



# Evaluation of Technopath Controls on the ARCHITECT Family of Instruments

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## Abstract

**Introduction:** Quality controls are an important part of laboratory testing to ensure that released results meet the required quality in regards to accuracy and precision of patient results. Consolidation of controls is a current trend in laboratories to simplify QC testing. Multi-constituent control panels (MCCs) offered by Technopath Manufacturing Ltd. cover a wide range of clinical chemistry and immunoassay analytes for both serum and urine.

**Objective:** The goal of this study was to evaluate the performance of the Multichem S Plus, Multichem IA Plus and Multichem U control panels on the ARCHITECT family of instruments. Precision and accuracy compared to the target value were evaluated.

**Methods:** The three control panels were evaluated for a minimum of 30 days. Testing was performed on two ARCHITECT c8000 and three ARCHITECT i2000<sub>SR</sub> instruments. Data presented here are from the following serum clinical chemistry analytes: ALT, AST, total bilirubin, chloride, total cholesterol, creatinine (picrate), glucose, potassium, total protein, sodium, triglycerides and urea; the following immunoassay analytes: CEA, total PSA, free T3, free T4, TSH, troponin-I, total beta HCG, estradiol, ferritin, FSH, vitamin B12 and vitamin D; and the following clinical chemistry urine analytes: chloride, creatinine (picrate), glucose, potassium, sodium and urea. The Multichem S Plus and IA Plus panels are serum based with three control levels; the Multichem U panel is prepared from human urine with two control levels. All data were collected via AbbottLink, allowing for automated data retrieval. Means, standard deviations and ranges were calculated for all controls. Sigma Metrics were also calculated for each analyte.

**Results:** The %CV for the 12 clinical chemistry analytes with the Multichem S Plus control ranged from 0.46 to 5.33%. The %CV for the 6 clinical chemistry urine analytes with the Multichem U control ranged from 0.51 to 3.2%. For both control panels, the majority of the CVs were less than 2%. The %CV for the 12 immunoassay analytes with the Multichem IA Plus control ranged from 1.34 to 18.87% (Tnl, Level 1); however the majority of the CVs were less than 5%. Overall, little variation was seen from instrument to instrument.

**Conclusions:** The Technopath S Plus, IA Plus and U controls performed well and demonstrated similar performance to the routine internal laboratory quality controls. The use of these MCCs reduced the number of controls required for the analytical quality control testing of both clinical chemistry and immunoassay analytes with no compromise to quality.

## Background

Efficient analytical and quality control is important for testing laboratories to ensure that released results meet the required quality in regards to accuracy and precision. Consolidation of quality controls simplifies workflow in the laboratory. However, changing of quality controls necessitates careful evaluation by the laboratory. Technopath Manufacturing Ltd (Ballina, Ireland) recently introduced multi-constituent controls (MCC) for use with the Abbott ARCHITECT instruments that allows one control to be used for the majority of the assays available in the routine lab on the ARCHITECT instruments. The performance of the Technopath Multichem S Plus, Multichem IA Plus and Multichem U control panels were evaluated in comparison to the laboratory's current QC methods on two ARCHITECT c8000 and three ARCHITECT i2000<sub>SR</sub> instruments at Winchester Medical Center in Winchester, VA.

## Materials & Methods

Technopath Multichem S Plus, U and IA Plus controls are prepared from human serum or urine to which purified biochemical material (extracts of human and animal origin), chemicals, drugs, preservatives and stabilizers are added. The S Plus and IA Plus controls are provided in liquid form and stored frozen (-20 to -80°C) until use. Once thawed, the material is stored at 2-8°C and stable for 10 days unless otherwise stated in the lot specific data sheets. The S Plus controls have three levels covering

## Materials & Methods (cont'd)

60 analytes. The IA Plus covers 45 analytes with three control levels. The U controls are provided in liquid form and stored at 2-8°C. Once the material is opened, it should be stored tightly capped at 2-8°C and is stable for 30 days unless otherwise stated in the lot specific data sheets. Thirteen analytes are included in the U control at two different levels.

Testing was performed on two ARCHITECT c8000 and three ARCHITECT i2000<sub>SR</sub> instruments. The three control panels were evaluated for a minimum of 30 days in parallel with the lab's routine QC controls. The routine QC controls included Bio-Rad Unassayed Multiqual Chemistry controls, Liquichek Urine Chemistry, Liquichek Immunoassay Plus, Liquichek Fertility, and Liquichek Cardiac Plus LT.

Data presented here are from the following serum clinical chemistry analytes: ALT, AST, total bilirubin, chloride, total cholesterol, creatinine (picrate), glucose, potassium, total protein, sodium, triglycerides and urea; the following immunoassay analytes: CEA, total PSA, free T3, free T4, TSH, troponin-I, total beta HCG, estradiol, ferritin, FSH, vitamin B12 and vitamin D; and the following clinical chemistry urine analytes: chloride, creatinine (picrate), glucose, potassium, sodium and urea. All data were collected via AbbottLink, allowing for automated data retrieval. Means, standard deviation and range were calculated for all controls.

Sigma-metrics were calculated for each analyte at each control level on each instrument using peer means and CV and Total Allowable Error (TEa) from the literature according to the following equation: Sigma-metric = (TEa - Bias)/CV. TEas were defined based on multiple sources, including the Clinical Laboratory Improvement Amendments (CLIA), The Royal College of Pathologists of Australasia (RCPA), Desirable Biological Variation Database<sup>1</sup>, Riilibak (Guidelines of the German Federal Medical Council), and literature references<sup>2</sup>.

## Results

The %CV for the 12 clinical chemistry analytes with the Multichem S Plus control ranged from 0.46% (Potassium) to 5.33% (Total Bilirubin).

The %CV for the 6 clinical chemistry urine analytes with the Multichem U control ranged from 0.51% (Chloride) to 3.2% (Urea). For both control panels, the majority of the CVs were less than 2%.

The %CV for the 12 immunoassay analytes with the Multichem IA Plus control ranged from 1.34% (Estradiol) to 18.87% (Troponin I, Level 1). The majority of the CVs were less than 5%. Overall, little variation was seen from instrument to instrument.

World class Six Sigma performance was seen with both Technopath and BioRad controls on the majority of analytes and control levels evaluated.

Analytical performance of the Technopath controls are summarized in the following tables.

## Conclusions

- The Technopath S Plus, IA Plus and U controls performed well and demonstrated similar performance to the routine internal laboratory quality controls.
- The use of these MCCs reduced the number of controls required for the analytical quality control testing of both clinical chemistry and immunoassay analytes with no compromise to quality.

## References

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ABBOTT ARCHITECT c8000 and i2000<sub>SR</sub> are trademarks of Abbott Laboratories.

## Results (cont'd)

### Multichem S Plus

| Assay                | Units  | Level   | Inst    | N  | Expected Mean | Mean   | SD    | CV   |
|----------------------|--------|---------|---------|----|---------------|--------|-------|------|
| ALT                  | U/L    | Level 1 | c8000#1 | 49 | 30.3          | 28     | 1.13  | 4.02 |
|                      |        |         | c8000#2 | 51 | 30.3          | 28.4   | 1.14  | 4.02 |
|                      |        | Level 2 | c8000#1 | 49 | 112           | 108.8  | 1.72  | 1.58 |
|                      |        |         | c8000#2 | 53 | 112           | 108.4  | 1.51  | 1.39 |
|                      |        | Level 3 | c8000#1 | 47 | 240           | 231.3  | 4.71  | 2.04 |
|                      |        |         | c8000#2 | 51 | 240           | 230.1  | 3.65  | 1.59 |
| AST                  | U/L    | Level 1 | c8000#1 | 52 | 43.9          | 43.4   | 0.86  | 1.97 |
|                      |        |         | c8000#2 | 51 | 43.9          | 42.3   | 0.75  | 1.78 |
|                      |        | Level 2 | c8000#1 | 51 | 128           | 127.4  | 1.58  | 1.24 |
|                      |        |         | c8000#2 | 53 | 128           | 125.1  | 1.23  | 0.98 |
|                      |        | Level 3 | c8000#1 | 49 | 255           | 251.4  | 1.89  | 0.75 |
|                      |        |         | c8000#2 | 51 | 255           | 247.5  | 1.72  | 0.7  |
| Chloride             | mmol/L | Level 1 | c8000#1 | 55 | 85.1          | 84.77  | 0.65  | 0.77 |
|                      |        |         | c8000#2 | 47 | 85.1          | 85.49  | 0.68  | 0.8  |
|                      |        | Level 2 | c8000#1 | 51 | 95.6          | 94.81  | 0.8   | 0.84 |
|                      |        |         | c8000#2 | 48 | 95.6          | 95.23  | 0.76  | 0.79 |
|                      |        | Level 3 | c8000#1 | 49 | 110           | 109.09 | 0.77  | 0.7  |
|                      |        |         | c8000#2 | 47 | 110           | 109.23 | 0.58  | 0.53 |
| Cholesterol          | mg/dL  | Level 1 | c8000#1 | 46 | 103           | 104.5  | 0.96  | 0.92 |
|                      |        |         | c8000#2 | 45 | 103           | 105    | 2.07  | 1.97 |
|                      |        | Level 2 | c8000#1 | 46 | 157           | 161.1  | 1.83  | 1.14 |
|                      |        |         | c8000#2 | 46 | 157           | 160.5  | 2.45  | 1.52 |
|                      |        | Level 3 | c8000#1 | 45 | 248           | 253.7  | 3.08  | 1.21 |
|                      |        |         | c8000#2 | 45 | 248           | 253    | 2.37  | 0.94 |
| Creatinine (picrate) | mg/dL  | Level 1 | c8000#1 | 46 | 0.697         | 0.7    | 0.01  | 1.91 |
|                      |        |         | c8000#2 | 46 | 0.697         | 0.7    | 0.02  | 2.41 |
|                      |        | Level 2 | c8000#1 | 49 | 1.97          | 1.99   | 0.03  | 1.6  |
|                      |        |         | c8000#2 | 48 | 1.97          | 2      | 0.04  | 1.94 |
|                      |        | Level 3 | c8000#1 | 48 | 5.02          | 6.09   | 0.07  | 1.15 |
|                      |        |         | c8000#2 | 46 | 5.02          | 6.11   | 0.07  | 1.18 |
| Glucose              | mg/dL  | Level 1 | c8000#1 | 49 | 50.8          | 51.6   | 0.54  | 1.05 |
|                      |        |         | c8000#2 | 47 | 50.8          | 51.8   | 0.58  | 1.12 |
|                      |        | Level 2 | c8000#1 | 50 | 133           | 133    | 1.27  | 0.95 |
|                      |        |         | c8000#2 | 48 | 133           | 134.7  | 1.3   | 0.97 |
|                      |        | Level 3 | c8000#1 | 48 | 292           | 287.7  | 2.35  | 0.82 |
|                      |        |         | c8000#2 | 47 | 292           | 292    | 3.16  | 1.08 |
| Potassium            | mmol/L | Level 1 | c8000#1 | 55 | 2.42          | 2.57   | 0.03  | 1.18 |
|                      |        |         | c8000#2 | 47 | 2.42          | 2.57   | 0.025 | 0.98 |
|                      |        | Level 2 | c8000#1 | 51 | 3.77          | 3.94   | 0.03  | 0.74 |
|                      |        |         | c8000#2 | 48 | 3.77          | 3.94   | 0.04  | 0.88 |
|                      |        | Level 3 | c8000#1 | 50 | 6.76          | 6.87   | 0.06  | 0.86 |
|                      |        |         | c8000#2 | 47 | 6.76          | 6.88   | 0.03  | 0.46 |
| Sodium               | mmol/L | Level 1 | c8000#1 | 55 | 121           | 120.7  | 1.13  | 0.93 |
|                      |        |         | c8000#2 | 47 | 121           | 121.26 | 0.96  | 0.79 |
|                      |        | Level 2 | c8000#1 | 51 | 141           | 140.56 | 1.11  | 0.79 |
|                      |        |         | c8000#2 | 48 | 141           | 141.14 | 1.24  | 0.88 |
|                      |        | Level 3 | c8000#1 | 50 | 161           | 161.18 | 1.2   | 0.74 |
|                      |        |         | c8000#2 | 47 | 161           | 161.68 | 0.88  | 0.55 |
| Total Bilirubin      | mg/dL  | Level 1 | c8000#1 | 46 | 0.998         | 0.94   | 0.05  | 5.33 |
|                      |        |         | c8000#2 | 43 | 0.998         | 0.93   | 0.04  | 4.06 |
|                      |        | Level 2 | c8000#1 | 46 | 2.64          | 2.48   | 0.07  | 2.81 |
|                      |        |         | c8000#2 | 48 | 2.64          | 2.49   | 0.08  | 3.13 |
|                      |        | Level 3 | c8000#1 | 46 | 5.55          | 4.84   | 0.19  | 3.89 |
|                      |        |         | c8000#2 | 47 | 5.55          | 4.88   | 0.19  | 3.98 |
| Total protein        | g/dL   | Level 1 | c8000#1 | 58 | 4.61          | 4.66   | 0.04  | 0.81 |
|                      |        |         | c8000#2 | 53 | 4.61          | 4.68   | 0.04  | 0.83 |
|                      |        | Level 2 | c8000#1 | 57 | 6.52          | 6.61   | 0.06  | 0.83 |
|                      |        |         | c8000#2 | 55 | 6.52          | 6.64   | 0.05  | 0.74 |
|                      |        | Level 3 | c8000#1 | 55 | 8.75          | 8.8    | 0.04  | 0.5  |
|                      |        |         | c8000#2 | 53 | 8.75          | 8.85   | 0.04  | 0.47 |
| Triglycerides        | mg/dL  | Level 1 | c8000#1 | 50 | 55.3          | 59.1   | 1.19  | 2.01 |
|                      |        |         | c8000#2 | 47 | 55.3          | 59.9   | 2.15  | 3.59 |
|                      |        | Level 2 | c8000#1 | 48 | 133           | 136.6  | 1.85  | 1.36 |
|                      |        |         | c8000#2 | 48 | 133           | 138.5  | 2.05  | 1.48 |
|                      |        | Level 3 | c8000#1 | 47 | 223           | 223.6  | 1.96  | 0.88 |
|                      |        |         | c8000#2 | 47 | 223           | 225.1  | 3.07  | 1.37 |
| Urea                 | mg/dL  | Level 1 | c8000#1 | 43 | 8.54          | 8.3    | 0.28  | 3.33 |
|                      |        |         | c8000#2 | 48 | 8.54          | 8.3    | 0.18  | 2.18 |
|                      |        | Level 2 | c8000#1 | 44 | 39.2          | 38.6   | 0.88  | 2.29 |
|                      |        |         | c8000#2 | 50 | 39.2          | 38.8   | 0.78  | 2.02 |
|                      |        | Level 3 | c8000#1 | 42 | 63.8          | 62.8   | 1.44  | 2.28 |
|                      |        |         | c8000#2 | 48 | 63.8          | 63     | 1.15  | 1.82 |

### Multichem IA Plus

| Assay          | Units  | Level   | Inst    | N  | Expected Mean | Mean   | SD    | CV    |
|----------------|--------|---------|---------|----|---------------|--------|-------|-------|
| CEA            | ng/mL  | Level 1 | i2000#1 | 37 | 2.22          | 2.12   | 0.11  | 5.29  |
|                |        | Level 2 | i2000#1 | 37 | 16.8          | 16.58  | 0.67  | 4.01  |
|                |        | Level 3 | i2000#1 | 37 | 43.3          | 43.59  | 1.57  | 3.6   |
| Estradiol      | pg/mL  | Level 1 | i2000#2 | 39 | 48.4          | 52     | 3.25  | 6.25  |
|                |        | Level 2 | i2000#2 | 37 | 159           | 165.4  | 3.6   | 2.18  |
|                |        | Level 3 | i2000#2 | 37 | 515           | 528.5  | 7.06  | 1.34  |
| Ferritin       | ng/mL  | Level 1 | i2000#1 | 40 | 20.3          | 21.03  | 0.95  | 4.5   |
|                |        |         | i2000#3 | 28 | 20.3          | 19.82  | 0.91  | 4.59  |
|                |        | Level 2 | i2000#1 | 40 | 160           | 160.29 | 4.28  | 2.67  |
|                |        |         | i2000#3 | 26 | 160           | 158.85 | 4.93  | 3.1   |
|                |        | Level 3 | i2000#1 | 40 | 326           | 331.26 | 9.68  | 2.92  |
|                |        |         | i2000#3 | 28 | 326           | 331.52 | 11.75 | 3.55  |
| Free T3        | pg/mL  | Level 1 | i2000#1 | 35 | 2.09          | 1.7    | 0.09  | 5.47  |
|                |        | Level 2 | i2000#1 | 35 | 4.33          | 4.2    | 0.16  | 3.81  |
|                |        | Level 3 | i2000#1 | 36 | 9             | 9.1    | 0.33  | 3.6   |
| Free T4        | ng/dL  | Level 1 | i2000#1 | 48 | 0.57          | 0.5    | 0.03  | 5.98  |
|                |        |         | i2000#2 | 39 | 0.57          | 0.53   | 0.02  | 3.81  |
|                |        | Level 2 | i2000#3 | 47 | 0.57          | 0.53   | 0.03  | 5.07  |
|                |        |         | i2000#1 | 47 | 1.69          | 1.68   | 0.04  | 2.36  |
|                |        | Level 3 | i2000#1 | 38 | 1.69          | 1.71   | 0.04  | 2.25  |
|                |        |         | i2000#3 | 45 | 1.69          | 1.69   | 0.05  | 3.17  |
| FSH            | mIU/mL | Level 1 | i2000#1 | 47 | 3.05          | 2.98   | 0.1   | 3.37  |
|                |        |         | i2000#2 | 38 | 3.05          | 3.05   | 0.1   | 3.28  |
|                |        | Level 2 | i2000#2 | 38 | 6.2           | 6.1    | 0.18  | 3.02  |
|                |        |         | i2000#2 | 37 | 17.8          | 17.4   | 0.6   | 3.46  |
|                |        | Level 3 | i2000#2 | 37 | 44.6          | 42.9   | 1.3   | 3.03  |
|                |        |         | i2000#1 | 43 | 0.05          | 0.04   | 0     | 8.3   |
| Tnl            | ng/mL  | Level 1 | i2000#1 | 39 | 0.05          | 0.05   | 0.01  | 11.28 |
|                |        |         | i2000#3 | 34 | 0.05          | 0.05   | 0.01  | 18.87 |
|                |        | Level 2 | i2000#1 | 43 | 0.4           | 0.36   | 0.01  | 2.91  |
|                |        |         | i2000#2 | 37 | 0.4           | 0.39   | 0.01  | 2.5   |
|                |        | Level 3 | i2000#3 | 32 | 0.4           | 0.39   | 0.02  | 6.44  |
|                |        |         | i2000#1 | 43 | 3.27          | 2.94   | 0.16  | 5.54  |
| Total beta-hCG | mIU/mL | Level 1 | i2000#2 | 37 | 3.27          | 2.99   | 0.07  | 2.36  |
|                |        |         | i2000#3 | 34 | 3.27          | 3.035  | 0.17  | 5.46  |
|                |        | Level 2 | i2000#1 | 36 | 5.78          | 4.17   | 0.3   | 7.08  |
|                |        |         | i2000#3 | 25 | 5.78          | 3.9    | 0.26  | 6.63  |
|                |        | Level 3 | i2000#1 | 38 | 5.05          | 4.22   | 1.24  | 5.31  |
|                |        |         | i2000#3 | 27 | N/A           | 24.28  | 1.32  | 5.46  |
| Total PSA      | ng/mL  | Level 1 | i2000#1 | 38 | 505           | 437.02 | 12.4  | 2.84  |
|                |        |         | i2000#3 | 28 | 505           | 422.21 | 10.51 | 2.49  |
|                |        | Level 2 | i2000#1 | 34 | 0.53          | 0.47   | 0.02  | 4.01  |
|                |        |         | i2000#2 | 36 | 4.52          | 4.22   | 0.15  | 3.49  |
|                |        | Level 3 | i2000#1 | 36 | 20.5          | 19.65  | 0.73  | 3.69  |
|                |        |         | i2000#2 | 39 | 0.13          | 0.12   | 0.01  | 3.84  |
| TSH            | uIU/mL | Level 1 | i2000#2 | 36 | 0.13          | 0.13   | 0.01  | 4.01  |
|                |        |         | i2000#3 | 34 | 0.13          | 0.12   | 0.01  | 4.09  |
|                |        | Level 2 | i2000#1 | 40 | 4.09          | 3.92   | 0.11  | 2.82  |
|                |        |         | i2000#2 | 38 | 4.09          | 3.95   | 0.09  | 2.16  |
|                |        | Level 3 | i2000#3 | 32 | 4.09          | 3.99   | 0.15  | 3.79  |
|                |        |         | i2000#1 | 39 | 23.7          | 23.6   | 0.98  | 4.13  |
| Vitamin B12    | pg/mL  | Level 1 | i2000#2 | 37 | 23.7          | 23.59  | 0.58  | 2.45  |
|                |        |         | i2000#3 | 34 | 23.7          | 23.85  | 0.83  | 3.46  |
|                |        | Level 2 | i2000#1 | 36 | 274           | 260.5  | 16.01 | 6.15  |
|                |        |         | i2000#2 | 35 | 274           | 271.3  | 17.51 | 6.45  |
|                |        | Level 3 | i2000#1 | 35 | 547           | 544.8  | 29.55 | 5.42  |
|                |        |         | i2000#2 | 34 | 547           | 574.4  | 23.87 | 4.16  |
| Vitamin D      | ng/mL  | Level 1 | i2000#1 | 34 | 963           | 959.3  | 71.2  | 7.42  |
|                |        |         | i2000#2 | 33 | 963           | 1013.5 | 40.94 | 4.04  |
|                |        | Level 2 | i2000#2 | 33 | 8.65          | 8.1    | 0.14  | 1.7   |
|                |        |         | i2000#2 | 35 | 20            | 20.8   | 0.74  | 3.56  |
|                |        | Level 3 | i2000#2 | 34 | 34.6          | 38.2   | 0.95  | 2.5   |