## Case Study #5: Impression 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 impression at levels 2 through 5. The following was the AST report generated using MSDRx®, Maine Standards Data Reduction software:

**GC 3 AST - Method: UV IFCC**

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

**Data Set**

| L | X | Rep 1 | Rep 2 | Rep 3 |
|---|---|---|---|---|
| B | N/A | 1 | 2 | 2 |
| 1 | 1.0 | 4 | 5 | 4 |
| 2 | 2.0 | 363 | 305 | 270 |
| 3 | 3.0 | 675 | 602 | 529 |
| 4 | 4.0 | 868 | 805 | 780 |
| 5 | 5.0 | 1095 | 1027 | 1051 |

☐ Accept ☐ Comments

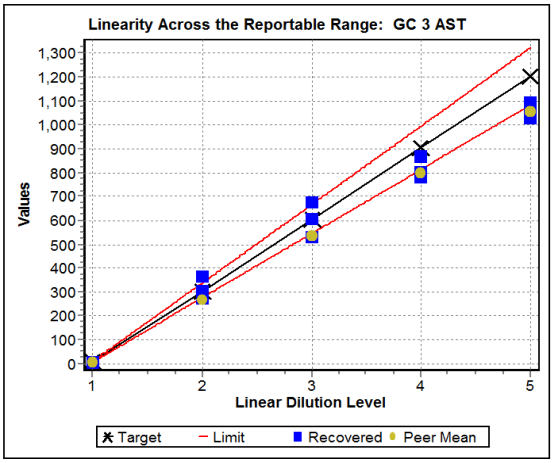
Tested 4.33 to 1,057.7 U/L

Validated _____ to _____ U/L

Mean versus Target Regression
y = 0.874x + 29.979

**Linearity Results**

| 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 Maine Standards Company 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 - Method: UV IFCC**

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

**Data Set**

| L | X | Rep 1 | Rep 2 | Rep 3 |
|---|---|---|---|---|
| B | N/A | 1 | 2 | 2 |
| 1 | 1.0 | 3 | 4 | 4 |
| 2 | 2.0 | 247 | 248 | 247 |
| 3 | 3.0 | 499 | 500 | 501 |
| 4 | 4.0 | 784 | 786 | 782 |
| 5 | 5.0 | 1016 | 1021 | 1022 |

☐ Accept ☐ Comments

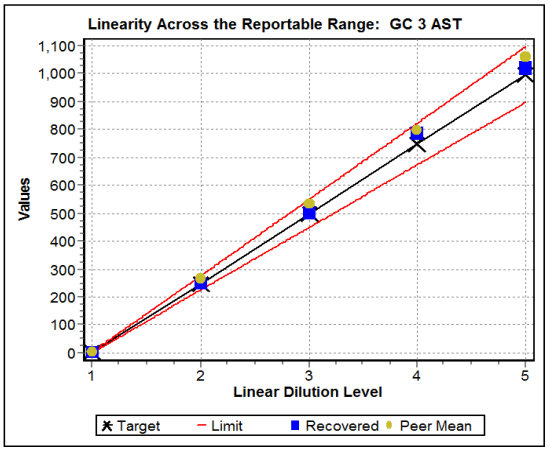
Tested 3.67 to 1,019.7 U/L

Validated 3.67 to 1,019.7 U/L

Mean versus Target Regression
y = 1.035x - 5.043

**Linearity Results**

| 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:** Maine Standards Company 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.


221 US ROUTE 1 • CUMBERLAND FORESIDE, MAINE 04110
TEL: 207.892.1300 • FAX: 207.892.2266 • TOLL-FREE: 800.377.9684
www.mainestandards.com