



## TECHNICAL BULLETIN

Date: September 1, 2004

**To: Users of all variants of BD Vacutainer® SST<sup>ã</sup> (glass and plastic) on the following immunoassay systems:**

- **DPC IMMULITE<sup>ã</sup>, IMMULITE<sup>ã</sup> 1000, IMMULITE<sup>ã</sup> 2000 and IMMULITE<sup>ã</sup> 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<sup>TM</sup> glass and BD Vacutainer® SST<sup>TM</sup> Plus (plastic) tubes on the systems listed above. BD Vacutainer® SST<sup>TM</sup> II tubes also showed elevated Total T3 assay values, but were unaffected for Total T4 and Cortisol assays when performed on the systems listed above. In all cases, 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](http://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 above systems (see attached list of 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 Vacutainer® SST<sup>TM</sup> II tube

Additional information can be obtained through your local BD representative. We also can be contacted via e-mail at [Vacutainer\\_TechServices@BD.com](mailto: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 7305 – Ex US

## BD Vacutainer® Serum and SST™ II Tube Catalog Numbers Attachment to Technical Bulletin VS7305

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 VS7305 (see table below 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 Vacutainer® SST™ II tube

**Note:** There may be other reference numbers of BD Vacutainer® serum tubes without gel separator which can be specific to your region or country. If you wish to use these tubes, please contact your local BD representative.

### Europe

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
367643	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Safety Closure
367614	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Safety Closure
367624	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Safety Closure
367625	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Safety Closure
367694	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Safety Closure
367615	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Safety Closure
368975	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Safety Closure
369032	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Safety Closure
367837	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Safety Closure
368815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Safety Closure
367895	16x100mm	10.0ml	Plastic	Serum	BD Hemogard™ Safety Closure
367896	16x100mm	10.0ml	Plastic	Serum	BD Hemogard™ Safety Closure
367958	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Safety Closure
367953	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Safety Closure
367954	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Safety Closure
367955	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Safety Closure
367956	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Safety Closure
367957	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Safety Closure
366644	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Safety Closure
366566	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Safety Closure
368498	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Safety Closure

## BD Vacutainer® Serum and SST™ II Tube Catalog Numbers Attachment to Technical Bulletin VS7305

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 VS7305 (see table below 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 Vacutainer® SST™ II tube

**Note:** There may be other reference numbers of BD Vacutainer® serum tubes without gel separator which can be specific to your region or country. If you wish to use these tubes, please contact your local BD representative.

### Asia Pacific

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
366434	13x75mm	5.0ml	Glass	Serum	Conventional Stopper
369614	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Stopper
369612	13x75mm	3.0ml	Glass	Serum	BD Hemogard™ Stopper
369615	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Stopper
366431	13x100mm	7.0ml	Glass	Serum	Conventional Stopper
366430	16x100mm	10.0ml	Glass	Serum	Conventional Stopper
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper
367896	16x100mm	10.0ml	Plastic	Serum	BD Hemogard™ Stopper
367958	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Stopper
367953	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Stopper
367954	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Stopper
367955	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Stopper
367956	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Stopper
367957	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Stopper
368972	16x100mm	8.5ml	Plastic	SST II	Conventional Stopper

## BD Vacutainer® Serum and SST™ II Tube Catalog Numbers Attachment to Technical Bulletin VS7305

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 VS7305 (see table below 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 Vacutainer® SST™ II tube

**Note:** There may be other reference numbers of BD Vacutainer® serum tubes without gel separator which can be specific to your region or country. If you wish to use these tubes, please contact your local BD representative.

### Japan

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
366434	13x75mm	5.0ml	Glass	Serum	Conventional Stopper
369615	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper
367953	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Stopper
367955	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Stopper
367957	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Stopper
367528	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Stopper
368640	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Stopper
368972	16x100mm	8.5ml	Plastic	SST II	Conventional Stopper
367520	13x100mm	5.0ml	Plastic	SST II	Conventional Stopper

### Central America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
366434	13x75mm	5.0 ml	Glass	Serum	Conventional Stopper
366431	13x100mm	7.0 ml	Glass	Serum	Conventional Stopper
366430	16x100mm	10.0 ml	Glass	Serum	Conventional Stopper
367812	13x75mm	4.0 ml	Plastic	Serum	BD Hemogard™ Stopper
367815	13x100mm	6.0 ml	Plastic	Serum	BD Hemogard™ Stopper
367819	13x100mm	6.0 ml	Plastic	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0 ml	Plastic	Serum	Conventional Stopper

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### 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 Vacutainer® SST™ II tube

**Note:** There may be other reference numbers of BD Vacutainer® serum tubes without gel separator which can be specific to your region or country. If you wish to use these tubes, please contact your local BD representative.

### S. Latin America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
<b>Brazil</b>					
367612	13x75mm	3.0ml	Glass	Serum	BD Hemogard™ Stopper
367793	13x75mm	4.0ml	Glass	Serum	BD Hemogard™ Stopper
369614	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Stopper
366430	16x100mm	10.0ml	Glass	Serum	Conventional Stopper
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper
367958	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Stopper
367955	13x100mm	5.0ml	Plastic	SST II	BD Hemogard™ Stopper
367957	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Stopper
<b>Argentina</b>					
369794	13x100mm	6.0ml	Glass	Serum	BD Hemogard™ Stopper
366430	16x100mm	10.0ml	Glass	Serum	Conventional Stopper
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
<b>Chile</b>					
369612	13x75mm	3.0ml	Glass	Serum	BD Hemogard™ Stopper
369614	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Stopper
366430	16x100mm	10.0ml	Glass	Serum	Conventional Stopper
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
367958	16x100mm	8.5ml	Plastic	SST II	BD Hemogard™ Stopper
367957	13x75mm	3.5ml	Plastic	SST II	BD Hemogard™ Stopper
<b>Peru/Ecuador/Bolivia</b>					
366430	16x100mm	10.0ml	Glass	Serum	Conventional Stopper
369615	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper

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### 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 Vacutainer® SST™ II tube

**Note:** There may be other reference numbers of BD Vacutainer® serum tubes without gel separator which can be specific to your region or country. If you wish to use these tubes, please contact your local BD representative.

### N. Latin America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
<b>Mexico</b>					
366381	10.25x64mm	3.0ml	Glass	Serum	Conventional Stopper
369614	13x75mm	5.0ml	Glass	Serum	BD Hemogard™ Stopper
368124	13x100mm	7.0ml	Glass	Serum	BD Hemogard™ Stopper
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
368175	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0 ml	Plastic	Serum	Conventional Stopper
<b>Colombia</b>					
366381	10.25x64mm	3.0ml	Glass	Serum	Conventional Stopper
366434	13x75mm	5.0ml	Glass	Serum	Conventional Stopper
366431	13x100mm	7.0ml	Glass	Serum	Conventional Stopper
366430	16x100mm	10.0ml	Glass	Serum	Conventional Stopper
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
<b>Venezuela</b>					
366381	10.25x64mm	3.0ml	Glass	Serum	Conventional Stopper
366431	13x100mm	7.0ml	Glass	Serum	Conventional Stopper
366668	13x75mm	3.0ml	Plastic	Serum	Conventional Stopper
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper