



TECHNICAL BULLETIN

Date: September 1, 2004

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

- **DPC IMMULITE®, IMMULITE® 1000, IMMULITE® 2000 and IMMULITE® 2500**

Subject: Elevated Total T3, Total T4 and Cortisol Assay Values

Dear Valued Customer,

Due to reports from DPC, BD has initiated an in-depth investigation concerning elevated Total T3, Total T4 and Cortisol assay values (~15-30%) when using BD Vacutainer® SST™ glass and Plus plastic tubes with the systems listed above. The values are elevated compared to samples collected in BD Vacutainer® glass serum tubes without gel separator. BD is diligently working to resolve this issue. We will keep you apprised of the progress as more information becomes available. A similar bulletin was issued to Beckman Coulter and Bayer customers regarding T3 assay interference. Additionally, the most current updates can be obtained at www.bd.com/vacutainer.

When interpreting Total T3, Total T4 and/or Cortisol 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, BD has determined that the following tubes can be used when performing these respective assays on the systems above (see attached table for recommended catalog numbers):

Total T3

- BD Vacutainer® plastic serum tube without gel separator (Note: In development of its package insert reference range for Total T3, DPC has taken into consideration the observed difference between glass and plastic BD Vacutainer® serum tubes without gel separator. Glass serum tubes may be used for this assay if the users have established their own reference range using a glass serum tube.)

Total T4 and Cortisol

- BD Vacutainer® serum tube (glass or plastic) without gel separator

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
VS 7304 - US

**BD Vacutainer® Serum Tube Catalog Numbers
Attachment to Technical Bulletin VS7304**

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, BD has determined that the following tubes can be used when performing these respective assays on the systems listed in Technical Bulletin VS7304 (see table above for recommended catalog numbers):

Total T3

- BD Vacutainer® plastic serum tube without gel separator (Note: In development of its package insert reference range for Total T3, DPC has taken into consideration the observed difference between glass and plastic BD Vacutainer® serum tubes without gel separator. Glass serum tubes may be used for this assay if the users have established their own reference range using a glass serum tube.)

Total T4 and Cortisol

- BD Vacutainer® serum tube (glass or plastic) without gel separator