SIEMENS

Urgent Medical Device Correction

13-30

May 2013

Dimension Vista® Systems

PREALB Flex® reagent cartridge (K7064 SMN 10445906)
Calibration Failure due to Percent Deviation >5%

Our records indicate that your laboratory uses **PREALB Flex® reagent cartridges (Catalog # K7064, SMN 10445906) on the Dimension Vista® System**.

Affected PREALB Flex® reagent cartridges (Catalog # K7064 SMN 10445906):12258MA, 12306MA, 12339MA, 13030MA, 13037MA and future lots until further notice.

Reason for Voluntary Field Action
Siemens Healthcare Diagnostics has confirmed that PREALB Flex® reagent cartridge lots listed above are exhibiting an increased rate of failed calibrations because the difference between the measured and expected values at Calibration Level 6 exceeds (Acceptance Criteria Percent Deviation < 5%).

Risk to Health
PREALB lots which fail calibration are not able to generate patient results. If you obtained an acceptable calibration, patient results are acceptable.

Actions to be taken
If you experience a failed calibration you may take the following steps to continue running PREALB:

- Review the calibration details under the Analyte Results section, view the replicates to make sure that level 6 is the only reason for the failed calibration curve (each of the calibration points bias for level 1 to level 5 have to be below 5% Percent Deviation)
- If level 6 is the only calibrator level that has a Percent Deviation greater than 5, the calibration curve can be manually accepted and controls processed.
- Assay range for PREALB should be lowered to 40 mg/dL. This will force the Vista to perform auto-dilutions on any result >40mg/dL

The attached procedures provide instructions to Review Calibration and Change Assay Range.

The root cause of the issue is actively being investigated and Siemens will notify customers when they can resume normal calibration procedures.

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PREALB Calibration Failure due to Percent Deviation >5%

The contents of this letter should be discussed with the Medical Director.

Please complete the attached form and fax back to 1-302-631-8467 to indicate that you have received this information. Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation is causing in your laboratory.

Please refer to Section 6 of the Dimension Vista System Operator's Guide pages 6-21 to 6-27 for instructions on Reviewing Calibration.

Review a Calibration

A calibration alert message indicates when a calibration is complete and awaiting review.

1. Press the **Advanced** icon, then the **Calibration** icon. Select **Calibration by Lot** from the menu.

2. Select the appropriate PREALB reagent lot.

3. Review the pending calibration data.

Note: Specifically review the Analyte Results section for all 6 calibrator levels and determine which levels Bias failed the Percent Deviation > $|5|$ % criteria. If only level 6 has failed the Bias criteria then manually accept the calibration. If any other calibrator level fails then repeat calibration, with continued failed calibrations contact your local Siemens Representative.

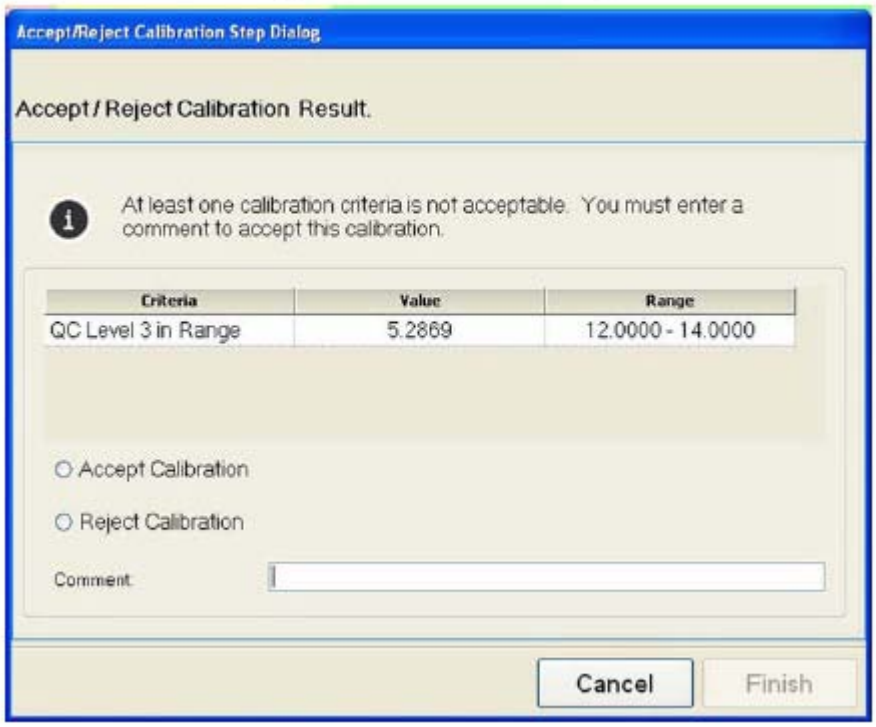
4. Your choices for responding are described in Table 6-2. Select the appropriate choice from the **Actions** menu.

Table 6-2: Calibration Actions

Action	*Effect*
Show Details	Display calibration data and acceptance criteria, if failed review information.
Print Report	Prints a hardcopy report.
Accept Calibration	Store the calibration in the system.
Reject Calibration	Discard calibration data and start over.
Compare coefficients	Compare current and previous coefficients for the method.
Calibration Comments	Enter operator comments before calibration is accepted.

Note: Once the accept/reject calibration icon is selected the dialog box will open, shown in Figure 6-15. Select the Accept Calibration radio icon and enter the following comment, **"This calibration curve to be utilized with Siemens recommended work around".** Retain a copy of this letter with the calibration printed report for your laboratory records.

Figure 6-15: Calibration Error Dialog



5. Press **Finish** and retain the printed copy for laboratory records.

To change the Assay Range please refer to Section 9 Advanced Functions Method Configuration pages 9-25

Method Configuration

Note: Changes to method configurations made from either screen are applied to each side of a Dimension Vista® 3000T System. The left instrument is the primary data source. Changes made on the right in un-twinned mode will be overwritten by the left instrument when twinned.

Use this procedure to change the assay range for PREALB method.

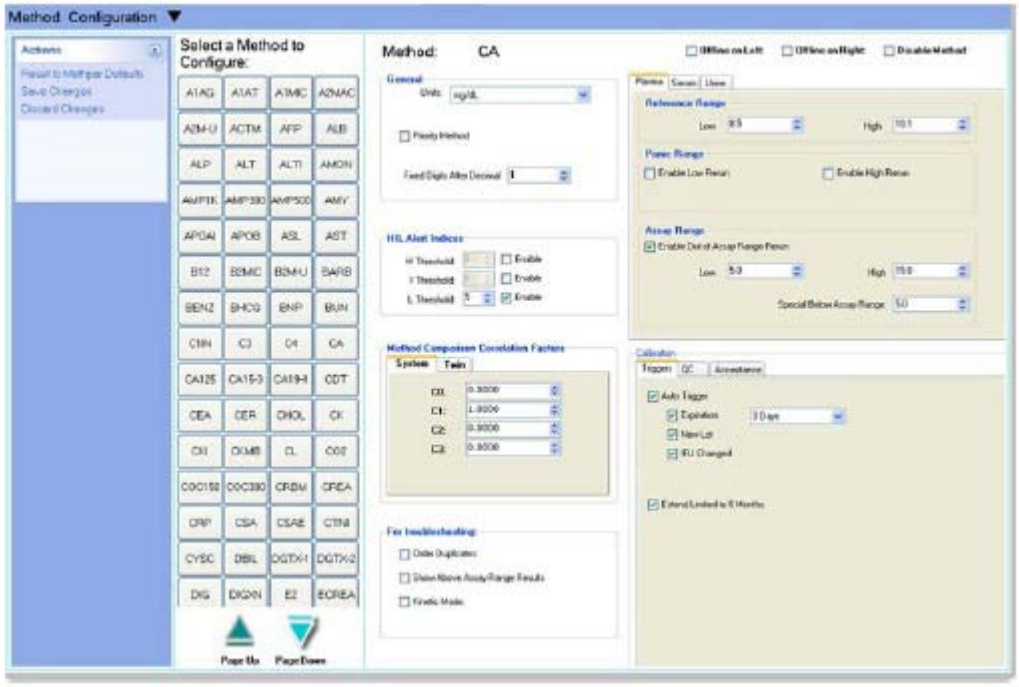
To change this information, display the Method Configuration screen:

1. Press the **Advanced** icon, then the **Configuration** icon.

2. Select **Method Configuration** from the menu.

3. Select **Modify Method Configuration** from the Actions menu.

Figure 9-12: Dimension Vista® System Method Configuration Screen



4. Select **PREALB** method from the list.

5. On the right side of the screen, select the appropriate fluid type. Change default high value in the Assay range field **(the high value should be changed from 60 to 40 mg/dL)**. Be sure to update all fluid types relevant to the method.

6. Select **Save Changes** from the Actions menu.

Note: Once an acceptable lot of PREALB is available, the assay range will need to be manually adjusted back to 60mg/dl for the appropriate fluid types. This adjustment can be performed following the above Method Configuration steps.

FIELD CORRECTION EFFECTIVENESS CHECK

Vista PREALB Flex reagent cartridge (K7064 SMN 10445096)

Potential for Calibration Failure due to Acceptance Criteria Percent Deviation >| 5 | % multiple lots

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Medical Device Correction dated May 2013 regarding Dimension Vista PREALB (K7064). 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 you read and understand the contents of this Urgent Medical Device Correction?	Yes ☐	No ☐
Name of person completing questionnaire:		

Title:

Institution: Instrument Serial Number(s):

Street:

City: State: Phone:

Customer Sold to #: Customer Ship to #

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