

# DADE BEHRING

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## To whom it may concern

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*Date*  
2007-12-03

### **Field Correction on Complement Reagents (OWZD11) Lot No. 542849 on the BCS® and BCT® Systems**

Dear Valued Dade Behring Customer,

Our records indicate that you have received Complement Reagents (OWZD11), lot no. 542849.

The purpose of this letter is to inform you about a performance issue of the Complement Reagents, lot no. 542849. This lot shows an unexpected high variation which is indicated in most cases by recovery of Control Plasma N and Control Plasma P outside the confidence range.

**Therefore, we ask you to discontinue the use of and discard the affected lot as well as any remaining inventory.**

In case the exclusion of a complement deficiency is solely based on results obtained with the affected lot of Complement Reagents we do recommend to retest the respective patient sample.

If you have concerns or need assistance with the information outlined in this communication, please contact your local Dade Behring Technical Assistance Center.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred this lot.

We apologize for the inconvenience this action may have caused and thank you for your continued support of Dade Behring Hemostasis products.



Director  
Quality Systems & Compliance



Marketing Manager  
Global Marketing Hemostasis

*As of November 6, 2007, Dade Behring Inc. is a wholly owned subsidiary of Siemens Medical Solutions Diagnostics. In the short term, while we are working toward a legal integration of the two companies, please be aware that customer communications and legal documents will use either the Siemens Medical Solutions Diagnostics or the Dade Behring name, as appropriate.*