SIEMENS

Urgent Medical Device Correction
Updated Information

VC-16-01A.B.US

June 3, 2016

Dimension Vista® System

Blood Urea Nitrogen (BUN) Flex® Reagent Cartridge Well-to-Well Accuracy Shifts

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

Dimension Vista® BUN

Table 1.

Assay	Catalog Number	Siemens Material Number (SMN)	Dimension Vista Flex Lot Number	Expiration Date	1st Distribution Date
BUN	K1021	10445159	16004AB	2017-01-03	2016-01-11
			16033AC	2017-02-01	2016-02-18
			16034AA	2017-02-02	2016-02-17
			16048AA	2017-02-16	2016-03-02
			16055AA	2017-02-23	2016-03-15
			16055AB	2017-02-23	2016-03-15
			16062AA	2017-03-02	2016-04-21
			16062AB	2017-03-02	2016-04-21

And ALL future Vista BUN Flex reagent cartridges lots until further notice

Reason for Correction

In February 2016, Siemens Healthcare Diagnostics issued field corrective action letter VC-16-01.B.US, informing customers of well-to-well accuracy shifts for specific lots of Dimension Vista BUN causing inaccurate patient and/or Quality Control results. At that time, preliminary investigation demonstrated loss of enzymatic activity of the GLDH reagent wells made from a specific mold/cavity.

We have since confirmed complaints on additional Vista BUN Flex cartridge lots, suggesting an additional cause of reduced GLDH activity.

Action: See page 6.

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Siemens is actively investigating the root cause of the issue and working to implement a solution. This issue affects all future lots of reagent until a solution is implemented. Not all flexes or wells are impacted. The issue is of low frequency, affecting approximately 1 out of 100 wells

- If calibration is performed using an unaffected well and samples are subsequently tested using an affected well, BUN results may be falsely depressed by up to approximately 50% across the concentration range of 11 – 784 mg/dL [4 – 280 mmol/L]. If QC is run using an affected reagent well in this scenario, QC *will* detect the issue.
- If calibration is performed using an affected well and samples are subsequently tested using an unaffected well, BUN results may be falsely elevated by up to approximately 64% across the concentration range of 15 – 740 mg/dL [5 – 264 mmol/L]. QC *may or may not* detect the issue.

  When calibration is performed using an affected well and:
  - If QC is immediately tested afterwards from the same affected well set, the recovery will appear acceptable as the calibration and QC will be affected similarly.
  - If QC is run in using an unaffected reagent well, QC will detect this issue.

Based on this new information, Dimension Vista BUN customers are advised to follow the instructions in this letter under the section, "Actions to be Taken by the Customer" to manage BUN testing.

Risk to Health

With the exception of Kt/V calculations, BUN is generally not used in isolation for diagnosis but is correlated with creatinine, clinical presentation, and other testing to assess renal function. The risk to health as a result of this issue is remote and limited to falsely depressed BUN results. When used as part of the BUN to creatinine ratio for investigations of diminished renal perfusion, a falsely depressed BUN may potentially over-estimate kidney function and may lead to a delay in the follow-up for kidney disease. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Siemens preliminary investigation determined cavity B4 is impacted. In our efforts to work with customers to ensure the integrity of BUN results while further internal investigation is being conducted the following actions are recommended. The actions below will aid in the detection of affected reagent well sets. The use of the combined **Actions #1, #2 and #3 are strongly recommended to minimize the usage of affected reagent wells.**

- Action #1: Inspect the Vista BUN flex mold/cavity (Figure 1) and discard flexes with cavity B4.
- Action #2: Turn off BUN auto-calibration
- Action #3: Configure multiple BUN QC panel shift times

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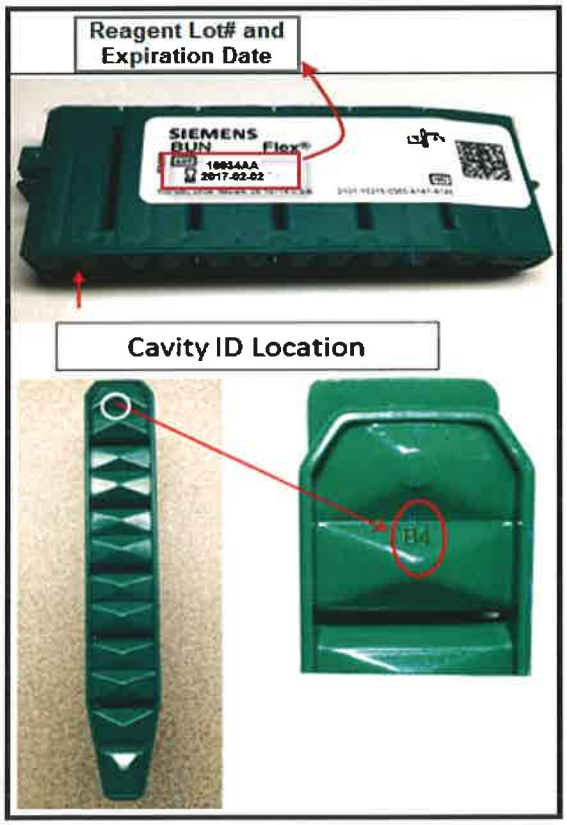
Action #1: Inspect the Vista BUN flex mold/cavity and discard flexes with cavity B4

- Each Vista BUN Flex reagent cartridge has a mold/cavity identification on the bottom.
- Inspect the bottom of each Vista BUN Flex reagent cartridge of the affected lots listed in Table 1.
- Identify the cavity numbers as shown in Figure 1
- Siemens recommends removing the individually wrapped flexes of the impacted Vista BUN lots only as needed rather than all at once.
- Discard all Vista BUN Flex reagent cartridges with cavity number B4. Vista BUN Flex reagent cartridges that do not have cavity number B4 may continue to be used. The remaining reagent cartridges may then be loaded onboard the instrument for use however, actions #2 and #3 are strongly recommended.

Figure 1 Cavity Identification



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Action #2: Turn off BUN auto-calibration

By disabling the auto trigger function of the BUN method and running QC as described below, you will minimize the likelihood of using an affected well. Assess QC recovery in order to verify the calibration. If QC is within acceptable range as outlined below, then patient sample processing can proceed.
Note: In very rare circumstances (1/100 chance) if calibrating on an affected well QC will be in range however moving to an unaffected well would cause a shift in all test results.

Navigate to **Advanced > Configuration > Method Configuration**, select BUN from the test menu and press **Modify Method Configuration.** Uncheck the box for Auto Trigger located under the Calibration Triggers tab at the bottom right of the screen and then from the Actions menu **Save Changes**.

If recalibrating an in-use reagent lot:

a- Access the Reagent Inventory screen.

b- Unload any BUN Flex cartridges with a test count of less than (<) 420.

c- If there are no BUN Flex cartridges remaining in inventory with a test count of 420 then load a BUN Flex cartridge.

d- Order and assess BUN QC **prior** to recalibrating the reagent lot.

- If these QC results are acceptable, you may recalibrate and follow the instructions of Action #3 below.
- If the QC is out of range, unload and reload the Flex cartridge, which forces the system to transition to a fresh well set prior to repeating QC.

Please contact the Siemens Customer Care Center or your local Siemens technical support representative if further QC recovery issues are still observed.

If calibrating a new reagent lot:

a- If calibrating a new reagent lot, order the calibration and QC. Since each well has 70 tests, both calibration and QC will process from one well.

b- Unload and reload this Flex cartridge and process QC again. Processing in this way forces the system to use a fresh well set for the second set of QC.

- If QC is within range, you may continue to process the BUN assay. Please also follow the instructions of Action #3 below.
- If QC is out of range for this second series of QC, unload and reload the Flex cartridge again before repeating the QC.

Please contact the Siemens Customer Care Center or your local Siemens technical support representative if further QC recovery issues are still observed.

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Action #3: Configure multiple BUN QC panel shift times

This action is recommended in order to increase the frequency of BUN QC testing. Processing QC at increased frequency will further assist in the detection of affected reagent well sets. **Please follow your normal laboratory practices if QC is out of range.**

Dimension Vista® software permits configuration of six auto-scheduled QC shift times. It is recommended that each laboratory configure multiple QC shifts for automatic BUN QC processing to occur throughout the workday. To minimize the amount of control material used, the operator may choose to create a new panel containing only the BUN method and a specific control level of their choosing.

- In order to take full advantage of this feature, the customer should set the shift intervals with frequent QC runs planned during peak BUN test usage periods.
- Low periods of BUN usage, such as scheduled down times (e.g. Off-Peak Activities), do not require additional QC runs.

The Dimension Vista® System Operator's Guide 2012/01 Chapter 6 will assist with creating and scheduling a BUN QC panel. The Operator's Guide is available on Siemens Document Library for reference.

a- Define QC Shift Times

b- QC Panels

c- Set Schedule for a QC Panel

As an alternative, or supplementary to the above actions, the operator can manually order Vista BUN QC every 50 samples, which will ensure QC is performed on every reagent well set.
Note: Customer must manually order QC for every 50 samples

- If QC is within range, proceed with patient sample processing.
- If QC is out of range, repeat any patient samples that were processed during the times period between the failed QC and prior acceptable QC results.

Please review this letter with your Medical Director.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Discard all Vista BUN Flex reagent cartridges with cavity number B4 (as described on Figure 1)

Review your inventory to determine your laboratory's credit needs and provide the information to Siemens for reporting to the authorities.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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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.

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Children's Action: June 8, 2014

1) Inventory checked. Lots 16033AC and 16055AB currently on board Vista Mpls. Calibration/QC reviewed = OK Flex not ID'd with B4 well designation.

2) Increased QC frequency to 4x daily @ 0900, 1400, 2200, and 0445 per notice.

3) Auto-calibration turned off. Education on manual trigger calibration is posted and will occur individually

4) Urgent Device Correction Notice VC-16-01A.B.US is faxed to Siemens, posted near analyer, loaded to MTS for required staff review.

5) Wasted flex inventory credit request posted @ Vista

6) Magnifying glass obtained to read tiny well code.

7) Reviewed with Medical Director Tim Casey 6/7/16

Linda Jacoby

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FIELD CORRECTION EFFECTIVENESS CHECK / CREDIT FORM

Dimension Vista® System

Blood Urea Nitrogen BUN Well-to-Well accuracy shifts

Lots 16004AB, 16033AC, 16034AA, 16048AA, 16055AA, 16055AB, 16062AA, 16062AB and ALL future lots until further notice

VC-16-01A.B.US

Complete and return the Field Correction Effectiveness Check Form within 30 days

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UMDC VC-16-01A.B.US dated June 3, 2016 regarding Dimension Vista® Blood Urea Nitrogen (BUN) Flex® Reagent Cartridge Well-to-Well Accuracy Shifts.

Please response to the questions and indicate the appropriate answer. Fax this completed effectiveness check form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the UMDC instructions provided in this letter. Yes ☒ No ☐
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes ☒ No ☐

If the answer to the question#2 above is yes, please use the table below to document the product credit quantities

For credit request:

Remove the individually wrapped flexes of the impacted Vista BUN lots only as needed rather than all at once. Multiple forms can be completed for credit request as the laboratories use the product inventory.

Product Description Lot #	Quantity of Affected flexes in your inventory that have been discarded	Total Credit Quantity of flexes Required per lot
16004AB		
✓ 16033AC		
16034AA		
16048AA		
16055AA		
✓ 16055AB		
16062AA		
16062AB		

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