



TECHNICAL SERVICE BULLETIN 2010-002

Date Issued: June 15, 2010

Product:

VALIDATE[®] Product	REF
GC 3bcc	1300bcc
UC 5bcc	705bcc

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

Explanation: Maine Standards Company is pleased to introduce VALIDATE[®] test kits designed for labs performing calibration verification / linearity testing for Amylase using the Beckman AMY7 reagent.

Information below is from our Beckman Pricelists and shows the expected ranges the products will cover.

GC 3: Order No. 1300bcc, Storage: -10 to -25°C \$153.00		
Five Levels plus a base matrix, 3 mL per level		
Analyte	Range*	
ALP (Alkaline Phosphatase)	5 - 1,000	U/L
ALT (Alanine Aminotransferase)	5 - 400	U/L
AMY (Amylase)	5 - 1,200	U/L
AST (Aspartate Aminotransferase)	5 - 400	U/L
CK (Creatine Kinase)	5 - 1,200	U/L
GGT (Gamma Glutamyltransferase)	5 - 750	U/L
LD (Lactate Dehydrogenase)	5 - 750	U/L
LIP (Lipase)	10 - 200	U/L

UC 5: Order No. 705bcc**, Storage: -10 to -20°C \$124.00		
Five Levels and a 'zero', 3 mL per level		
Analyte	Range*	
µALB (Micro Albumin)	2 - 300	mg/L
AMY (Amylase)**	5 - 1200	U/L

Test kits also contain PAMY as part of the AMY component

Necessary Actions: Labs using the Beckman AMY7 (Ref A71607) reagent should perform their calibration verification / linearity testing using VALIDATE[®] GC 3bcc for serum amylase and UC 5bcc for urine amylase.

Labs using the AMY7 and performing calibration verification / linearity testing with Chem 4bc, GC 3bc, or UC 5bc should refer to Maine Standards Company TSB 2010-001 for necessary actions.

Labs using the Beckman AMY reagent (Ref 442775) should perform their calibration verification / linearity testing using VALIDATE[®] GC 3bc for serum amylase and UC 5bc for urine amylase.

Peer Group: 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
GC 3bcc	AMY_03
UC 5bcc	AMY_03

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