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TECHNICAL BULLETIN

Date: August 20, 2004

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

- Beckman Coulter Access®, Access® 2, UniCel™ DxI 800, SYNCHRON LX®i 725, and
- Bayer ADVIA® Centaur and ACS:180

Subject: Elevated Total T3 Assay Values

Dear Valued Customer,

Due to reports from the above listed diagnostic instrument manufacturers, BD has initiated an in-depth investigation concerning elevated Total T3 assay values (~20-58%) when using BD Vacutainer® SST™ glass and Plus plastic tubes with the systems listed above. The values are elevated when compared to samples collected in BD Vacutainer® serum tubes without gel separator. BD is diligently working to resolve this issue in cooperation with these companies. We will keep you apprised of the progress as more information becomes available. Additionally, the most current updates can be obtained at www.bd.com/vacutainer.

When interpreting Total T3 results, you are advised to do so in the context of other laboratory test results, as well as the patients' clinical presentation.

In the interim and until further notice, you are advised to use BD Vacutainer® serum tubes without gel separator (see attached list of catalog numbers) for performing a Total T3 assay on the systems listed above.

BD Technical Services 1-800-631-0174 or your local BD representative can provide additional information on these tubes. We also can 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 commitment to provide you with superior products and services.

Thank you for your patience and continued support on this matter.

Sincerely,

A handwritten signature in blue ink that reads "Ana K. Stankovic".

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

Attachment: BD Vacutainer® serum tube catalog numbers
VS7298

**BD Vacutainer® Serum Tube Catalog Numbers
Attachment to Technical Bulletin VS7298**

North America

Catalog Number	Size	Draw Volume	Material	Closure Type
366434	13x75mm	5.0ml	Glass	Conventional Stopper
366431	13x100mm	7.0ml	Glass	Conventional Stopper
366430	16x100mm	10.0ml	Glass	Conventional Stopper
369615	13x100mm	7.0ml	Glass	BD Hemogard™ Stopper
367812	13x75mm	4.0ml	Plastic	BD Hemogard™ Stopper
367815	13x100mm	6.0ml	Plastic	BD Hemogard™ Stopper
367820	16x100mm	10.0ml	Plastic	BD Conventional Stopper

In the interim and until further notice, you are advised to use BD Vacutainer® serum tubes without gel separator (see list of catalog numbers above) for performing a Total T3 assay on the systems listed in Technical Bulletin VS7298.