

Date: August 27, 2021
 To: Director of Clinical Laboratories Director of Transfusion Services
 From: JD Pettyjohn, Chief Operating Officer
 Re: FDA Platelet Guidance – New Implementation Date – September 2021

In May, we provided an update on your implementation plans for the FDA’s September 2019 guidance on *Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion*. As a reminder, the guidance relates to additional bacterial testing of all platelet components.

Lifesouth will begin shipping platelets sampled via Large Volume Delayed Sampling (LVDS) as early as **September 28th**.

LifeSouth Implementation Plan

As previously communicated, we will use a combination approach:

1. Manufacturing apheresis platelets stored in 100% plasma using Large Volume Delayed Sampling (LVDS) bacterial testing, which moves us to seven-day apheresis platelet products,¹
2. Manufacturing pooled platelets and apheresis platelets stored in additive solution (PAS) using Large Volume Delayed Sampling (LVDS) bacterial testing resulting in a 5-day product,²
3. Increasing the production and availability of pathogen reduced platelets,³ and
4. In emergency-need situations, manufacturing platelets using the two-step testing process which requires either a secondary culture or rapid testing.⁴

Because we will only use a two-step process in emergency situations, most platelet components we provide will not require additional rapid testing for bacterial contamination by your hospital. Any components provided with the two-step testing method and pathogen reduced platelets are considered special orders and are not eligible for consignment.

Eligibility for 5-day vs 7-day Storage

Please be aware that eligibility for 5-day vs 7-day storage depends on bag manufacturer:

Bag Type	Approved for
Terumo Apheresis Platelets stored in 100% Plasma	7-day storage
Trima Apheresis PAS-F platelets (stored in platelet additive solution)	5-day storage
Haemonetics Acrodose PPlus System (Pooled Platelets)	5-day storage
INTERCEPT® Blood System for Platelets (Pathogen Reduced Platelets)	5-day storage

Hospital Implementation Requirements

To help ensure availability of platelets for patients, LifeSouth strongly encourages your hospital to:

1. Confirm that all the new platelet product codes have been entered into your computer system. Visit our website for the most up to date copy of these codes: <https://www.lifesouth.org/hospital-notifications-product-codes/>
2. Implement acceptance of low count platelet products in transfusion protocols >2.2 x 10e11, and
3. Make note of the updated service fee schedules related to the additional bacterial testing services.

Should you have questions or need to schedule a call, please contact your local management team or JD Pettyjohn, Chief Operating Officer at jdpettyjohn@lifesouth.org or Chris Lough, Vice President of Medical Services at cmlough@lifesouth.org.

¹ Apheresis platelet products sampled by LVDS at > 48 hours (7-day product)
² Pooled platelet products sampled by LVDS at > 36 hours (5-day product)
³ Pathogen reduced platelets using the Cerus Intercept Blood System (5-day product); refer to our website for more information and product codes (https://www.lifesouth.org/app/uploads/2020/10/Hospital_Letter_for_Pathogen_Reduction.pdf)
⁴ Limited production (emergency use) sampled at > 24 hours (3-day product, with second step required to extend to 7 days)