



TECHNICAL SERVICE BULLETIN 2010-001

Date Issued: May 24, 2010

Product:

VALIDATE [®] Product	REF
Chem 4bc	104bc
GC 3bc	1300bc
UC 5bc	705bc

Subject: Introduction of Beckman-Coulter[®] AMY7 reagent (Ref A71607)

Explanation:

The VALIDATE[®] products listed above are manufactured to the current Beckman Coulter Amylase (AMY) reagent (Ref 442775). Typical Values in the VALIDATE[®] package inserts reflect typical recoveries when using the AMY reagent with an Analytical Range of 5 – 800 U/L.

Beckman Coulter is introducing a new Amylase (AMY7) reagent (Ref A71607) with an Analytical Range of 5 – 1200 U/L. Due to enzyme substrate method differences between the AMY and AMY7 reagents, AMY, recoveries will differ.

Necessary Actions:

Chem 4bc and GC 3bc: Labs using the VALIDATE[®] Chem 4bc and GC 3bc kits with the AMY7 reagent will need to perform a dilution to recover a value near the upper limit of the AMY7 method as Level 4 and Level 5 typically recover above the reportable range. The suggested dilution is **3 Parts of Level 3** and **1 part of Level 4**. For AMY7 Amylase only, the lab should run Levels 1, 2, and 3, plus the dilution. If reporting results to Maine Standards Company Data Reduction Department, please use the attached **Dilution Data Submission Form** to ensure that your data is processed properly.

UC 5bc: Labs using VALIDATE[®] UC 5bc with the AMY7 reagent will recover 5 levels within the reportable range of the method. Labs should compare the results to their acceptance criteria for Amylase to evaluate if the range coverage is adequate.

Peer Group: The AMY7 method is different from the AMY method and will require labs to submit updated Peer Group Method information to Maine Standards Company. Labs that have transitioned to the AMY7 reagent, or will be transitioning prior to their next calibration verification / linearity testing event, should refer to the method codes below and use the attached **Method Update Form** to submit the change(s) to Maine Standards Company Data Reduction. This will ensure that results are grouped with and compared to other Beckman users with the AMY7 reagent.

Product	AMY7 Method ID
Chem 4bc	AMY_03
GC 3bc	AMY_03
UC 5bc	AMY_03

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