

Laboratories at Adventist Healthcare Washington Adventist Hospital, Shady Grove Medical Center and Germantown Emergency Center


Date: 6/9/2016

LABORATORY ALERT

Subject:

BUN Flex Reagent Cartridge Well-to-Well Accuracy Shifts

The Laboratory is informing you of the following:

Reagent Name:	BUN Reagent Flex current and all future lot numbers
Issue identified:	Siemens issued letter informing customers of well-to-well accuracy shifts for specific lots of Dimension Vista BUN causing inaccurate patient and/or Quality Control results. The investigation demonstrated loss of enzymatic activity of the GLDH reagent wells made from a specific mold/cavity.
Action to Take:	<ol style="list-style-type: none"> 1. Identify the cavity numbers as shown in Figure 1 below. 2. Siemens recommends removing individually wrapped flexes of the BUN reagent as needed rather than all at once. 3. Discard all Vista BUN flex reagent cartridges with cavity number B4.
Figure 1:	 <p>The figure shows a Siemens BUN Flex reagent cartridge. The top part of the image shows the cartridge with a label that includes 'Reagent Lot# and Expiration Date'. The bottom part of the image shows the cartridge with a label that includes 'Cavity ID Location'. A red circle highlights the cavity ID location on the cartridge.</p>
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