



Helping all people
live healthy lives

TECHNICAL BULLETIN

Date: October 29, 2004

To: Users of all variants of BD Vacutainer® SST™ glass and Plus plastic and SST™ II tubes on the following immunoassay systems:

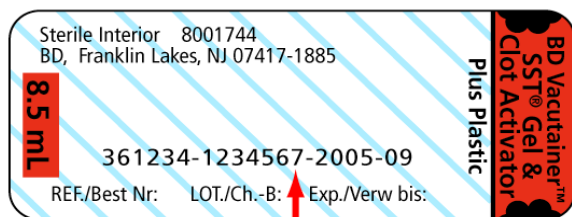
- Abbott Diagnostics' AUSZYME® Monoclonal Assay
- Bayer ADVIA Centaur® and ACS:180®
- Beckman Coulter Access®, Access® 2, UniCel® DxI 800, SYNCHRON LX®i 725
- DPC IMMULITE®, IMMULITE® 1000, IMMULITE 2000® and IMMULITE® 2500

**Subject: Immunoassay Interference Update –
Clinical Validations of Adjusted BD Vacutainer® SST™ and SST™ II Product for Affected Instrument Systems Complete**

Dear Valued Customer,

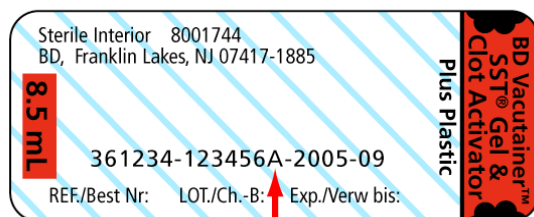
This letter is to inform you that BD has completed its clinical validations of adjusted BD Vacutainer® SST™ glass and Plus plastic and SST™ II blood collection tubes, and has initiated production of adjusted products. The adjusted products will resolve the previously communicated assay interferences. Once available, and until a new label design can be implemented, the adjusted products can be clearly recognized by the inclusion of an Alpha Character (A, B, C, D or E) at the end of the product lot number identification, for example: lot number 123456A. This Alpha Character lot number distinction will be clearly visible on all levels of packaging. Note that the lot numbers of the non-adjusted products are numeric only.

Example of Tube Label of **Non-Adjusted** Product



Numeric Character

Example of Tube Label of **Adjusted** Product



Alpha Character

See attachment for examples of Alpha Character lot number distinction on Shelf Pack and Case Carton labeling.

Recognizing the time required to re-supply our product pipeline, BD is prepared to prioritize the supply of adjusted product to those customers that are utilizing the affected instrument systems referenced above. Please contact your BD Sales Representative to discuss your immediate product needs and to determine local product availability. We can also be contacted via e-mail at Vacutainer_TechServices@BD.com.

If you are utilizing an affected system, you are advised to continue operating under the previously cited product restrictions (ref. Technical Bulletin VS 7313 dated 9/23/04) until you receive adjusted product. Technical Bulletins related to these assay interferences can be found at www.bd.com/vacutainer.

The BD team has worked very hard with our instrument company partners over the past few months to resolve this issue. We apologize for any inconvenience this issue may have caused you, the members of your team, and of course your patients.

Sincerely,



Ana K. Stankovic, MD, PhD, MSPH
Worldwide Medical Director
BD Diagnostics - Preanalytical Systems



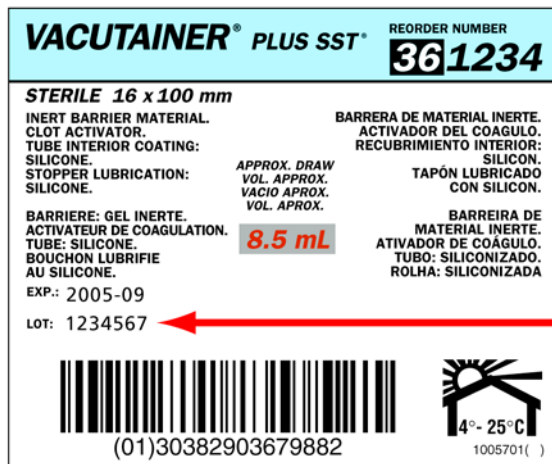
John D. Boselli, PE
WW VP Quality Management and Regulatory Compliance
BD Diagnostics - Preanalytical Systems

Attachment: Examples of Alpha Character lot number distinction on Shelf Pack and Case Carton labeling VS 7340

Examples of Alpha Character lot number distinction on Shelf Pack and Case Carton labeling

Attachment to Technical Bulletin VS7340

Example of Shelf Pack Label of Non-Adjusted Product:



Numeric Character

Example of Shelf Pack Label of Adjusted Product:

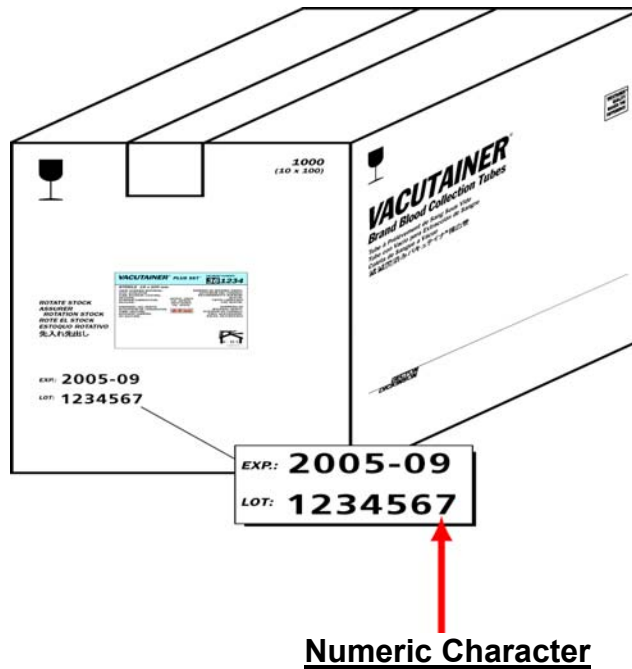


Alpha Character

Examples of Alpha Character lot number distinction on Shelf Pack and Case Carton labeling

Attachment to Technical Bulletin VS7340

Example of Case Carton Label of Non-Adjusted Product:



Example of Case Carton Label of Adjusted Product:

