



# DATA REDUCTION REPORT INFORMATION



Maine Standards Data Reduction Reports contain two sections – the first section is the linearity analysis of your data and the second section is an analysis of your results as compared to results from your peer group. Both sections of the report are explained below.

## LINEARITY ANALYSIS

**Data Table:** Displays your results as submitted to Maine Standards Company.

Data Set				
L	X	Rep 1	Rep 2	Rep 3
0	N/A	1	2	2
1	1.0	6	5	6
2	2.0	179	177	179
3	3.0	351	358	354
4	4.0	522	523	526
5	5.0	698	716	720

'L' represents the bottle Level tested.

'X' represents the 'effective X' value of L. The 'effective X' is the linear dilution level of the material tested. If no dilutions were performed, the X column will display a value corresponding to the product level 1-5 (Note: not all products contain Level 6 and Level 6 'X' will not correspond to bottle level). If you prepared a dilution for the analyte, an asterisk "\*" will appear in the L column and the 'effective X' value of the dilution will be displayed in the X column.

Effective X values are used in target value calculations and are represented on the x-axis of the linearity graph.

Reps 1, 2, 3 represent your data, as reported to Maine Standards Company. Each replicate reported to Maine Standards Company is now evaluated by our MSDRx<sup>®</sup> software program in relation to the other data points reported at that level. If the evaluation determines that a replicate is likely a clerical error, MSDRx<sup>®</sup> omits the replicate from analysis and the replicate is displayed in the 'Data Table' of the linearity report with a gray background.

L	X	Rep 1	Rep 2	Rep 3
0	N/A			
1	1.0	1	1	100
2	2.0	2	2	2
3	3.0	3	3	3
4	4.0	4	4	4
5	5.0	5	5	5

**Range Information:** Includes information to assist in the evaluation of the acceptability of results. Range 'Tested' is the mean value of the lowest results reported to the mean of the highest results

<input type="checkbox"/> Accept	<input type="checkbox"/> Comments
Tested 5.7 to 711.3 mg/dL	
Validated 5.7 to 711.3 mg/dL	
Mean versus Target Regression $y = 1.008x - 1.817$	

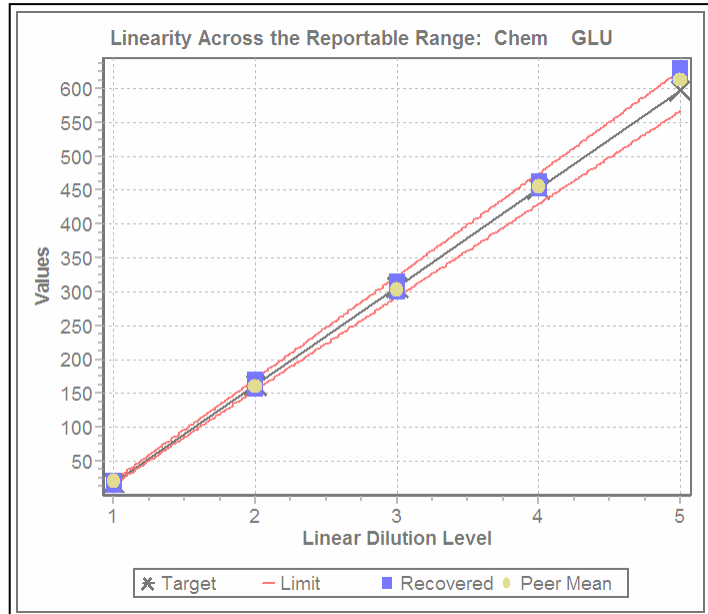
reported, whether or not those values fall outside the applied limits. Level Zero or Base Matrix results are NOT included in linearity analysis. If all levels tested fall within the applied limits, the range 'Validated' will display the mean of the lowest level tested to the mean of the highest level tested. If the mean at any level falls outside the applied limits, the low and high values for Range 'Validated' will be blank. The user is required to evaluate the significance of the flagged level and determine and record the range across which the assay is clinically validated.

**Regression Equation ( $y = \text{slope} * x + y\text{-intercept}$ ):** The data set regression equation is calculated using the target values as the 'x' values and your recovered values as the 'y' values and is expressed in the units of measure for the analyte. **Note:** This equation is not the equation for the line plotted on the graph and cannot be used to determine target values from actual results.

**Linearity Graph:** Displays your individual recovered values for each linear dilution level (effective X value) versus your calculated target values.

Your recovered values are represented by the blue squares and the target values are represented by the X's on the graph. The X's may not be visible if recovered values are close to target values. Also displayed are the allowable limits for linearity.

If Peer Group data is available, your graph will also display the Peer Mean values as yellow circles. This display makes it easy to visually see how your method linearity compares to peer mean linearity.



**Results Table:** Displays the results of your linearity analysis

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	12.665	11.000	1.665	<b>** 13.1%</b>	1.267	10%
2.0	161.000	164.330	3.330	2.1%	16.100	10%
3.0	309.335	307.670	1.665	0.5%	30.933	10%
4.0	457.670	457.670	0.000	0.0%	45.767	10%
5.0	606.005	623.670	17.665	2.9%	60.601	10%

**Applied limits:** The '+/- Limit' and the '% Limit' are the allowable absolute and percent limits, respectively, around your target values. Fifty percent of the total allowable error, as defined by CLIA (42 CFR 493) and/or other published industry accepted standards, is used in the linearity analysis. Fifty percent of the total allowable error for linearity is based on comparison of output from the Maine Standards Company data reduction method and the method outlined in CLSI (formerly NCCLS) EP-6A.

The '+/- Diff' is the absolute difference between your mean value and the calculated target value and the '% Diff' is the percent difference between your mean value and the calculated target value for each 'Effective X' value.

+/- Diff	% Diff	+/- Limit	% Limit
0.17	20.5%	3.00	N/A
0.33	0.2%	7.52	5%
0.17	0.1%	14.99	5%
0.67	0.1%	22.47	5%
64.17	<b>** 10.7%</b>	29.94	5%

These differences are compared to the allowable limits at each Effective X value to determine acceptability of your results. Most allowable error limits are an absolute value and a percentage, whichever is greater.

In the case of the GLU results shown here, the allowable error limit is 3.00 mg/dL or 5%, whichever is greater. For the Effective X value of 1.0 in the GLU example, 3.00 mg/dL is greater than 5% of the target value, so, a limit of 3.00 mg/dL is applied. For Effective X values 2.0 through 5.0, 5% of the target value is greater than 3.00 mg/dL, so, a limit of 5% is applicable. When the percent limit is applicable, the '+/- Limit' column will display the allowable difference around the target value.

Differences are displayed as **bolded** with a "\*\*\*" flag if the mean result value falls outside the applied limits, as shown here with Effective X value 5.0.

**Maine Standards Company analysis is generated solely on the statistical evaluation of the data. Clinical significance of differences needs to be considered in the interpretation of the results.**

In the GLU example, the absolute limit of 3.00 mg/dL is applied to Effective X of 1.0; the '+/- Diff' is less than 3.00 mg/dL, therefore, the absolute difference is not flagged. For X values 2.0 through 5.0, the 5% limit is applied. In this case Effective X of 5.0 difference falls outside the applied limit and the % difference is **bolded** and flagged.

**Target value calculation:** Target values for each linear dilution level are based on the actual recovered values submitted.

X	Target
1.0	19.33
2.0	163.67
3.0	308.00
4.0	452.33
5.0	596.67

In rare cases the target value may be a negative number and while this may not make sense from a clinical perspective, the linearity analysis is still valid. An explanation of the target calculation can be found on Maine Standards internet site <http://www.mainestandards.com/targets.htm>.

## PEER GROUP ANALYSIS

**Participating in Maine Standards Company Peer Group Analysis:** In order to be included in and receive Peer Group Analysis from Maine Standards Company, you must complete the Peer Group Set-Up Packet. This packet will provide us with the necessary method information required to ensure that your results are included in, and are compared to, the proper peer results. Linearity and Peer Group analyses are provided free of charge with the purchase of any VALIDATE® calibration verification / linearity material.

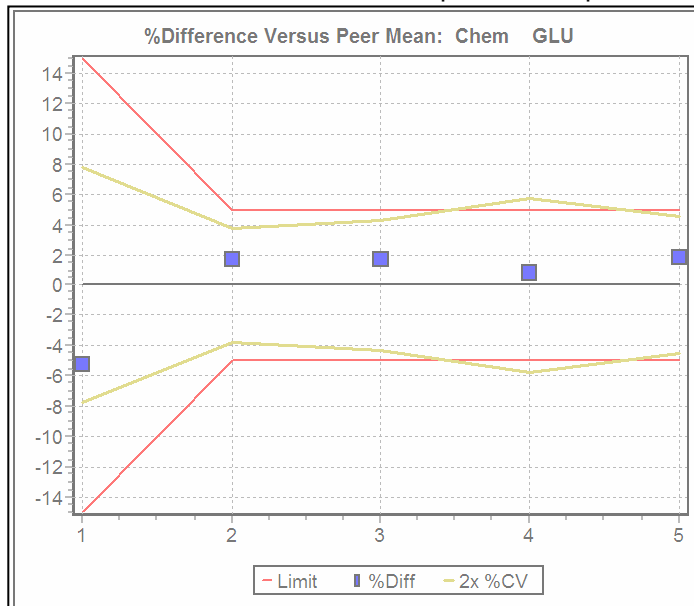
**Peer statistics table:** Displays the statistical information for your peer group. Statistics provided are the peer mean, the number of labs in your peer group, the number of data sets included in the peer, the Standard Deviation (SD) of the peer mean and the % Coefficient of Variation (% CV) of the peer mean.

Peer Statistics					
X	Peer Mean	Num Labs	Data Sets	SD	%CV
1	20.03	26	26	0.78	3.89%
2	161.56	26	26	3.01	1.86%
3	302.43	26	26	6.43	2.13%
4	454.04	26	26	13.02	2.87%
5	612.20	26	26	13.87	2.26%

The number of labs in your peer and the number of data sets may vary per level depending upon the results reported by level from each customer.

**Percent difference versus peer mean graph:** Displays your mean recovered values as compared to peer means at each linear dilution level. Your mean results are plotted as a percent difference from the peer means. The red lines on the graph represent the allowable error for each level. The yellow lines represent two times the percent Coefficient of Variation for each level.

This display makes it easy to visually see your deviation versus peer means.



**Peer comparison table:** Displays your mean values for each linear dilution level as compared to

X	Peer Mean	Your Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	5.23	5.67	0.44	8.4%	3.00	N/A
2.0	178.91	178.33	0.58	0.3%	8.95	5%
3.0	349.58	354.33	4.75	1.4%	17.48	5%
4.0	526.70	523.67	3.03	0.6%	26.33	5%
5.0	709.96	711.33	1.37	0.2%	35.50	5%

the peer means. '+/- Diff' is the absolute difference between your mean value and the Peer Mean. '% Diff' is the percent difference between your mean value and the Peer Mean for each 'Effective X' value.

An evaluation of the deviation from the peer mean is also provided. The '+/- Limit' and the '% Limit' are the allowable absolute and percent limits, respectively, around your mean values.

**Applied limits:** Fifty percent of the total allowable error, as defined by CLIA (42 CFR 493) and/or other published industry accepted standards, is used in Peer Analysis.

The '+/- Diff' and '% Diff' are compared to the allowable limits at each Effective X value to determine

+/- Diff	% Diff	+/- Limit	% Limit
0.44	8.4%	3.00	N/A
0.58	0.3%	8.95	5%
4.75	1.4%	17.48	5%
3.03	0.6%	26.33	5%
1.37	0.2%	35.50	5%

acceptability of your results as compared to your peers. Most allowable error limits are an absolute value and a percentage, whichever is greater. If the difference is greater than the limits set, the difference will be **bolded** with a '\*\*\*' flag.

In the case of the GLU shown here, the allowable error limit is 3.00 mg/dL or 5%, whichever is greater. For Effective X values 2.0 through 5.0, 5% of the target value is greater than 3.00 mg/dL, so, a limit 5% is applied. When the percent limit is applied, the '+/-

Limit' column will display the calculated absolute limit around your mean.

In the GLU example, the absolute limit of 3.00 mg/dL is applied to Effective X 1.0; the '+/- Diff' is less than 3.00 mg/dL. For X values 2.0 through 5.0, the 5% limit is applied and the pass / fail indication is displayed in the '% Diff' column. In this case, all results are within allowable limits, so none of the actual differences are flagged.



## DATA REDUCTION REPORT INFORMATION



**Insufficient Data for Peer Analysis:** In some cases there may be insufficient data available to provide Peer Group statistics for a particular analyte. This can occur if the peer data does not pass a statistical check, or if there are fewer than 10 labs reporting data for a particular analyte / method. The statement “No Peer Data Available” will be displayed over the Peer Statistics and Peer Comparison Tables and no % Difference plot will be displayed.

However, if any peer data is available, you will receive a report detailing the Peer Minimum, Peer Median and Peer Maximum for each linear dilution level as well as a comparison of your mean to the Peer Median. In this instance, no % Difference plot will be displayed.

### **Additional Information:**

For information on the calculations used in Maine Standards Data Reduction Linearity and Peer Group Analysis, please visit [www.mainestandards.com/Analysis.htm](http://www.mainestandards.com/Analysis.htm).

For information on Total Allowable Error Limits please see: **42 CFR 493: Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications. Paragraph 793.1255(b) (2)**

We are dedicated to providing the highest quality materials and the best customer support in the linearity market. Importantly, the Quality System for Maine Standards Company, LLC is registered to ISO13485:2003.

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