



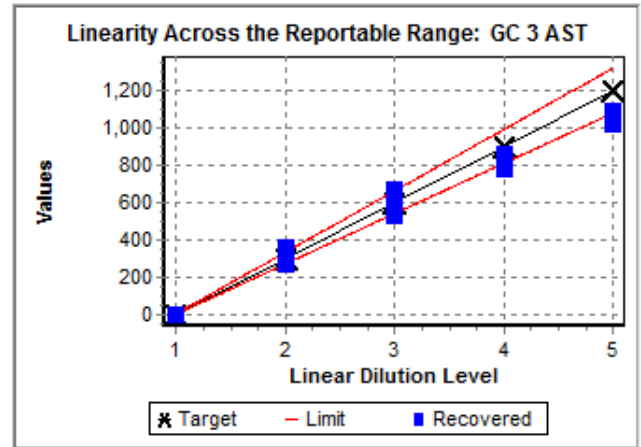
Case Study #5: Imprecision of Repetitions at Levels 2 through 5

Initial Results: A laboratory performed routine calibration verification / linearity testing using VALIDATE® GC3. Results for all enzymes demonstrated imprecision at levels 2 through 5. The following AST report was generated using MSDRx®, LGC Maine Standards Data Reduction software:

GC 3 AST

suggested total allowable error is 5 U/L or 20%, whichever is greater

L	X	Rep 1	Rep 2	Rep 3		
B	N/A	1	2	2	<input type="checkbox"/> Accept <input type="checkbox"/> Comments	
1	1.0	4	5	4	Tested 4.33 to 1,057.7 U/L	
2	2.0	363	305	270	Validated _____ to _____ U/L	
3	3.0	675	602	529	Mean versus Target Regression $y = 0.874x + 29.979$ $r^2 = 0.9843$ SE _{y,x} = 50.1	
4	4.0	868	805	780		
5	5.0	1095	1027	1051		
X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	7.50	4.33	** 3.17	42.3%	2.50	N/A
2.0	306.33	312.67	6.34	2.1%	30.63	10%
3.0	605.17	602.00	3.17	0.5%	60.52	10%
4.0	904.00	817.67	86.33	9.5%	90.40	10%
5.0	1,202.83	1,057.67	145.16	** 12.1%	120.28	10%



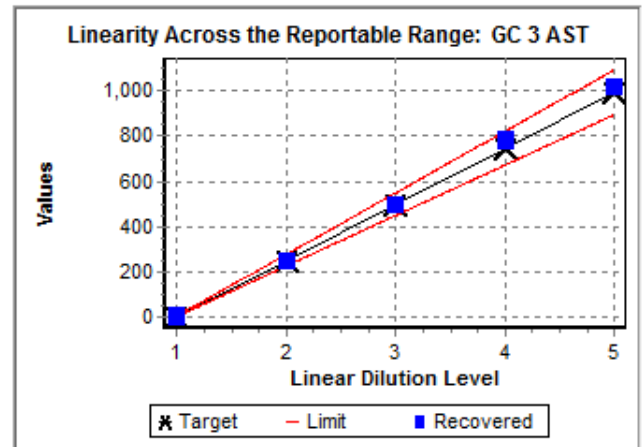
The laboratory contacted LGC Maine Standards Technical Support. Technical Support advised the laboratory that the results were not consistent with Peers and that the curve does not demonstrate typical reproducibility of repetitions of levels 2 through 5.

Troubleshooting: The laboratory took the troubleshooting step of contacting the instrument manufacturer and requested a service call. During the service call, a cracked sample syringe case was discovered and replaced. To confirm the issue was corrected the laboratory re-ran their VALIDATE® GC3 test kit. The updated MSDRx® report for AST showed that all levels were within the statistical limits and precision of the repetitions at all levels acceptable. The laboratory accepted the updated results and determined that they had validated the linearity across the reportable range of the method.

GC 3 AST

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L	X	Rep 1	Rep 2	Rep 3		
B	N/A	1	2	2	<input type="checkbox"/> Accept <input type="checkbox"/> Comments	
1	1.0	3	4	4	Tested 3.67 to 1,019.7 U/L	
2	2.0	247	248	247	Validated 3.67 to 1,019.7 U/L	
3	3.0	499	500	501	Mean versus Target Regression $y = 1.035x - 5.043$ $r^2 = 0.9992$ SE _{y,x} = 10.8	
4	4.0	784	786	782		
5	5.0	1016	1021	1022		
X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	2.17	3.67	1.50	69.1%	2.50	N/A
2.0	250.33	247.33	3.00	1.2%	25.03	10%
3.0	498.50	500.00	1.50	0.3%	49.85	10%
4.0	746.67	784.00	37.33	5.0%	74.67	10%
5.0	994.83	1,019.67	24.84	2.5%	99.48	10%



Summary: LGC Maine Standards Technical Support advised that recovery and reproducibility was not consistent with Peers. In this case, a cracked syringe case caused the impression seen between repetitions. This case study emphasizes that calibration and running QC may not always detect instrument issues.