



TECHNICAL SERVICE BULLETIN 20-002

Date Issued: June 11, 2020

Subject: VALIDATE® GC3 1300re Shift in Lipase Recovery

VALIDATE®	REF	LOT
VALIDATE® GC3	1300re	13AN106190 13AS343190

Explanation:

Customers may observe suppressed recovery values for Lipase in VALIDATE® GC3 when they transition to Roche Lipase colorimetric reagent lots 444363, 444369, 444370, 444371, 452289, 452302, 452305, 452312, 460108, or 464734.

Other third-party controls demonstrate a similar recovery challenge on these reagent lots. Roche has indicated that patient samples are not affected. New Roche reagent lots that address this issue are now available for the cobas® 8000 and should be available in the June/July timeframe for the cobas® 6000.

If your laboratory is using one of the above stated Roche reagent lots, the current VALIDATE® GC3 1300re product can still be utilized to characterize the assay's linearity, particularly in the clinical range area of lipase. Run the product as indicated, calculate the linearity (either using MSDRx or as indicated in the package insert) and assess linearity.

If the assay is linear, but recovering lower values than stated in the package insert, consider the clinical significance between your Level 5 recovery and the method's claimed range of 300 U/L. Then either:

- Document the decision to validate the full range of Lipase (based on clinical significance);
- Truncate the validated range to the Level 5 recovery; or
- Call Roche to see if they have an unaffected Lipase reagent lot available.

Alternatively, LGC offers additional VALIDATE® GC3 product SKUs in which the Level 5 lipase value will recover closer to Roche's full claimed range of 300 U/L. For more information, please contact us at msc.techsupport@lgcgroup.com or 1-207-892-1300 for more information.

We apologize for any inconvenience this may have caused your laboratory

Contact Information:

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