

Urgent Field Safety Notice

12-65

December 2012

Dimension[®] Clinical Chemistry System

Total Iron Binding Capacity (DF84 IBCT)

Change in Assay Range, Analytical Measurement Range (AMR) and Analytical Sensitivity

Our records indicate that you have received Dimension[®] Total Iron Binding Capacity (IBCT, Catalog # DF84) Flex[®] reagent cartridges.

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)
Total Iron Binding Capacity	IBCT	DF84	10444944

The following Dimension IBCT (DF84) lots are currently in-date:

Lot #	Expiration Date		Lot #	Expiration Date
BA3016	2013-01-16		BB3184	2013-07-03
EC3045	2013-02-14		EC3219	2013-08-07
EA3073	2013-03-14		EC3220	2013-08-08
DC3102	2013-04-12		GA3248	2013-09-05
FC3122	2013-05-02		FB3290	2013-10-17
EA3157	2013-06-06			

Reason for Voluntary Field Action

Through monitoring of method performance Siemens Healthcare Diagnostics has determined the analytical sensitivity claim of 6 µg/dL (1.1 µmol/L) in the Instructions for Use (IFU) is no longer valid. Siemens is conducting a voluntary corrective action for Dimension Total Iron Binding Capacity (IBCT) to modify the analytical sensitivity claim to 36 µg/dL (6.44 µmol/L).

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101
Newark, DE 19714-6101

800-441-9250
www.siemens.com/diagnostics

Page 1 of 3

Risk to Health

Risk to health is absent. This issue has no impact on clinical interpretation of IBCT results since patient values are approximately 7-fold higher than the revised analytical sensitivity claim. Therefore, no look back is mandated as the clinical utility of the IBCT assay remains intact.

Actions to be taken by Customer

Effective immediately, the analytical sensitivity claim for IBCT has been modified from 6 µg/dL (1.1 µmol/L) to 36 µg/dL (6.44 µmol/L). This change impacts the low end of the assay range, which should be modified in the method parameters in your Dimension® analyzer. Additionally, results less than 36 µg/dL (6.44 µmol/L) should be reported as “<36 µg/dL” (6.44 µmol/L).

The IBCT method settings for the serum assay range can be edited by performing the following steps:

- From the Operating Menu, press F6: SYSTEM CONFIG > F1: METHOD PARAM
- At the prompt, type your password and press ENTER
- Select the IBCT assay by pressing the assigned key
- Move the cursor to enter the modified assay range parameters by changing the lower limit from 0 µg/dL to 36 µg/dL (6.44 µmol/L). The upper limit remains unchanged.
- Press F5: STORE & PRINT
- Press Exit to return to the Operating Menu

Please make this adjustment to middleware products or Laboratory Information Systems (LIS) as appropriate for your laboratory.

Beginning with Flex® reagent lot GA3334, the Dimension® IBCT IFU will contain the new analytical sensitivity, lower limit of the assay range and lower limit of Analytical Measurements Range (AMR). Lot GA3334 will be available for distribution by December 2012

Please complete the attached form and fax it to (302) 631-8467 to indicate that you have received this information.

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 has caused. If you have any questions, please contact your Siemens Technical Solutions Center or your local Siemens technical support representative.

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension® Clinical Chemistry System

Total Iron Binding Capacity (DF84 IBCT) Change in Assay Range, Analytical Measurement Range (AMR) and Analytical Sensitivity

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated December 2012 regarding Dimension® Total Iron Binding Capacity (IBCT, Catalog #DF84) Flex® reagent cartridges, letter # 12-65.

Please respond to the question below and Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. I have read and understood the Urgent Medical Device Correction instructions provided in the December 2012 letter # 12-65 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
(302) 631-8467**