



Date: December 29, 2020

To: Director of Clinical Laboratories
Director of Transfusion Services

From: JD Pettyjohn, VP of Operations

Re: FDA Platelet Guidance – New Implementation Date – October 1, 2021

On December 17, the FDA updated its September 2019 [Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion](#)¹. As a reminder, the guidance is related to enhanced patient safety that involves additional bacterial testing of all platelet products. 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.

This delay does not impact the hospital's most recent fee schedule. Your hospital will not be billed for any additional bacterial testing until much closer to the new implementation date.

While the extension allows for additional preparation time, prior to the implementation date, 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 $>2.2 \times 10^{11}$,
3. Implement product codes for all possible platelets produced², and
4. Prepare for pricing changes based on increased production and testing costs.

As the implementation date approaches, LifeSouth will again offer a series of webinars to our hospitals to help review the FDA guidance requirements, provide greater detail about the implementation plan and to explain needed hospital preparations. Should you have questions or need to schedule a call, please contact your local management team or JD Pettyjohn, VP of Operations at jdpettyjohn@lifesouth.org.

¹ <https://www.fda.gov/media/123448/download>

² Product codes are found here:

https://www.lifesouth.org/app/uploads/2020/11/Platelet_Related_Product_Codes_Bacterial_Monitoring.pdf