

# Example Report



REPORT: LINEARITY /  
CALIBRATION VERIFICATION



<b>1</b>	GLU - Glucose	<b>6</b>	Part #: 1100ro
	Method: GLUC3	<b>7</b>	Description: GC1
<b>2</b>	Method Type: Hexokinase/G6PDH	Units: mg/dL	Lot #: 10690551
	Account #: 125212	<b>8</b>	Expiration: 01/02/2025
<b>3</b>	Company:		Submission ID: 25-273597
	Facility: MAIN LAB	<b>9</b>	TEa: 6.00 mg/dL or 8.00 %, whichever is greater
	Analyzer: Cobas Pro		Source: LGC
<b>4</b>	Serial #:		Applied limit: 50%
	Model: Roche Diagnostics - cobas® - Pro		Comments:
<b>5</b>	Test Date: 12/18/2024		
	Technician: James Smith		

## Test Information

- 1** Analyte and analyte abbreviation
- 2** Analyte method, method type and units selected
- 3** Account number, company name and facility name for the submission
- 4** Analyzer name, serial number and model
- 5** Date the test was performed and which Technician performed it
- 6** VALIDATE part number and product name
- 7** VALIDATE product lot number and expiration date
- 8** Submission ID associated with this report
- 9** Total Allowable Error, source and applied limit

### Data Set

	Level 1	Level 2	Level 3	Level 4	Level 5
Effective X	1.00	2.00	3.00	4.00	5.00
Replicate 1	4.32	180.22	355	555.4	700
Replicate 2	4.04	178.44	350.89	522.6	692.96
Replicate 3	4.5	175.2	340.45	500.22	655

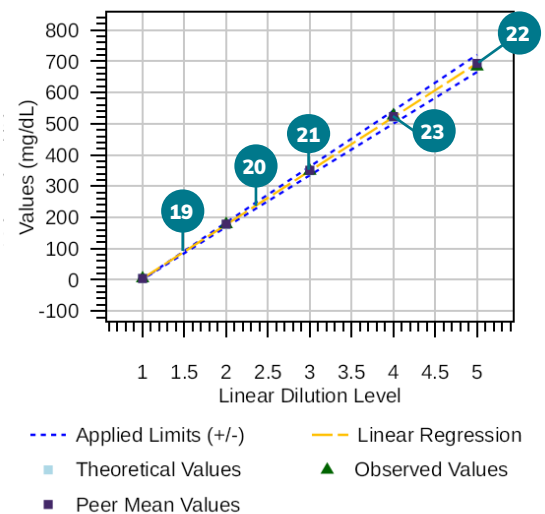
### Linearity Data Analysis

Effective X	1.00	2.00	3.00	4.00	5.00
Theoretical Value	4.29	176.53	348.78	521.03	693.27
Observed Mean	4.29	177.95	348.78	526.07	682.65
+/- Difference	0.00	1.42	0.00	5.05	10.62
% Difference	0.00	0.80	0.00	0.97	1.53
+/- Limit	3.00	7.06	13.95	20.84	27.73
% Limit	N/A	4.00	4.00	4.00	4.00

Regression: Theoretical vs. Observed Mean  $y = 0.990x + 2.736$   $r^2 = 0.996$

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

Linearity across the reportable range



## Data Set

- 10** Displays the data set submitted

### Linearity Data Analysis

- 11** Levels represent the bottle level tested
- 12** Represents the effective x of each level
- 13** The theoretical value calculated from the best-fit line
- 14** The observed mean of your data set
- 15** The +/- Difference is the absolute difference between the calculated theoretical value (target) and your mean
- 16** The % Difference is the percentage difference between the calculated theoretical value (target) and your mean
- 17** The +/- and % Limit are the allowable absolute and percent limits around your theoretical values. LGC Maine Standards uses 50% of the Total Allowable Error to determine applied limits.
- 18** The slope and intercept are calculated using the theoretical values as the 'x' values and the recovered values as the 'y' values. The regression equation is in the format of slope-intercept formula,  $y = mx + b$ , where "m" is the slope and "b" is the y-intercept.

## Linearity Graph

- 19** The blue dashed lines represent the applied limits
- 20** The yellow dashed line represents the linear line
- 21** The green triangles represent your observed values
- 22** The light blue square represents the calculated theoretical value and may not be visible behind the green triangle
- 23** The purple square represents the peer mean and may not be visible behind the green triangle

Peer Group Statistics

Effective X	1.00	2.00	3.00	4.00	5.00
# Labs	262	269	269	269	269
# Data Sets	596	621	622	621	621
Peer Mean	4.04	178.44	350.89	522.60	692.96
Peer SD	0.27	3.48	6.79	10.28	13.95
Peer %CV	6.73	1.95	1.93	1.97	2.01

Peer Group Comparison

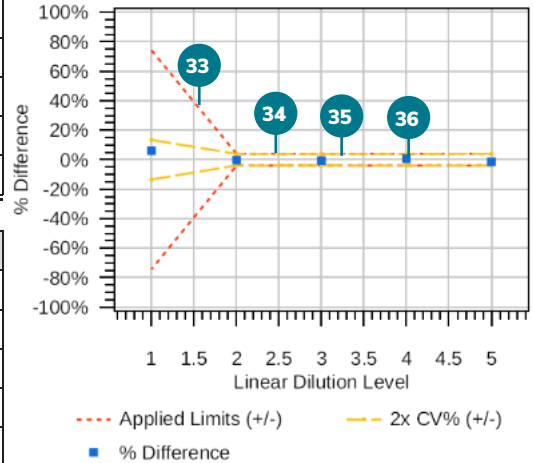
Effective X	1.00	2.00	3.00	4.00	5.00
Peer Mean	4.04	178.44	350.89	522.60	692.96
Observed Mean	4.29	177.95	348.78	526.07	682.65
+/- Difference	0.25	0.49	2.11	3.47	10.31
% Difference	6.17	0.28	0.60	0.66	1.49
+/- Limit	3.00	7.14	14.04	20.90	27.72
% Limit	N/A	4.00	4.00	4.00	4.00

Data Review

Manufacturers Range: 2.00 to 750.00 mg/dL  
 Tested Range: 4.29 to 682.65 mg/dL  
 Verified Range: 4.29 to 682.65 mg/dL

Authorizing Signature: \_\_\_\_\_  
 Name: \_\_\_\_\_

% Difference Versus Peer Mean: GC1 GLU



Peer Group Statistics

- 24 Effective X represents the level tested
- 25 The total number of labs in the peer group
- 26 The total number of data sets in the peer group
- 27 The Mean, SD and %CV of data in the peer group

Peer Group Comparison

- 28 The average of all other labs in the peer group
- 29 Your observed mean
- 30 The +/- difference is the absolute difference between the peer mean and your observed mean
- 31 The % difference is the percent difference between the peer mean and your observed mean
- 32 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 red dotted line represents the applied limits
- 34 The yellow dotted line represents two times the percent Coefficient of Variation for each level
- 35 0% represents the peer mean
- 36 The blue squares represent the mean of your replications

Data Review

- 37 The manufacturers reportable range for the analyte and the tested portion of that range which has been verified
- 38 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.

# Example Report

REPORT: CALIBRATION  
VERIFICATION



<p><b>1</b> Anti-TPO - Anti-Thyroid Peroxidase</p> <p><b>2</b> Method: A-TPO / ATPO</p> <p>Method Type: ECLIA Competition Units: IU/mL</p> <p>Account #: 125212</p> <p>Company:</p> <p><b>3</b> Facility: MAIN LAB</p> <p>Analyzer: Cobas Pro</p> <p>Serial #:</p> <p><b>4</b> Model: Roche Diagnostics - cobas® - Pro</p> <p>Test Date: 08/05/2025</p> <p><b>5</b> Technician: James Smith</p>	<p><b>6</b> Part #: 2400-0254</p> <p>Description: aTPO</p> <p><b>7</b> Lot #: 10734323</p> <p>Expiration: 03/17/2028</p> <p><b>8</b> Submission ID: 25-273597</p>
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## Test Information

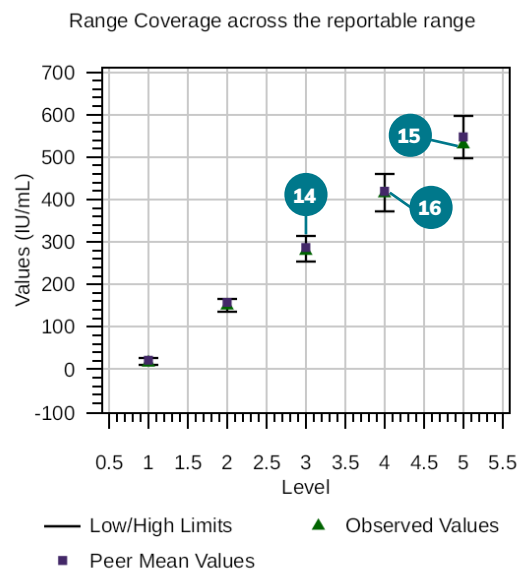
- 1** Analyte and analyte abbreviation
- 2** Analyte method, method type and units selected
- 3** Account number, company name and facility name for the submission
- 4** Analyzer name, serial number and model
- 5** Date the test was performed and which Technician performed it
- 6** AccuTrak part number and product name
- 7** AccuTrak product lot number and expiration date
- 8** Submission ID associated with this report

**9** Data Set

	Level 1	Level 2	Level 3	Level 4	Level 5
Replicate 1	11	162	259	411	502
Replicate 2	19	142	306	431	531
Replicate 3	16	145	271	400	555

**10** Range Coverage Analysis

Level	1	2	3	4	5
<b>11</b> High Limit	26.70	165.00	314.00	459.00	598.00
<b>12</b> Low Limit	9.30	135.00	253.00	373.00	498.00
<b>13</b> Observed Mean	15.33	149.67	278.67	414.00	529.33



## Data Set

- 9** Displays the data set submitted

## Range Coverage Analysis

- 10** Levels represent the bottle level tested
- 11** Represents the High Limit of each level
- 12** Represents the Low Limit of each level
- 13** The observed mean of your data set

## Range Coverage Graph

- 14** The black solid lines represent the Low/High Limits
- 15** The green triangles represent your observed values
- 16** The purple square represents the peer mean and may not be visible behind the green triangle

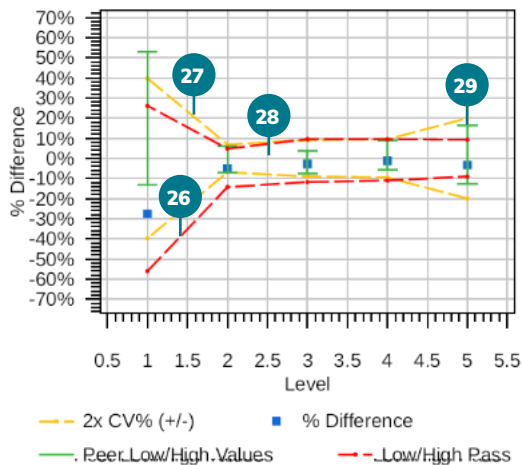
Peer Group Statistics

Level	1	2	3	4	5
# Labs	14	14	14	14	14
# Data Sets	14	14	14	14	14
Peer Mean	21.17	157.48	286.71	419.21	547.45
Peer SD	4.21	5.43	12.91	19.89	54.61
Peer %CV	19.87	3.45	4.50	4.74	9.98

Peer Group Comparison

Level	1	2	3	4	5
Peer Mean	21.17	157.48	286.71	419.21	547.45
Observed Mean	15.33	149.67	278.67	414.00	529.33
Low Pass	9.30	135.00	253.00	373.00	498.00
High Pass	26.70	165.00	314.00	459.00	598.00
Min Peer Value	18.33	146.33	265.00	396.00	477.00
Max Peer Value	32.33	167.00	297.33	456.00	637.67

% Difference Versus Peer Mean: aTPO Anti-TPO



Data Review

Manufacturers Range: 5.00 to 600.00 IU/mL  
Tested Range: 15.33 to 529.33 IU/mL  
Verified Range: 15.33 to 529.33 IU/mL

Authorizing Signature: \_\_\_\_\_  
 Name: \_\_\_\_\_

Peer Group Statistics

- 17 Levels represent the bottle level tested
- 18 The total number of labs in the peer group
- 19 The total number of data sets in the peer group
- 20 The Mean, SD and %CV of data in the peer group

Peer Group Comparison

- 21 The mean of all other labs in the peer group
- 22 Your observed mean
- 23 Low Pass value for the analyte
- 24 High Pass value for the analyte
- 25 The Min and Max Values within the peer data set

Peer Graph

- 26 The red dotted line represents the Low/High pass values for the analyte
- 27 The yellow dotted line represents two times the percent Coefficient of Variation for each level
- 28 0% represents the peer mean
- 29 The solid green lines represent Peer Low/High values within the peer data set

Data Review

- 30 The manufacturers reportable range for the analyte and the tested portion of that range which has been verified
- 31 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.