

Case Study #2: Recalibration Does Not Correct Nonlinear Response, Additional Troubleshooting Used

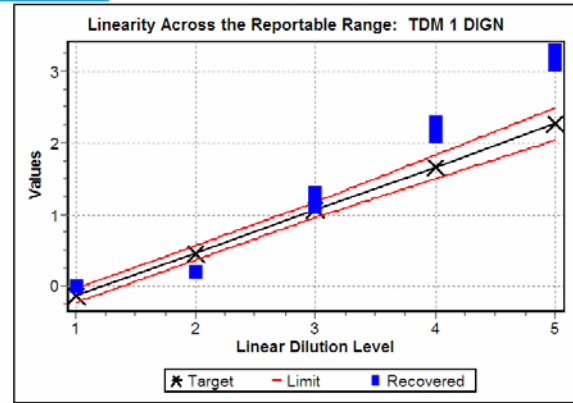
Initial Results: A laboratory performed routine calibration verification / linearity testing using VALIDATE[®] TDM1. One analyte tested was Digoxin. The following was the report generated using MSDRx[®], the Maine Standards Data Reduction software:

TDM 1 DIGN

published CLIA total allowable error is 0.2 ng/mL or 20%, whichever is greater

L	X	Rep 1	Rep 2	Rep 3	Accept	Comments
B	N/A				<input type="checkbox"/>	
1	1.0	0	0	0	<input type="checkbox"/>	Tested 0.00 to 3.20 ng/mL
2	2.0	0.2	0.2	0.2	<input type="checkbox"/>	Validated _____ to _____ ng/mL
3	3.0	1.2	1.1	1.3	<input type="checkbox"/>	Mean versus Target Regression $y = 1.400x - 0.133$
4	4.0	2.2	2.3	2.1	<input type="checkbox"/>	
5	5.0	3.1	3.2	3.3	<input type="checkbox"/>	

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	-0.133	0.000	** 0.133	100.0%	0.100	N/A
2.0	0.467	0.200	** 0.267	57.2%	0.100	N/A
3.0	1.067	1.200	0.133	** 12.5%	0.107	10%
4.0	1.667	2.200	0.533	** 32.0%	0.167	10%
5.0	2.267	3.200	0.933	** 41.2%	0.227	10%



The laboratory contacted Maine Standards Company Technical Support. Technical Support advised the laboratory that results were not consistent with Peers or with typical product performance. The experiment was showing nonlinearity in the method, and recovery was well below the typical range of the product.

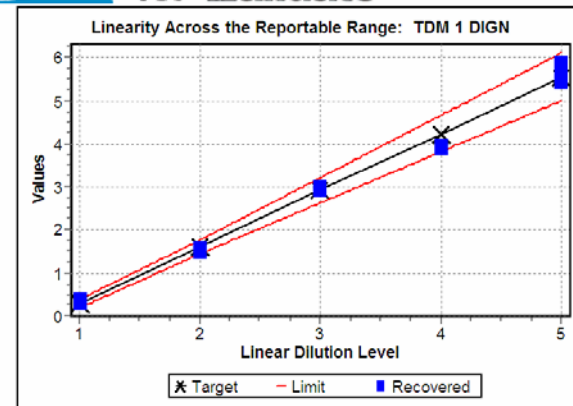
Troubleshooting: The laboratory took the troubleshooting step of recalibrating their DIGN assay. However, the calibration failed. After several unsuccessful attempts to recalibrate the DIGN assay, the laboratory requested a service call from the instrument manufacturer. During the service call, a probe alignment issue was discovered and corrected. To confirm that the nonlinear response was corrected, the laboratory re-ran the calibration verification / linearity testing. The updated MSDRx[®] report 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.

TDM 1 DIGN

published CLIA total allowable error is 0.2 ng/mL or 20%, whichever is greater

L	X	Rep 1	Rep 2	Rep 3	Accept	Comments
B	N/A				<input type="checkbox"/>	
1	1.0	0.38	0.29	0.33	<input type="checkbox"/>	Tested 0.33 to 5.65 ng/mL
2	2.0	1.48	1.59	1.54	<input type="checkbox"/>	Validated 0.33 to 5.65 ng/mL
3	3.0	2.93	3.0	2.96	<input type="checkbox"/>	Mean versus Target Regression $y = 0.991x - 0.016$
4	4.0	3.96	3.9	3.93	<input type="checkbox"/>	
5	5.0	5.88	5.42	5.65	<input type="checkbox"/>	

X	Target	Mean	+/- Diff	% Diff	+/- Limit	% Limit
1.0	0.296	0.333	0.037	12.5%	0.100	N/A
2.0	1.611	1.537	0.074	4.6%	0.161	10%
3.0	2.926	2.963	0.037	1.3%	0.293	10%
4.0	4.241	3.930	0.311	7.3%	0.424	10%
5.0	5.556	5.650	0.094	1.7%	0.556	10%



Summary: In this case, routine calibration verification / linearity testing demonstrated nonlinear response across the reportable range of the method and Maine Standards Company Technical Support advised that recovery was not consistent with Peers. Recalibration did not correct the response, and service was called. System maintenance, recalibration, and repeating the calibration verification / linearity testing verified the method's correct response.

765 ROOSEVELT TRAIL • WINDHAM, MAINE 04062

TEL: 207.892.1300 • FAX: 207.892.2266 • TOLL-FREE: 800.377.9684

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