



Urgent Field Safety Notice

DC-19-02.A.OUS

Siemens Healthcare Diagnostics Inc.

July 2019

Dimension® clinical chemistry system

Ferritin (FERR) Reagent - Negative Bias with Lot EA9227

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

Table 1. Dimension Ferritin (FERR)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	1 st Distribution Date (YYYY-MM-DD)
Ferritin (FERR)	RF440	10444946	EA9227	2019-08-15	2018-09-11

Reason for Notice

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

Siemens Healthcare Diagnostics has confirmed that the Dimension® Ferritin (FERR) Flex® reagent lot listed in Table 1 may exhibit a negative bias during the open well stability time period. Siemens has determined that FERR values can potentially decrease by -50% at a concentration of 22 ng/mL [$\mu\text{g/L}$] and -48% at a concentration of 285 ng/mL [$\mu\text{g/L}$] after a 10 day open well period. Siemens has also determined that FERR values can potentially decrease by approximately -15% after a 3 day open well period. Quality control and patient samples are affected similarly.

Risk to Health

When the issue occurs, the potential exists for misinterpretation of ferritin levels. Clinical impact would be mitigated by correlation to clinical history and symptomology and by interpretation with other laboratory diagnostic testing such as other markers of iron status and/or hematologic studies. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard the Dimension Ferritin Reagent lot listed in Table 1.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Review your inventory of this product to determine your laboratory's replacement needs and to provide information to Siemens 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 Customer Care Center or your local Siemens 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 Customer Care Center or your local Siemens technical support representative.

Dimension and Flex are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension Ferritin (FERR) Negative Bias with Lot EA9227

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice DC-19-02.A.OUS dated July 2019 regarding Ferritin (FERR) Reagent - Negative Bias with Lot EA9227. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
FERR, RF440, SMN# 10444946, lot EA9227	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form to your local Siemens Technical Support Representative. .

If you have any questions, contact your local Siemens Technical Support Representative.