

# TECHNICAL SERVICE BULLETIN 2021-003



**Date Issued:** March 3, 2021

**Subject:** Update to CM2 402re Kit Configuration

This Technical Bulletin is to announce that VALIDATE<sup>®</sup> CM2 (Order Number 402re) test kit is now a two set product.

- The VALIDATE<sup>®</sup> CM2 (402re) Set 1 contains hsCRP, TNT and NT-proBNP and is labeled on the kit bottle as **CM2**.
  - The NT-proBNP in Set 1 is targeted to validate Roche's NT-proBNP entire measuring range (5-35,000 pg/mL).
- The VALIDATE<sup>®</sup> CM2 (402re) Set 2 contains NT-proBNP (Clinical Range) and is labeled on the kit bottle as **NT-proBNP (CR)**.
  - The NT-proBNP (Clinical Range) in Set 2 is targeted to validate the clinically significant portion of the NT-proBNP (50-5000 pg/mL) range.

The NT-proBNP (Clinical Range) allows for confirmation of linearity within the clinically significant portion of the NT-proBNP range based on data generated by the Mayo Clinic and from the Roche proBNP product insert. It is not required that laboratories run this test set, but is included if the laboratory would like to assess linearity within the clinical range of NT-proBNP.

For questions or additional information, please contact LGG Maine Standards Technical Support department.

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