

January 11, 2019

To: Directors of Clinical Laboratories
Directors of Transfusion Services

Subject: FDA Guidance, Summary of the Dec 2018 Draft Guidance concerning Bacterial Risk Control Strategies for Platelets for Transfusion

The FDA Draft Guidance for Industry “**Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion**” was recently updated and re-released as a draft in December 2018. The timeline for finalization of the guidance is currently unknown, and may still be subject to changes. Once released as a final guidance, the recommendations therein would need to be implemented within 12 months of issue.

Listed below are the options presented in the draft guidance as it currently stands. For reference, LifeSouth currently manufactures 5-day storage products utilizing primary culture with the BacT/ALERT® technology.

5-day Storage Products

- 1) Primary culture with secondary culture performed no earlier than Day 3

Note: *Primary culture sample must be obtained at least 24 hours after collection and must incubate for at least 12 hours prior to release*

- 2) Primary culture with secondary rapid test performed within the 24 hours prior to transfusion
- 3) Use Pathogen Reduction Technology (PRT), which is currently only available for apheresis products

7-day Storage Products (only available for apheresis products at this time)

- 1) Primary culture with secondary culture performed no earlier than Day 4
- 2) Primary culture with secondary rapid test performed within the 24 hours prior to transfusion
- 3) Large volume delayed sampling: sampling must occur at least 48 hours after collection and must incubate for at least 12 hours prior to release

LifeSouth Community Blood Centers is monitoring the situation closely. Each of the options presented, for both 5 and 7-Day products, poses unique challenges which are poised to affect the availability of the platelet supply, as well as logistics of distribution at blood centers across the U.S.

Currently, LifeSouth produces a limited amount of pathogen reduced platelet products (Cerus INTERCEPT™) and performs secondary rapid testing (Verax PGD®) to produce 7-day products in some markets. We continue to explore the viability of the options presented and will be following the progress of the guidance to determine the best course of action should it become finalized in its current form.

If you have any questions or concerns, please feel free to contact Chris Lough, M.D., VP of Medical Services at (352) 224-1644 or cmlough@lifesouth.org or Jill Evans, VP Strategy Implementation at (352) 224-1634 or jaevans@lifesouth.org.