SIEMENS

Urgent Field Safety Notification

12-05B

March 2012

Dimension Vista® Systems

Correction/New Information

Vista Magnesium Flex® reagent cartridge K3057 – Bias

Lots 11263AC, 11286AB, 11306BA, 11332AB, 11332AC, 12010AB

Our records indicate that you may have received the Urgent Field Safety Notice from February 2012 (12-05) stating:

> "Our records indicate that your laboratory has the Dimension Vista® System and runs the Vista Magnesium (MG) method. Siemens has confirmed a negative shift of approximately 0.2mg/dL [0.08 mmol/L] in patient and QC when using Vista Magnesium lot 11263AC, 11286AB, 11306BA, 11332AB, 11332AC and/or 12010AB."

At this time Siemens Healthcare Diagnostics is conducting a voluntary recall for Dimension Vista® MG Flex® reagent cartridge lots 11263AC, 11286AB, 11306BA, 11332AB, 11332AC and 12010AB.

Please follow the steps below:

1. **Immediately discontinue the use of the correlation factor** as previously stated in the Urgent Field Safety Notification dated February 2012.
2. For your convenience, 2 cartons of a new lot of Vista MG are being shipped to you at no charge.
3. **While you are awaiting receipt of this new lot of reagent**:
   - Magnesium measurements should be performed using an alternate methodology; if such methodology is readily accessible.
   - **For laboratories without ready access to an alternate methodology for magnesium measurement and using lots 11263AC, 11286AB, 11306BA, 11332AB, 11332AC or 12010AB.:**
     - DO NOT use the correlation factor to correct magnesium results.
     - Instructions for removal of the correlation factor are attached.
     - All results outside the reference range should be submitted for confirmatory testing by a different methodology
     - All concerned clinicians should be fully notified of the magnesium bias test results.

Contact your Siemens Customer Service Center to report your no-charge replacement needs at 888-588-3916.

If you have technical questions or concerns, please contact the Siemens Technical Solutions Center at 800-441-9250 for further assistance. Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

Siemens Healthcare Diagnostics

P.O Box 6101
Newark, DE 19714-6101

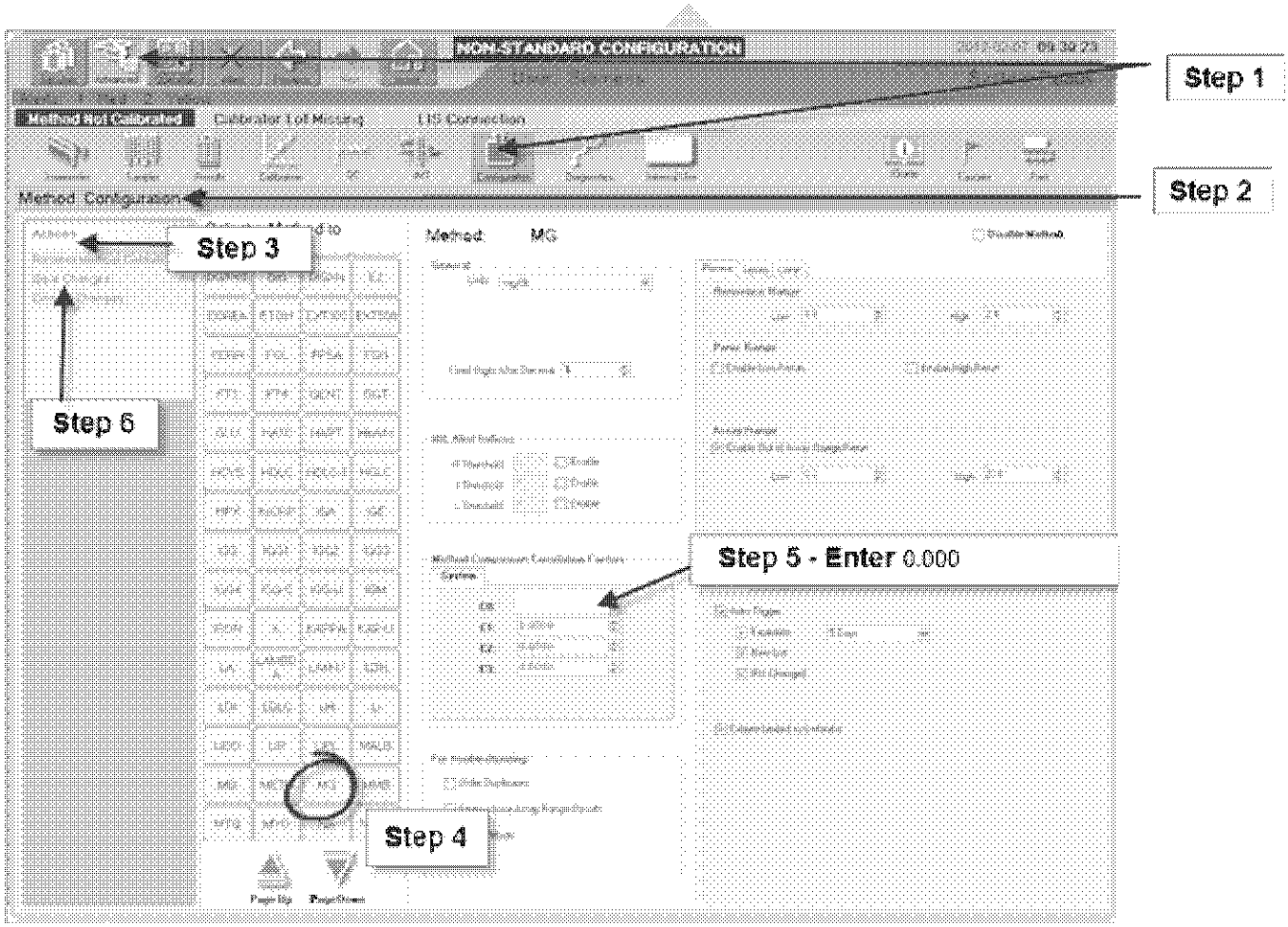
800-441-9250
www.siemens.com/diagnostics

Attachment A:

Procedure for removing the Correlation Factor for MG

To remove the correlation factor, use the Method Configuration screen:

1. Press Advanced > Configuration.
2. Select Method Configuration from the menu.
3. Select Modify Method Configuration from the Actions menu.
4. Select the MG method from the list.
5. Enter 0.00 in the C0: field.
6. Select Save Changes from the Actions menu.



FIELD CORRECTION EFFECTIVENESS CHECK

Correction/New Information

Vista Magnesium Flex® reagent cartridge K3057 – Bias

Lots 11263AC, 11286AB, 11306BA, 11332AB, 11332AC, 12010AB

Dear Customer:

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice **Correction/New Information** dated March 2012 regarding Dimension Vista® Magnesium K3057 lots 11263AB, 11286AB, 11306BA, 11332AC, 12010AB.

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. Did we effectively communicate all necessary information? Yes ☐ No ☐

   If you selected No, please explain below.

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

3. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number(s):

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT 302-631-8467.