

TECHNICAL SERVICE BULLETIN 2024-027



Date Issued: Dec 4, 2024

Subject: VALIDATE® GC3 (1300ab) Design Change

Explanation:

We are pleased to announce that VALIDATE® GC3 (1300ab) is now 5-levels for all analytes, and targeting Abbott's new ALT2, AST2, and GGT2 assays. The upper end of all methods will now be targeted in Level 5 instead of Level 6 for the Abbott ARCHITECT /ALINITY platforms.

The 6th level was originally included in the GC3 kit to meet the Flex Rate Measuring Interval for the following analytes on the Abbott ARCHITECT: ALP, ALT, AMY, AST, GGT and LD. Based on our field data, most customers are using the Flex Rate Measuring Interval and would have range coverage with a 5-level product. Customers not using the Flex Rate Measuring Intervals will have range coverage using levels 3 or 4, depending on analyte. Please see the Typical Recovered Values section of your lot specific VALIDATE product insert for more information on if you should utilize level 3 or 4 to obtain a value when NOT using Flex Rate Measuring Intervals.

Please see the chart below for the typical coverage of VALIDATE® GC3 (1300ab).

Analyte	Units	Analyzer Range	Validate Range	Percent Coverage
ALP	U/L	9 – 4555	10 – 4228	0.02% – 93%
ALT	U/L	7 – 3258	9 – 3114	0.06% – 96%
AMY	U/L	4 – 6554	7 – 6332	0.05% – 97%
AST	U/L	5 – 4001	7 – 3977	0.05% – 99%
CK	U/L	7 – 4267	10 – 4102	0.07% – 96%
GGT	U/L	5 – 7782	9 – 7294	0.05% – 94%
LD	U/L	30 – 4500	25 – 4382	-0.1% – 97%
LIP	U/L	3.1 – 1200	7 – 1124	0.3% – 94%

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

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