

Submission Summary

Linearity & Calibration Verification

Analyzer: Test
Serial#: 85050

Account: 125212
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
SKU: 1300AB
Comments:

Lot #: 10534898
Expiration: 12/28/23

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

REPORT: LINEARITY / CALIBRATION VERIFICATION

LD - Lactate Dehydrogenase

Method: Lactate Dehydrogenase
Method Type: Enzymatic UV **Units:** U/L

Account #: 25212
Company: LGC Maine Standards
Facility: St. Mary's Regional Testing Center
Analyzer: Test
Serial #: 85050
Model: Roche Diagnostics - cobas® - 8000
Test Date: 05/02/2023
Technician:

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

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

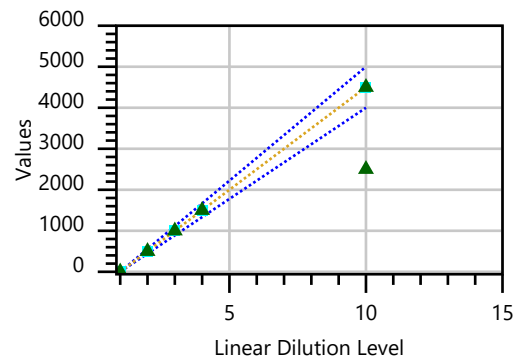
Linearity Data Analysis

	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 Mean $y = 0.536x + 410.881$ $r^2 = 0.848$

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

Linearity across the reportable range



Applied Limits
Theoretical Values
Linear Regression
Observed Values

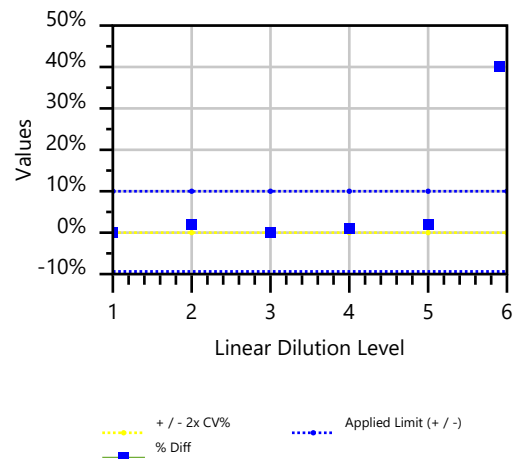
Peer Group Statistics

	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

% Difference Versus Peer Mean: GC3 LD



+ / - 2x CV%
% Diff
Applied Limit (+ / -)

Data Review

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

Authorizing Signature: _____
Name:

Date: 05/02/2023