

TECHNICAL SERVICE BULLETIN

25-022



Date Issued: Dec 16, 2025

Subject: VALIDATE[®] CM3 (409ro) LP(a) Method Update – Lot 10799050 or higher

Explanation:

We are pleased to announce that VALIDATE[®] CM3 (409ro), for Roche cobas[®], now targeting the Tina-Quant Lipoprotein (a) Gen.2 Molarity assay, offers Homocysteine (HCY) and Lipoprotein (a) (Lp(a)) for easy, fast, efficient calibration verification and linearity testing.

When combined with Creatine Kinase-MB (CK-MB) and Myoglobin (MYO) in VALIDATE[®] CM1 (401ro), High Sensitivity C-Reactive Protein (hs-CRP), N-Terminal Pro hormone Brain Natriuretic Peptide (NT-proBNP) and Troponin I (Tnl) in VALIDATE[®] CM2 (402re) and High Sensitivity Troponin T (hsTnT) in VALIDATE[®] hsTroponin (405ro) laboratories can challenge the reportable range of Roche cobas[®] cardiac related assays.

Please see the chart below for the typical coverage of the updated VALIDATE[®] CM3 (409ro).

Analyte	Units	Analyzer Range	VALIDATE Range	Percent Coverage
HCY	μmol/L	3 – 50	6 – 50	6% – 100%
Lp(a)	nmol/L	7 – 240	14 – 238	3% – 99%

Please contact LGC Maine Standards Technical Support if you have any questions at 1-800-377-9684.

Contact Information: Technical Support Department
LGC Clinical Diagnostics, Inc.
221 US Route 1
Cumberland Foreside, ME 04110
Phone: 1-800-377-9684
+1-207-892-1300
Fax: +1-207-892-2266
E-mail: msc.techsupport@LGCGroup.com