Implementing 7 Day Platelet Dating with the Platelet PGD® Test

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The Verax Biomedical Platelet Pan Genera Detection (PGD®) Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in platelet components. It is the only day of transfusion test that has been cleared by the FDA as a "safety measure"[1] and is the sole rapid test for extending the expiration date of apheresis platelets in 100% plasma for up to seven days when using containers cleared by FDA for 7-day dating.[2] The PGD test also helps to assure the safety of five-day dated platelets for transfusion.[3] An apheresis platelet may be transfused for up to 24 hours after a non-reactive PGD test result.[4]

The efficacy of platelets stored for seven days has been shown to not be different than a platelet stored for five days and is addressed in a separate White Paper (WP002).

Platelets produced with pathogen-reduction technology are currently not approved for storage beyond 5 days.

This White Paper addresses the implementation of the PGD test in a hospital blood bank or transfusion service.

PGD TESTING FREQUENCY

It is important to note that platelets do not need to be repeatedly tested on storage days 4, 5, 6, and 7. They need only be tested once within 24 hours prior to transfusion. Both the December 2018 FDA Draft Guidance, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion,[5] and the Platelet PGD test package insert[6] make this clear. Each institution should establish its optimal testing strategy. For example, hospital staff may identify platelets likely to be transfused on a specific day and test only those. If a component is not transfused within 24 hours following testing, it needs to be retested only within 24 hours of its expected transfusion. Experience at many institutions has shown that the vast majority of platelets are tested only one time, even if stored for 7 days.

TRAINING

Verax Biomedical (Verax) Technical Support staff provides installation and customized on-site training. Training sessions last approximately 2 to 2.5 hours and can include up to four technologists per session. Train-the-trainer sessions and quizzes are also offered. Certificates of competency and/or train-the-trainer certificates are issued to everyone trained by Verax.

The following items are provided by Verax:

- Training checklists.
- Color-coded, step-by-step, laminated work instructions describing how to run controls and how to process a platelet sample. These work instructions can also be used as a job aid.

- Familiarization panels. This panel comprises 10 blind-coded tubes that contain different strains of bacteria or saline. Platelets from a non-reactive unit are added to each tube prior to testing. The panel allows a new user to see what results may look like when testing a reactive platelet, including a variety of line intensities, as well as results for a non-reactive platelet.
- "Competency devices." These are mock devices that show examples of reactive results of varying intensities to assist technologists in identifying reactive results and distinguishing them from nonreactive results. These mock devices may be used to assist with training and for assessing competency throughout the year.

Consultation on integrating PGD into laboratory workflow is available from Verax either prior to or following training.

VALIDATION

A bacteria panel, part number 0820000, is available from ZeptoMetrix, Buffalo, NY (http://www.zeptometrix.com/). This frozen panel comprises 12-members: 2 negative, 5 Gram-positive and 5 Gram-negative samples. When reconstituted with platelets, each tube contains sufficient volume for two tests. Platelet units used for reconstitution can be up to 10 days post-collection. The panel is also available from Fischer Scientific, Pittsburgh, PA (https://www.fishersci.com/us/en/home.html) where it may be ordered as part number 22-156-706 or as the ZeptoMetrix part number, 0820000.

QUALITY CONTROL

Platelet PGD Controls, part number P30C, can be ordered directly from Fisher Healthcare (https://www.fishersci.com/shop/products/platelet-pgd-controls/23051002#?keyword=p30c) as Catalog No.23-051-002. Platelet PGD Controls include positive and a negative external control. PGD Control vials contain sufficient volume to generate 30 positive and 30 negative test results.

Upon request, an Internal Quality Control Plan (IQCP) template is available from Verax. This template is designed to assist a customer in performing a risk assessment to evaluate the possibility of running external controls less frequently than CLIA requirements (i.e., daily). As noted in the Platelet PGD package insert, external PGD Controls are to be tested when a new shipment of Test Devices or Reagents is received, when a new lot of Test Devices or Reagents is opened, when a new technologist is trained and as specified by the user facility. More information about IQCPs is available from the Centers for Medicare and Medicaid Services (CMS) at: https://www.cms.gov/regulations-and-guidance/legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.

Procedural Control Windows are located at the both ends of each PGD test device. These windows color shift from yellow to a blue-purple to indicate that sample has migrated through the Test Device and test results are ready to be interpreted.

PROFICIENCY TESTING

Proficiency testing material is available through the College of American Pathologists (CAP). The CAP offers 2 different Proficiency Panels – a 2-member and a 5-member set (order codes BDPV or BDPV5, respectively). Descriptions of the two can be found and orders can be placed on the CAP website (www.cap.org) for BDPV and BDPV5.

The catalog states:

- The Centers for Medicare & Medicaid Services (CMS) requires proficiency testing for bacterial detection in platelets.
- Survey BDPV is designed for donor centers/laboratories that are associated with a CMS-certified microbiology laboratory with the same CLIA number and are participating in an approved proficiency testing program for bacterial detection.
- Survey BDPV5 is designed for donor centers/laboratories that are performing bacterial detection for the purposes of platelet unit screening and are not associated with a CMS-certified microbiology laboratory with the same CLIA number

INFORMATION TECHNOLOGY

The establishment needs a process/system for accurate relabeling and product release prior to implementing outdate extension. The establishment may need to (re)configure its laboratory information system (LIS) to enable product code modification and relabeling using new E-codes (see **LABELING**, below) after testing is completed. Changes to an institution's LIS may be performed by information technology staff as part of their routine support functions so there are likely to be no to minimal external costs associated with these LIS updates. The system must assure that all products outdate within 24 hours following PGD testing and no later than the end of Day 7.

There are no extra costs associated with implementing new E-codes (see **LABELING**, below).

REGISTRATION

Extending platelet dating beyond five days requires relabeling the component, which is defined by FDA as manufacturing. Therefore, if you extend platelet dating, you are required to register as a blood establishment and list your (platelet) product with FDA no later than 5 days after implementation of dating extension (21 CFR 607.21). Variance applications are no longer necessary.

Initial registrations and renewals must be submitted electronically using the Electronic Blood Establishment Registration and Product Listing system (eBER). The eBER record includes fields for establishment types, blood products and processes and replaces Form FDA 2830.

As described in 21 CFR 607.21, annual renewal of the registration is to be completed between Oct. 1 and Dec. 31 and product listings are to be updated semi-annually (June and December). Reminders for annual registration renewal are sent electronically each year on or about October 1st.

If your institution is currently performing other manufacturing (e.g., irradiating blood components; pre-storage leukocyte reduction; washing, freezing, deglycerolizing red cells), your establishment should already be registered with FDA. If your institution is already registered, then simply update your existing registration.

Importantly, as noted in Draft Guidance, if your transfusion service performs secondary testing on platelets that will retain their original five-day expiration dating, you are not required to register for this testing. You are not extending the dating period, are not relabeling platelet components and, therefore, not performing manufacturing.[7]

FDA has provided step by step instructions for completing the eBER record in a document, "BER Instructions for Completing the Electronic Blood Establishment Registration and Product Listing Form," which is available at: https://www.fda.gov/media/116432/download. The BER instruction document includes a link to a collection of frequently asked questions and their answers.

If your institution is not already registered with FDA, you will need to set up an account prior to registering your establishment. Click on the following link to create an account:

> https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm?CFID=14371273&CFTOKEN=3bf68105249a55d0-A85D0D0F-1372-5AE1-674338933A9DF71D

When you are completing the "Process Definitions" section, choose:

> "Bacterial Testing: is a qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in leukocyte reduced apheresis platelets or pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets within 24 hours prior to transfusion as a safety measure following testing with a growth-based quality control test cleared by the FDA for platelet components."

In the "Product Definitions" section, choose:

> "Platelets Extended Dating: Platelets that have been tested for bacteria using an FDA-cleared bacterial detection device labeled as a "safety measure", following testing with a growth-based quality control test cleared by the FDA for platelet components, that can support extending the expiration date of platelets past 5 days. Platelets shall be stored in a container that is approved or cleared to store platelets up to 7 days."

The eBER record requires the entry of a Dun & Bradstreet (D&B) D-U-N-S Number. As described in the BER Instructions for Completing the Electronic Blood Establishment Registration and Product Listing Form, an Establishment DUNS number is "a unique nine-digit identifier for businesses, which is generated by Dun & Bradstreet. The DUNS number is the required Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act [see 21 CFR 607.25(a)]." More information on DUNS numbers is available on the Dun & Bradstreet website. According to the D&B website, obtaining a D-U-N-S number is free and can be obtained in 30 days or less.

If your establishment intends to distribute products to other facilities, indicate on your FDA registration that you are "storing and distributing." However, if your institution further manages platelet outdate by sending platelets that are in your inventory and will expire soon to another location, FDA will consider this activity inventory management, which does not require registration as "storing and distributing."

Registered establishments are inspected by the FDA. Effective May 2, 2019 **there is no longer a set schedule for inspections.** The requirement for biennial inspections has been replaced with a risk-based assessment by the local FDA field offices to establish the frequency of inspections.

< https://www.federalregister.gov/documents/2019/04/02/2019-06187/removal-of-certain-time-of-inspection-and-duties-of-inspector-regulations-for-biological-products >

If you have questions about registering your establishment or listing your products, contact a CBER representative by phone at 240-402-8360 or by email at bloodregis@fda.hhs.gov .

AABB STANDARDS

In 2016, the 30th edition of the AABB Standards for Blood Banks and Transfusion Services addressed extending platelet storage beyond five days. Standard 5.1.8A permits Apheresis Platelets Leukocytes Reduced to have a seven-day expiration "only if 1) storage containers are cleared or approved by the FDA for 7-day platelet storage, and 2) labeled with requirement to test every product stored beyond 5 days with a bacteria detection device cleared by the FDA and labeled as a 'safety measure.'"[8]

OPERATIONS

Documentation

Verax can provide draft SOPs for use as starting points for writing SOPs. Verax can also provide worksheet templates for recording PGD test results.

Testing strategies

Transfusion must occur within 24 hours following PGD testing. Some institutions test during the night shift so that PGD-tested units "expire" at or near midnight. Other institutions choose to test throughout the day, which ensures that units are always available and distributes the workload across shifts. There is no need to test each platelet component every day that it is in storage. For example, a platelet that outdates at midnight on day 5 may be tested for the first time on day 6 (or day 7) and may be transfused within 24 hours of this testing as long as transfusion occurs before midnight on day 7.

Staffing

Fifty (50) hospital transfusion services that utilize the Platelet PGD Test were selected randomly and contacted by Verax staff. All 50 implemented and performed PGD testing with existing staff and 98% said PGD testing was easier to perform or similar to other tests run in their laboratory.[9] Dunbar et al. implemented testing of every platelet in inventory without the need for additional staffing.[10]

LABELING

Bacterial Detection Testing and Expiration Dating

21CFR 606.121c(4)(i) states that the container label must include the expiration date, including the day; month; and year, and, if the dating period for the product is 72 hours or less, the hour of expiration.

Draft Guidance says, "If secondary testing of platelets is performed consistent with this guidance, and the expiration date is extended to 6 or 7 days based on the bacterial testing performed, the blood establishment or transfusion service that performed the secondary testing must update the container label to reflect the new expiration date…"[11] The new expiration date and time may be handwritten as only the following information need be machine-readable: (a) a unique facility identifier, (b) lot number relating to the donor, (c) product code, and (d) ABO and Rh of the donor.[12]

Bacterial Detection Testing and Product Codes

The International Council for Commonality in Blood Banking Automation (ICCBBA; https://www.iccbba.org/home) Information Standard for Blood and Transplant (ISBT) 128 E-code database (ISBT 128 Product Description Code Database) contains product codes created for platelet components

that are dating extended following performance of a bacterial detection test labeled as a "safety measure." Note that product codes do not need to change if dating is not extended. Codes are available for each member of up to a triple collection.

The attributes added to the end of each description indicate when the unit is tested. For example, when testing is performed prior to midnight of Day 5, D5 codes are used to extend the outdate to Day 6.

Refer to Table 1, below, for the following examples.

- A platelet is collected on Feb 1 and will expire on Feb 6th, which is Day 5.
- If the platelet is tested at 3pm on Day 5 (Feb 6th) and the platelet is being date extended, the platelet will now expire at 3pm Day 6 (Feb 7th). A product code for "Bacterial test D5" should be applied when the unit is tested. For example, if the unit is the first container of a triple collection, product code E9229 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Bacterial test D5 could be used. See list of product codes on the following page.
- If the unit is tested on Day 6 (Feb 7), a product code with the attribute "Bacterial test D6" should be used.
- If the platelet is tested at (or after) midnight on Day 5, which is really Day 6 (Feb 7th), the platelet would expire 24 hours from the time of testing (Feb 8th) and the "Bacterial test D6" code is used.
- If the unit is tested on Day 7 (Feb 8), a product code for "Bacterial test D7" should be used. NOTE: The expiration cannot be later than midnight on Day 7.

Table 1: Examples of Platelet Dating

Collected on	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Calendar	Feb 1	Feb 2	Feb 3	Feb 4	Feb 5	Feb 6	Feb 7	Feb 8
Expiration Date						Day 5	Day 6	Day 7

The following product codes were added in February 2018.

Leukoreduced Platelets

Day 5:

E9228 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial test D5
E9229 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Bacterial test D5
E9230 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Bacterial test D5
E9231 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|Bacterial test D5

Day 6:

E9232 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial test D6
E9233 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Bacterial test D6
E9234 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Bacterial test D6
E9235 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|Bacterial test D6

Day 7:

E9236 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial test D7
E9237 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Bacterial test D7
E9238 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Bacterial test D7
E9239 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|Bacterial test D7

Irradiated Platelets

Day 5:

E9240 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|Bacterial test D5
E9241 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|1st container|Bacterial test D5
E9242 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|2nd container|Bacterial test D5
E9243 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|3rd container|Bacterial test D5

Day 6:

E9244 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|Bacterial test D6
E9245 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|1st container|Bacterial test D6
E9246 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|2nd container|Bacterial test D6
E9247 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|3rd container|Bacterial test D6

Day 7:

E9248 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|Bacterial test D7
E9249 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|1st container|Bacterial test D7
E9250 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|2nd container|Bacterial test D7
E9251 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|3rd container|Bacterial test D7

Irradiated and Leukoreduced Platelets

Day 5:

E9252 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|Bacterial test D5
E9253 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Bacterial test D5
E9254 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|Bacterial test D5
E9255 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|Bacterial test D5

Day 6:

E9256 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|Bacterial test D6
E9257 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Bacterial test D6
E9258 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|Bacterial test D6
E9259 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|Bacterial test D6

Day 7:

E9260 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|Bacterial test D7
E9261 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Bacterial test D7
E9262 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|Bacterial test D7
E9263 Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|Bacterial test D7

Additional product codes have been approved by the ICCBBA for use when extending platelet dating. However, there are no regulatory requirements to use the new codes. Codes that have been used for date-extended platelets have not been and will not be retired; they may continue to be used. Some institutions choose to use the same code for platelets date-extended to Day 6 and to Day 7.

New product codes can be requested from ICCBBA. ICCBBA has stated that codes created from existing attributes are generally available within 1 month of request. If an appropriate product description code cannot be found in the "ISBT 128 Product Description Code Database," a product request can be submitted via the "ISBT 128 Product LookUp Web Application." Additional information can be found at: https://www.iccbba.org/isbt-128-basics/frequently-asked-questions/technical-frequenlty-asked-questions2#q1

At a minimum, the unit's container label must be revised with the new expiration date/time, based on the PGD testing date/time.

Documentation

It is a regulatory requirement for each establishment to write and follow Standard Operating Procedures that describe the institution's processes for testing and extending platelet expiration dating.

PLATELET STORAGE BAGS FOR 7-DAY PLATELET SHELF-LIFE

Amicus (Fresenius) and Trima (Terumo BCT) platelet bags have received FDA clearance for 7-day platelet shelf-life of apheresis platelets stored in 100% plasma. Photos of these bags are shown in Appendix 2 of this report. Both FDA clearances require that, for storage up to 7 days, every "product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."

Amicus Platelet Storage Bags

The Fenwal Amicus Separator System allows the operator to adjust the volume of storage fluid during platelet collection. This adjustability is intended to maximize collection efficiency.

Two checks are required to qualify a platelet unit for dating extension: the number of platelets and the storage fluid volume, which includes the anticoagulant (ACD). Fresenius Kabi determined that, **if the number of platelets in the unit is between 3.0 – 4.7 x 10^{11}, AND the storage fluid volume of the unit is ≥255mL, the platelet unit meets the volume qualification for a shelf-life of up to 7 day**s. If those two conditions are not met, dating extension to 7 days may still be possible. Fresenius Kabi developed a guide to help in determining if the component's combination of number of platelets and fluid volume meet the volume qualification. This Guide is reproduced in Appendix 1 of this report.

Trima Platelet Storage Bags

Apheresis platelets in 100% plasma in Terumo BCT bags do not have a plasma volume requirement for extending storage through 7 days. Therefore, any apheresis platelet suspended in plasma in a Terumo storage container is eligible for dating extension to 7 days with safety measure testing.

CUSTOMER SUPPORT

For technical support, contact Verax Biomedical at vts@veraxbiomedical.com or call 508-688-2992 or 425-736-9392. For customer support and to place an order, visit: https://www.fishersci.com or contact Fisher Scientific Customer Service at 1.800.640.0640.

SUMMARY AND CONCLUSION

Implementation of 7-day dating of apheresis platelets is easily achievable. Favorable cost/benefit calculations have been reported, although each institution should perform its own analysis.[13] Extended dating has been demonstrated to lower platelet outdate rates. For example, Dunbar reported the outdate rate at her institution has decreased from 5% to 1% since the formal implementation of routine use of Day 6/7 platelets.[14]

PGD testing provides cost-savings and enhances platelet safety while reducing the platelet outdate rate, which increases platelet availability, improves management of rare components, and helps to assure therapeutic use of the donor's gift.

REFERENCES

[1] http://wayback.archive-it.org/7993/20170112210611/http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/SubstantiallyEquivalent510kDeviceInformation/ucm272231.htm

[2] US Food and Drug Administration. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance

[3] Draft Guidance *op. cit*.

[4] https://www.veraxbiomedical.com/wp-content/uploads/2019/06/Platelet-PGD-Test-US-Rev-J-June-2019-Version.pdf

[5] *Id*

[6] https://www.veraxbiomedical.com/wp-content/uploads/2019/06/Platelet-PGD-Test-US-Rev-J-June-2019-Version.pdf

[7] Draft Guidance *op. cit.*

[8] Standards for Blood Banks and Transfusion Services. 30th ed. 2016. AABB. Bethesda.

[9] Hornbaker N, Rasmusson P, Lee W, Sanders J. Pan Genera Detection (PGD®) Testing for Bacteria in Platelets at 50 US Institutions. Transfusion 2012;52(S):206A

[10] Dunbar NM, Dumont LJ, Szczepiorkowski ZM. How do we implement Day 6 and Day 7 platelets at a hospital-based transfusion service? Transfusion 2016; 56:1262-1266

[11] Draft Guidance *op. cit.*

[12] Code of Federal Regulations 21 CFR 606.121(c)(13)(iii)

[13] Mintz PD. Seven-day platelet storage: Outdate reduction and cost savings (abstract). Ann Clin Lab Sci 2019;49(3):414.

[14] Dunbar N. AABB Audioconference handout. April 27, 2016

Appendix 1

FRESENIUS KABI

Platelets Pheresis, Leukocytes Reduced stored in 100% plasma manufactured with the Fenwal Amicus Separator may qualify for an extended shelf-life of up to 7 days.

A check of the platelet unit volume allows the end user to quickly determine if a Platelet Pheresis, Leukocytes Reduced unit stored in 100% plasma qualifies for an extended shelf-life of up to 7 days, provided it tests negative with a bacterial detection device cleared as a safety measure as described in the draft version of the Bacterial Testing draft guidance by FDA.[1]

In general, if the *Number of Platelets* in the unit is in the range of **$3.0 - 4.7 \times 10^{11}$**, **AND** the *Minimum Storage Fluid Volume* of the unit is **255mL or higher**, a platelet unit meets the volume qualification for a shelf-life of up to 7 days* (**Table 1**). Should a platelet unit contain a volume of less than 255mL, or contain less than 3.0×10^{11} or more than 4.7×10^{11} platelets, refer to **Table 2** to determine if the apheresis platelet unit meets the volume requirement for an extended shelf-life of up to 7 days*.

Table 1:

Number of Platelets ($\times 10^{11}$)	Minimum Storage Fluid Volume (mL) Including ACD pH ≥ 6.2	Meet Criteria
< 3.0	-	Refer to Table 2
3.0 – 4.7	**≥ 255mL**	**Acceptable**
3.0 – 4.7	< 255mL	Refer to Table 2
> 4.7	-	Refer to Table 2

Example 1: If a platelet unit manufactured with the Fenwal Amicus Separator contains 3.7×10^{11} platelets and has a volume of 243ml (*minimum* storage fluid volume required for 7 day storage is **239mL**, see Table 1), the shelf-life of the unit can be extended to 7 days if tested negative with a bacterial detection device cleared as a safety measure, since the minimum storage fluid volume requirement of 239mL is met.

Example 2: If a platelet unit manufactured with the Fenwal Amicus Separator contains 3.4×10^{11} platelets and has a volume of 221mL (minimum storage fluid volume required for 7 day storage is **230mL** see Table 1), this unit does not qualify for an extended shelf-life of up to 7 days, and is limited to a shelf-life of up to 5 days

[1] Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, Draft 03/2016, available online at http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM425952.pdf (last visited July 28, 2016).

Appendix 1 (continued)

TABLE 2: Amicus Platelets Pheresis, Leukocytes Reduced stored in 100% plasma minimum storage fluid volume to extend shelf-life of up to 7 days*

Number of Platelets ($\times 10^{11}$)	Minimum Storage Fluid Volume (mL) Including ACD pH ≥ 6.2	Number of Platelets ($\times 10^{11}$)	Minimum Storage Fluid Volume (mL) Including ACD pH ≥ 6.2
2.3	180	4.4	252
2.4	185	4.5	253
2.5	191	4.6	254
2.6	196	4.7	255
2.7	201	4.8	370
2.8	205	4.9	382
2.9	210	5.0	382
3.0	214	5.1	392
3.1	219	5.2	392
3.2	222	5.3	402
3.3	226	5.4	402
3.4	230	5.5	410
3.5	233	5.6	410
3.6	236	5.7	420
3.7	239	5.8	420
3.8	241	5.9	428
3.9	244	6.0	428
4.0	246	6.1	438
4.1	248	6.2	438
4.2	250	6.3	444
4.3	251	6.4	444

* Platelets Pheresis, Leukocytes Reduced may be stored in the platelet storage container(s) for up to 7 days at 20°C to 24°C with continuous agitation. The Amicus platelet storage container is cleared to store Platelets Pheresis, Leukocytes Reduced in 100% plasma for up to 7 days. Additionally, for platelet units stored past 5 days and through 7 days, every product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."

References:

- Amicus Separator Operator's Manual Section A.5

Appendix 2

How to Identify Terumo Trima and Fenwal Amicus Storage Containers

- **Terumo Trima**

Shoulders are squared

Clamp is dark blue

Port to spike is on right

- **Fenwal Amicus**

Shoulders are rounded

Port to spike is in center

Clamp is light blue