

BD Diagnostics
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TECHNICAL BULLETIN

Date: November 05, 2004

To: Users of all variants of BD Vacutainer® SST™ glass and Plus plastic and SST™ II tubes on DPC IMMULITE®, IMMULITE® 1000, IMMULITE 2000® and IMMULITE® 2500 instrument systems.

Subject: DPC reports negative bias (-15 to -20%) for FSH Immunoassay on IMMULITE® systems.

On November 1, 2004 Diagnostics Products Corporation (DPC) informed BD of a negative bias (Approximately -15 to -20%) on FSH assays for the systems referenced above with specimens collected in BD Vacutainer® SST™ glass and Plus plastic and SST™ II tubes. This interference is related to the previously cited interferences (Total T3, Total T4 and Cortisol) on these systems and, **has been resolved by BD scientists and engineers through the introduction of Adjusted Products.** BD Technical Bulletin VS 7313 details the previously cited interferences. BD Technical Bulletin VS 7340 details the completion of validations of Adjusted Product. These bulletins are available at www.bd.com/vacutainer.

Interim Solution for those customers without Adjusted Product: DPC has recommended the use of BD Vacutainer® Plastic Serum Tubes without gel separator. The attached tables provide specific catalog numbers for interim tube solutions.

Additional information on these tubes and affected systems can be obtained through your local BD representative. We can also 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

A handwritten signature in blue ink that reads 'John D. Boselli'.

John D. Boselli, PE
WW VP Quality Management and Regulatory Compliance
BD Diagnostics - Preanalytical Systems

Attachment: BD Vacutainer® Plastic Serum Tubes Without Gel Separator
VS 7345

**BD Vacutainer® Plastic Serum Tubes Without Gel Separator
Attachment to Technical Bulletin VS7345**

Until Adjusted Product can be obtained, you are advised to use only the BD Vacutainer® Plastic Serum Tubes referenced in the worldwide tables below for the instrument/assay combinations referenced in Technical Bulletin VS 7345.

Please Note: Catalog numbers 367813, 367814, and 366668 are BD Vacutainer® Partial Draw Serum tubes that have been intentionally excluded from the tables below as they are **not acceptable** for the instrument/assay combinations listed in Technical Bulletin VS7345. Please reference Technical Bulletin VS7329 (available at www.bd.com/vacutainer) for details on these BD Vacutainer® Partial Draw Serum Tubes.

North America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
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

Europe

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
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

Asia Pacific

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
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

Japan

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper

**BD Vacutainer® Plastic Serum Tubes Without Gel Separator
Attachment to Technical Bulletin VS7345**

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Central America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
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

S. Latin America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
Brazil					
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper
Argentina					
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
Chile					
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
Peru/Ecuador/ Bolivia					
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper

N. Latin America

Catalog Number	Size	Draw Volume	Material	Description	Closure Type
Mexico					
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
Colombia					
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367815	13x100mm	6.0ml	Plastic	Serum	BD Hemogard™ Stopper
Venezuela					
367812	13x75mm	4.0ml	Plastic	Serum	BD Hemogard™ Stopper
367820	16x100mm	10.0ml	Plastic	Serum	Conventional Stopper