



## Urgent Field Safety Notice

[BR-09110]

July 2010

**Complement Reagent (OWZD11), Lot Number 542865**

### **Potential for falsely increased or decreased results on the BCS®/ BCS XP® Systems**

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Our records indicate that you have received Complement Reagent, lot 542865 and may use it for determination of Complement on the BCS®/ BCS XP® system.

Siemens Healthcare Diagnostics has confirmed that falsely increased or decreased values may be observed with the above mentioned lot of Complement Reagent. Almost all calibration curves are invalid due to a high CV of duplicate determinations, and a high variability in control recovery has been observed. Generally the affected lot of Complement Reagent is visually showing a higher sedimentation rate of the erythrocytes.

The purpose of this letter is to advise you **not to use the affected lot of Complement Reagent on the BCS®/ BCS XP® Systems**. Please note, that the determination of Complement Reagent application on the BCT® or as Manual Method is not affected.

Please consult with your laboratory director regarding re-evaluation of previous test results from plasma samples treated with this lot number of Complement Reagent. If you have any questions or need assistance with obtaining replacement product, contact your local Siemens representative.

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 whom you may have transferred these of Complement Reagent.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) has been notified of this action.

We apologize for the inconvenience that this situation has caused.

Thank you for your patience and continued support.

Sincerely,

  
Product Manager  
Auditing & Quality System Projects

  
Head of  
Global Marketing Hemostasis Reagents

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[Tracking Number]

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