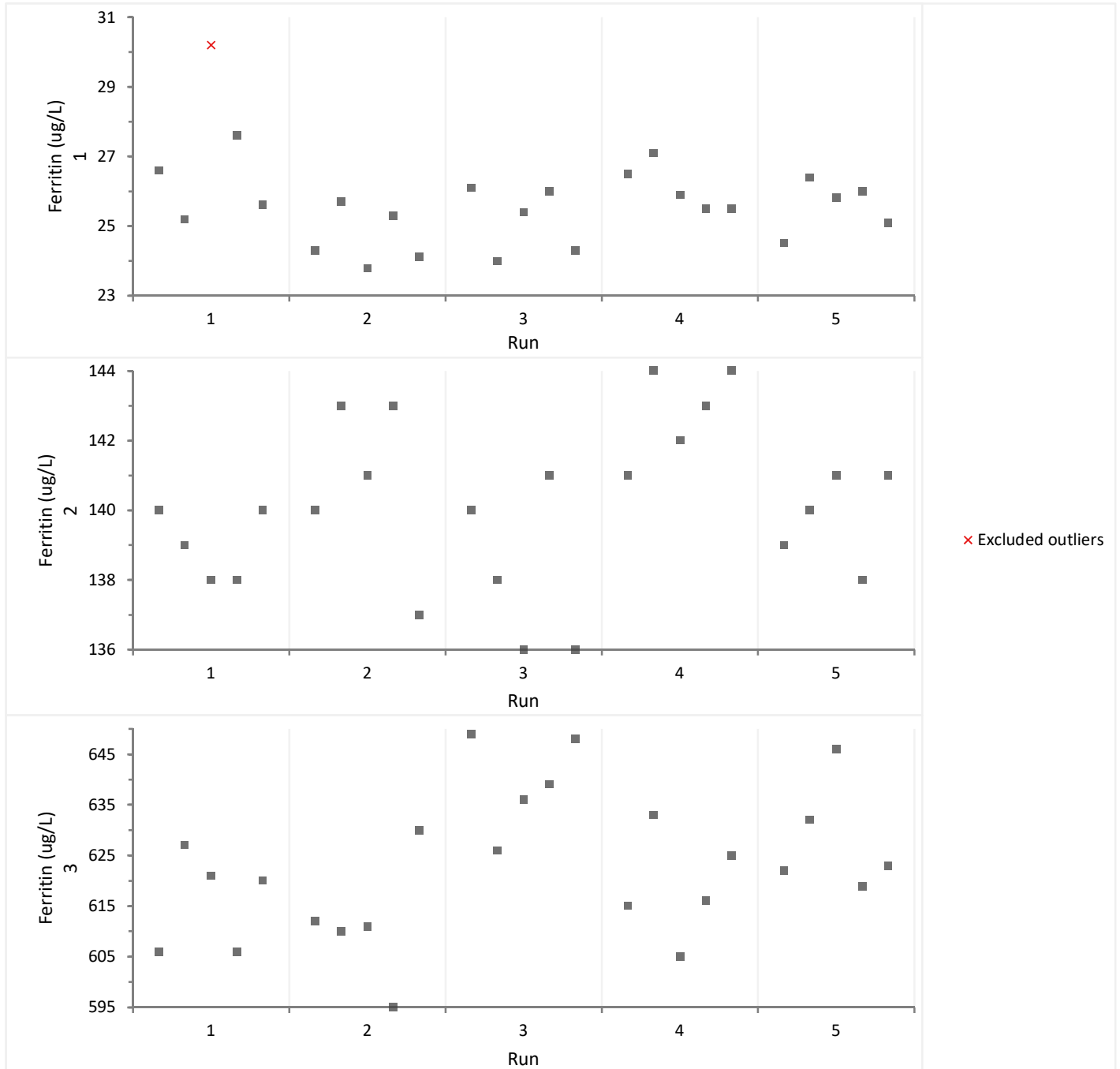


MSA: Ferritin

CLSI EP15-A3 - Table 8

Last updated 10 August 2018 at 12:24 by Simon

Descriptives



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| Sample, Run, # | Outlier # | Outlier | Mean | SD | Z | Critical value |
|----------------|-----------|---------|-------|------|------|----------------|
| 1, 1, 3 | 1 | 30.2 | 25.70 | 1.35 | 3.34 | 3.14 |

Outliers excluded from analysis.

| | |
|--------|-----------------------------------|
| N | 74 |
| Design | 3 Sample x 5 Run x 5 Observations |

Unequal number of observations for all possible combinations of factor levels.

| | |
|--------------------|-----------------|
| Measuring interval | 25.51 to 622.88 |
|--------------------|-----------------|

MSA: Ferritin

CLSI EP15-A3 - Table 8

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Precision

| Sample | Mean | Within Run SD | Within Run CV | Total SD | Total CV |
|--------|--------|---------------|---------------|----------|----------|
| 1 | 25.51 | 0.86 | 3.4% | 1.01 | 4.0% |
| 2 | 140.12 | 1.78 | 1.3% | 2.39 | 1.7% |
| 3 | 622.88 | 10.65 | 1.7% | 14.70 | 2.4% |

Sample 1

| Component | SD | CV | Expected SD / CV | p-value |
|-------------|------|------|------------------|---------------------|
| Within Run | 0.86 | 3.4% | 3.3% | 0.4023 ¹ |
| Between Run | 0.53 | 2.1% | | |
| Total | 1.01 | 4.0% | 5.3% | 0.9154 ¹ |

H0: $\sigma \leq \sigma_0$

The imprecision is less than or equal to the expected imprecision.

H1: $\sigma > \sigma_0$

The imprecision is greater than the expected imprecision.

¹ Do not reject the null hypothesis at the 5% familywise (1.67% individual) significance level.

X² test

| | SD | Expected SD | X ² statistic | DF | p-value |
|------------|------|-------------|--------------------------|------|---------|
| Within Run | 0.86 | 0.84 | 19.87 | 19 | 0.4023 |
| Total | 1.01 | 1.35 | 8.91 | 16.0 | 0.9154 |

ANOVA

| Source | Type I SS | DF | MS | Expected MS |
|--------|-----------|----|------|--|
| Run | 8.34 | 4 | 2.09 | $\sigma_{Error}^2 + 4.792\sigma_{Run}^2$ |
| Error | 14.09 | 19 | 0.74 | σ_{Error}^2 |

MSA: Ferritin

CLSI EP15-A3 - Table 8

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Sample 2

| Component | SD | CV | Expected SD / CV | p-value |
|-------------|------|------|------------------|---------------------|
| Within Run | 1.78 | 1.3% | 2.0% | 0.9915 ¹ |
| Between Run | 1.59 | 1.1% | | |
| Total | 2.39 | 1.7% | 3.4% | 0.9945 ¹ |

H0: $\sigma \leq \sigma_0$

The imprecision is less than or equal to the expected imprecision.

H1: $\sigma > \sigma_0$

The imprecision is greater than the expected imprecision.

¹ Do not reject the null hypothesis at the 5% familywise (1.67% individual) significance level.

X² test

| | SD | Expected SD | X ² statistic | DF | p-value |
|------------|------|-------------|--------------------------|------|---------|
| Within Run | 1.78 | 2.80 | 8.05 | 20 | 0.9915 |
| Total | 2.39 | 4.76 | 2.88 | 11.5 | 0.9945 |

ANOVA

| Source | SS | DF | MS | Expected MS |
|--------|-------|----|-------|--|
| Run | 63.44 | 4 | 15.86 | $\sigma_{\text{Error}}^2 + 5\sigma_{\text{Run}}^2$ |
| Error | 63.20 | 20 | 3.16 | σ_{Error}^2 |

MSA: Ferritin

CLSI EP15-A3 - Table 8

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Sample 3

| Component | SD | CV | Expected SD / CV | p-value |
|-------------|-------|------|------------------|---------------------|
| Within Run | 10.65 | 1.7% | 1.6% | 0.2958 ¹ |
| Between Run | 10.13 | 1.6% | | |
| Total | 14.70 | 2.4% | 2.8% | 0.7265 ¹ |

H0: $\sigma \leq \sigma_0$

The imprecision is less than or equal to the expected imprecision.

H1: $\sigma > \sigma_0$

The imprecision is greater than the expected imprecision.

¹ Do not reject the null hypothesis at the 5% familywise (1.67% individual) significance level.

X² test

| | SD | Expected SD | X ² statistic | DF | p-value |
|------------|-------|-------------|--------------------------|------|---------|
| Within Run | 10.65 | 9.97 | 22.86 | 20 | 0.2958 |
| Total | 14.70 | 17.44 | 7.65 | 10.8 | 0.7265 |

ANOVA

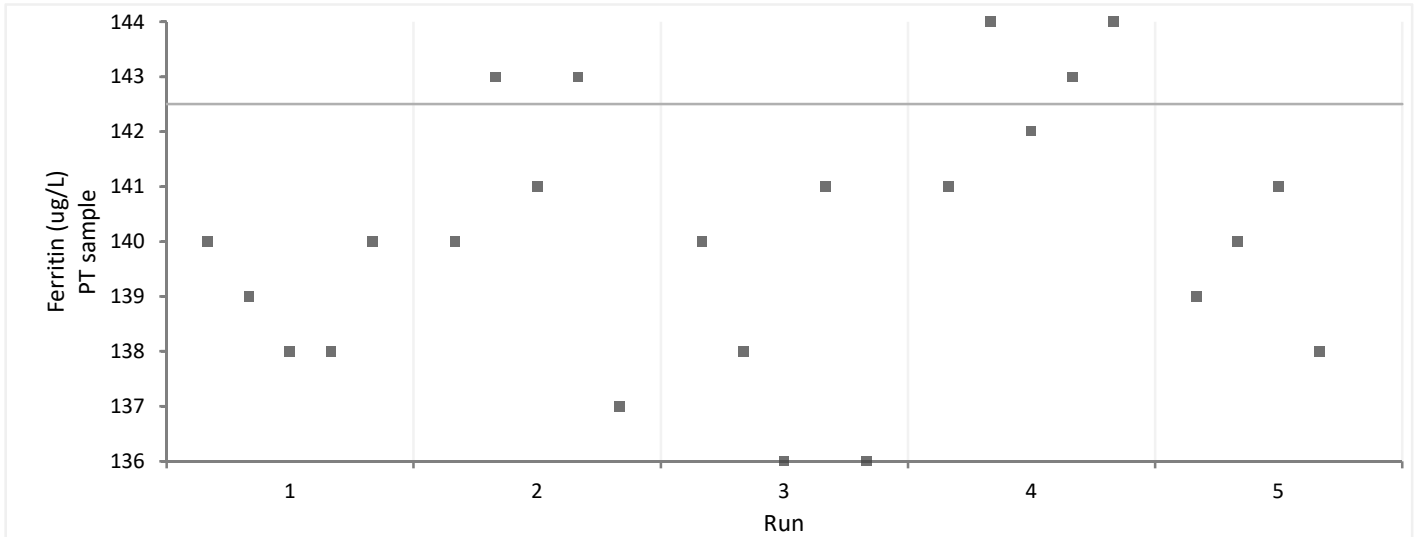
| Source | SS | DF | MS | Expected MS |
|--------|---------|----|--------|--|
| Run | 2506.24 | 4 | 626.56 | $\sigma_{\text{Error}}^2 + 5\sigma_{\text{Run}}^2$ |
| Error | 2270.40 | 20 | 113.52 | σ_{Error}^2 |

MSA: Ferritin

CLSI EP15-A3: Example 1Z

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Descriptives



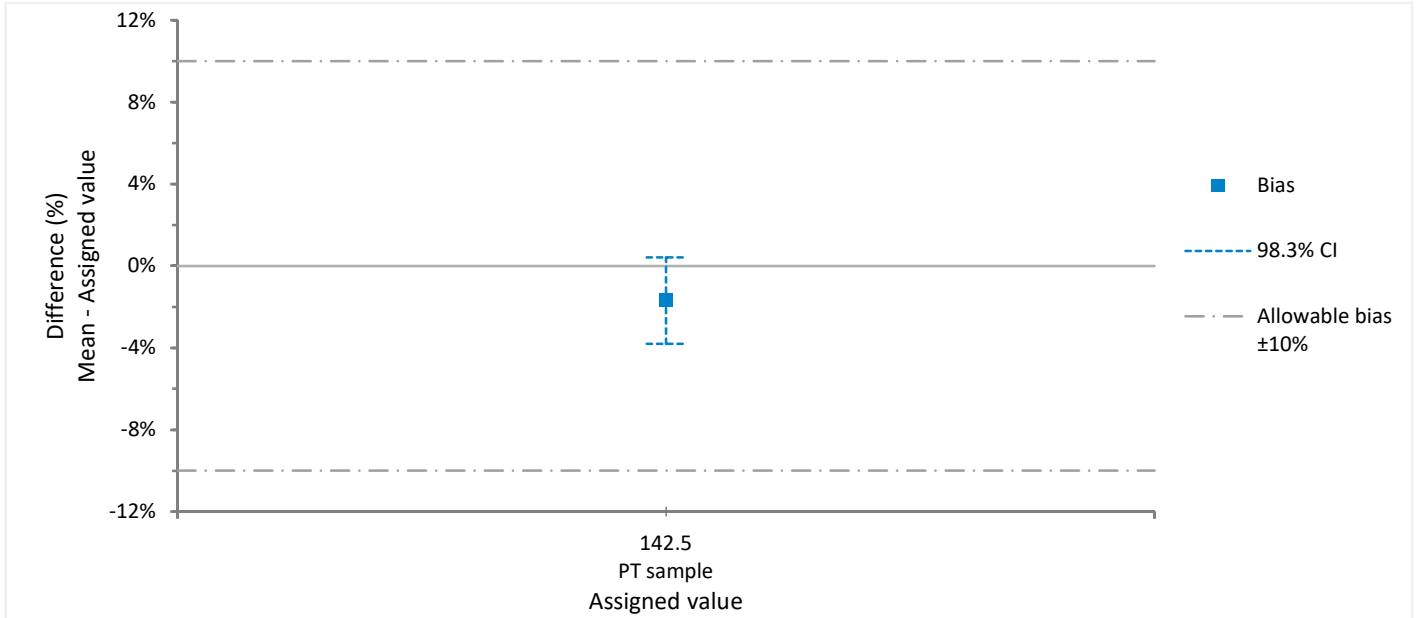
N | 24
 Design | 5 Run x 5 Observations

Unequal number of observations for all possible combinations of factor levels.

| | Assigned value | Uncertainty SE | DF |
|-----------|----------------|----------------|----|
| PT sample | 142.5 | 0.69 | 42 |

| | N | Mean | Mean SE | Recovery |
|-----------|----|-------|---------|----------|
| PT sample | 24 | 140.1 | 0.82 | 98.3% |

Trueness



| Assigned value | Mean | Bias | 98.3% CI | Allowable bias | p-value |
|----------------|-------|-------|---------------|----------------|---------------------|
| 142.5 | 140.1 | -1.7% | -3.8% to 0.4% | ±10.0% | 0.0456 ¹ |

H0: $\delta = 0$

The bias is equal to 0.

H1: $\delta \neq 0$

The bias is not equal to 0.

¹ Do not reject the null hypothesis at the 1.67% significance level.

Student's t-test

| Assigned value | Difference | SE | t statistic | DF | p-value |
|----------------|------------|-----|-------------|------|---------|
| 142.5 | -2.4 | 1.1 | -2.25 | 11.1 | 0.0456 |