

Case Study #4: Low Bilirubin Recovery at All Levels and Results Appear Visually Nonlinear

Initial Results: A laboratory performed routine calibration verification / linearity testing using VALIDATE® GC 4. Results for both Total Bilirubin and Direct Bilirubin were well below the upper range of the method, and were visually nonlinear. The following was the TBIL report generated for using MSDRx®, the Maine Standards Data Reduction software:

GC 4 TBIL

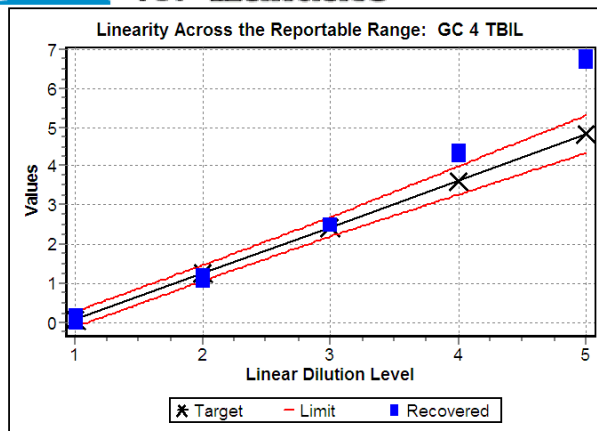
published CLIA total allowable error is 0.4 mg/dL or 20%, whichever is greater



L	X	Rep 1	Rep 2	Rep 3
1	1.0	0.2	0.2	0.0
2	2.0	1.2	1.1	1.2
3	3.0	2.5	2.5	2.5
4	4.0	4.4	4.3	4.3
5	5.0	6.8	6.7	6.7

Accept Comments
 Tested 0.13 to 6.73 mg/dL
 Validated _____ to _____ mg/dL
 Mean versus Target Regression
 $y = 1.383x - 0.415$

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	0.083	0.133	0.050	60.2%	0.200	N/A
2.0	1.267	1.167	0.100	7.9%	0.200	N/A
3.0	2.450	2.500	0.050	2.0%	0.245	10%
4.0	3.633	4.333	0.700	** 19.3%	0.363	10%
5.0	4.817	6.733	1.916	** 39.8%	0.482	10%



The laboratory contacted Maine Standards Company Technical Support. Technical Support advised the laboratory that the results were not consistent with Peers and that the curve was typical of product that was not stored properly. The proper storage conditions for VALIDATE® GC 4 is -10 to -25°C in a non-frost free freezer. More details regarding the need for non-frost-free freezers are provided in Technical Service Bulletin 11-007.

Troubleshooting: The laboratory took the troubleshooting step of reordering a fresh kit of GC 4 and rerunning the calibration verification / linearity experiment. The updated MSDRx® report for TBIL shows that all Levels are within the statistical limits. The laboratory accepted the updated results and determined that they had validated the linearity across the reportable range of the method.

GC 4 TBIL

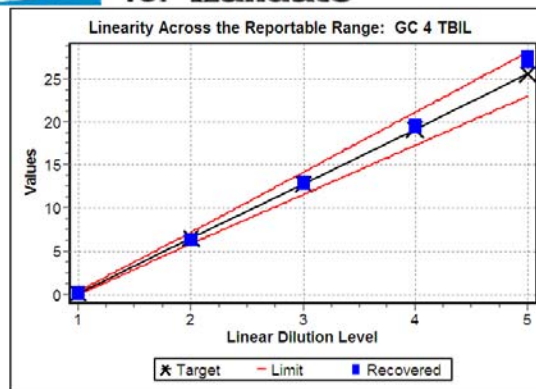
published CLIA total allowable error is 0.4 mg/dL or 20%, whichever is greater



L	X	Rep 1	Rep 2	Rep 3
1	1.0	0.3	0.2	0.2
2	2.0	6.4	6.4	6.4
3	3.0	12.9	12.9	13.0
4	4.0	19.5	19.5	19.6
5	5.0	27.1	27.6	27.2

Accept Comments
 Tested 0.23 to 27.30 mg/dL
 Validated 0.23 to 27.30 mg/dL
 Mean versus Target Regression
 $y = 1.059x - 0.356$

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	0.172	0.233	0.061	35.5%	0.200	N/A
2.0	6.522	6.400	0.122	1.9%	0.652	10%
3.0	12.872	12.933	0.061	0.5%	1.287	10%
4.0	19.222	19.533	0.311	1.6%	1.922	10%
5.0	25.572	27.300	1.728	6.8%	2.557	10%



Summary: Maine Standards Company Technical Support advised that recovery was not consistent with Peers. In this case, improper storage damaged the VALIDATE® test set. This case study emphasizes the need to store products per the manufacturer's instructions. Storage requirements for VALIDATE® products are printed on the kit boxes, bottle labels and in the package inserts.