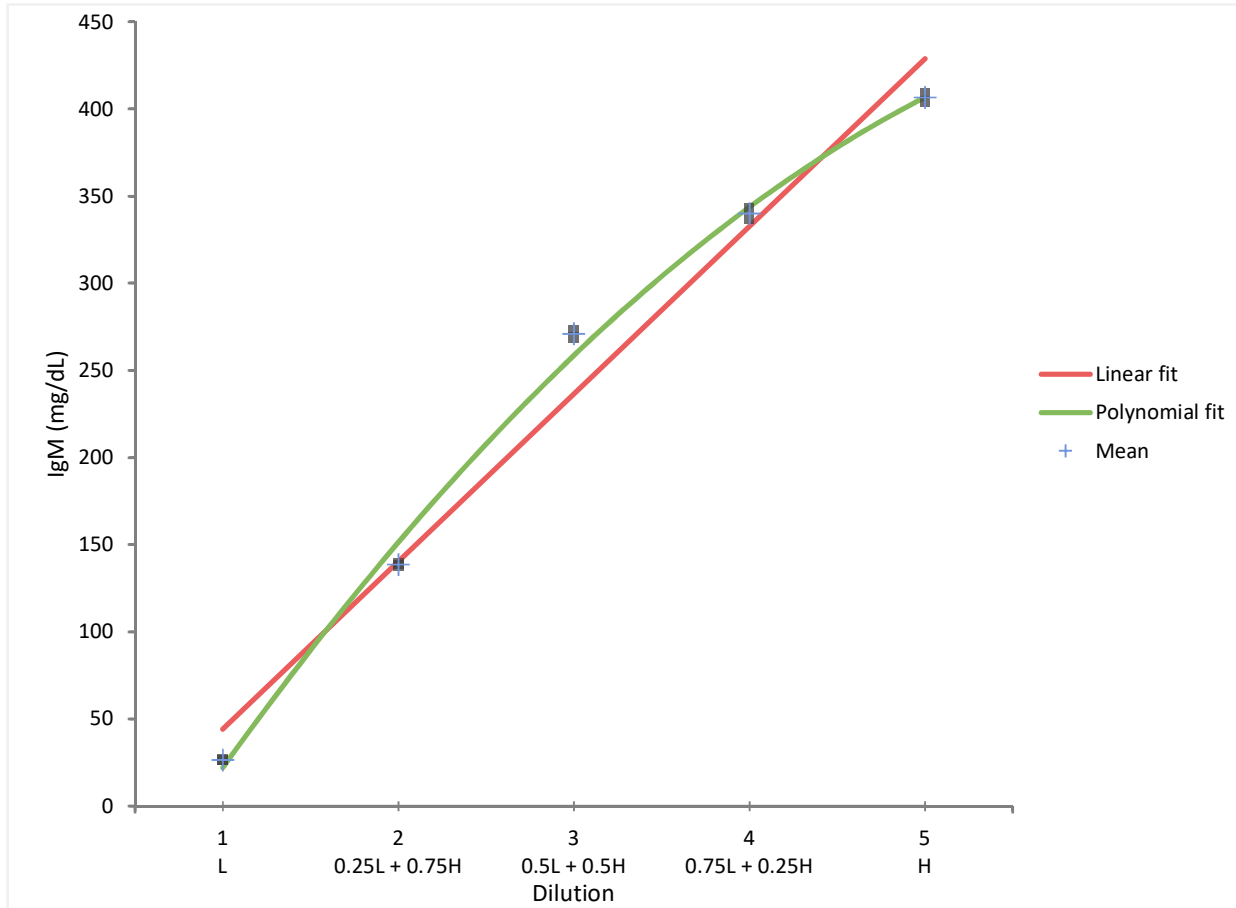


Descriptives



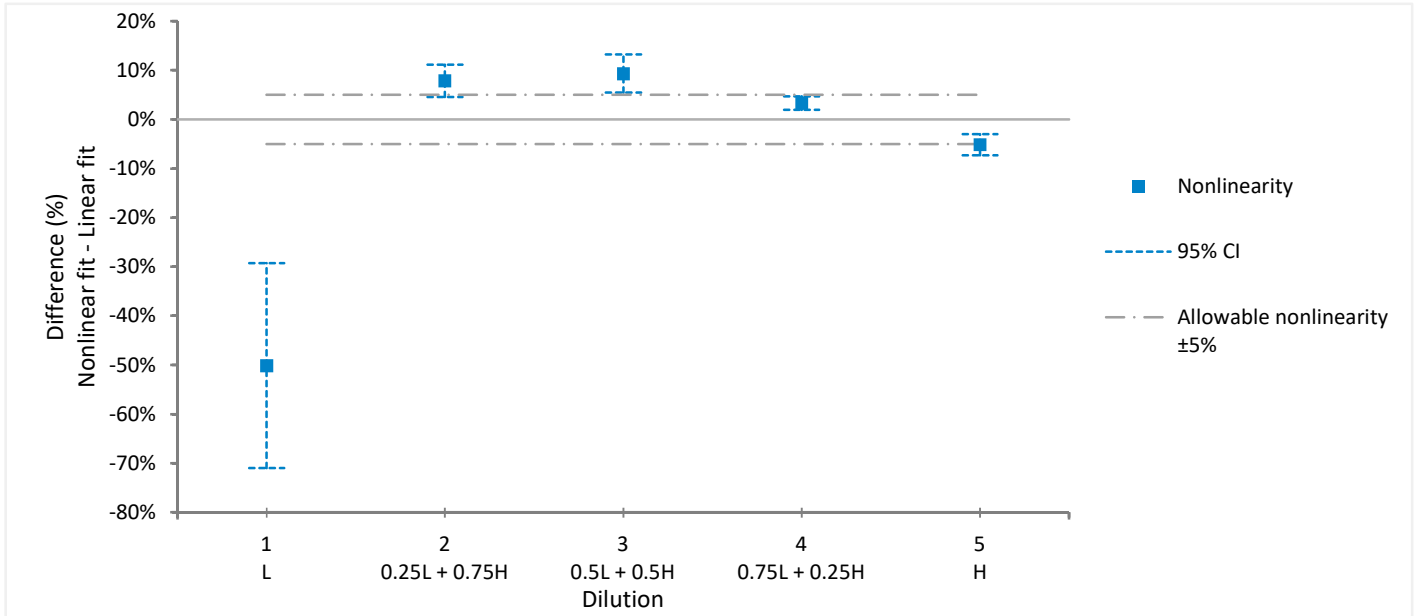
N | 10
Design | 5 Dilution x 2 Observations

Measuring interval | 26.35 to 406.50

Precision

| Dilution | Mean | SD | CV | Allowable SD / CV |
|----------|--------|------|------|----------------------|
| 1 | 26.35 | 0.21 | 0.8% | 2.0% |
| 2 | 138.50 | 0.71 | 0.5% | 2.0% |
| 3 | 271.00 | 2.83 | 1.0% | 2.0% |
| 4 | 340.00 | 4.24 | 1.2% | 2.0% |
| 5 | 406.50 | 3.54 | 0.9% | 2.0% |
| Pooled | | 2.79 | 0.9% | 2.0% |

Linearity



| Dilution | Linear fit | Nonlinear fit (2nd order polynomial) | Nonlinearity | 95% CI | Allowable nonlinearity |
|----------|------------|--------------------------------------|--------------|------------------|------------------------|
| 1 | 44.11 | 22.00 | -50.1%* | -71.0% to -29.3% | ±5.0% |
| 2 | 140.29 | 151.35 | 7.9%* | 4.6% to 11.2% | ±5.0% |
| 3 | 236.47 | 258.58 | 9.4%* | 5.5% to 13.2% | ±5.0% |
| 4 | 332.65 | 343.71 | 3.3% | 1.9% to 4.7% | ±5.0% |
| 5 | 428.83 | 406.72 | -5.2%* | -7.3% to -3.0% | ±5.0% |

* Performance requirement not met.

Fit Model

Linear fit

RMSE | 22.82

| Parameter | Estimate | SE | t | DF | p-value |
|-----------|----------|--------|---|----|---------|
| Constant | -52.07 | 16.924 | - | - | - |
| X | 96.18 | 5.1028 | - | - | - |

2nd order polynomial fit

RMSE | 10.30

| Parameter | Estimate | SE | t | DF | p-value |
|----------------|----------|--------|-------|----|---------------------|
| Constant | -129.5 | 15.624 | - | - | - |
| X | 162.5 | 11.907 | - | - | - |
| X ² | -11.06 | 1.9469 | -5.68 | 7 | 0.0008 ¹ |

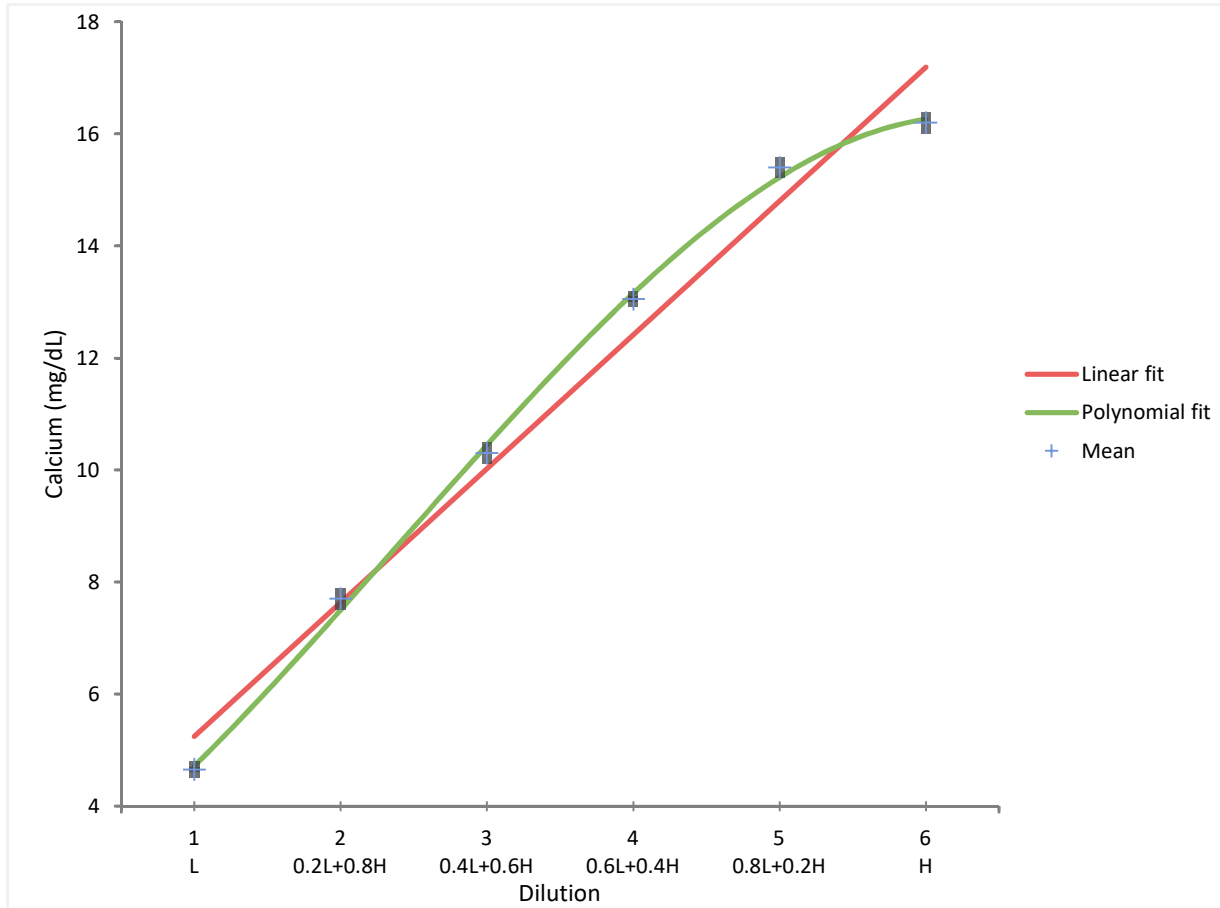
¹ Nonlinear parameter is different from 0 at the 5% significance level.

3rd order polynomial fit

RMSE | 10.32

| Parameter | Estimate | SE | t | DF | p-value |
|----------------|----------|--------|-------|----|---------|
| Constant | -97.48 | 35.884 | - | - | - |
| X | 117.6 | 46.906 | - | - | - |
| X ² | 6.080 | 17.410 | 0.35 | 6 | 0.7388 |
| X ³ | -1.904 | 1.9223 | -0.99 | 6 | 0.3601 |

Descriptives



N | 12
Design | 6 Dilution x 2 Observations

MSA: Calcium

CLSI EP06-A - Appendix C

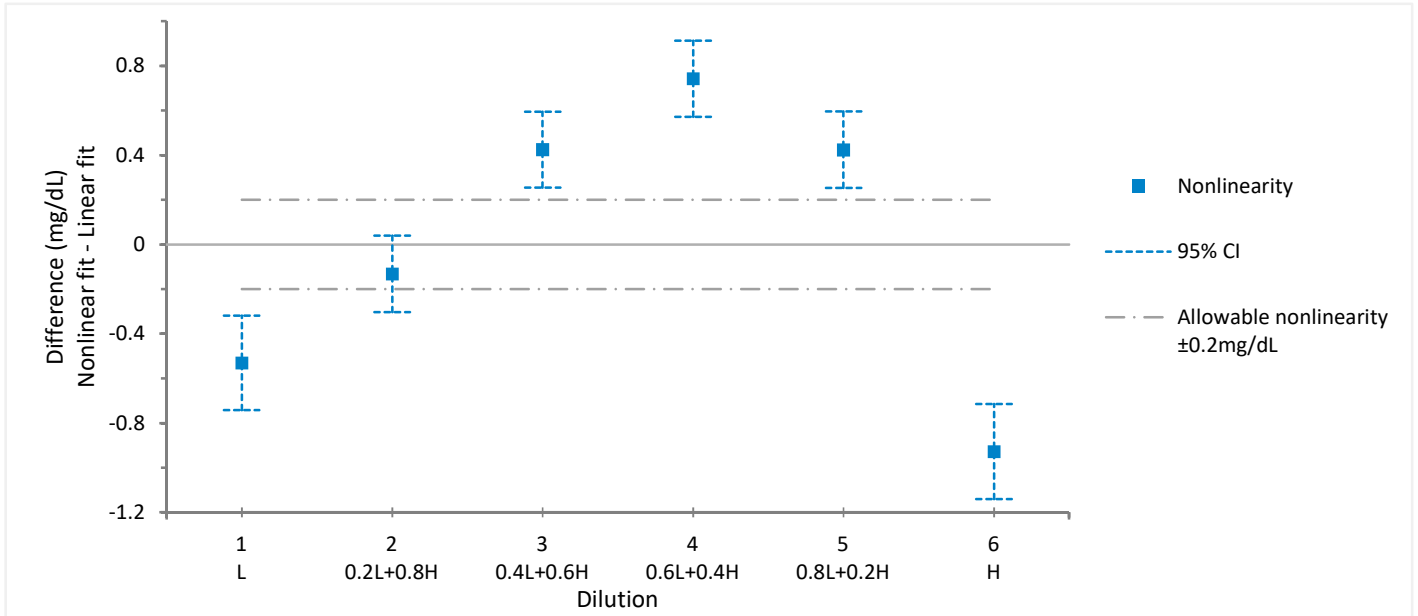
Last updated 10 August 2018 at 12:14 by Simon

Measuring interval | 4.65 to 16.20

Precision

| Dilution | Mean | SD | CV |
|----------|-------|------|------|
| 1 | 4.65 | 0.07 | 1.5% |
| 2 | 7.70 | 0.14 | 1.8% |
| 3 | 10.30 | 0.14 | 1.4% |
| 4 | 13.05 | 0.07 | 0.5% |
| 5 | 15.40 | 0.14 | 0.9% |
| 6 | 16.20 | 0.14 | 0.9% |
| Pooled | | 0.12 | 1.3% |

Linearity



| Dilution | Linear fit | Nonlinear fit (3rd order polynomial) | Nonlinearity | 95% CI | Allowable nonlinearity |
|----------|------------|--------------------------------------|--------------|----------------|------------------------|
| 1 | 5.25 | 4.71 | -0.53 * | -0.74 to -0.32 | ±0.20 |
| 2 | 7.63 | 7.50 | -0.13 | -0.30 to 0.04 | ±0.20 |
| 3 | 10.02 | 10.45 | 0.42 * | 0.25 to 0.59 | ±0.20 |
| 4 | 12.41 | 13.15 | 0.74 * | 0.57 to 0.91 | ±0.20 |
| 5 | 14.80 | 15.22 | 0.42 * | 0.25 to 0.60 | ±0.20 |
| 6 | 17.19 | 16.26 | -0.93 * | -1.14 to -0.72 | ±0.20 |

* Performance requirement not met.

Fit Model

Linear fit

RMSE | 0.67

| Parameter | Estimate | SE | t | DF | p-value |
|-----------|----------|---------|---|----|---------|
| Constant | 2.857 | 0.43923 | - | - | - |
| X | 2.389 | 0.11278 | - | - | - |

2nd order polynomial fit

RMSE | 0.31

| Parameter | Estimate | SE | t | DF | p-value |
|----------------|----------|----------|-------|----|---------------------|
| Constant | 0.8150 | 0.39535 | - | - | - |
| X | 3.920 | 0.25865 | - | - | - |
| X ² | -0.2188 | 0.036170 | -6.05 | 9 | 0.0002 ¹ |

¹ Nonlinear parameter is different from 0 at the 5% significance level.

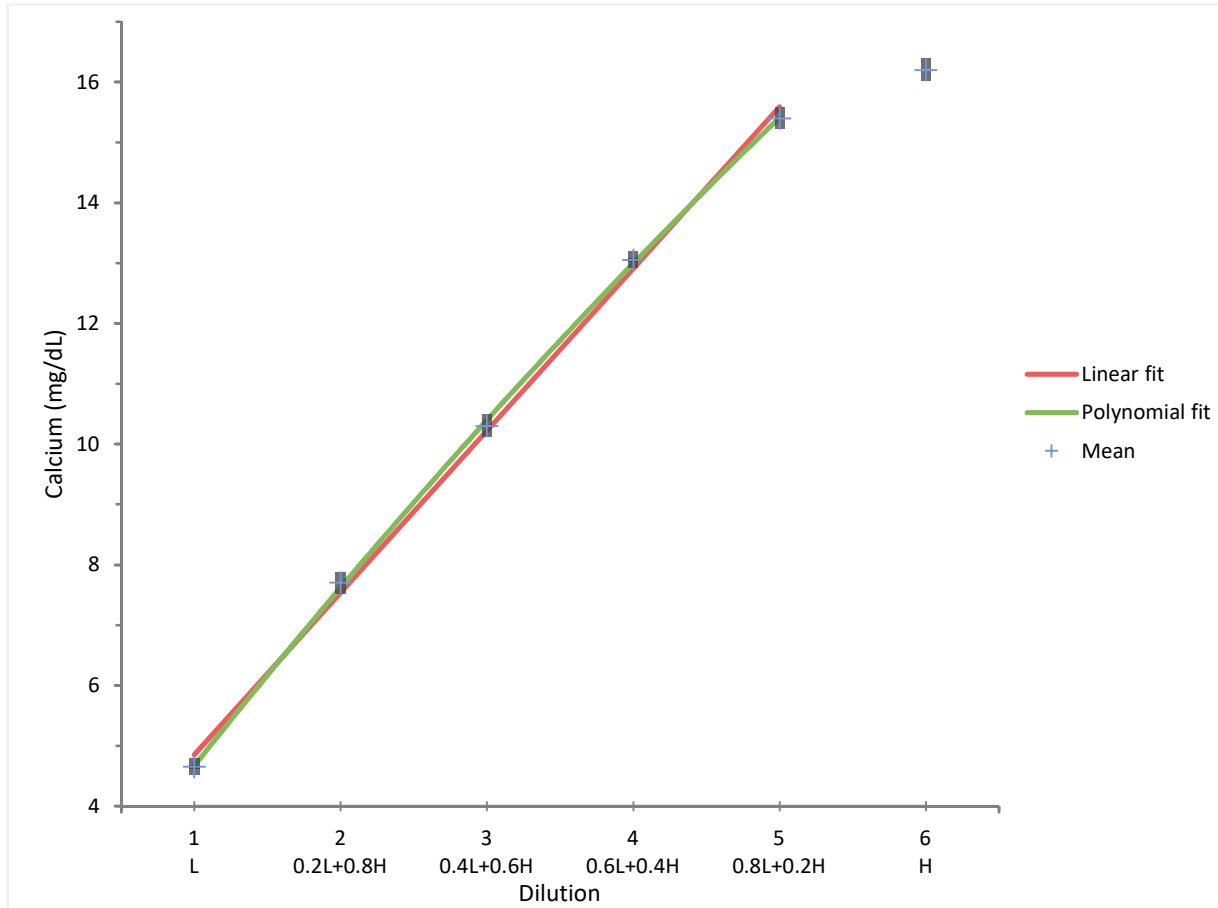
3rd order polynomial fit

RMSE | 0.20

| Parameter | Estimate | SE | t | DF | p-value |
|----------------|----------|----------|-------|----|---------------------|
| Constant | 2.483 | 0.50280 | - | - | - |
| X | 1.821 | 0.57290 | - | - | - |
| X ² | 0.4764 | 0.18332 | 2.60 | 8 | 0.0317 ¹ |
| X ³ | -0.06620 | 0.017324 | -3.82 | 8 | 0.0051 ¹ |

¹ Nonlinear parameter is different from 0 at the 5% significance level.

Descriptives



N | 12
Design | 6 Dilution x 2 Observations

MSA: Calcium

CLSI EP06-A - Appendix C

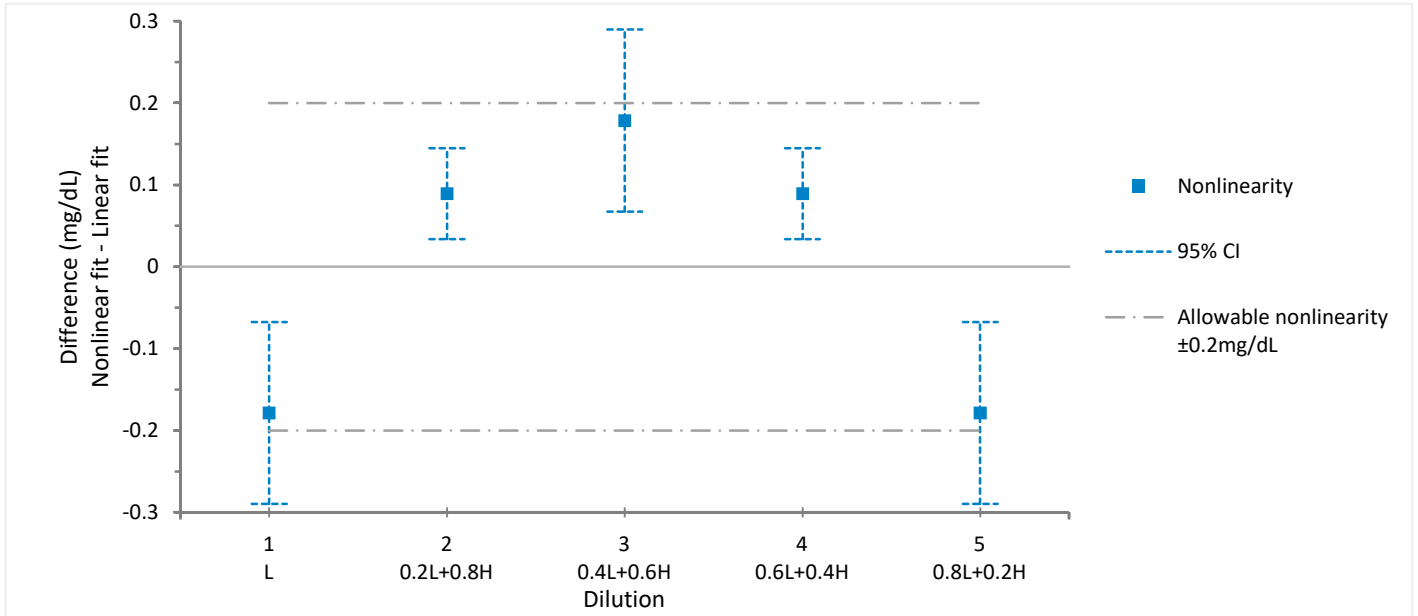
Last updated 10 August 2018 at 12:14 by Simon

| | |
|--------------------|---------------|
| Measuring interval | 4.65 to 16.20 |
| Reduced interval | 4.65 to 15.40 |

Precision

| Dilution | Mean | SD | CV |
|----------|-------|------|------|
| 1 | 4.65 | 0.07 | 1.5% |
| 2 | 7.70 | 0.14 | 1.8% |
| 3 | 10.30 | 0.14 | 1.4% |
| 4 | 13.05 | 0.07 | 0.5% |
| 5 | 15.40 | 0.14 | 0.9% |
| 6 | 16.20 | 0.14 | 0.9% |
| Pooled | | 0.12 | 1.3% |

Linearity



| Dilution | Linear fit | Nonlinear fit (2nd order polynomial) | Nonlinearity | 95% CI | Allowable nonlinearity |
|----------|------------|--------------------------------------|--------------|----------------|------------------------|
| 1 | 4.85 | 4.67 | -0.18 | -0.29 to -0.07 | ±0.20 |
| 2 | 7.54 | 7.62 | 0.09 | 0.03 to 0.14 | ±0.20 |
| 3 | 10.22 | 10.40 | 0.18 | 0.07 to 0.29 | ±0.20 |
| 4 | 12.91 | 12.99 | 0.09 | 0.03 to 0.14 | ±0.20 |
| 5 | 15.59 | 15.41 | -0.18 | -0.29 to -0.07 | ±0.20 |

Fit Model

Linear fit

RMSE | 0.20

| Parameter | Estimate | SE | t | DF | p-value |
|-----------|----------|----------|---|----|---------|
| Constant | 2.165 | 0.15097 | - | - | - |
| X | 2.685 | 0.045518 | - | - | - |

2nd order polynomial fit

RMSE | 0.12

| Parameter | Estimate | SE | t | DF | p-value |
|----------------|----------|----------|-------|----|---------------------|
| Constant | 1.540 | 0.18863 | - | - | - |
| X | 3.221 | 0.14375 | - | - | - |
| X ² | -0.08929 | 0.023505 | -3.80 | 7 | 0.0067 ¹ |

¹ Nonlinear parameter is different from 0 at the 5% significance level.

3rd order polynomial fit

RMSE | 0.13

| Parameter | Estimate | SE | t | DF | p-value |
|----------------|----------|----------|-------|----|---------|
| Constant | 1.470 | 0.46623 | - | - | - |
| X | 3.319 | 0.60943 | - | - | - |
| X ² | -0.1268 | 0.22620 | -0.56 | 6 | 0.5954 |
| X ³ | 0.004167 | 0.024975 | 0.17 | 6 | 0.8730 |