



Dear [Salutation],

Earlier this year, we communicated Vitalant's high level strategic response to the FDA Final Guidance "[Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion](#)" ("Final Guidance") released on September 30, 2019.

The FDA's deadline of March 2021 for guidance implementation remains in place and we continue to actively work toward meeting this target. We sincerely thank all of our hospital partners for prioritizing conversations about the Final Guidance over the past several months amidst COVID-19 response.

Vitalant's Approach to Product Offerings

As we communicated earlier this year, 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 fewer available units. 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 the total number of options, to improve inventory management and facilitate customer ease of use

Vitalant is moving forward with the options outlined below 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.

What options will Vitalant offer?

At the start of Final Guidance implementation, Vitalant will offer both 5-day Large Volume Delayed Sampling (LVDS) and Pathogen Reduction Technology (PRT) platelet product options to our hospital customers.

Vitalant will implement and begin billing for 5-day LVDS platelets on March 16, 2021. As one of the first blood centers to adopt PRT, Vitalant currently offers PRT platelets in all markets and is expanding our PRT platelet capacity to meet growing patient needs throughout 2020.

The 5-day LVDS option available now does represent a shorter shelf-life than currently available conventional platelets of around half a day. 5-day LVDS is a stepping stone to 7-day LVDS, which expands shelf life. Vitalant is actively working to make 7-day LVDS available as quickly as possible. In the interim, we will work with organizations that wish to utilize rapid testing to extend shelf life of 5-day LVDS.

Regardless of whether you intend to adopt LVDS, PRT or some combination of the two as your platelet product strategy, Vitalant asks that all of our hospital partners be prepared to accept both products in the event product substitutions are necessary. This means updating your computer systems to **accept both LVDS and PRT platelets provided by Vitalant**. To protect and sustain the national platelet supply, Vitalant may need to supply products interchangeably on occasion. If circumstances require Vitalant to substitute platelet products, you will be charged for the product received. Your local contacts will communicate in advance of any product substitutions.

Service Agreement Modifications and Fees:

Effective March 16, 2021, a single donor LVDS platelet will become Vitalant's default platelet product and will replace any existing non-PRT platelet product(s) ordered by your organization. If your organization wishes to pursue PRT platelets as an option, please reach out to your [Regional Account Manager](#) as soon as possible as additional steps must be taken. Vitalant is asking its customers to commit to a weekly volume of PRT platelets in order to

assist in planning our collection and manufacturing of these products. We encourage our customers to notify us as soon as possible on your desire for PRT platelets so Vitalant can plan accordingly.

Effective March 16, 2021, platelet fees will increase as follows:

- LVDS platelet fee: contracted single donor platelet (SDP) fee + \$75.00 (an increase of \$75.00 from your current platelet price)
- PRT platelet fees should be discussed with your Regional Account Manager.

Implementing the Final Guidance will change product dating and will likely alter product availability. As responsible stewards of the blood supply, Vitalant will implement a no returns policy on LVDS or PRT platelets effective March 16, 2021. Vitalant will continue to provide PRT at standing committed volumes.

At this time, we request the following actions from your facility. Please:

- Work with your Regional Account Manager to discuss the best platelet product mix for your organization.
- If your organization would like to move forward with PRT platelets as part of your platelet strategy, work with your Regional Account Manager to have a signed amendment in place by November 1, 2020 in order to avoid any implementation delays due to necessary operational adjustments.
- Ensure additional ISBT codes are entered into your system no later than March 16, 2021. These codes will be sent to you separately. Codes must be entered by this date to ensure you can receive platelet products.

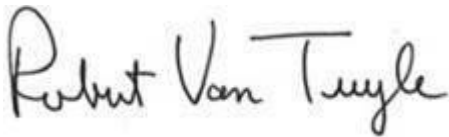
What about new platelet product innovations?

As a leader in transfusion medicine, Vitalant remains committed to assessing and providing innovative blood products to our hospital customers. There are several innovations on the horizon, and we are closely monitoring or actively part of developing additional products, including 7-day LVDS platelets, 6- or 7-day PRT platelets, cold-stored platelets and frozen platelets. We will update you as more information on these products becomes available.

We look forward to continuing the conversation with your organization about implementation of this Guidance. As always, your Vitalant [Regional Account Manager and Medical Director](#) will be your primary points of contact throughout this process.

Thank you for your continued partnership.

Regards,



Rob Van Tuyle
President, Blood Services
Vitalant



Ralph R. Vassallo, MD, FACP
EVP / Chief Medical & Scientific Officer
Vitalant