

TECHNICAL SERVICE BULLETIN

25-021



Date Issued: Jan 20, 2026

Subject: VALIDATE® CM2 (402re) Design Change – Lot 10789909 or higher

Explanation:

We are pleased to announce that VALIDATE® CM2 (402re), for Roche cobas®, is now available as one set. This design change has improved product stability so that it no longer needs to be shipped frozen and will now be shipped with frozen gel packs and indicated with “Cool Arrival” on the packing slip. This item may arrive thawed when received at your facility. Thawing of the product during shipment will not adversely impact product performance. Once the product arrives at your facility, immediately store frozen as directed by the temperature range on the kit.

VALIDATE® CM2 (402re) offers High Sensitivity C-Reactive Protein (hs-CRP), N-Terminal Pro hormone Brain Natriuretic Peptide (NT-proBNP) and Troponin I (Tnl) for easy, fast, efficient calibration verification and linearity testing.

When combined with Creatine Kinase-MB (CK-MB) and Myoglobin (MYO) in VALIDATE® CM1 (401ro), Homocysteine (HCY) and Lipoprotein(a) (LP(a)) in VALIDATE® CM3 (409ro) and High Sensitivity Troponin T (hsTnT) in VALIDATE® hsTrop (405ro) laboratories can challenge the reportable range of Roche cobas® cardiac related assays.

Please see the chart below for the typical coverage of VALIDATE® CM2 (402re).

Analyte	Units	Analyzer Range	VALIDATE Range	Percent Coverage
hsCRP	mg/L	0.15 – 20	0.5 – 19	2% – 95%
NT-proBNP	pg/mL	36 – 35,000	61.3 – 30,606	0.1% – 87%
Troponin I	ng/mL	0.3 – 25	0.7 – 26.2	2% – 105%

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

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