From:	Blood Service Notices and Alerts
To:	
Subject:	Blood Service Notice: IMPORTANT Blood Service Notice: Cutover Packet and Resources for Vitalant's Bacterial Mitigation Implementation
Date:	Monday, May 17, 2021
Attachments:	

Information included on preparing your facility for Large Volume Delayed Sampling and Pathogen Reduction Technology implementation

Dear [Salutation],

Vitalant will soon begin implementation of our compliance plan with FDA's Final Guidance "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion".

Vitalant's implementation plan includes:

- Rolling implementation across Vitalant service areas of 7-Day Large Volume Delayed Sampling (no sooner than 48 hours after collection) platelet products (LVDS 48-hour/7-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 offered by Vitalant should licensure for any locations be delayed.
- Ongoing availability of Pathogen Reduction Technology (PRT) platelets
- 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 products will no longer be available.

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. This email serves 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.

Products will continue to be billed based on the product code and pricing for LVDS 48-hour/7-day and PRT will follow your hospital's agreed upon rates. Price changes were provided to the appropriate contacts within your organization through contract updates and/or formal notification in a letter titled "Legal notice – Increased Platelet Production Cost and Corresponding Fee increase." Please refer all questions regarding pricing to your local Regional Account Manager.

Vitalant has developed a comprehensive cutover packet to serve as a resource to help you prepare for the cutover time frame when your facility transitions to LVDS 48-hour/7-day and/or PRT and to provide transparency on changes you will experience.

We request the following actions from your facility. Please:

- **Thoroughly review the "Bacterial Mitigation Final Guidance Cutover Packet for Hospitals" and associated resources, which can all be found on our hospital website here.**
- Ensure all ISBT 128 product codes listed under "Large Volume Delayed Sampling (LVDS) and Pathogen Reduction Technology (PRT) Codes" are entered into your systems as soon as possible. Codes are available here.
    - NOTE: Vitalant has added codes for Variable-Yield (also known as Low-Yield) products to the website. Please enter these codes as well.

Variable-Yield platelet components are the result of inadvertent under-collection or unavoidable manufacturing losses. While not intentionally manufactured and not part of Vitalant's strategic response to the Final Guidance, they are a viable option for patient transfusion. More information on Variable-Yield platelets is available in the cutover packet.

Thank you for your continued partnership as we work through implementation of FDA's Final Guidance. If you have questions as you review the cutover packet and associated resources, please reach out to your local Vitalant contacts.