

## URGENT INFORMATION

### FIELD CORRECTIVE ACTION

#### Calcium P FS Cat. No. 1 1181 - Erroneous results in myeloma patients

**Date:** September 1, 2009

**Product:** Calcium P FS Cat. No. 1 1181

Lots: 8599, 9462, 9750, 9832, 11286, 11979, 12006

**Explanation:** As reported by a customer a falsely low calcium value was found in a patient sample of a myeloma patient. The measured result using Calcium P FS (two-step method) was 3.9 mg/dL (0.98 mmol/L). Measurement with a different calcium method (CPC) gave 8.7 mg/dL (2,2 mmol/L).

The cause was unspecific turbidity by precipitation of a paraprotein. DiaSys is currently working on a reagent modification which will avoid the unspecific reaction.

**Impact on patient results:** Samples of patients with myeloma or suspected for myeloma might give falsely low values.

**Measures:** In cause of implausible calcium results in samples of myeloma patients the measurement should be repeated using a different method.

We recommend the use of Calcium AS FS (Cat. No. 1 1130...) or Calcium CPC FS (Cat. No. 1 1121...) as these methods have been proved to give correct results.

DiaSys has announced the reagent failure to the relevant authority BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte).

Please inform all users of the reagent immediately.

We would like to ask you to fill in and sign attached confirmation that you have received and communicated this information to all of your customers. Please send it back to us by fax or as scan until **September 15, 2009**.

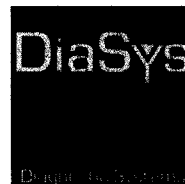
Please be assured that DiaSys is doing the utmost to improve the reagent. Based on first evaluation data of a modified reagent we expect that the next lot produced will not show the deficiency anymore. We will keep you informed. Of course, we will replace the defective reagent as soon as new material is available.

DiaSys apologizes for all inconveniences caused by this and hope for your understanding.

Sincerely yours,

DiaSys Diagnostic Systems GmbH

  
Product/Project Management



**URGENT INFORMATION  
CONFIRMATION OF RECEIPT**

To:

DiaSys Diagnostic Systems GmbH

Alte Strasse 9

65558 Holzheim

**Fax: +49 6432 9146 32**

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**We have received above mentioned information and have advised all users accordingly.**

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**Company, Country**

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**Name**

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**Date**

**Signature**