



## Information Regarding Flagged Data

Occasionally a laboratory's MSDRx<sup>®</sup> report may include an analyte that has one or more levels flagged. This document was designed in an effort to help the laboratory understand the significance of the flag and what this means to the linearity results.

Maine Standards Company uses fifty percent of the total allowable error, as defined by CLIA (42 CFR 493) and/or other published industry accepted standards, in the linearity analysis of each analyte. Each laboratory is responsible for establishing performance specifications for calibration verification for each analyte tested, as defined by CLIA (42 CFR 493), paragraph 493.1255(b) (2).

### Example: 1

Chem 7 ETOH  
published CLIA total allowable error is 25%

L	X	Rep 1	Rep 2	Rep 3	<input type="checkbox"/> Accept	<input type="checkbox"/> Comments
0	N/A					
1	1.0	5.2	5.5	4.7		Tested 5.1 to 554.7 mg/dL
2	2.0	151.5	156.1	153.4		Validated _____ to _____ mg/dL
3	3.0	295.8	289.2	297		Mean versus Target Regression $y = 0.951x + 6.225$
4	4.0	432.9	429.5	422		
5	5.0	559.8	551.8	552.5		

  

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	6.50	5.13	1.37	<b>** 21.1%</b>	0.81	12.5%
2.0	150.93	153.67	2.74	1.8%	18.87	12.5%
3.0	295.37	294.00	1.37	0.5%	36.92	12.5%
4.0	439.80	428.13	11.67	2.7%	54.98	12.5%
5.0	584.23	554.70	29.53	5.1%	73.03	12.5%

### Example: 2

Chem 7 CREA  
published CLIA total allowable error is 0.3 mg/dL or 15%, whichever is greater

L	X	Rep 1	Rep 2	Rep 3	<input type="checkbox"/> Accept	<input type="checkbox"/> Comments
0	N/A					
1	1.0	1.5	1.6	1.5		Tested 1.53 to 30.13 mg/dL
2	2.0	7.6	7.5	7.7		Validated _____ to _____ mg/dL
3	3.0	14.3	14.5	14.4		Mean versus Target Regression $y = 0.987x + 0.638$
4	4.0	22.1	22.1	22.2		
5	5.0	30.4	29.3	30.7		

  

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	0.178	1.533	<b>** 1.355</b>	N/A	0.150	N/A
2.0	7.444	7.600	0.156	2.1%	0.558	7.5%
3.0	14.711	14.400	0.311	2.1%	1.103	7.5%
4.0	21.978	22.133	0.155	0.7%	1.648	7.5%
5.0	29.244	30.133	0.889	3.0%	2.193	7.5%

In example 1, ETOH level 1 was flagged because the difference between the target value of 6.50 mg/dL and the measured value of 5.13 mg/dL is 21.1%. This is greater than 12.5%, which is half of CLIA's published total allowable error. The lab must then determine if the difference of 1.37 mg/dL at a level of 6.50 mg/dL is clinically significant. If it is determined that the difference is not clinically significant, then to complete the report, the laboratorian would record the range determined to be clinically validated. (Example: Validated 5.1 to 554.7 mg/dL).

In example 2, CREA level 1 was flagged because the difference between the target value of 0.17 mg/dL and the measured value of 1.53 mg/dL is 1.35 mg/dL. This is greater than 0.15 mg/dL, which is half of CLIA's published total allowable error. If this difference is considered clinically significant by the lab, then appropriate troubleshooting and retesting may be required. Data can be re-submitted to Maine Standards Data Reduction Department at any time. To complete the report, the laboratorian would then record the range determined to be clinically validated.

If you have any further questions regarding your reports, please contact Maine Standards Company Technical Support at 1-800-377-9684 or [techsupport@mainestandards.com](mailto:techsupport@mainestandards.com)

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