



Bacterial Mitigation Final Guidance
Cutover Packet for Hospitals

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Introduction

Project Background and Overview

On September 30, 2019, the FDA released the Final Guidance “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion”. In December 2020, the FDA updated its Final Guidance and extended the deadline for implementation from March 31, 2021 to October 1, 2021. Since the announcement and subsequent deadline extension, Vitalant has worked collaboratively with our hospital partners on substantial planning for implementation of this Final Guidance.

Vitalant will implement LVDS 48-hour/7-day on a rolling basis in our regional blood centers. Hospitals could begin receiving LVDS products as early as July 1, 2021. [The email sent to hospital contacts on Monday, May 17 served as your 30-day notification of this change.](#) You will receive an additional notification via paper insert in your blood product shipping containers 7 days prior to the cutover in the regional blood center that primarily serves your organization, as well as a reminder a day before you should expect to receive your first LVDS 48-hour/7-day platelets.

The methods of bacterial mitigation proposed in the Final Guidance that reduce bacterial contamination risk by more than 50 percent will result in increased cost and may impact platelet availability. To best meet our customers' needs for platelets, bacterial mitigation must be balanced in a way that reduces the risk of bacterial contamination without compromising platelet supply. Vitalant evaluated all options listed in the Final Guidance with three key considerations in mind:

1. Provide a safe and sufficient supply of platelets
2. Provide cost-effective options for our hospital customers
3. Limit total number of options to improve inventory management and facilitate ease of use

Vitalant is moving forward with Large Volume Delayed Sampling (LVDS) 48-hour/7-day and Pathogen Reduction Technology (PRT), [also known as psoralen-treated platelets](#), to meet the key considerations listed above, to continue to provide organizations clinical choices and to leverage our national footprint. We have prioritized transfusion-ready options that do not require additional testing.

- NOTE: Vitalant is rapidly working to have all locations obtain LVDS 48-hour/7-day licensure at time of implementation. LVDS 36-hour/5-day will only be offered by Vitalant should licensure for any locations be delayed.
- NOTE: As Vitalant implements LVDS 48-hour/7-day on a rolling basis across service areas, there may be a short period where your facility receives a combination of conventional (i.e., the single donor platelet product you have historically received from Vitalant), LVDS (36-hour/5-day and/or 48-hour/7-day, depending on licensure timing) and PRT products. As we become fully implemented, conventional will no longer be available.

As a leader in transfusion medicine, Vitalant remains committed to assessing and providing innovative blood products. We will update you as information on new products becomes available.

Local Vitalant Contacts

As your organization prepares for implementation of this Final Guidance, please continue to work with your local Vitalant contacts. Information for local contacts can be found here:

<https://hospitals.vitalant.org/For-Customers/Blood-Center-Directory.aspx>

Where to Access Online Resources

A copy of this document along with additional resources can be found on our hospital website here:

<https://hospitals.vitalant.org/Education-Reference/Bacterial-Mitigation-Final-Guidance.aspx>

Administrative Impacts

Billing and Invoicing from Vitalant

Invoicing for LVDS 48-hour/7-day and PRT platelets will be presented in a manner that is consistent with how conventional platelets have historically been invoiced. Additional information has been added to the product description to assist with distinguishing between the different products shipped. Pricing for LVDS 48-hour/7-day and PRT platelet products will follow your hospital's agreed upon rates. Products will continue to be billed based on the product code. You will now see additional product codes, which will be priced accordingly.

Vitalant will implement LVDS 48-hour/7-day on a rolling basis in our regional blood centers. Hospitals could begin receiving LVDS products as early as July 1, 2021. The [email sent to hospital contacts](#) on Monday, May 17 served as your 30-day notification of this change. Please contact your local Regional Account Manager to discuss PRT charges.

Sample documents are provided as Appendix A and Appendix B to assist with the reconciliation process between the packing slip received and the associated invoice. Sample documents are provided from our two primary billing systems:

- [Appendix A](#): The first, titled "National Invoicing Example," is specific to the system supporting all Vitalant service areas throughout the U.S. apart from the Northeast areas listed below.
- [Appendix B](#): The second, titled "Northeast Invoicing Example," is specific to Vitalant's Illinois, Ohio, and Pennsylvania service areas until they are integrated into Vitalant's national systems.
- NOTE: Prices noted on the sample documentation are for example purposes only. They do not reflect contracted pricing.

National Invoicing:

Vitalant recommends using the Shipping Date, Shipment Number, and Product Description to reconcile between the Packing Slip and Invoice.

Northeast Invoicing:

Vitalant recommends using the Shipment Date, Reference Number, and ISBT Product Code to reconcile between the Packing Slip and Invoice. The description noted on the Detail Invoice clearly identifies the platelet as either a conventional, LVDS 48-hour/7-day, or PRT platelet product (may be listed as psoralen-treated platelets).

Note: Transfusion services customers in our Northeast service areas will see a very similar Packing Slip and Invoice format.

Special Note:

Washed, Pooled, Variable-Yield, and Frozen platelet products will not be assigned new ISBT codes when they are converted to the LVDS operational process. Pricing changes for these specific products will be effective starting October 1, 2021.

Hospital Process Adjustments – Coding and Billing for PRT Administered in the Outpatient Setting

Cerus has a resource available (link below) to assist with your hospital's coding and billing process for PRT products administered in the outpatient setting.

- [Cerur Coding and Billing Information: INTERCEPT® platelet and plasma products administered in the outpatient setting](#)

Hospital Process Adjustments – Accepting PRT

Your facility should **be prepared to receive a PRT product** to ensure the availability of supply in the event a rare product is needed, there is platelet product supply shortage, etc. The following checklist will help ensure your hospital is prepared to receive PRT in anticipation of these instances:

- Hospital IT team:
 - **Build the products into your system.**
 - Please use this reference to identify all codes that need to be uploaded: <https://hospitals.vitalant.org/Education-Reference/ISBT-Codes.aspx>
 - **Ensure your facility is prepared to assign PRT platelets to patients.**
 - PRT platelets are acceptable for patients requiring irradiated products, and as approved by your medical director or current transfusion policy as an alternative to CMV seronegative or CMV Safe product attributes (AABB standard 5.19.4.1 for irradiation of blood products considers the FDA-approved method of pathogen reduction equivalent to irradiation). Modern Blood Bank/Transfusion Service IT Systems include safeguards to prevent the transfusion of non-irradiated/non-CMV negative-tested products to patients at risk of TA-GVHD or the complications related to CMV. Hospitals that are currently using PRT have applied a variety of IT solutions to avoid the need to manually override these safeguards when assigning PRT to patients, including:
 - If the system's algorithm allows for one permissible attribute, then change the attributes of PRT and irradiated platelets to IRRPR and the attributes of PRT and CMV-negative platelets to CMVPR.
 - If the system's algorithm allows for multiple attributes, then the algorithm can be edited to where both IRR and PR attributes are acceptable. The same would apply for the CMV and PR attributes.
 - If the system uses an error checking table where the algorithm references a table of acceptable product codes for irradiated products and CMV negative products, then PRT products can be added to these tables for equivalency.
 - **Ensure your clinical teams are aware of PRT as an alternative product.**
 - The hospital IT system may require updates to notify ordering clinicians that PRT may be dispensed as an alternative to irradiated and/or CMV negative (or CMV safe) platelets. If your hospital IT system utilizes a bedside transfusion management system, updates must be applied so that the system can scan in the PRT label.
 - Update Computerized Physician Order Entry (CPOE) to include notification that psoralen-treated platelets (PRT) may be dispensed as an alternative to irradiated/CMV-negative platelets.

- If implemented, update bedside Hospital Information System (HIS) blood product administration system (i.e., eTAR, BPAM) to read new product barcode.
 - **Ensure your billing and reimbursement team is aware of these key points.**
 - There are a few key points to remember when establishing your billing for PRT. CMS recognizes PRT as a blood product, not as a procedure, which is why PRT should be billed using CMS' established P-code (P9073), not a CPT code.
 - Centers for Medicare & Medicaid Services (CMS) granted a HCPCS Level II code for pathogen-reduced (PR) platelet components allowing hospitals to bill and secure reimbursement in the outpatient treatment setting.
 - CMS determines P-code payment rate annually, effective January 1st.
 - Use the appropriate P-code (P9073) – not CPT code – for third party payer billing of PRT provided in the hospital outpatient setting.
 - Hospital charge for PRT should reflect the entire product cost, not just the blood supplier's incremental fee for the product.
 - Ensure that hospital chargemaster entry for P9073 is accurate and up to date.
- Hospital Clinical Staff:
 - Ensure your clinical staff are provided the resource titled "Psoralen Treated Platelet Administration" which includes information about "psoralen treated" (psoralen treated = PRT) label on the product, reiterates ability to use as a CMV seronegative and irradiation substitute and provides contraindications. This resource can be found [here](#).

Hospital Checklist for Assessing / Discontinuing Use of Bacterial Testing Safety Measures (such as Verax)

If your facility is currently utilizing bacterial testing safety measures such as Verax to extend shelf life of platelet products, you will need to assess, and potentially discontinue, use of these measures **as they must not be used to extend shelf life of LVDS 48/7-day or PRT products.**

Hospital checklist for assessing / discontinuing use of bacterial testing safety measures such as Verax:

- Update standard operating procedures
- Notify vendor of discontinuation of supply orders
- Archive training materials and equipment
- Staff education
 - Identify products for which bacterial testing safety measures such as Verax testing is acceptable for use
 - Bacterial testing safety measures such as Verax **may** be utilized to extend expiration dates on the following products:
 - Bacterial monitoring ≥ 24 hours
 - Bacterial monitoring ≥ 36 hours i.e., LVDS 36-hour/5-day
 - Bacterial testing safety measures such as Verax **NOT** be utilized to extend expiration dates on the following products:
 - Leukocytes reduced bacterial monitoring 7D (LVDS 48-hour/7-day)
 - Leukocytes reduced psoralen treated (PRT)

- Review product labels to ensure staff can readily identify products for which bacterial testing safety measures such as Verax may or may not be used
- Update LIS as applicable
 - ISBT codes
 - Testing process
 - Labeling process

Product Specifications

Current Platelet Product Portfolio

As stated, bacterial mitigation must be balanced in a way that reduces the risk of bacterial contamination while not compromising platelet supply. To meet FDA bacterial mitigation recommendations, Vitalant will produce both LVDS 48-hour/7-day and PRT platelets. LVDS and PRT platelets both result in increased patient safety with reduced residual risk of bacterial contamination. Both LVDS and PRT are leukoreduced during the apheresis collection process.

| Method | Expiration (Days) | Hospital Testing | Usable Lifespan (Days) |
|-------------------------------------|-------------------|---------------------|------------------------|
| Current 24 ^{hr} sample | 5 | No testing required | 3.5 – 4 |
| LVDS 48 ^{hr} sample | 7 | No testing required | 4.5 – 5 |
| Pathogen Reduction Technology (PRT) | 5 | No testing required | 4 – 4.5 |

NOTE: Vitalant is rapidly working to have all locations obtain LVDS 48-hour/7-day licensure at time of implementation. While LVDS 36-hour/5-day is not represented in the chart above, LVDS 36-hour/5-day may be offered by Vitalant should licensure for any locations be delayed.

Large Volume Delayed Sampling (LVDS):

Vitalant has been an industry leader in large volume sampling as we were already sampling larger-than-required volumes before release of the Final Guidance. LVDS provides the best combination of usable product life and availability for our customers and patients.

The strategy of large volume delayed sampling involves taking larger sample volumes from each platelet unit and inoculating aerobic and anaerobic culture media 36-48 hours after collection, rather than the 24-hour interval that is now widely used. The increased sample volume of at least 16 mL per unit, and additional incubation time prior to sampling results in increased bacterial detection. Primary culture LVDS is a single-step test mitigation strategy as no additional steps must be taken prior to release for transfusion. To maximize usable component availability, Vitalant will produce LVDS 48-hour/7-day platelets with bacterial sampling occurring no sooner than 48 hours after component collection.

As noted, Vitalant is rapidly working to have all locations obtain LVDS 48-hour/7-day licensure at time of implementation. LVDS 36-hour/5-day may be offered by Vitalant should licensure for any locations be delayed.

Pathogen Reduction Technology (PRT):

As one of the first blood centers to adopt PRT, Vitalant currently offers PRT platelets and is expanding our capacity to meet growing patient need.

PRT is a treatment rather than a test and utilizes a photochemical process to kill or inactivate a wide range of bacteria, viruses, parasites, as well as residual donor white blood cells. In the U.S., Cerus' brand of PRT product - INTERCEPT® PRT - has been approved for platelet treatment since 2014. INTERCEPT® PRT treatment utilizes ultraviolet A (UVA) light and psoralen to irreversibly block the replication of DNA and RNA. PRT is a single-step strategy that requires no additional bacterial mitigation steps prior to release for transfusion. PRT eliminates the need for bacterial testing and does not require CMV serologic testing or component irradiation to meet specific patient transfusion needs.

The following image is from Cerus' PRT Implementation Guide. You can access this valuable resource in its entirety here:

- [Cerus PRT: Implementation Guide for Hospitals](#)

| | | |
|---|----------------------------|--|
|  | Bacteria | The FDA Guidance ¹ and AABB Standard 5.15.2 ³ state that pathogen reduction (PR) can be used in place of bacterial testing. ^{1,3} |
|  | T-cells | The INTERCEPT Blood System is approved by the FDA and meets requirement of AABB Standard 5.19.3.1 ³ as an alternative to gamma irradiation for the prevention of transfusion-associated graft-versus-host disease TA-GVHD ^{1,2,3} |
|  | CMV | PR provides cytomegalovirus (CMV) inactivation levels, ² meeting AABB Standard 5.19.2 ³ requiring methods to reduce CMV transmission risk. |
|  | Protozoan Parasites | PR is an FDA recommended option to mitigate Babesia transfusion transmission for the states required to implement a strategy. ⁴ PR is also FDA approved to reduce the risk of <i>T. Cruzi</i> and <i>Plasmodium</i> parasite transfusion transmission. ² For centers with approved FDA variance: PR can be used in place of deferral for otherwise-eligible donors who traveled to a malaria-endemic area ⁵ |
|  | Emerging Pathogens | WHO, ⁶ European Centre for Disease Prevention and Control (ECDC) ⁷ and FDA Guidance for Zika ⁸ state that PR** can be used in place of Zika testing or importing from non-endemic areas. |

+ Transfusion-Associated Graft vs. Host Disease

**Data for pathogen reduction of Zika virus by the INTERCEPT Blood System, pathogen reduction system, has been submitted for FDA review.

There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19 and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process.

Note: in Cerus' PRT Implementation Guide (as you can see in the chart above), PR stands for "pathogen reduced" and is equivalent to PRT.

Platelet Component Appearance

- LVDS platelets:
 - Have the same appearance as current conventional components.
- PRT platelets:
 - The PRT platelet bags are 2.8 inches longer than conventional platelet bags.
 - INTERCEPT® Blood System for Platelets is the brand name of the psoralen treatment process and is embossed across the top of the bag.
 - Hospitals may choose to add an additional label or tie tag to components to indicate that psoralen-treated platelets are an approved alternative to irradiation and CMV serologic testing. The language provided below is an example of what some hospital

transfusion services have used for tie tags. This would need to be worded in compliance with hospital policy.

Example Hospital Tie Tag for PRT Platelets

PSORALEN TREATMENT of platelets is an FDA approved alternative to IRRADIATION of platelets.

PSORALEN TREATMENT also meets AABB CMV Mitigation Standards

PSORALEN-TREATED platelet products can be used interchangeably with conventional platelets.



ISBT Codes

Regardless of whether you select LVDS, PRT or some combination of the two as your platelet product strategy, Vitalant requests all hospital partners be prepared to accept both products so we can maximize inventory management effectiveness across the nation. This means updating your computer systems to accept both products.

ISBT codes for all LVDS and PRT products (and label examples for many) can be found here: <https://hospitals.vitalant.org/Education-Reference/ISBT-Codes.aspx>

Codes for LVDS 36-hour/5-day and Variable-Yield products are also available at the same link and are recommended for entry.

Storage of LVDS and PRT Products

Per FDA, blood suppliers are responsible for informing hospitals of the type of storage container the platelets are stored in, for example, whether the storage container is approved for 5-day storage or 7-day storage.

Vitalant will be providing our customers with the following products:

- Leukocytes reduced bacterial monitoring \geq 36 hours (LVDS 36-hour/5-day)
 - NOTE: Vitalant is rapidly working to have all locations obtain LVDS 48-hour/7-day licensure at time of implementation. LVDS 36-hour/5-day will only be required should licensure for any locations be delayed.
- Leukocytes reduced bacterial monitoring 7D (LVDS 48-hour/7-day)
- Leukocytes reduced psoralen treated (PRT)

The platelets labeled leukocytes reduced bacterial monitoring \geq 36 hours (LVDS 36-hour/5-day) and leukocytes reduced bacterial monitoring 7D (LVDS 48-hour/7-day) will be collected utilizing Fresenius-Kabi Amicus and Terumo Trima collection sets. Storage containers for both collection sets are approved for 7-day storage.

The platelets labeled leukocytes reduced psoralen treated (PRT) will be manufactured utilizing Cerus psoralen treatment and the storage container is approved for 5-day storage.

Clinical Considerations

PRT and LVDS: Clinically Interchangeable

PRT and LVDS platelets can be used interchangeably according to U.S. standards of care across broad patient populations. Extensive clinical trial data and hemovigilance data have shown no unexpected adverse events with PRT across multiple age ranges, including neonates to adults, and across multiple disease states.

- Contraindications for PRT platelets:
 - Patients with a history of hypersensitivity reactions to amotosalen or other psoralens
 - PRT platelets have been approved in Europe since 2002 and in the United States since 2014.
 - No cases of psoralen or amotosalen hypersensitivity have been reported after millions of PRT transfusions.
 - Neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth less than 375 nm
 - The American Academy of Pediatrics-Clinical Practice Guidelines recommend a spectrum between 430-490 nm for intensive phototherapy; which is outside of the bounds of the listed PRT contraindication. None of the neonatal phototherapy devices currently approved for market in the U.S. emit a peak wavelength below 425 nm, and/or a lower bound of the emission bandwidth less than 375 nm.
 - No photosensitivity reactions have been reported in neonates undergoing phototherapy who have received PRT platelets.
- Efficacy of PRT and/or LVDS platelets:
 - Mildly reduced post-transfusion platelet corrected count increments (CCI) have been reported with PRT platelets when compared to conventional platelets. However, multiple large-scale clinical trials have shown a lack of correlation between CCI response and bleeding outcomes. Meta-analysis and clinical experience to date has demonstrated no differences in mortality, clinically significant bleeding, or severe bleeding between patients receiving PRT and conventional platelets.
 - Studies and international experience support platelet transfusion effectiveness up to 7 days of storage with no significant differences in clinical outcome or significant bleeding risk. Therefore, both 5-day components (i.e., PRT and LVDS 36-hour/5-day) and 7-day conventional platelets (LVDS 48-hour/7-day) may be used interchangeably throughout the accepted product dating.

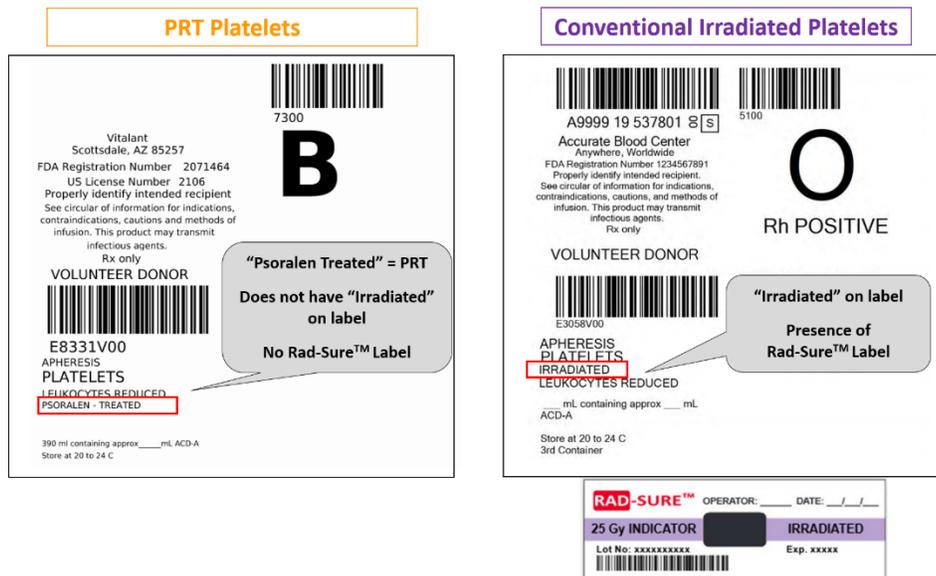
Key Points

- PRT and conventional platelets are both effective in addressing clinical hemostasis.
- A need for platelets may be filled with conventional or PRT platelets interchangeably as necessary. Vitalant will communicate with your facility if a need for substitution arises.
- The contraindications for PRT platelets are generally not applicable for the vast majority of patients.

Additional Clinical Considerations for PRT

Additional clinical considerations for PRT:

- Irradiation:
 - PRT platelets do not require irradiation to prevent transfusion-associated graft-versus-host disease (TA-GVHD) as the PRT treatment itself inactivates residual donor leukocytes. AABB standard 5.19.4.1 for irradiation of blood products considers the FDA-approved method of pathogen reduction equivalent to irradiation.
 - The PRT platelet label will not state “Irradiated”, nor will it have a Rad-Sure™ sticker on the component. Instead, the PRT platelet will be labeled as “Psoralen-Treated” indicating they have undergone PRT treatment. “Psoralen-Treated” refers to the psoralen/UVA light used in the PRT treatment process. Hospitals may choose to add an auxiliary sticker or tie tag to the component to address PRT irradiation equivalence, however, this would be based on institutional policy.
 - Example comparison of PRT and conventional irradiated platelet product labels:



Key Points

- AABB standard 5.19.4.1 for irradiation of blood products considers the FDA-approved method of pathogen reduction equivalent to irradiation.
- PRT platelets do not require irradiation to mitigate transfusion-associated graft-versus-host disease.
- A need for irradiated platelets may be filled with conventional irradiated platelets or PRT platelets interchangeably. Vitalant will communicate with your facility if a need for substitution arises.
- PRT Platelets are labeled as “Psoralen-Treated” and do not have “Irradiated” on the label nor a Rad-Sure™ sticker.
- Policies, procedures and order sets (if required) that reference “Irradiated Platelets” should be updated to include PRT platelets as an acceptable alternative if necessary.

- CMV Mitigation:
 - PRT treatment is effective in inactivating a wide range of viruses, including CMV. AABB Standard 5.9.2 requires a hospital policy to reduce CMV transmission risk. For hospitals that use CMV seronegative testing to meet this mitigation measure, PRT would also meet this requirement.
 - Note: All Vitalant products are leukoreduced and all platelet products received from Vitalant, including LVDS, should be considered CMV safe.

Key Points

- PRT platelets do not require CMV testing to mitigate CMV transmission risk.
- A need for CMV seronegative platelets may be filled with conventional seronegative platelets or PRT platelets interchangeably. Vitalant will communicate with your facility if a need for substitution arises.
- PRT Platelets are labeled as “Psoralen-Treated” and may not have “CMV Negative” on the label. CMV negative DOES print on PRT labels if the DIN was CMV tested for any reason. For example, if there was a concurrent red blood cell unit Vitalant needed to test for CMV, the CMV result would print on the PRT label.
- Policies, procedures and order sets (if required) that reference “CMV-Negative” platelets should be updated to include PRT platelets as an acceptable alternative if necessary.
- All Vitalant products are leukocyte reduced and are considered CMV safe.

The following resources from Cerus are also available:

- [Cerus PRT: Reducing the Risk of Cytomegalovirus \(CMV\) Transfusion Transmission](#)
- [Cerus: Methodologies for Reducing the Risk of TA-GVHD from Platelet Transfusions](#)
- [Cerus PRT: Implementation Guide for Hospitals](#)

Additional Clinical Considerations for Variable-Yield (also known as Low-Yield)

Variable-Yield platelet components are the result of inadvertent under-collection or unavoidable manufacturing losses. While not intentionally manufactured, they are often a viable option for patient transfusion.

Definition of Variable-Yield platelet products from Vitalant:

- Yield of $\geq 2.5 \times 10^{11}$ but $< 3.0 \times 10^{11}$ (Vitalant Transfusion Service customers may receive units for specifically-identified patients $\geq 2.2 \times 10^{11}$)

The FDA requires standard dose apheresis platelet components to contain at least 3.0×10^{11} platelets per unit. Variable-Yield apheresis platelets contain less than 3.0×10^{11} ; about 3-17% fewer platelets than the standard apheresis unit minimum. The FDA allows Variable-Yield conventional or pathogen-reduced platelets provided they are labeled with the actual platelet content. Variable-Yield platelets undergo the same safety measures as all other components and may be distributed for patient use in the same manner as standard dose platelet components.

The collection and manufacturing steps required for LVDS and PRT platelets result in platelet loss and fewer available units. Transfusion of Variable-Yield platelets is a strategy for optimizing the use of available resources and prevent inventory shortages.

- Efficacy of Variable-Yield platelets:
 - Clinical trial data and international experience support the concept that lower-dose platelets may be used for patient transfusion needs. Compared to a standard or high-dose strategy, low-dose platelet transfusions have not been found to be associated with clinically significant increased bleeding risk. Low-dose platelet transfusions may, however, lead to shorter transfusion intervals. From an international perspective, the minimum accepted platelet content for apheresis units is lower (e.g., $\geq 2.0 - 2.5 \times 10^{11}$ platelets/unit) than in the United States. No detrimental clinical effects or increased platelet usage has been noted in these other countries when transfusing platelets containing a lower platelet yield.
- Indications:
 - Clinical experience to date has predominantly provided support for lower-dose platelets in prophylactic transfusion settings. Pediatric patients may also benefit from lower dose platelets as they may not require adult level dosing. No studies to date have evaluated the effectiveness of Variable-Yield platelets in supporting actively bleeding patients. For these patients, a higher post-transfusion platelet threshold is desired to support active hemostasis. Therefore, a standard dose platelet (if available) may be better suited to address patients with active bleeding.
- Labeling Requirements:
 - Variable-Yield apheresis platelet ISBT codes are available via the following link: <https://hospitals.vitalant.org/Education-Reference/ISBT-Codes.aspx>
 - Actual platelet yield is noted on the label
A tie tag indicating “low platelet yield component” will be attached.



Inventory Management

Responsible Stewardship and Platelet Inventory Management

LVDS and PRT platelets both result in platelet component production losses due to required processing changes. In combination with the relatively short shelf life of platelets, this may impact product availability, requiring flexible processes and inventory management practices to responsibly steward this critical resource.

Regardless of whether a hospital intends to adopt LVDS, PRT, or some combination of the two as their platelet product strategy, Vitalant has asked that all our hospital partners be prepared to accept both products in the event product substitutions are necessary. This means updating hospital computer systems to accept both LVDS 48-hour/7-day and LVDS 36-hour/5-day platelets as well as PRT platelets provided by Vitalant. To protect and sustain the national platelet supply, Vitalant may need to supply products interchangeably on occasion to meet surge demand.

The components provided by Vitalant are all approved by the FDA to deliver a therapeutic platelet dose. While Vitalant will produce LVDS 48-hour/7-day conventional platelets, on occasions LVDS 36-hour/5-day platelets may be obtained from other facilities to meet inventory challenges or specific patient needs.

As outlined, implementing the Final Guidance changes product dating and will likely alter product availability. As responsible stewards of the blood supply, Vitalant will continue to adhere to a no returns policy on all platelet products.

Product Availability, Expiration and Timing Considerations

The various options outlined in the Final Guidance present different options for expiration and potential shelf-life.

Managing platelet inventory as we collectively transition to LVDS 48-hour/7-day

Moving to LVDS 48-hour/7-day platelets will increase the available shelf-life by ~1 additional day (versus the conventional 24-hour culture platelet products historically available from Vitalant). Currently platelets are delivered to hospitals generally with a maximum of 3 days remaining prior to expiration. LVDS 48-hour/7-day products will be delivered to hospitals with a maximum of 4 days remaining. This additional shelf-life will provide additional opportunity to use these platelets before they expire.

Continue to work closely with your local Hospital Services team members to responsibly steward platelet products by strategizing on inventory levels to both meet patient demand and avoid expirations.

As you assess your inventory management practices, evaluate your past usage to help determine the appropriate inventory level at which to replenish:

- If you order daily, then you should order a replenishment quantity to get you back to one day's worth of usage.
- If you order every other day, then order a replenishment quantity to get you back to two days' worth of usage.
- Depending on the variability of your usage (e.g., if you have a trauma center) then you may want to add some units to handle spikes in demand.

Your local Vitalant partners can provide your ordering data (historical deliveries and returns) to help with determining your inventory levels. Coupled with your organization's internal expiration data and true utilization (i.e., how many ordered products were utilized for patient transfusions), your local Vitalant partners can assist you in determining best practices for inventory levels within your facility.

Managing a potential dual inventory with varying shelf-lives

Important note: The conventional platelets that you received prior to bacterial mitigation implementation and PRT platelets both have a 5-day shelf-life. Consequently, the expiration date will be sooner than an LVDS 48-hour/7-day platelet that was received around the same time. Vitalant strongly recommends you manage your inventory so that you are issuing on a first expired, first out (FEFO) model instead of a first in, first out (FIFO) model.

Guidelines to help manage on a FEFO basis:

- Store your products by expiration date on your agitators.
- Assign each shelf on your agitator an expiration timeframe.
- Move the platelets to the next shelf as the remaining shelf-life changes to provide a visual cue to your team on which products expire next.

Please be aware that the LVDS48-hour/7-day platelets are the same size as conventional platelets and that the PRT platelets are larger. If you receive PRT platelets make sure you have sufficient space in your agitators for the larger size. See "Platelet Component Appearance" section under "Product Specifications" for additional detail.

Managing HLA-matched platelet products

The manufacturing time of LVDS 48-hour/7-day platelets results in extended time from collection to product availability versus your current experience. LVDS 48-hour/7-day platelets are held for an additional 24 hours prior to bacterial sampling. **Please consider this increased manufacturing time when ordering specialized platelet products that may require specific donor collection.**

In general, you should request HLA-matched platelet products as far in advance of patient transfusion as possible because of the additional time it takes to find and recruit matched volunteer blood donors. While units may be available on shelves for less-difficult-to-match patients, many require specific donor recruitment.

What to Expect Cutover Week (Implementation Schedule)

What should I expect as my platelet inventory transitions to the LVDS 48-hour/7-day platelet under the FDA Large Volume Delayed Sampling plan with a 48-hour hold?

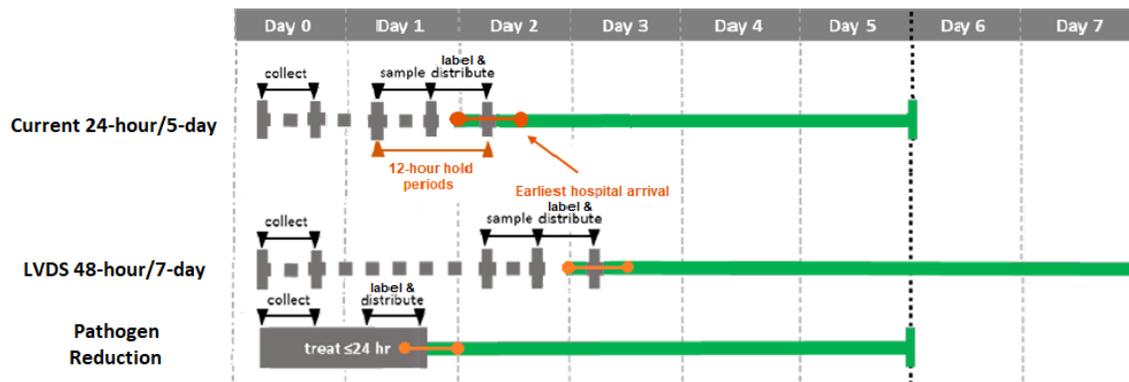
Vitalant is committed to keeping you informed as we move through this platelet bacterial testing transition together. Hospitals could begin receiving LVDS products as early as July 1, 2021. You will receive notification via paper insert in your blood product shipping containers 7 days prior to the cutover in the regional blood center that primarily serves your organization, as well as a reminder a day before you should expect to receive your first LVDS 48-hour/7-day platelets.

Below is a summary of the process changes. Please note the changes in time between:

- The collection and the time the bacterial culture sample is taken
- The time that product is available to distribute
- The extended shelf life of the product

LVDS SAMPLING PLAN:

Sampling Plans for Various Platelet Product Types



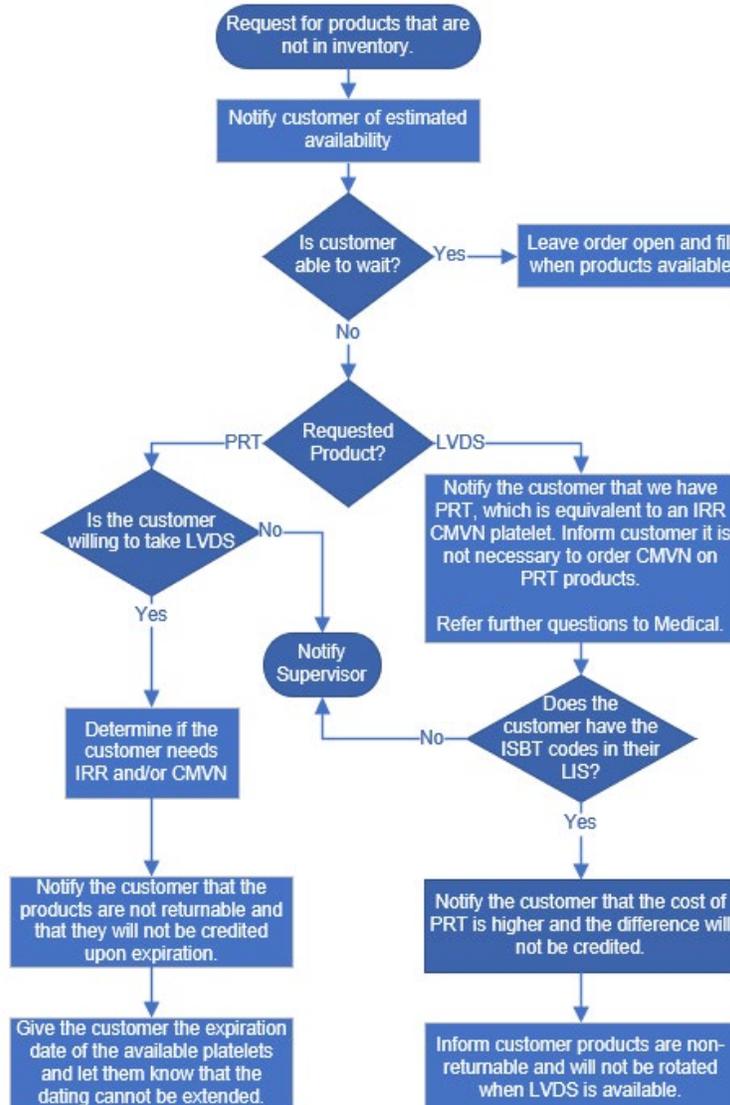
During the week that your blood center transitions to the FDA LVDS 48-hour/7-day bacterial sampling plan, you will experience the following:

1. A mixed inventory in the first week:
 - a. The Vitalant lab will begin sampling platelets via the FDA LVDS 48-hour/7-day sampling plan on a specific collection date. All products collected prior to that date will follow the current sampling plan; all products collected on or after that date will follow the LVDS 48-hour/7-day pathway. As Vitalant's LVDS implementation is rolling across our sites, you may still receive conventional platelet products as remaining Vitalant centers transition after your area.
 - b. Hospital customers may receive LVDS 48-hour/7-day products when ordering for STOCK shipments and products tested under the current pathway when ordered for immediate patient need (STAT and ASAP) as all product transitions to the LVDS 48-hour/7-day sampling plan.
2. Invoice changes
 - a. Products will continue to be billed based on the product code. You will now see additional product codes, which will be priced accordingly.
 - b. Platelet products produced using the LVDS 48-hour/7-day sampling plan have a different product code than the conventional platelet products you are receiving today.
 - c. Price difference between current conventional platelet product and LVDS 48-hour/7-day platelet.
 - d. Price changes have been provided in advance via contract updates and/or formal notification via a letter titled "Legal notice – Increased Platelet Production Cost and Corresponding Fee increase."

3. Product dating changes
 - a. STOCK orders will be filled with the goal for you to receive product with 2 or more days remaining on them prior to expiration.
 - b. STAT and ASAP orders will be filled using the first expired, first out (FEFO) model. Please check your expiration dates carefully and manage your inventory accordingly.
 - c. Please keep in mind that PRT products have a 5-day shelf life. Customers who order both products will be managing products with both a 5-day and 7-day shelf life going forward. Please see the “Product Availability, Expiration and Timing Considerations” section of this document under “Inventory Management” for tips on managing a dual inventory.

Product Substitutions Scenario(s) and Process

Should the need arise for Vitalant to provide PRT products to your facility as a substitute for LVDS 48-hour/7-day, your local Vitalant contacts will use the following flowchart as a guide for their conversation with your facility’s staff. This resource is included in this document to provide transparency around the substitution process and to help you set expectations with your teams.



References

- Butler C, Doree C, Estcourt LJ, et al. Pathogen-reduced platelets for the prevention of bleeding. Cochrane Database Syst Rev 2013;(3):CD009072.
- INTERCEPT® Blood System for Platelets [Package Insert]. Concord, CA: Cerus Corporation; May 28, 2019. 6. INTERCEPT® Blood System for Plasma [Package Insert]. Concord, CA: Cerus Corporation; May, 1 2020.
- https://hcp.intercept-usa.com/hcp-resources/implementation?utm_source=ARC
- AABB. Standards for Blood Banks and Transfusion Services 32nd Edition. (AABB, Bethesda, MD, 2019).

Appendix A: National Invoicing Example

Packing Slip

Number **0000019421796**



External Order #: OR20-0105177

Date and time: 04/21/2021 19:21

Facility: TEST CUSTOMER (0000729998)

6210 East Oak Street

Scottsdale, AZ-85257

EXAMPLE

Packing Slip

Number 0000019421796



Date and time 04/21/2021 19:21
Facility TEST CUSTOMER (0000729998)
 6210 East Oak Street
 Scottsdale, AZ-85257 1

Account Number 0000100300

Remarks

All blood components in this shipment have been inspected and found to be suitable for distribution.

Packed by: _____
 Inspected By: _____

External Order #: OR20-0105177

| Suppl | Donation No / Lot No | ABO | Unit | Qty | Collection Date | EXP | Modifiers | SFC |
|-------|----------------------|-----|------|-----|-----------------|-----|-----------|-----|
|-------|----------------------|-----|------|-----|-----------------|-----|-----------|-----|

AphPLTS - 7 d|ACD-A/LR<5lg6 (E5030V00)

3401 W14282112345200C O + 1 04/15/2021 04/22/2021 23:59
 

AphPLTS|ACD-A|LR<5E6|Psoralen-treated (E8331V00)

3401 W14282112345100E O + 1 04/17/2021 04/22/2021 23:59
 

AphPLTS|ACD-A/LR<5lg6 (E3077V00)

3401 W14282112345000G O + 1 04/17/2021 04/22/2021 23:59
 

| TOTAL DISTRIBUTION | A | A- | A+ | AB | AB- | AB+ | B | B- | B+ | O | O- | O+ | QTY | Vol |
|--------------------|---|----|----|----|-----|-----|---|----|----|---|----|----|-----|-----|
| E8331V00 | | | | | | | | | | | | 1 | 1 | |
| E3077V00 | | | | | | | | | | | | 1 | 1 | |
| E5030V00 | | | | | | | | | | | | 1 | 1 | |
| CUMUL | | | | | | | | | | | | 3 | 3 | |



Vitalant
 1524 W 14TH ST, SUITE 120
 Tempe AZ 85281
 Phone : 602-414-3540
 Fax : 602-437-6929
 Email : ar@Vitalant.org
 Tax ID : 86-0098929

Customer Name : Test Customer
 Customer Number : 729998
 Invoice Number : 3966932
 Invoice Date : 22-APR-21
 PO Number : NA
 Due Date : 22-MAY-21

| | Net Quantity | Amount Due |
|--|-------------------------------------|-------------------|
| Current Net Charges (shipments less returns) | | |
| Platelets | 3 | \$2,640.00 |
| | Total Due for Current Period | \$2,640.00 |

Remit to:
 Vitalant
 DEPT 880337
 PO BOX 29650
 PHOENIX AZ 85038-9650

729998
 Test Customer
 6210 East Oak Street
 Scottsdale AZ 85257

| Description | Quantity | Price | Amount Due |
|---|----------|------------------------|-------------------|
| Platelets | | | |
| PLATELETS - 7d LEUKOCYTES REDUCED | 1 | \$875.00 | \$875.00 |
| APHERESIS PLATELETS ACD-A LR<5E6 PSORALEN-TREATED | 1 | \$965.00 | \$965.00 |
| PLATELETPHERESIS LEUKOCYTES REDUCED | 1 | \$800.00 | \$800.00 |
| | | Total Platelets | \$2,640.00 |
| | | Total | \$2,640.00 |

EXAMPLE

| Date | Shipment Number | Description | Donation/Ref | Qty | Price |
|------------------------|--|--|------------------|----------|-------------------|
| Platelets | | | | | |
| 21-APR-21 | 0000019421796 | PLATELETS - 7d LEUKOCYTES REDUCED | W14282112345200C | 1 | \$875.00 |
| 21-APR-21 | 0000019421796 | APHERESISPLATELETS ACD-A LR<5E6 PSORALEN-TREATED | W14282112345000G | 1 | \$800.00 |
| 21-APR-21 | 0000019421796PLATELETPHERESIS LEUKOCYTES REDUCED | | W14282112345100E | 1 | \$965.00 |
| Total Platelets | | | | 3 | \$2,640.00 |
| Total | | | | | \$2,640.00 |

EXAMPLE

Appendix B: Northeast Invoicing Example

NOTE: Prices noted in this sample documentation are for example purposes only. They do not reflect contracted pricing.

VITALANT PITTSBURGH, PA

PRODUCT MANAGEMENT
SHIPPING DOCUMENT

System Date/Time: 04/20/2021 15:30

Page 1

CUSTOMER ID: VALI
VALIDATION GENERAL HOSPITAL
758 EAST MAIN STREET
ABERDEEN, MD 21001

REFERENCE NUMBER: 1082
PO NUMBER :
Regular

| | | | | |
|-------|-------------------------|----|---------------|------------|
| E3087 | APH PLATELETS LR CONT 1 | O+ | W087521000202 | 04/25/2021 |
| E5370 | LR APH PLATELETS-1, LVD | O+ | W087521000201 | 04/27/2021 |
| E8333 | SDP/ACD-A/LR/PSORALEN-T | O+ | W044621000154 | 04/26/2021 |

***** BILLING SUMMARY *****

| PRODUCT | ABO/RH | SRV CODE | DESCRIPTION | QUANTITY |
|---------|--------|----------|-------------|----------|
| E3087 | O+ | | | 1 |
| E5370 | O+ | | | 1 |
| E8333 | O+ | | | 1 |

PRODUCTS SHIPPED

| | |
|-------|---|
| E3087 | 1 |
| E5370 | 1 |
| E8333 | 1 |
| TOTAL | 3 |

ALL COMPONENTS APPEAR SUITABLE FOR USE UPON SHIPMENT: _____

ALL COMPONENTS APPEAR SUITABLE FOR USE UPON RECEIPT : _____

VITALANT

REMIT TO: 29668 NETWORK PLACE
CHICAGO, IL 60673-1296

INVOICE

Invoice#: VALI-1 Customer#: VALI
Payment Terms: 30 days
*interest assessed monthly on
outstanding balances*
Blanket PO#: _____
Page: 1
NPI: _____

BILL TO:

VALIDATION GENERAL HOSPITAL
758 EAST MAIN STREET
ABERDEEN, MD 21001

SHIP TO:

VALIDATION GENERAL HOSPITAL
758 EAST MAIN STREET
ABERDEEN, MD 21001

SUMMARY FOR Apr-16-2021 TO Apr-30-2021

| PRODUCT CODE | DESCRIPTION | QUANTITY SHIP/ (RETURN) | UNIT PRICE | TOTAL |
|---------------------------------|-------------------------------|-------------------------|------------|-----------------|
| 3AS100 | SINGLE DONOR PLATELETPHERESIS | 1 | 800.00 | 800.00 |
| 3LC100 | APH, PLTS, LR, LVDS | 1 | 875.00 | 875.00 |
| 3PT100 | SAMPLE PSORALEN TREATED SDP | 1 | 965.00 | 965.00 |
| BALANCE DUE THIS INVOICE | | | | 2,640.00 |

QUESTIONS REGARDING THIS INVOICE CALL: (888) 396-3957

| | | | | |
|------------|------------|--------|--------|---------|
| AGING DAYS | 0-30 | 31-60 | 61-90 | over 90 |
| | \$2,640.00 | \$0.00 | \$0.00 | \$0.00 |

VITALANT

DETAIL INVOICE

Invoice#: VALI-1

Customer#:

Blanket PO#:

BILL TO: VALIDATION GENERAL HOSPITAL

Page: 1 Of 1

NPI:

NOTICE: The patient information contained in this invoice is confidential and further disclosure is prohibited without consent of the person to whom it pertains or unless otherwise authorized by law. CPT codes are for information purposes only, and should be assessed prior to billing based on the patients medical purpose at the facility.3AS100

| PROD/ SVC CODE | UNIT ID | PRODUCT ID | DESCRIPTION/CPT PATIENT NAME | QUANTITY SHIPPED/ (RETURNED | UNIT PRICE | TOTAL |
|--------------------------|---------------|---------------|---------------------------------|-----------------------------------|---------------|------------|
| Shipment Date: Apr-20-21 | | | | Order Number: 00001082 | | Order PO#: |
| 3AS100 | W087521000202 | E3087 | SINGLE DONOR PLATELETPHERESIS | 1 | 800.00 | 800.00 |
| 3LC100 | W087521000201 | E5370 | APH, PLTS, LR, LVDS | 1 | 875.00 | 875.00 |
| 3PT100 | W044621000154 | E8333 | PSORALEN TREATED SDP | 1 | 965.00 | 965.00 |
| BALANCE DUE THIS INVOICE | | | | | | 2,640.00 |