

REPORT: LINEARITY / CALIBRATION VERIFICATION



1 ALB - Albumin

Method: Albumin

Method Type: BCG Units: g/dL

Account #: 125212
Company: LGC Maine Standards

Facility: Testing Site 1

Analyzer: ALINITY 2

Serial #:
Model: Abbott - ARCHITECT / ALINITY - ALINITY

Test Date: 04/07/2023

Part #: 1100sd
Description: GC1
Lot #: 10661914

7 | Lot #: 10661914 Expiration: 12/27/2023 Submission 23-006675

TEa: 0.20 g/dL or 10.00 %, whichever is greater

Source: MSC Applied Limit: 50%

Comments:

Test Information

Analyte and analyte abbreviation

2 Analyte method, method type and units selected

Account number, company name and facility name for the submission

Analyzer name, serial number and model

5 Date the test was performed and which Technician performed it

- VALIDATE part number and product name
- VALIDATE product lot number and expiration date
- 8 Submission ID associated with this report
- Total Allowable Error, source and applied limit

10	Data Set								
		Level 1	Level 2	Level 3	Level 4	Level 5			
	Replicate 1	1	3	5	7	9			
			11	*	•				
	Lincovity Data Analysis								

12	Linearity Data Analys	is					
		Leve	el 1	Level 2	Level 3	Level 4	Level 5
13	Effective X	1.0	00	2.00	3.00	4.00	5.00
14	Theoretical Value *	1.0	00	3.00	5.00	7.00	9.00
	Observed Mean	1.0	00	3.00	5.00	7.00	9.00
15 —	+/- Difference	0.0	00	0.00	0.00	0.00	0.00
16	% Difference	0.00	9 %	0.00 %	0.00 %	0.00 %	0.00 %
100	+/- Limit	0.1	10	0.15	0.25	0.35	0.45
17	% Limit		·	5.00 %	5.00 %	5.00 %	5.00 %

Regression: Theoretical vs. Observed Mean $y = 1.000 x + 0.000 r^2 = 1.000$

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

Linearity across the reportable range 10 9 8 7 6 values 5 4 3 0 3 À. 5 1 Linear Dilution Level ▲ Observed Values Peer Mean -- Applied Limit (+ / -) Linear Regression

Linearity Graph

10 The blue dashed lines represent the applied limits

Theoretical Values

- The yellow dashed line represents the linear line
- 21 The green triangles represent your observed values
- 22 The teal square represents the theoretical value (target) and may not be visible behind the green triangle
- The purple square represents the peer mean and may not be visible behind the green triangle

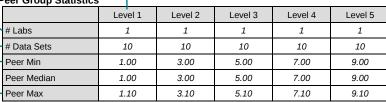
Data Set

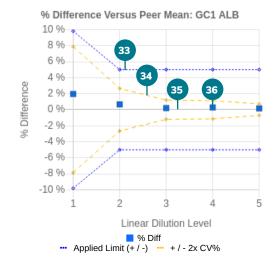
Displays the data set submitted

Linearity Data Analysis

- Levels represent the bottle level tested
- Represents the effective x of each level
- 13 The theoretical value calculated from the best-fit line
- The observed mean of your data set
- 15 The +/- Difference is the absolute difference between the theoretical value (target) and your mean
- The % Difference is the percent difference between the theoretical value (target) and your mean
- The +/- and % Limit are the allowable absolute and percent limits around your theoretical values (targets). LGC Maine Standards uses 50% of the Total Allowable Error to determine applied limits.
- The slope and intercept are calculated using the target values as the 'x' values and the recovered values as the 'y' values

Peer Group Statistics





Peer Group Comparison

· co. c.oup companion								
	Level 1	Level 2	Level 3	Level 4	Level 5			
Peer Mean	1.02	3.02	5.01	7.02	9.02			
Observed Mean	1.00	3.00	5.00	7.00	9.00			
+/- Difference	0.02	0.02	0.01	0.02	0.02			
% Difference	0.02%	0.01%	0.00%	0.00%	0.00%			
+/- Limit	0.10 g/dL	0.15 g/dL	0.25 g/dL	0.35 g/dL	0.45 g/dL			
% Limit		5.00%	5.00%	5.00%	5.00%			
	Observed Mean +/- Difference % Difference +/- Limit	Peer Mean 1.02 Observed Mean 1.00 +/- Difference 0.02 M Difference 0.10 g/dL	Peer Mean 1.02 3.02 Observed Mean 1.00 3.00 +/- Difference 0.02 0.02 % Difference 0.02% 0.01% +/- Limit 0.10 g/dL 0.15 g/dL	Peer Mean 1.02 3.02 5.01 Observed Mean 1.00 3.00 5.00 +/- Difference 0.02 0.02 0.01 % Difference 0.02% 0.01% 0.00% +/- Limit 0.10 g/dL 0.15 g/dL 0.25 g/dL	Peer Mean 1.02 3.02 5.01 7.02 Observed Mean 1.00 3.00 5.00 7.00 +/- Difference 0.02 0.02 0.01 0.02 % Difference 0.02% 0.01% 0.00% 0.00% +/- Limit 0.10 g/dL 0.15 g/dL 0.25 g/dL 0.35 g/dL			

Data Review

Reportable Range: 0.40 to 10.50 g/dL 1.00 to 9.00 g/dL Verified Range:

Generated by $\mathsf{MSDRx}^{\mathbb{R}}$ Template: 0.92



Authorizing Signature: Name:

Date: 04/07/2023

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Peer Group Statistics

- 24 Levels represent the bottle level tested
- The total number of labs in the peer group
- The total number of data sets in the peer group
- The min, max and mean of data in the peer group

Peer Group Comparison

- The average of all other labs in the peer group
- Your observed mean
- The +/- difference is the absolute difference between the peer mean and your observed mean
- The % difference is the percent difference between the peer mean and your observed mean
- The +/- and % limit is the allowable absolute and percent limits around the peer mean. LGC Maine Standards uses 50% of the Total Allowable Error to determine limits.

Peer Graph

- 33 The blue dotted line represents the applied limits
- The yellow dotted line represents two times the percent Coefficient of Variation for each level
- 0% represents the peer mean
- The blue squares represent the mean of your replications

Data Review

- The reportable range for the analyte and the portion of that range which has been verified
- The name of the person signing off on the report and their authorizing signature

Note: If there are less than ten labs in the peer group, the peer comparison section of your report will only show the min, median and max of those laboratories.