

August 24, 2006

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**Field Correction**  
**Dimension<sup>®</sup> clinical chemistry system**  
**Ethyl Alcohol (ALC) Flex<sup>®</sup> reagent cartridge (DF18)**

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Dear Dade Behring Customer:

Our records indicate that your facility uses the Ethyl Alcohol (ALC) Flex<sup>®</sup> reagent cartridge (Catalog Number DF18) on the Dimension<sup>®</sup> clinical chemistry system.

Dade Behring has received customer inquiries regarding the AL2-08 sample from the College of American Pathologist (CAP) 2006 Serum Alcohol Survey AL2-B. This ethanol-free sample, containing 51.9 mg/dL isopropanol and 23.5 mg/dL acetone, has an acceptable alcohol result range of 0-9 mg/dL. Some customers reported ALC results outside of this range. We are communicating with CAP regarding the Survey results.

**Dade Behring has confirmed that isopropanol may falsely elevate ALC results on the Dimension<sup>®</sup> system.** The magnitude of the inaccuracy is dependent on the amount of isopropanol in the sample. Testing by Dade Behring has shown the following:

At an ethyl alcohol concentration of 100 mg/dL [22 mmol/L], isopropyl alcohol of 51 mg/dL [8.5 mmol/L] increases the ALC result by 11 mg/dL [2.4 mmol/L]; isopropyl alcohol of 254 mg/dL [42.3 mmol/L] increases the ALC result by 44 mg/dL [9.6 mmol/L].

In an ethyl alcohol-free sample, isopropyl alcohol of 51 mg/dL [8.5 mmol/L] gives an ALC result of 13 mg/dL [2.8 mmol/L]; isopropyl alcohol of 254 mg/dL [42.3 mmol/L] gives an ALC result of 63 mg/dL [13.7 mmol/L].

Preliminary investigation indicates the interference from isopropanol is related to the alcohol dehydrogenase (ADH) reagent, and we are investigating root cause and potential solutions. No interference from acetone at concentrations up to 100 mg/dL was detected.

The ALC package insert has been updated to reflect interference from isopropanol. We recommend that you consider the impact of this update on how you use the ALC method in your laboratory, including any use of results for law enforcement purposes.

If you have any questions regarding this information, please contact the Dade Behring Technical Assistance Center at (800) 441-9250. Please forward this notification to anyone to whom you have distributed this product.

Sincerely,

Sr. Product Manager  
Dade Behring Inc.