

TECHNICAL BULLETIN

Date: November 10, 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 Interferences when using BD Microtainer® Tubes on select Instrument Systems

Dear Valued Customer,

In conjunction with our investigations of interferences associated with the use of all variants of BD Vacutainer® SST™ glass and Plus plastic and SST™ II tubes on select instrument systems (ref. Technical Bulletin VS 7313 dated 9/23/04), BD has determined that select BD Microtainer® Tubes may exhibit similar biases when used on the systems listed above. Although BD and our instrument company partners have not received significant related complaint activity for these products, until further notice, we are advising our customers to discontinue the use of select BD Microtainer® Tubes (see Table 1) for the specific instrument/assay combinations listed in Table 2.

BD is working collaboratively with each of these instrument companies to resolve this issue. **BD scientists and engineers are in the process of validating adjusted product that ensures clinical performance on these systems.** We expect adjusted product to be available in the coming weeks. We will keep you apprised of our progress as additional information becomes available. Current updates can be obtained at www.bd.com/vacutainer.

Until adjusted product is available, we recommend the following interim solutions for low specimen volume immunoassay testing for the affected instrument/assay combinations:

- 1) **Unaffected BD Microtainer® Tubes** – BD Microtainer® Tubes that are unaffected can be used for all immunoassay testing for which plasma has been validated in your laboratory as the specimen of choice. See Table 3.
- 2) **BD Vacutainer® glass pediatric low draw (2-3 ml) serum tubes** – Low draw BD Vacutainer® glass serum tubes can be used for immunoassay testing. See Table 4.
- 3) **Use of unaffected instrument systems** – If an instrument system other than those noted above can be used for testing of the implicated immunoassays, the laboratory may continue to use the affected BD Microtainer® Tube products.

If none of the above solutions are acceptable or you have additional questions, you are advised to contact BD Technical Services at 1-800-631-0174 or your local BD Sales Representative. We can also be contacted via e-mail at Vacutainer_TechServices@BD.com. Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

We apologize for any inconvenience this may cause you. We have taken this action in accordance with our continued commitment to provide you with superior products and services.

Thank you for your patience and support as we work to resolve this issue.

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

VS 7326

Table 1: Affected BD Microtainer® Tubes

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™
365950	365957	No additive	Red Flo-Top
365952	365971	Lithium Heparin*	Green Flo-Top
365951	365956	SST™	Gold Flo-Top
365954	365959	SST™ amber reservoir	Gold Flo-Top
365953	365958	PST™*	Mint green Flo-Top

* Please note that the corresponding BD Microgard™ (Green and Mint Green) are unaffected – see Table 3)

Table 2: Restricted Instrument/Assay Combinations

Instrument Company and System	Specific Assay Cited*
Abbott Diagnostics	AUSZYME® Monoclonal Assay HbsAg
Bayer Healthcare Diagnostics Division ADVIA Centaur® ACS:180®	Total T3, Total T4, Folate BA, Vitamin B12, BR and FSH
Beckman Coulter, Inc. Access®, Access® 2, UniCel® DxI 800, SYNCHRON LX® I 725	Total T3
Diagnostics Products Corporation (DPC) IMMULITE®, IMMULITE® 1000, IMMULITE 2000®, IMMULITE® 2500	Total T3, Total T4, Cortisol, and FSH

*Note: BD and our instrument company partners are in the process of evaluating these potential interferences. The results of these evaluations (% bias) will be posted on the BD website (www.bd.com/vacutainer) once this information becomes available.

Table 3: Unaffected BD Microtainer® Tubes

Reorder Number (CE)	Reorder Number (Non-CE)	Description	Closure Type
365975	365974	EDTA	Lavender BD Microgard™
365955	365973	EDTA	Lavender Flo-Top
365966	365965	Lithium Heparin	Green BD Microgard™
365986	365985	PST	Mint green BD Microgard™
365988	365987	PST amber reservoir	Mint green BD Microgard™

Please Note: BD Microtainer® Glucose tubes with Grey BD Microgard™ closure (reorder numbers 365992 and 365993) are not affected and can be used for their intended purpose.

Table 4: BD Vacutainer® glass pediatric low-draw serum tubes

Reorder Number (CE)	Reorder Number (Non-CE)	Description	Closure Type
367611	369611	13 X 75mm 2.0ml draw volume	Red BD Hemogard™
367612	369612	13 X 75mm 3.0ml draw volume	Red BD Hemogard™
N/A	366381	10.25 X 64mm 3.0ml draw volume	Red Conventional
366653	N/A	10.25 X 64mm 2.0ml draw volume	Red Conventional