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TECHNICAL BULLETIN

Date: September 22, 2004

To: Users of all variants of BD Vacutainer® SST™ glass and Plus plastic tubes on the Bayer ADVIA® Centaur and ACS:180® Immunoassay systems.

Subject: Immunoassay Interferences

Dear Valued Customer,

Bayer Healthcare Diagnostics Division has recently alerted BD (ref. Bayer Customer Bulletin, Sept. 04) of assay interferences when using BD Vacutainer® SST™ glass and Plus plastic tubes on the ADVIA® Centaur and ACS:180® systems. The values (see table below) are elevated when compared to samples collected in BD Vacutainer® glass serum tubes without gel separator. These interferences are in addition to the previously reported (ref. BD Technical Bulletin VS7300, Aug. 25, 2004) elevated T3 (total) interference on this system.

The additional assays cited include:

Total T4, 18% on Avg. positive bias reported	BR, 19% on Avg. positive bias reported
Folate BA, 32% on Avg. positive bias reported	FSH, 26% on Avg. negative bias reported
VB 12, 38% on Avg. positive bias reported	

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) when performing the assays listed above on both the ADVIA® Centaur and ACS:180® systems.

BD and Bayer are working collaboratively to resolve this issue. BD scientists and engineers are in the process of validating reformulated designs that restore clinical performance for these assays. BD's validation practices will also ensure the ongoing performance of our products on unaffected systems. We will keep you apprised of our progress as additional information becomes available. Current updates can be obtained at www.bd.com/vacutainer. 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 further 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,

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 7312 – Ex US

**BD Vacutainer® Serum Tube Catalog Numbers
Attachment to Technical Bulletin VS7312**

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 the assays listed in Technical Bulletin VS7312 on both the ADVIA® Centaur and ACS:180® systems. 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
Attachment to Technical Bulletin VS7312**

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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

**BD Vacutainer® Serum Tube Catalog Numbers
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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
Colombia				
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