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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 VS7298, Aug. 20, 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. 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 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 7311 - US

**BD Vacutainer® Serum Tube Catalog Numbers
Attachment to Technical Bulletin VS7311**

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 VS7311 on both the ADVIA® Centaur and ACS:180® systems.

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	Conventional Stopper