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Urgent Field Safety Notice:

Dimension Vista® System

Dimension Vista High Density Lipoprotein Cholesterol (HDLC)
Potential for Erroneous Result with Flex® Reagent Lot 20062BA

Dear Sirs,

Our records indicate that your facility may have received the following product:

Table 1. Dimension Vista® Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	1st Distribution Date (YYYY-MM-DD)
Dimension Vista High Density Lipoprotein Cholesterol (HDLC) Flex® Reagent Cartridge	K3048A	10464340	20062BA	2021-03-02	2020-03-26

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the product listed in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the potential for erroneous results due to discolored reagent observed in some wells 5 and 6 of Dimension Vista® High Density Lipoprotein Cholesterol (HDLC) Flex® reagent cartridges lot 20062BA. Most erroneous HDLC results are accompanied by a Dimension Vista System “Abnormal Reaction” [E145] comment however, there have been reports of erroneous HDLC results generated without the presence of an Abnormal Reaction comment.

The frequency of this issue is very low and is not observed on every Dimension Vista HDLC Flex reagent cartridge or well within lot 20062BA.

If an HDLC Quality Control (QC) or patient result is obtained with an “Abnormal Reaction” [E145] comment, the Dimension Vista Operators Guide, states the results should not be reported. If an HDLC QC or patient result is obtained without an “Abnormal Reaction” [E145]: comment, a falsely depressed or elevated result ranging from -200% to 128% may be observed.

Risk to Health

When this issue occurs, the potential exists for misinterpretation of HDLC, which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical history and presentation and by laboratory testing for other lipid parameters such as low-density lipoprotein cholesterol (LDLC) and/or triglycerides. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

For the product listed in Table 1, please perform the following steps:

- Please review this letter with your Medical Director.
- Discontinue use of and discard the lot listed in Table 1.
- Review your inventory of this lot to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the Authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days to Siemens Healthineers for reporting to the Authorities.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers Technical Support Representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers Technical Support Representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

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