



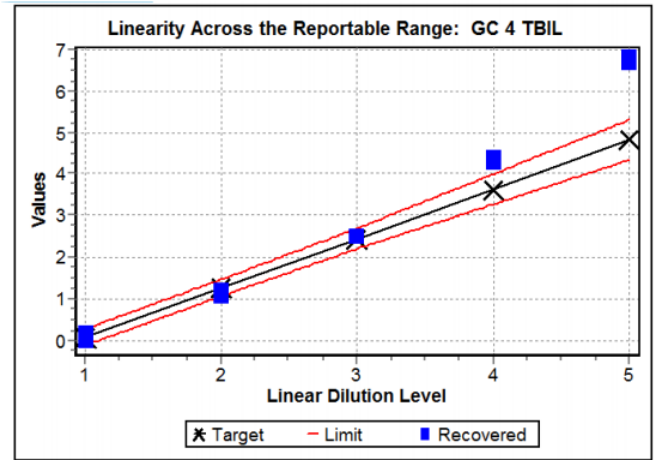
Case Study #4: Low Bilirubin Recovery at All Levels and Results Appear Visually Nonlinear

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 TBIL report was generated using MSDRx®, the LGC 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		
B	N/A				<input type="checkbox"/> Accept <input type="checkbox"/> Comments	
1	1.0	0.2	0.2	0.0	Tested 0.133 to 6.73 mg/dL	
2	2.0	1.2	1.1	1.2	Validated _____ to _____ mg/dL	
3	3.0	2.5	2.5	2.5	Mean versus Target Regression	
4	4.0	4.4	4.3	4.3	y = 1.383x - 0.415	
5	5.0	6.8	6.7	6.7	r ² =0.9721 SE _{y,x} =0.4	
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%



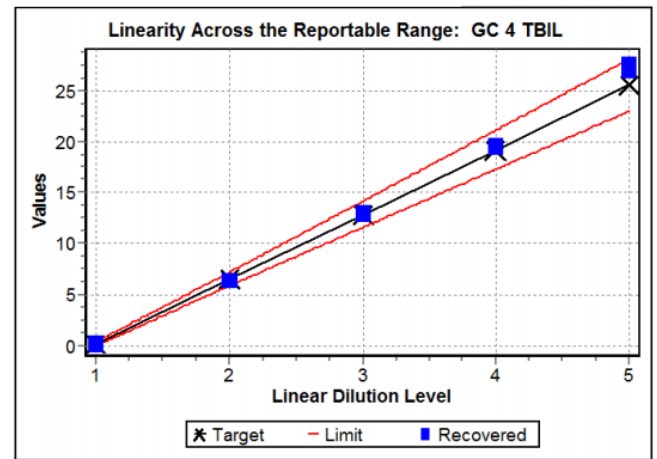
The laboratory contacted LGC Maine Standards Technical Support. Technical Support advised the laboratory that the results were not consistent with Peers and that the curve was typical of product that was not stored properly. The proper storage conditions for VALIDATE® GC 4 is -10 to -25°C in a non-frost-free freezer. More details regarding the need for non-frost-free freezers are provided under General Technical Service Bulletins located at www.mainestandards.com/support/tech-bulletins.php.

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

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L	X	Rep 1	Rep 2	Rep 3		
B	N/A				<input type="checkbox"/> Accept <input type="checkbox"/> Comments	
1	1.0	0.3	0.2	0.2	Tested 0.233 to 27.30 mg/dL	
2	2.0	6.4	6.4	6.4	Validated 0.233 to 27.30 mg/dL	
3	3.0	12.9	12.9	13.0	Mean versus Target Regression	
4	4.0	19.5	19.5	19.6	y = 1.059x - 0.356	
5	5.0	27.1	27.6	27.2	r ² =0.9980 SE _{y,x} =0.5	
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: LGC Maine Standards 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.