SIEMENS

Dimension® Clinical Chemistry Systems

Dimension® TACR Assay (DF107/DC107)

Low Bias on Patient Results

Our records indicate that you have received the following products:

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Tacrolimus	**TACR**	**DF107**	**10444938**	**BB4087**
		DC107	**10445012**	**3BD029**

Reason for Field Action

Siemens Healthcare has confirmed customer complaints of low patient sample recovery with Dimension® TACR Flex reagent cartridge lot BB4087 and its linked calibrator lot 3BD029. Quality Control (QC) materials have not exhibited recovery outside of the expected range.

Internal complaint testing versus our reference LC/MS method confirmed an average bias of -1.6 ng/mL [-2.1 nmol/L], across the assay range. Individual patients, particularly samples with lower TACR values (< 5 ng/mL [6.5 nmol/L]), may show more bias due to the typical precision of each methodology. We observed some low patient LCMS tacrolimus samples (< 5 ng/mL [6.5 nmol/L]) that generated results below the Dimension Tacrolimus assay range (< 1.2 ng/mL [1.6 nmol/L]).

In April 2013, Siemens communicated that we would be implementing linking of specific Dimension TACR calibrator lots with specific Dimension TACR Flex lots in mailing number 13-24, Follow Up Information for Urgent Medical Device Recall. TACR reagent lot BB4087 and calibrator lot 3BD029 were the first lots to use this process. We are investigating and will implement additional controls to ensure acceptable bias prior to any future shipments.

Risk to Health

Falsely low Tacrolimus results across the assay range may lead to alterations in dosing. Tacrolimus is typically dosed to meet the minimum required concentration to prevent organ toxicity while maintaining graft acceptance and avoidance of graft versus host disease.

Look Back Statement

Siemens Healthcare Diagnostics Inc.

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

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

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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 for tests conducted on lot BB4087/3BD029.

Actions to be Taken by Customer

Customers should immediately discard any remaining Dimension® TACR Flex® lot BB4087 and calibrator lot 3BD029. There is no replacement product available at this time. Please complete the attached Field Correction Effectiveness Check to receive credit for discarded product. Siemens is working diligently to restore supply as quickly as possible.

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.

Dimension® is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Dimension TACR Assay (DF107/DC107) Low Bias on Patient Results

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated July 2013 regarding Dimension TACR Assay low bias on patient results. 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. I have read and understood the Urgent Field Safety Notice instructions provided in the July 2013 letter. Yes   No

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

Name of person completing questionnaire:

Assay and Lot	Quantity Disposed
DF107 TACR BB4087	
DC107 TACR calibrator 3BD029	

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO YOUR LOCAL SIEMENS TECHNICAL
SUPPORT REPRESENTATIVE