12-Hour Hold in Large Volume Delayed Sampling of Platelet Products: Is it Needed?

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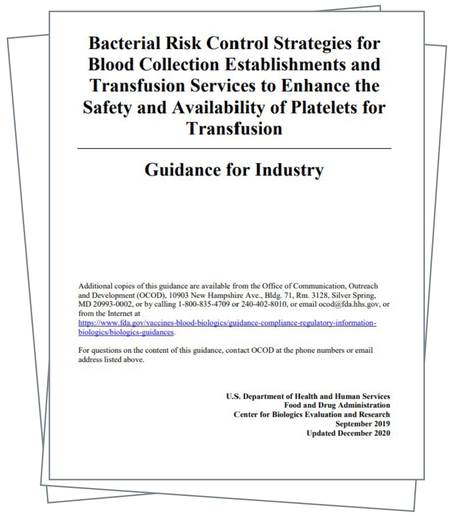
Background/Case Studies:

FDA guidance, finalized in December 2020, requires large volume delayed sampling (LVDS) with a 12-hour hold prior to release to reduce the risk of bacterial contamination of platelet products. Microbially contaminated products accounted for 24 (13%) fatalities reported to the FDA for fiscal years 2016-2020, with bacterial contamination of platelets accounting for 10 of the 24. However, the initial hold for the first 12 hours of incubation reduces the available time on this product for use in a patient. Our center gathered retrospective data to determine the effectiveness of the 12-hour hold inpreventing release of contaminated products.



Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion

Guidance for Industry

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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U.S. Department of Health and Human Services
Food and Drug Administration
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FDA guidance, finalized in December 2020, requires large volume delayed sampling (LVDS)

Study Design/Methods:

Our center's blood establishment computer system was queried for all apheresis platelet culture data, including the number of hours after incubation that bacterial culture samples flagged positive. In addition, confirmatory gram stain and agar plate culture results were abstracted for those platelet products that initially flagged positive.

Results/Findings:

Since implementation of LVDS in 2021, our center has had 52 apheresis platelet products that initially flagged positive on an automated culture system (BacT Alert Virtuo, BioMerieux). The average length of time to a positive flag was 61 hours after inoculation, or 109 hours following collection.
Of the total 52 positive flags, 6 (11.5%) flagged positive within the 12-hour hold period. Of the six that flagged positive, four showed organisms on gram stain that were able to be cultured on agar and identified, equating to a true positive rate of 66%. Data presented last year by our center showed a true positive rate of 37.5% when looking at all positive flags during the entire 6-day incubation period. Although the true positive rate during the 12-hour hold appears higher than the rate during the entire incubation period, the data sets are too small to show statistical significance. The organisms recovered in the four that showed growth on agar were: one Bacillus cereus group, two *Streptococcus gallolyticus ssp pasturianus*, and one *Streptococcus mitis/Streptococcus oralis*.

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Conclusion:

Since the implementation of LVDS, our center's data show that we have had 52 apheresis platelet products initially flag positive with flags occurring on average 61 hours after incubation but with 6 flagging within the 12-hour hold. True positive rate for flags within the 12-hour hold is 66%, appearing to be higher than the true positive rate of 37.5% seen overall for all positive flags, although the numbers are too small for statistical significance. More data is needed to determine if this trend persists. Importantly, in our experience, the 12-hour hold has prevented the release of four contaminated units to patients.