheet 36C-D4C-7, p 8, if used after culture with LVDS ≥36 hours.

- **Two-Step Strategies with Secondary Rapid Bacterial Testing:**

This section describes options for secondary testing using rapid bacterial testing.
- Step 1 is either Primary Culture at ≥24 hours OR LVDS at ≥36 hours
- Step 2 Rapid Bacterial Test must be performed no more than 24 hours prior to release for transfusion.
- May performed between the time of expiration by primary culture to the expiration day per container/product.
- Refer to package insert for detailed instructions.

1) ***If step 1 is Primary Culture at ≥24 hours,* then step 2 is:**
   a) **Secondary Rapid Bacterial Test for 5-day expiration**:
      1. Applies to SDPs stored in plasma or PAS (test each SDP component if original collection is split into multiple components) and pre-storage pools of WBD platelets.

2. Required for transfusion on day 4 and day 5 when step 1 is primary culture for platelets labeled with 5-day expiration.
3. Refer to Reference Sheet 24C-R-5, p 6.

OR

b) **Secondary Rapid Bacterial Test for 7-day expiration:**

1. Applies to SDPs stored in plasma (test each SDP component if original collection is split into multiple components).
2. Requires both FDA approved safety measure and 7-day storage container.
3. Refer to Reference Sheet 24C-R-5, p 6.

2) ***If step 1 is culture with LVDS at ≥36 hours*****, then step 2 is:**

a) **Secondary Rapid Bacterial Test for 7-day expiration:**

1. Applies to SDPs stored in plasma (test each component).
2. Requires both FDA approved safety measure and 7-day storage container.
3. Refer to package insert and Reference Sheet 36C-R-7, p 9.

- **Mitigation strategies for single units of WBD platelets and post-storage pools of WBD platelets** Refer to Reference Sheets on pages 12–14. Single unit WBD platelets and post-storage pools are tested using single step strategies unique to these components.

Planning Hospital Inventory

In reviewing the strategies above and the discussion on safety and efficacy below, it is important to remember that every risk control strategy is supported by the FDA and are 'therapeutically equivalent', however, each methodology will have some impact on platelet quality, dose, availability and other factors that could affect clinical utility. These tradeoffs, including the resources needed to implement or accommodate new safety measures, are not always readily apparent and do not always point in the same direction, so it is critical for hospitals to build in flexibility to the products they will accept to assure maintenance of an adequate inventory.

Blood centers should also understand that different patient populations may be best served by different mitigation strategies and that discussions with hospital customers are essential to meet patients' needs. This section provides expert opinion on some of these issues. However, evidence supporting these differences is lacking, therefore, the authors urge readers to consult the references.

In the interest of ensuring maximum platelet availability, hospital transfusion services are encouraged to be ready to accept and use all products, which would include having the ability to perform one secondary testing measure. Table 5 at the end of this document provides sample questions for blood centers and hospitals to ask of one another in preparation for implementation of the FDA Guidance.

Relative Safety

All bacterial risk control strategies outlined in the FDA Guidance are expected to improve safety beyond the former standard testing approach of primary culture at 24 hours after collection.[4–7] Notably, no strategy has been shown to eliminate all contaminants.[8] Importantly AABB will keep the industry informed as new data emerge both on residual risk and on efficacy.

These methods improve upon our current method: Meta-analyses determined the rate of detection by current methods (primary culture at ≥ 24 hours with expiration at day 5). Using data that relied chiefly on primary culture with 5 day outdate, the rate of detection was 1:1961, but false-negative results due to sampling error were common and primary culture sensitivity was only 31%.[2,3] The residual rate of bacterial contamination after primary culture based on studies using a secondary test ranged from 1:1075 to 1:11111.

LVDS ≥ 36 or 48 hours allows some additional time for any contaminating bacteria to proliferate compared to sampling at 24 hours, thus reducing the risk of false-negative primary culture results. Similarly, because secondary cultures occur days after primary culture, contaminating bacteria have had more time to move beyond the lag phase of growth, further increasing the detection rate.

Rapid testing is FDA-approved to detect concentrations of bacteria above ~10^3-10^5 CFU/mL. As severe sepsis tends to occur at ~10^5 CFU/mL and higher this indicates a mitigation of risk.[9] Bacterial culture can theoretically detect any level of bacteria if sampling error does not occur, which is why secondary culture has a higher rate of sensitivity compared to rapid testing.[3]

Pathogen reduction technology (PRT) is expected to reduce the risk of sepsis close to zero, although rare cases associated with PRT platelet transfusions have been reported.[8]

Relative Efficacy

- *Storage age of platelets.* Controlled recovery and survival studies with autologous platelets have shown that platelet recovery and survival continuously decline over storage time.[10] Although fresher units (<2-3 days of storage) consistently resulted in a higher corrected count increments (CCIs) when compared to older units in hematology-oncology patients, no associated impact on bleeding events or other clinically relevant associations were identified.[11] MacLennan et al.'s recent study compared the CCIs between 2- to 5-day- and 6- to 7-day-stored platelet transfusions. They found 6- to 7-day-stored platelets to be non-inferior to 2- to 5-day-stored platelets. The authors did not detect differences between bleeding events and intervals to the next transfusion, suggesting these differences may not be clinically apparent or significant.[12]
- *Comparisons between PRT (INTERCEPT blood system) and untreated platelets*. Large RCTs have consistently showed lower CCIs, decreased transfusion intervals, more platelet refractoriness, and/or more bleeding events with PRT platelets. The US SPRINT trial found significantly lower CCIs and a shorter interval between transfusions.[13] A subanalysis of this trial reported significantly more minor bleeding events in the PRT group.[14] In an European study, PRT-treated platelets were found to have lower CCIs, and the recipients had more higher-grade bleeding events than recipients of untreated platelets.[15] This study compared three groups: 1) PRT-treated platelets in PAS, 2) untreated platelets in PAS, 3) untreated platelets in plasma. PRT-treated platelets in PAS were non-inferior compared to untreated PAS platelets but were not non-inferior compared to untreated platelets in plasma for Grade ≥2A bleeding.[15] However, Janetzko et al in a smaller RCT found lower mean 1 hour and 24-hour CCIs in response to PRT-

treated platelets when compared to untreated apheresis platelets, but the differences were not significant.[16]

In terms of both INTERCEPT and Mirasol (notably the majority of studies were using INTERCEPT; Mirasol treated platelets are not available in the US) A recent Cochrane analysis found moderate-quality evidence for no increase in clinically significant bleeding complications (WHO Grade ≥2A). The same analysis found high-quality evidence that patients who received PRT-treated platelets required more platelet transfusions, probably due to a shorter time between transfusions and a significantly lower 24-hour count increment.[17]

Considerations for Different Patient Populations

Platelet availability needs vary markedly between hospitals based on the types of procedures performed, patient populations, and patient volume. The distance from the transfusion service to the blood supplier and the ability to rapidly obtain platelet units can be a factor with inventory decisions.

Similarly, the feasibility of secondary testing may vary between hospitals, based on staffing and logistical resources. Hospitals with secondary testing methods in place should have greater flexibility in terms of the different mitigation strategies available (please visit AABB's platelet page for resources to assist hospitals with preparing for secondary testing).

- *Trauma and substantial hemorrhage.* The rapid availability of platelet components is essential to avoid delays and treat coagulopathy associated with massive hemorrhage in severe trauma. Therefore, hospitals with large trauma patient volumes may prefer strategies that maximize rapid platelet availability. For patients with major bleeding or coagulopathy, platelets stored in plasma are usually preferred.
- *Hematology-oncology.* For hematology-oncology patients, platelets with the best post-transfusion recovery and platelet survival may be helpful as they should increase transfusion intervals.
- *Pediatrics.* Platelet transfusions for neonates are generally given to treat active bleeding or mitigate the risk of intraventricular hemorrhage.[18-20] For older infants and children, the primary indication for a platelet transfusion is prophylaxis for chemotherapy-induced thrombocytopenia.[21] For these indications, the post-transfusion recovery/survival should be considered. Smaller bleeding patients with limited vascular access and volume overload concerns may benefit from platelets stored in plasma. Finally, PRT platelets are contraindicated in patients undergoing phototherapy using devices that emit a peak energy wavelength less than 425 nm; however, most UV lights used to treat neonates with bilirubinemia use wavelengths of 430 -490 nm.[21]

Small-volume transfusion services. Although all transfusion services desire the freshest possible platelets resulting in the highest post-transfusion platelet counts, smaller volume services should consider the benefit of having a 7-day apheresis platelet, which could decrease the rate of product outdates and increase availability.

Additional Considerations for Blood Centers: Although the March 2020 AABB survey of transfusion services and blood centers that closed on April 5th suggests that most hospitals desire ready-to-use products that provide a combination of safety, ease of implementation, logistics, and value, blood centers should recognize the unique needs of transfusion services and differing resources. Additionally, due to supply chain and other concerns, blood centers are encouraged to have multiple methods available. Lastly, blood center decision drivers should include the preferences of their hospital partners although the logistics and cost of providing multiple mitigation strategies may also be a factor.

The mitigation options will require planning and anticipation of resource utilization. For example, each new product type is associated with incremental monthly quality control testing, labeling, and ordering logistics. New primary and secondary testing strategies, PRT protocols with resultant testing changes, new product codes and outdates, and labeling changes all require vendor and in-house information technology staff support to modify and validate regulated software.

Many mitigation options will result in changes to platelet collection procedures to offset decreased split rates due to higher sampling volumes. Changes include compensatory lengthening of the collection procedures or software upgrades to increase separator efficiency. Also, programming the plasma volume to accommodate PRT collection limitations (also known as guard bands) or increase volume removed for testing could be necessary to decrease the rate of discards resulting from platelet collections that exceed collection bag storage specifications. Further product and co-component losses are expected due to mitigation efforts that increase primary culture false-positive rates or add secondary testing false-positive results, which also require efforts to enact and reverse co-component quarantines while communicating with hospitals. AABB will provide resources to assist blood collectors to maximize platelet availability including holding workshops, etc.

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Appendix – Reference Tables

Table 1. Mitigation Strategies Available for Different Platelet Components

Mitigation Strategy	Apheresis Platelet stored in Plasma	Apheresis Platelet stored in Platelet Additive Solution (PAS)	Whole Blood Derived Platelet
PRT (exp day 5)	X	X	
LVDS ≥ 36 (exp day 5)	X	X	X
LVDS 4≥ 8 (exp day 7)	X		
Primary culture ≥ 24 (exp day 3)	X	X	X
PC ≥ 24 and SC Day 3 (exp day 5)	X	X	X
PC ≥ 24 and SC Day 4 (exp day 7)	X		
LVDS 36 and SC Day 4 (exp day 7)	X		
PC ≥ 24 and RT	X	X	X
LVDS ≥ 36 and RT	X		

PRT = Pathogen reduction technology; LVDS= Large-volume delayed sampling

Table 2. Date of Expiration with Approximate Time of Release from Blood Center and Approximate Shelf Life in Hospital

	Mitigation Method	Day of Expiration	Day of Release from Blood Center	Shelf Life in Hospital
Pathogen Reduction	PR stored in plasma or PAS	Day 5	Middle to late day 1	3-4 days
<u>One-Step</u> Culture	LVDS 36 hours	Day 5	Middle to late day 2	2-3 days (can be extended with secondary testing)
	LVDS 48 hours	Day 7 (plasma)	Early to middle day 3	4-5 days
	PC 24	Day 3	Early to middle day 2	1 day (can be extended with secondary testing)
<u>Two-Step</u> PC + Secondary Culture	PC 24 and SC Day 3	Day 5	Middle to late day 2*	3-4 days
	PC 24 and SC Day 4	Day 7 (plasma)	Middle to late day 2*	5-6 days
PC + Rapid Test	PC 24 and RT	Day 5 OR Day 7 (plasma)	Early to middle day 2*	3 days 5 days (plasma)
LVDS + Culture	LVDS 36 and SC Day 4	Day 7 (plasma)	Middle to late day 2*	4-5 days (plasma)
LVDS + Rapid Test	LVDS 36 and RT	Day 7 (plasma)	Middle to late day 2*	4-5 days (plasma)

PR = Pathogen reduction; PAS = Platelet additive solution; LVSDS = Large-volume delayed sampling; PC = Primary culture; SC = Secondary culture; RT = Rapid test *Note: secondary culture and testing will likely be performed at the hospital

Table 3. Pathogen Reduction Technology (PRT) Special Considerations from the Blood Center and Transfusion Service Viewpoints

Single-Step Testing	Eligible Products	Advantages	Disadvantages	Regulatory Perspectives	Product Quality Considerations
PRT	• Amicus PAS • Trima Plasma	• Earliest available product release	• Two kits per collection for triples • Guard band limitations make for manufacturing complexity • May reduce split rate with partial-only PRT supply	• Requires FDA license if shipped across state lines • New PRT ISBT codes	• Lower CCI • Higher platelet refractoriness

PAS = platelet additive solution; ISBT = International Society of Blood Transfusion; CCI = corrected count increment.

Table 4. Single-Step Options, with Primary Culture (PC) at ≥ 24 Hours and Large-Volume Delayed Sampling (LVDS) at ≥ 36 and ≥ 48 Hours

Single-Step Testing	Eligible Products	Advantages	Disadvantages	Regulatory Perspectives
PC at ≥ 24 hours	• Amicus PAS • Amicus Plasma • Trima PAS • Trima Plasma • PSP WBD platelets	• Mother bag-only sampling • Lowest increase in inoculation volume • No additional testing by transfusion service if used by end of day 3 • Product release time same as pre-guidance practices	• Limited to 3-day product unless secondary testing applied	• Confusing 3-day product labeled as 5- day requires new control processes; tie tag (or similar method) indicating expiration on day 3 unless further tested by culture or rapid test
LVDS at ≥ 36 hours	• Amicus PAS • Amicus Plasma • Trima PAS • Trima Plasma • PSP WBD platelets	• 5-day product with no additional testing • No label changes needed	• Product release is held up by sampling timeline of 36 or 48 hours • Older product at the time of release • May reduce split rate and availability without longer donor procedures	• Confusing as some products with identical 5-day expiration ISBT labels require additional testing after day 3 (PC at 24-hour sampling), while others (LVDS at 36 hours) require no further testing; control processes required • Tie tag indicating expiration on day 5
LVDS at ≥ 48 hours	• Amicus Plasma • Trima Plasma	• 7-day product with no additional testing • Longest shelf life available to hospital without secondary testing		• New ISBT codes for 7-day products

PAS = platelet additive solution; PSP WBD = prestorage pools of whole-blood-derived platelets; CCI = corrected count increment

Table 5. Two-step strategies with Secondary Culture (SC) on Days 3 and 4 or Rapid Testing (RT)

Two-Step Testing	Eligible Products	Advantages	Disadvantages	Regulatory Perspectives
LVDS at ≥ 36 hours and SC at day 4	• Amicus Plasma • Trima Plasma	Extends to 7 days	• Logistics of sampling and culture • SC on split bags aerobic and anaerobic • Must hold an additional 12 hours •	• Requires FDA registration for transfusion services performing secondary testing to label with 7-day expiration (safety measure). • Transfusion service needs validated procedures to perform SC • Must determine quarantine period • New ISBT codes
LVDS at ≥ 36 hours and RT	• Amicus Plasma • Trima Plasma	Allows extension of shelf life after expiration on day 5 and extends to 6 or 7 days	• Must label with expiration time after each rapid test is performed	• Requires FDA registration for transfusion services performing RT to label with 7-day expiration (safety measure). • Rapid test validation, QC monitoring • Must determine quarantine period • Labeling • New ISBT codes
PC at ≥ 24 hours and SC at day 3	• Amicus PAS • Amicus Plasma • Trima PAS • Trima Plasma	• Extends to 5 days • SC is aerobic only	• SC on split bags (aerobic only) • Secondary culture may be done with any validated culture system. FDA safety	• Must establish processes/SOPs to manage culture, incubation, and

	• PSP WBD platelets	• Minimum Incubation period determined by hospital SOP (if transfusing on day 4 or 5.)	measure not required	labeling in hospital
PC at ≥ 24 hours and SC at day 4	• Amicus Plasma • Trima Plasma	• Extends to 7 days • Longest shelf life available to hospital	• SC on split bags aerobic and anaerobic • 12-hour incubation period • Secondary culture requires FDA safety measure and 7-day culture bag • BECS changes for blood center to manage PC and SC results on the same product	• Requires FDA license to ship across state lines • Requires FDA registration for transfusion services performing secondary testing to label with 7-day expiration (safety measure). • Must establish processes/SOPs to manage culture, incubation, and labeling in hospital • New ISBT codes
PC at ≥ 24 hours and RT	• Amicus PAS (5d) • Amicus Plasma • Trima PAS (5d) • Trima Plasma • PSP WBD platelets	• Allows extension of shelf life after days 3, 4, 5, 6, 7 for: -PSP WBD (5 days) -SDP PAS (5 days) -SDP Plasma (7 days) • Reduces wastage	• Must label with expiration time after each rapid test is performed	• Requires FDA registration for transfusion services performing RT to label with 7-day expiration (safety measure). • Rapid test validation, QC monitoring, competency assessment • Must establish processes/SOPs

				to manage testing and labeling • Need processes to accommodate mix of products expiring at 11:59 pm or at a specific time

SOPs = standard operating procedures; QC = quality control; PAS = platelet additive solution; PSP = prestorage pool;-WBD = whole-blood-derived; BECS = blood establishment computer system; FDA = Food and Drug Administration; PC = primary culture; SC = secondary culture; SDP = single-donor apheresis platelet

Table 5. Sample Questions for Hospitals and Blood Centers

Questions from a hospital transfusion service to its blood supplier(s):

1. What mitigation strategies do you plan to offer?
2. Are these 5-day or 7-day storage options?
3. What is your platelet availability?
4. What codes do I need to have available in my LIS to receive the new platelets?
5. Will you always have the same kind of platelets available, or should I expect variation in our platelet inventory?
6. Can you provide assistance or any educational resources to help us set up secondary testing strategies?
7. How will I know what platelets are being delivered so I can be prepared?

Questions from a blood supplier to its hospital customers:

1. Which mitigation strategy(s) do you prefer?
2. Are there any products you do not want?
3. Please rank 1-5 your platelet preference:
    a. One-step strategy for seven-day storage
    b. One step strategy for five-day storage with ability to extend storage with RT or secondary culture
    c. One step strategy for three-day storage with ability to extend storage with RT or secondary culture
    d. PRT platelets stored in PAS
    e. PRT platelets stored in plasma
4. How many platelets per year do you estimate needing?

PAS = platelet additive solution; PRT = pathogen reduction technology; LVDS = large-volume delayed sampling; RT = rapid test

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