

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 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 |

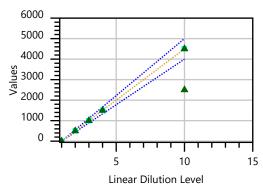
Linearity Data Analysis

| | 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





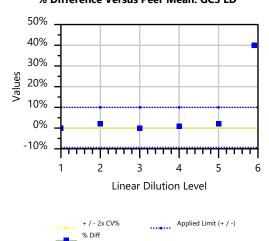
Peer Group Statistics

| | 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

| | 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



 Data Review
 Authorizing Signature:______
 Date:05/02/2023

 Reportable Range: 10.00 to 1.000.00 U/L
 Name:

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

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