

SIEMENS

To Whom It May Concern

Urgent Field Safety Notice

[BR-09608]

2008-08-25

Dimension Vista® Flex® reagent cartridge IGM (K7058), lot 07156MB Insufficient Filling

Dear Valued Customer,

Our records indicate that you have received the lot 07156MB of Dimension Vista® Flex® reagent cartridges for the determination of IGM (Product code K7058).

We have confirmed that lot 07156MB of IGM Flex® reagent cartridges may exhibit erroneous results. An insufficient filling in one of the 12 wells may cause an insufficient amount of a buffer component to be aspirated in up to 2% of the performed tests.

Please discontinue the use of Dimension Vista® IGM Flex® reagent cartridges, lot no. 07156MB and discard any remaining inventory of the affected lot.

If you have any questions or need assistance with replacement product, please contact your local 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 to whom you may have transferred this lot.

Please consult with your laboratory director regarding re-evaluation of previous results.

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

We apologize for the inconvenience this action may cause you and thank you for your continued support of Siemens Plasma Protein products.

Dade Behring Marburg GmbH, A Siemens Company

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Board of Management: Jean-François Bauer, Ed Leonard, Dr. Wilfried Meyers, Stefan Wolf
Chairman of the Supervisory Board: Prof. Dr. Dr. Uwe Bicker
Principal Office: Marburg/Lahn, registered in Marburg/Lahn HRB 2054

Dimension Vista® Flex® reagent cartridge IGM (K7058), lot 07156MB

Insufficient Filling

Sincerely,



Director
Auditing & Quality System Projects



Marketing Manager
Global Marketing Plasma Proteins

*As of November 6, 2007, Dade Behring Inc. is a wholly owned subsidiary of **Siemens**. 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 Healthcare Diagnostics Inc or the Dade Behring, Inc name, as appropriate.*