



TECHNICAL BULLETIN

Date: December 16, 2004

To: Users of BD Microtainer® 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 Microtainer® Tubes with the BD Microgard® Closure for
 Affected Instrument Systems Complete**

Dear Valued Customer,

This letter is to inform you that BD has completed its clinical validations of adjusted BD Microtainer® Tubes with BD Microgard™ Closure (Serum, SST™ and Amber SST™), and has initiated production of adjusted products (See Table 1 for specific catalog numbers). The adjusted products will resolve the previously communicated assay interferences (ref. Technical Bulletin VS 7326 dated 11/10/04). Once available, and until a new label design can be implemented, the adjusted products can be clearly recognized by the inclusion of the Alpha Character “D” at the end of the product lot number identification, for example: lot number 123456D. 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. Additionally, the case level packaging will have an **Orange Stripe** to help distinguish it from the unadjusted product. Please see Attachment for an example of the Alpha Character lot number distinction and Orange Stripe on the Case Carton of adjusted product.

Table 1: BD Microtainer® Tubes for which clinical validations of adjusted product have been completed.

Reorder Number (CE)	Reorder Number (Non-CE)	Description	Closure Type
365964	365963	No additive	Red BD Microgard™
365968	365967	SST™	Gold BD Microgard™
365979	365978	SST™ amber reservoir	Gold BD Microgard™

Please note that affected BD Microtainer® Tubes with Flo-Top closures have not been adjusted (See Table 2 for specific catalog numbers). For affected BD Microtainer® Tubes with Flo-Top closures, the previously cited product restrictions (ref. Technical Bulletin VS 7326 dated 11/10/04) are still in effect and will continue until further notice. Table 2 also lists Alternate BD Microtainer® Product Solutions.

Table 2: Affected BD Microtainer® Tubes that have not been adjusted, and Alternate BD Microtainer® Product Solutions

Affected BD Microtainer® Tubes that have <u>not</u> been adjusted			Alternate BD Microtainer® Product Solutions		
Reorder Number (CE)	Reorder Number (Non-CE)	Description	Reorder Number (CE)	Reorder Number (Non-CE)	Description
365950	365957	No additive, Red Flo-Top	365964	365963	No additive, Red BD Microgard™ - Adjusted Product Only
365952	365971	Lithium Heparin, Green Flo-Top	365966	365965	Lithium Heparin, Green BD Microgard™
365951	365956	SST™, Gold Flo-Top	365968	365967	SST™, Gold BD Microgard™ - Adjusted Product Only
365954	365959	SST™ amber reservoir, Gold Flo-Top	365979	365978	SST™ amber reservoir, Gold BD Microgard™ - Adjusted Product Only
365953	365958	PST™, Mint Green Flo-Top	365986	365985	PST, Mint Green BD Microgard™

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 with the products listed in Table 1, you are advised to continue operating under the previously cited product restrictions (ref. Technical Bulletin VS 7326 dated 11/10/04) 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: Example of Alpha Character lot number distinction and Orange Stripe on Case Carton labeling VS 7360

Example of Alpha Character lot number distinction and Orange Stripe on Case Carton labeling

Attachment to Technical Bulletin VS7360

Example of Case Carton Label of Non-Adjusted Product:



Numeric Character, No Orange Stripe

Example of Case Carton Label of Adjusted Product:



Alpha Character, and Orange Stripe