LIFESOUTH
Community Blood Centers

Date: May 6, 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 December, the FDA updated its 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. The FDA received numerous comments from blood collection establishments requesting an extension of the implementation timeframe because of various unforeseen challenges, including responding to the COVID-19 public health emergency.

The implementation date for the guidance has been extended to October 1, 2021.

LifeSouth Implementation Timeline

LifeSouth anticipates implementation in September. As previously communicated, we will use a combination approach:

1. Manufacturing apheresis platelets using Large Volume Delayed Sampling (LVDS) bacterial testing, which moves us to seven-day apheresis platelet products,[1]
2. Manufacturing pooled platelets 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.

As the October implementation date approaches, LifeSouth will again offer a series of webinars to our hospitals to help review the FDA guidance requirements and provide greater detail about our implementation plan.

Hospital Implementation Requirements

Please ensure that all the new Platelet Guidance related product codes have been entered into your system.

While the extension allows for additional preparation time, LifeSouth strongly encourages your hospital to:

1. Inform your clinicians of the changes and expected differences in platelet products,
2. Implement acceptance of low count platelet products in transfusion protocols >2.2 x 10e11,
3. Implement product codes for all possible platelets produced, and

Updated service fee schedules were released to outline changes to the additional testing services. Please note that no additional testing fees will be billed until the implementation of new services in the month of September.

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)