

Submission Summary Linearity & Calibration Verification



Analyzer: Test Account: 125212

Serial#: 85050 Company:

Facility: St. Mary's Regional Testing Center

Submission ID: 23-302763

Entry Type: Calibration Verification



The following data was processed through LGC Maine Standards' MSDRx® software program, using VALIDATE® Linearity and Calibration Verification materials. If you have any questions, please call LGC Maine Standards at 1 - 207 - 892 - 1300 or e - mail msc.datareduction@lgcgroup.com.Access historical reports at any time via msdrx.mainestandards.com.

To view the Analyte Report Explanation Guide, please visit: www.mainestandards.com/report_guide

Product: GC3 Lot #: 10534898 SKU: 1300AB Expiration: 12/28/23

Comments:

Code	Analyte	Method	Test Date	Verified Range	Status
LD	Lactate Dehydrogenase	Enzymatic UV	05/02/2023	27.5 to 2,527.50 U/L	

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REPORT: LINEARITY / CALIBRATION VERIFICATION



LD - Lactate Dehydrogenase

Method: Lactate Dehydrogenase

Method Type: Enzymatic UV U/L Units:

Account #:

Company: LGC Maine Standards

Facility: St. Mary's Regional Testing Center

Analyzer: Serial #: 85050

Model: Roche Diagnostics - cobas® - 8000

Test Date: 05/02/2023

Technician:

Part #: 1300ab Description: GC3 Lot #: 10634898 **Expiration:** 2/28/2023 Submission 3-302763

TEa: 5.00 U/L or 20.00 %, whichever is greater

Source: Applied limit: 50%

Comments:

Data Set

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Replicate 1	25	525	1025	1525	2025	2525
Replicate 2	30	530	1030	1530	2030	2530

Linearity Data Analysis

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Effective X	1	2	3	4	5	10.06
Theoretical Value *	27.50	527.50	1,027.50	1530	2030	2530
Observed Mean	30	530	1030	1530	2030	2530
+/- Difference	30	530	1030	1530	2030	2530
% Difference	30	530	1030	1530	2030	2530
+/- Limit	30	530	1030	1530	2030	2530
% Limit	30	530	1030	1530	2030	2530

Regression: Theoretical vs. Observed Meany = 0.536 x + 410.881 r2 = 0.848

(*) Theoretical values are calculated from the best-fit line between L1, L3.

Peer Group Statistics

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
# Labs	1	2	3	4	5	10.06
# Data Sets	27.50	527.50	1,027.50	1530	2030	2530
Peer Min	30	530	1030	1530	2030	2530
Peer Median	30	530	1030	1530	2030	2530
Peer Max	30	530	1030	1530	2030	2530

Peer Group Comparison

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Peer Mean	1	2	3	4	5	10.06
Observed Mean	27.50	527.50	1,027.50	1530	2030	2530
+/- Difference	30	530	1030	1530	2030	2530
% Difference	30	530	1030	1530	2030	2530
+/- Limit	30	530	1030	1530	2030	2530
% Limit	30	530	1030	1530	2030	2530

Reportable Range: 10.00 to 1,000.00 U/L Verified Range: 27.5 to 2,527.50 U/L

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Data Review

Authorizing Signature:

Name:

Date:05/02/2023

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