



Urgent Field Safety Notice

BR-10809

2009-07-21

Dimension Vista® System with Software Version 3.2.1 or earlier using Dimension Vista® B2MIC Flex reagent (K7024), Dimension Vista® ASL Flex reagent (K7022), and Dimension Vista® IGM Flex reagent (K7058)

Dear Customer:

Our records indicate that your laboratory uses Flex® reagent cartridge β 2-Microglobulin(K7024), Anti-Streptolysin O (K7022), and/or Immunoglobulin M (K7058) on the Dimension Vista® System.

Siemens Healthcare Diagnostics has confirmed that under certain conditions, using this software, falsely elevated results may be obtained particularly if the preceding serum sample has a higher volume and concentration of the affected β 2-Microglobulin, Anti-Streptolysin O, or Immunoglobulin M analytes.

For the ASL method a typical carryover of samples with concentrations at the upper reference range limit was observed to be in the range of 80 IU/ml on the Dimension Vista System. At similar preceding sample concentrations IGM and B2MIC do not show a significant carryover; however it can not be excluded that patient results may be influenced by preceding samples of higher concentrations.

In order to ensure valid test results, Siemens Healthcare Diagnostics will be providing a new Software version to you. **Until you have received the new software, the β 2-Microglobulin, Anti-Streptolysin O, or Immunoglobulin M assays must be run on the Dimension Vista® System in batch mode only, or on a different system, e.g., the BN system.** Your local service organization will support you in identifying the most practicable solution for you.

We recommend discussing the content of this letter with your laboratory director regarding the need to review previous test results, conduct patient follow up, and/or repeat testing, if appropriate.

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

Please forward this notification to anyone who is running the Dimension Vista® system and retain a copy with your files for future reference.

Siemens Healthcare Diagnostics Products GmbH

Emil-von-Behring-Straße 76 +49-(0)6421-394637
35041 Marburg, Germany

www.siemens.com/diagnostics

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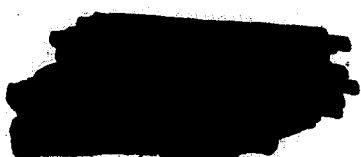
GPF-003-6 Version 2.0 Effective: 2009-01-19

Please be assured that all efforts are taken to solve the issue as soon as possible. We sincerely apologize for the inconvenience this action is causing in your lab and thank you for your close cooperation.

Sincerely,



Director
Quality Systems & Compliance



Senior Marketing Manager
Global Marketing Vista Plasma Proteins

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension Vista® System with Software Version 3.2.1 or earlier using Dimension Vista® B2MIC Flex reagent (K7024), Dimension Vista® ASL Flex reagent (K7022), and Dimension Vista® IGM Flex reagent (K7058

Dear Customer:

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated 2009-07-21 regarding potential sample carry over into the B2MIC, ASL and IGM assays by prior clinical chemistry samples. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare diagnostics at the fax number indicated at the bottom of this page.

1. Did your facility receive a field correction letter from Siemens Healthcare Diagnostics regarding _____ Yes No
[This question is necessary only if the Effectiveness Check Letter is mailed separately from the FCA Letter]
2. Did we effectively communicate all necessary information? Yes No
3. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes No
4. If the answer to Question 4 is Yes, do you intend to take the recommended action as requested? Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(###) ###-####

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