

# TECHNICAL SERVICE BULLETIN

## 2024-021



**Date Issued:** Mar 6, 2025

**Subject:** VALIDATE® TDM1 (301ab) Design change

**Explanation:**

Extensive market research concluded that the vast majority of customers are no longer utilizing N-Acetylprocainamide (NAPA), Procainamide (PROC), and Quinidine (QUIN) for diagnostic purposes. Therefore, VALIDATE® TDM1 (301ab), for Abbott ARCHITECT / ALINITY, now offers Acetaminophen (ACTM), Amikacin (AMIK), Carbamazepine (CARB), Digoxin (DIGN), Gentamicin (GENT), Phenobarbital (PHNO), Phenytoin (PHYT), Salicylate (SALY), Theophylline (THEO), Tobramycin (TOB), Valproic Acid (VALP) and Vancomycin (VANC) **without the N-Acetylprocainamide (NAPA), Procainamide (PROC), and Quinidine (QUIN)** analytes for easy, fast, efficient calibration verification and linearity testing.

This design change also included decreasing the fill volumes for Levels 1 - 5 from 5.0 mL to 3.0 mL.

Please see the chart below for the typical coverage of VALIDATE® TDM1 (301ab).

Analyte	Units	Analyzer Range	Validate Range	Percent Coverage
ACTM	µg/mL	3 – 377	10 – 342	2% – 91%
AMIK	µg/mL	2.3 – 50	1 – 41	-3% – 81%
CARB	µg/mL	1.9 – 20	3 – 16.6	6% – 81%
DIGN	ng/mL	0.19 – 5	0.4 – 4.3	4% – 85%
GENT	µg/mL	0.5 – 10	1 – 9	5% – 89%
PHNO	µg/mL	2 – 80	2 – 67	0% – 83%
PHYT	µg/mL	1.8 – 40	1 – 34	-2% – 84%
SALY	mg/dL	5 – 100	10 – 95	5% – 95%
THEO	µg/mL	2 – 40	1 – 34	-3% – 84%
TOB	µg/mL	0.3 – 10	0.4 – 8.4	1% – 84%
VALP	µg/mL	12.5 – 150	15 – 130	2% – 85%
VANC	µg/mL	1.4 – 100	5.8 – 81	4% – 81%

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

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