

# 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	

Generated by MSDRx® Template: 0.92

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## 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** 3-302763

ID:

**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	

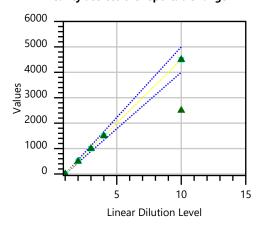
**Linearity Data Analysis** 

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	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.

#### Linearity accross the reportable range





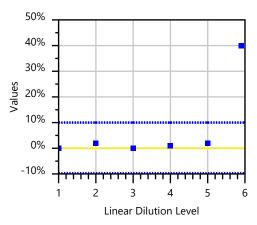
### **Peer Group Statistics**

	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

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	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



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