

Urgent Field Safety Notice

September, 2009

Dimension Vista[®] System

BUN Flex[®] reagent cartridges (K1021) Lot number 09154AE and 09187AA

Our records indicate that your laboratory uses the BUN Flex[®] reagent cartridges (K1021) on the Dimension Vista[®] System. Siemens has confirmed complaints of inaccurate results with the BUN Flex[®] reagent cartridge lots 09154AE and 09187AA. The test results may be falsely depressed or elevated; only portion of the lots are affected. The reported magnitude of the error may vary and may also affect QC recovery.

Siemens Healthcare Diagnostics is conducting a voluntary corrective action for Dimension Vista[®] BUN Flex[®] reagent cartridge lots 09154AE and 09187AA. Please immediately discontinue the use of BUN Flex[®] reagent cartridge lots 09154AE and 09187AA and discard. As a convenience, ten cartons of a new lot of Vista BUN are being shipped to you at no charge.

Contact your Siemens Customer Service Center at 800-241-0420 to report your additional no-charge replacement needs. Please consult with your laboratory director regarding re-evaluation of previous results.

We apologize for the inconvenience that this situation has caused. If you have any technical questions regarding this information, please contact Siemens Technical Solutions Center at 800-441-9250. Please forward this notification to anyone to whom you may have distributed this product.

Siemens Healthcare Diagnostics Inc.

09-20

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