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TECHNICAL BULLETIN

Date: August 25, 2004

To: Users of all variants of BD Vacutainer® SST™ tubes (glass and plastic) on the following immunoassay systems:

- Beckman Coulter Access®, Access® 2, UniCel™ Dxl 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 all variants of BD Vacutainer® SST™ tubes (glass and plastic) 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.

Additional information on these tubes can be obtained through your local BD representative. 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
VS7300 - exUS

**BD Vacutainer® Serum Tube Catalog Numbers
Attachment to Technical Bulletin VS7300**

In the Interim and until further notice, you are advised to use BD Vacutainer® serum tubes without gel separator (see list of catalog numbers below) for performing a Total T3 assay on the systems listed in Technical Bulletin VS7300. There may be other catalog numbers of BD Vacutainer® serum tubes without gel separator which are 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 | Closure Type |
|----------------|----------|-------------|----------|-----------------------------|
| 367643 | 13x75mm | 5.0ml | Glass | BD Hemogard™ Safety Closure |
| 367614 | 13x75mm | 5.0ml | Glass | BD Hemogard™ Safety Closure |
| 367624 | 13x75mm | 5.0ml | Glass | BD Hemogard™ Safety Closure |
| 367625 | 13x100mm | 7.0ml | Glass | BD Hemogard™ Safety Closure |
| 367694 | 13x100mm | 7.0ml | Glass | BD Hemogard™ Safety Closure |
| 367615 | 13x100mm | 7.0ml | Glass | BD Hemogard™ Safety Closure |
| 368975 | 13x75mm | 4.0ml | Plastic | BD Hemogard™ Safety Closure |
| 369032 | 13x75mm | 4.0ml | Plastic | BD Hemogard™ Safety Closure |
| 367837 | 13x100mm | 6.0ml | Plastic | BD Hemogard™ Safety Closure |
| 368815 | 13x100mm | 6.0ml | Plastic | BD Hemogard™ Safety Closure |
| 367895 | 16x100mm | 10.0ml | Plastic | BD Hemogard™ Safety Closure |
| 367896 | 16x100mm | 10.0ml | Plastic | BD Hemogard™ Safety Closure |

Asia Pacific

| Catalog Number | Size | Draw Volume | Material | Closure Type |
|----------------|----------|-------------|----------|----------------------|
| 366434 | 13x75mm | 5.0ml | Glass | Conventional Stopper |
| 369614 | 13x75mm | 5.0ml | Glass | BD Hemogard™ Stopper |
| 369612 | 13x75mm | 3.0ml | Glass | BD Hemogard™ Stopper |
| 369615 | 13x100mm | 7.0ml | Glass | BD Hemogard™ Stopper |
| 366431 | 13x100mm | 7.0ml | Glass | Conventional Stopper |
| 366430 | 16x100mm | 10.0ml | Glass | Conventional Stopper |
| 367812 | 13x75mm | 4.0ml | Plastic | BD Hemogard™ Stopper |
| 367815 | 13x100mm | 6.0ml | Plastic | BD Hemogard™ Stopper |
| 367820 | 16x100mm | 10.0ml | Plastic | Conventional Stopper |
| 367896 | 16x100mm | 10.0ml | Plastic | BD Hemogard™ Stopper |

Japan

| Catalog Number | Size | Draw Volume | Material | Closure Type |
|----------------|----------|-------------|----------|----------------------|
| 366434 | 13x75mm | 5.0ml | Glass | Conventional Stopper |
| 369615 | 13x100mm | 7.0ml | Glass | BD Hemogard™ Stopper |
| 367820 | 16x100mm | 10.0ml | Plastic | Conventional Stopper |

**BD Vacutainer® Serum Tube Catalog Numbers
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Central America

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

S. Latin America

| Catalog Number | Size | Draw Volume | Material | Closure Type |
|-----------------------------|----------|-------------|----------|----------------------|
| Brazil | | | | |
| 367612 | 13x75mm | 3.0ml | Glass | BD Hemogard™ Stopper |
| 367793 | 13x75mm | 4.0ml | Glass | BD Hemogard™ Stopper |
| 369614 | 13x75mm | 5.0ml | Glass | BD Hemogard™ Stopper |
| 366430 | 16x100mm | 10.0ml | Glass | Conventional Stopper |
| 367820 | 16x100mm | 10.0ml | Plastic | Conventional Stopper |
| Argentina | | | | |
| 369794 | 13x100mm | 6.0ml | Glass | BD Hemogard™ Stopper |
| 366430 | 16x100mm | 10.0ml | Glass | Conventional Stopper |
| 367815 | 13x100mm | 6.0ml | Plastic | BD Hemogard™ Stopper |
| Chile | | | | |
| 369612 | 13x75mm | 3.0ml | Glass | BD Hemogard™ Stopper |
| 369614 | 13x75mm | 5.0ml | Glass | BD Hemogard™ Stopper |
| 366430 | 16x100mm | 10.0ml | Glass | Conventional Stopper |
| 367812 | 13x75mm | 4.0ml | Plastic | BD Hemogard™ Stopper |
| 367815 | 13x100mm | 6.0ml | Plastic | BD Hemogard™ Stopper |
| Peru/Ecuador/Bolivia | | | | |
| 366430 | 16x100mm | 10.0ml | Glass | Conventional Stopper |
| 369615 | 13x100mm | 7.0ml | Glass | BD Hemogard™ Stopper |
| 367820 | 16x100mm | 10.0ml | Plastic | Conventional Stopper |

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N. Latin America

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