

Urgent Field Safety Notice

BR-08209

2009-05-20

Dimension Vista® B2-Microglobulin Flex reagent cartridge (K7024) Lot 09029MA

Reagent agglutination

Dear Customer:

Our records indicate that your laboratory has received Dimension Vista® B2MIC Flex reagent cartridge **(K7024) Lot 09029MA**. Siemens has confirmed calibration failures and out of range QC recovery with this flex reagent cartridge lot. Impact on patient results cannot be excluded.

Please immediately discontinue use of Dimension® B2MIC Flex® reagent cartridge lot 09029MA and discard any unused product. Please contact your Siemens Customer Service Center to report your no-charge replacement needs.

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

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

Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support. If you have any technical questions regarding this information, please contact your local Siemens Technical Solutions Center.

Sincerely,
Original signature is on file


Director
Quality Systems & Compliance

Original signature is on file


Product Manager
Global Marketing Vista Plasma Proteins

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GPF-003-6 Version 2.0 Effective: 2009-01-19