

November 1, 2019

Food and Drug Administration Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (FDA Bacterial Guidance)

Dear Valued Customer,

We at Terumo BCT, like you and the transfusion medicine community, are committed to blood safety and to providing the safest possible blood products for patients. We also understand that the FDA Bacterial Guidance will significantly impact blood center operations, and we are committed to help you implement bacterial risk control strategies that further enhance the safety of blood.¹

- Terumo BCT specialists will be available to help blood centers evaluate and implement the bacterial mitigation strategy that best meets their business and customer needs.
- Terumo BCT has software and analytic tools ready so blood centers can make business decisions based on data.
- Terumo BCT is developing upgraded Trima Accel collection sets to easily implement the large volume, delayed sampling (LVDS) strategy.

Terumo BCT is developing platelet collection sets for use with the Trima Accel[®] Blood Collection System with a 20 mL bacterial sampler pre-attached to each platelet bag to allow LVDS from individual daughter bags per the FDA Bacterial Guidance. Samplers will also be available as stand-alone accessories. These new samplers will provide the same convenience as current samplers, with volume markings and a needle for direct injection into BioMérieux BacT/ALERT culture bottles. We are working diligently to ensure stand-alone accessory samplers, followed by integrated samplers, are available in a timeframe that allows blood centers to implement the LVDS strategy within the deadline specified by the FDA Bacterial Guidance.¹

Each of the strategies outlined in the FDA Bacterial Guidance has its own set of challenges. One primary concern for blood centers is the impact of these strategies on platelet availability.² Both pathogen reduction (PR) and LVDS will result in roughly a 7% to 12% decrease in platelet productivity on Trima Accel.²

Terumo BCT recently released Trima Accel 7, which has been demonstrated to increase platelet productivity by 4% to 11%.^{3,4,5} Terumo BCT is dedicated to providing blood centers with the highest quality support and analytics to help blood centers make data-based business decisions.

Sincerely,



Michael Lees
VP Commercial, North America

¹U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikarostraat 41
1930 Zaventem
Belgium
Phone: +32.2.715.0590
Fax: +32.2.721.0770

Terumo BCT Asia Pte. Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517-12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Tokyo Opera City Tower 49F,
3-20-2, Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-1450,
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

Availability of Platelets for Transfusion. September 2019. <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>.

²SN4-28 FDA recommendations you love to hate: an update on babesia testing and bacterial risk control strategies. Presented by Donna Strauss, New York Blood Center Enterprises. AABB Annual Meeting; October 20, 2019; San Antonio, TX.

³Way B, Garrison C, Rosario R. Inova Blood Donor Center experience with Trima Accel 7. *Transfusion*. 2019. 59(S3): P-BB-26.

⁴Kaiser D, Ackerman A. Versiti Michigan experience with routine use of Trima Accel 7. *Transfusion*. 2019. 59(S3): P-BB-18.

⁵Gabiak S, Shook D, Zilich A, Davison A, Acherman A, Lakey S. Improvements achieved with Trima Accel 7 in a community blood center. *Transfusion*. 2019. 59(S3): P-BB-70.