**Supplementary materials**

**Sample size and rejection limits for detecting reagent lot variability: Analysis of the applicability of the CLSI EP26-A protocol to real-world clinical chemistry data**

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**Table S1.** Repeatability and within-laboratory imprecision of general chemistry and urine chemistry tests for Roche platforms

**Table S2.** Repeatability and within-laboratory imprecision of general chemistry and urine chemistry tests for Beckman coulter platforms

**Table S3.** Repeatability and within-laboratory imprecision of immunochemistry items

**Table S4.** Sample size and rejection limit to detect between-reagent lot variation of general chemistry tests depending on critical difference

**Table S5.** Sample size and rejection limit to detect between-reagent lot variation of urine chemistry tests depending on critical difference

**Table S6.** Sample size and rejection limit to detect between-reagent lot variation of immunochemistry tests depending on critical difference

**Figure S1**. Examples of evaluating reagent lot-to-lot differences of lactate dehydrogenase.

**Supplementary Table S1.** Repeatability and within-laboratory imprecision of general chemistry and urine chemistry tests for Roche platforms

| Analyte | Unit | Roche | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lab A | | | | | | Lab B | | | | | |
| Decision level 1 | | | Decision level 2 | | | Decision level 1 | | | Decision level 2 | | |
| Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) |
| ***General chemistry*** | | | | | | | | | | | | | |
| Alb | g/dL | 2.3 | 1.4 | 1.7 | 4.6 | 0.9 | 0.9 | 2.48 | 2.4 | 2.8 | 4.5 | 1.3 | 1.5 |
| ALP | IU/L | 28.3 | 1.9 | 2.1 | 254.7 | 1.2 | 1.2 | 29.9 | 3.3 | 5.7 | 276.3 | 1.3 | 3.1 |
| ALT | IU/L | 30.4 | 4.2 | 4.2 | 193.9 | 1.4 | 1.4 | 26.7 | 2.9 | 3.2 | 181.7 | 2.4 | 2.5 |
| Amyl | IU/L | 41.2 | 1.4 | 1.4 | 280.3 | 0.8 | 0.8 | 40.9 | 1.2 | 1.5 | 265.8 | 0.9 | 0.9 |
| AST | IU/L | 38.1 | 2.7 | 2.7 | 247.2 | 0.7 | 0.8 | 40.2 | 1.6 | 1.8 | 246.9 | 1.5 | 1.6 |
| BUN | mg/dL | 14.8 | 0.9 | 0.9 | 72.3 | 1.1 | 1.1 | 14.8 | 2.6 | 2.8 | 67.9 | 1.4 | 2.1 |
| Ca | mg/dL | 5.7 | 1.5 | 1.9 | 13.0 | 0.9 | 1.6 | 6.1 | 1.7 | 2.0 | 13.2 | 0.9 | 1.1 |
| Chol | mg/dL | 103.7 | 1.2 | 1.3 | 281.9 | 0.8 | 0.8 | 109 | 1.5 | 1.9 | 266.3 | 0.8 | 1.1 |
| CK | IU/L | 84.4 | 1.4 | 1.4 | 629.8 | 0.7 | 0.7 | 76.9 | 1.3 | 1.7 | 614.8 | 0.8 | 1.0 |
| Cl | mmol/L | 73.3 | 0.4 | 1.6 | 116.6 | 0.4 | 1.6 | 73.6 | 0.7 | 0.9 | 112.2 | 0.5 | 0.7 |
| Cr | mg/dL | 0.7 | 4.0 | 4.2 | 6.1 | 1.7 | 2.2 | 0.6 | 3.0 | 4.5 | 6.3 | 1.7 | 3.1 |
| Dbil | mg/dL | 0.3 | 3.8 | 6.1 | 3.2 | 1.5 | 1.7 | 0.3 | 2.0 | 2.9 | 3.1 | 1.3 | 1.5 |
| GGT | IU/L | 30.5 | 1.2 | 1.2 | 137.6 | 0.7 | 0.7 | 28.9 | 1.9 | 2.2 | 130.6 | 1.0 | 1.3 |
| Gluc | mg/dL | 55.6 | 0.9 | 1.1 | 369.1 | 0.9 | 0.9 | 58.2 | 0.9 | 1.1 | 344.2 | 0.8 | 1.0 |
| HDL | mg/dL | 22.8 | 0.6 | 0.6 | 62.5 | 1.9 | 1.9 | 19.2 | 1.5 | 2.2 | 48.8 | 1.0 | 1.7 |
| Iron | µg/dL | 70.8 | 1.7 | 1.7 | 228.4 | 0.7 | 0.8 | 74.7 | 0.7 | 1.4 | 233.6 | 0.4 | 0.9 |
| K | mmol/L | 2.6 | 0.5 | 0.9 | 7.5 | 0.6 | 1.1 | 2.7 | 2.2 | 2.3 | 7.8 | 0.6 | 0.7 |
| LDH | IU/L | 123.4 | 0.9 | 0.9 | 404 | 0.5 | 0.5 | 122.5 | 1.1 | 1.7 | 405.8 | 0.8 | 1.3 |
| LDL | mg/dL | 67.9 | 1.2 | 1.2 | 194.6 | 1.3 | 1.5 | 72.0 | 0.6 | 1.0 | 173.2 | 1.0 | 1.3 |
| Lipa | U/L | 26.1 | 0.4 | 0.4 | 119.2 | 0.7 | 0.9 | 23.1 | 2.2 | 2.4 | 170.5 | 1.1 | 1.3 |
| Mg | mg/dL | 1.1 | 1.4 | 2.0 | 3.9 | 1.4 | 1.4 | 1.1 | 1.1 | 3.3 | 3.9 | 1.1 | 2.3 |
| Na | mmol/L | 111.6 | 0.4 | 1.9 | 156.2 | 0.5 | 1.7 | 116.4 | 0.6 | 0.6 | 157.9 | 0.4 | 0.4 |
| P | mg/dL | 1.8 | 1.1 | 2.5 | 7.0 | 0.8 | 1.0 | 1.7 | 2.7 | 4.1 | 6.9 | 1.3 | 1.6 |
| Tbil | mg/dL | 0.5 | 4.7 | 5.4 | 6.5 | 0.8 | 0.8 | 0.5 | 2.2 | 2.6 | 6.5 | 1.2 | 1.5 |
| TCO2 | mmol/L | 13.4 | 6.7 | 6.7 | 24.4 | 8.0 | 8.0 | 13.9 | 3.8 | 6.0 | 21.9 | 3.7 | 5.3 |
| TG | mg/dL | 87.3 | 1.5 | 1.5 | 196.9 | 0.9 | 0.9 | 97.4 | 0.8 | 1.9 | 205.6 | 0.8 | 1.2 |
| TP | g/dL | 3.6 | 0.7 | 0.8 | 7.1 | 0.7 | 0.7 | 4.0 | 1.8 | 2.5 | 6.9 | 1.1 | 2.1 |
| UA | mg/dL | 3.1 | 1.2 | 1.2 | 9.6 | 1.0 | 1.2 | 3.4 | 1.5 | 1.7 | 9.1 | 1.0 | 1.2 |
| UIBC | µg/dL | 93.4 | 3.2 | 6.2 | 118.1 | 4.1 | 4.7 | 133.8 | 3.7 | 5.2 | 128.7 | 5.6 | 6.9 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Urine chemistry*** | | | | | | | | | | | | | |
| Alb (u) | mg/dL | 1.4 | 2.3 | 2.6 | 5.4 | 1.0 | 1.8 | 17.6 | 1.4 | 2.2 | 69.8 | 0.9 | 1.2 |
| Ca (u) | mg/dL | 6.8 | 1.4 | 7.2 | 10.1 | 1.5 | 5.7 | 7.1 | 1.6 | 1.8 | 10.7 | 1.5 | 1.5 |
| Cl (u) | mmol/L | 92.2 | 0.4 | 1.6 | 186.2 | 0.8 | 1.8 | 94.6 | 0.6 | 0.9 | 192 | 0.4 | 0.6 |
| Cr (u) | mg/dL | 59.0 | 1.3 | 5.2 | 129.6 | 1.4 | 6.1 | 65.0 | 1.8 | 3.3 | 150.5 | 1.8 | 2.9 |
| Gluc (u) | mg/dL | 28.7 | 1.3 | 3.9 | 294.4 | 0.7 | 1.7 | 28.2 | 1.5 | 1.6 | 278.8 | 0.7 | 0.9 |
| K (u) | mmol/L | 31.2 | 0.8 | 0.9 | 72.1 | 0.8 | 0.9 | 32.4 | 0.7 | 0.9 | 72.1 | 1.0 | 1.5 |
| Mg (u) | mg/dL | 5.0 | 2.0 | 2.2 | 11.3 | 0.9 | 5.9 | NT | NT | NT | NT | NT | NT |
| Na (u) | mmol/L | 78.0 | 0.9 | 3.6 | 169.2 | 0.8 | 3.2 | 84.8 | 1.0 | 1.2 | 180.6 | 0.4 | 0.5 |
| P (u) | mg/dL | 26.2 | 1.1 | 1.3 | 51.8 | 0.5 | 2.5 | 26.2 | 1.7 | 3.3 | 52.2 | 1.3 | 2.1 |
| TP (u) | mg/dL | 18.7 | 1.3 | 2.0 | 51.0 | 1.1 | 3.6 | 16.3 | 2.5 | 2.5 | 49.0 | 0.9 | 1.2 |
| UA (u) | mg/dL | 9.4 | 1.7 | 3.1 | 21.2 | 0.8 | 4.9 | 8.4 | 1.6 | 2.1 | 17.9 | 1.4 | 1.9 |
| Urea (u) | mg/dL | 420.7 | 1.8 | 1.8 | 713.6 | 1.5 | 2.0 | 424.5 | 1.9 | 2.7 | 725.6 | 2.3 | 2.8 |

Abbreviations: NT, not tested; Sr, repeatability; SWRL, within-laboratory imprecision; otherwise see Table 1.

**Supplementary Table S2.** Repeatability and within-laboratory imprecision of general chemistry and urine chemistry tests for Beckman Coulter platforms

| Analyte | Unit | Beckman Coulter | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lab A | | | | | | Lab C | | | | | |
| Decision level 1 | | | Decision level 2 | | | Decision level 1 | | | Decision level 2 | | |
| Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) |
| ***General chemistry*** | | | | | | | | | | | | | |
| Alb | g/dL | 2.2 | 0.7 | 0.9 | 4.4 | 0.8 | 0.8 | 2.4 | 0.8 | 1.3 | 4.2 | 0.6 | 1.2 |
| ALP | IU/L | 28.2 | 3.0 | 3.9 | 324 | 1.8 | 2.2 | 33.7 | 2.0 | 3.9 | 395.1 | 0.8 | 2.0 |
| ALT | IU/L | 33.6 | 2.1 | 2.8 | 207.7 | 1.1 | 1.2 | 28.6 | 2.9 | 3.8 | 196.1 | 0.6 | 1.2 |
| Amyl | IU/L | 36.7 | 1.9 | 1.9 | 279.7 | 1.6 | 1.6 | 36.9 | 1.4 | 1.6 | 291.2 | 0.5 | 0.9 |
| AST | IU/L | 42.0 | 2.3 | 2.4 | 264.3 | 1.5 | 1.5 | 43.0 | 1.8 | 1.8 | 254.4 | 0.4 | 2.1 |
| BUN | mg/dL | 15.5 | 2.6 | 2.6 | 72.0 | 1.8 | 1.8 | 14.7 | 0.6 | 1.4 | 71.9 | 0.4 | 1.5 |
| Ca | mg/dL | 5.7 | 1.1 | 1.3 | 12.8 | 0.7 | 0.8 | 6.4 | 0.6 | 0.9 | 13.4 | 0.4 | 0.7 |
| Chol | mg/dL | 105.2 | 0.8 | 1.1 | 282.8 | 0.8 | 0.9 | 112.3 | 0.7 | 1.0 | 286.8 | 0.5 | 0.8 |
| CK | IU/L | 87.5 | 1.7 | 2.2 | 695.3 | 0.8 | 1.1 | 81.4 | 1.4 | 1.8 | 648.2 | 0.4 | 1.3 |
| Cl | mmol/L | 77.4 | 0.9 | 0.9 | 118.5 | 0.6 | 0.6 | 76.2 | 0.6 | 0.7 | 118.1 | 0.6 | 0.7 |
| Cr | mg/dL | 0.8 | 2.6 | 2.6 | 6.4 | 1.9 | 2.0 | 0.8 | 1.2 | 2.4 | 6.5 | 0.6 | 1.9 |
| Dbil | mg/dL | 0.3 | 4.1 | 4.5 | 2.5 | 3.5 | 4.4 | 0.3 | 1.5 | 3.1 | 2.3 | 0.9 | 1.7 |
| GGT | IU/L | 28.1 | 1.9 | 2.2 | 121.3 | 0.8 | 1.2 | 24.8 | 1.5 | 2.0 | 122.7 | 0.8 | 1.0 |
| Gluc | mg/dL | 57.4 | 1.2 | 1.2 | 371.2 | 0.7 | 0.9 | 28.7 | 1.1 | 2.0 | 352.7 | 0.9 | 1.2 |
| HDL | mg/dL | 26.7 | 1.2 | 1.8 | 76.5 | 0.9 | 1.5 | 26.7 | 0.9 | 1.7 | 73.5 | 0.7 | 1.6 |
| Iron | µg/dL | 70.5 | 1.1 | 1.4 | 232.2 | 0.5 | 0.9 | 72.8 | 0.8 | 2.0 | 234.5 | 0.3 | 0.8 |
| K | mmol/L | 2.6 | 1.2 | 1.2 | 7.4 | 0.9 | 0.9 | 2.7 | 0.4 | 0.6 | 7.3 | 0.4 | 0.6 |
| LDH | IU/L | 113.4 | 2.9 | 3.1 | 369.5 | 2.1 | 3.0 | 105.8 | 1.1 | 2.1 | 364.7 | 1.1 | 2.2 |
| LDL | mg/dL | 59.8 | 1.9 | 2.4 | 162.8 | 1.1 | 1.4 | 66.9 | 0.9 | 1.8 | 170.3 | 0.7 | 1.7 |
| Lipa | U/L | 25.8 | 2.1 | 3.3 | 152.3 | 1.0 | 1.8 | 20.2 | 1.8 | 3.5 | 151.5 | 0.7 | 2.6 |
| Mg | mg/dL | 1.1 | 3.4 | 4.3 | 4.2 | 1.1 | 1.3 | 1.1 | 2.0 | 2.5 | 4.2 | 0.8 | 1.2 |
| Na | mmol/L | 112.7 | 0.7 | 0.8 | 155.6 | 0.6 | 0.6 | 112.9 | 0.5 | 0.7 | 159.4 | 0.6 | 0.7 |
| P | mg/dL | 2.0 | 2.1 | 2.1 | 7.1 | 1.1 | 1.1 | 2.0 | 1.0 | 2.3 | 7.4 | 0.7 | 1.1 |
| Tbil | mg/dL | 0.6 | 3.6 | 3.6 | 7.1 | 1.4 | 1.8 | 0.6 | 0.7 | 1.5 | 6.9 | 0.5 | 0.8 |
| TCO2 | mmol/L | 14.3 | 4.0 | 4.0 | 27.2 | 2.9 | 3.3 | 14.9 | 1.5 | 3.0 | 29.2 | 1.3 | 2.4 |
| TG | mg/dL | 91.2 | 0.8 | 1.1 | 201.8 | 1.1 | 1.2 | 100.5 | 0.6 | 4.1 | 232.4 | 0.3 | 2.0 |
| TP | g/dL | 3.7 | 1.2 | 1.3 | 7.2 | 0.9 | 1.1 | 4.1 | 0.7 | 1.4 | 6.9 | 0.3 | 0.9 |
| UA | mg/dL | 3.4 | 1.1 | 1.5 | 9.9 | 0.8 | 0.9 | 3.6 | 0.4 | 0.8 | 10.0 | 0.3 | 0.8 |
| UIBC | µg/dL | 111.7 | 1.8 | 1.9 | 141.5 | 2.3 | 2.3 | 143.3 | 2.4 | 4.1 | 138.7 | 1.3 | 4.0 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Urine chemistry*** | | | | | | | | | | | | | |
| Alb (u) | mg/dL | 1.8 | 6.5 | 6.5 | 5.3 | 2.4 | 2.4 | 26.4 | 2.0 | 3.5 | 286.8 | 1.3 | 1.9 |
| Ca (u) | mg/dL | 7.2 | 2.5 | 3.3 | 11.1 | 2.4 | 2.4 | 7.1 | 0.5 | 1.1 | 395.1 | 0.5 | 1.0 |
| Cl (u) | mmol/L | 102.9 | 0.7 | 0.7 | 201.3 | 0.7 | 0.7 | 102.7 | 0.3 | 0.8 | 255.0 | 0.4 | 0.6 |
| Cr (u) | mg/dL | 58.5 | 2.3 | 2.3 | 136.4 | 2.3 | 2.3 | 63.3 | 0.8 | 1.6 | 196.1 | 0.8 | 1.2 |
| Gluc (u) | mg/dL | 28.5 | 1.8 | 1.8 | 311.4 | 1.2 | 1.3 | 29.6 | 1.1 | 3.0 | 291.2 | 0.9 | 1.1 |
| K (u) | mmol/L | 31.3 | 1.1 | 1.3 | 71.0 | 1.3 | 1.7 | 31.8 | 0.5 | 0.9 | 364.7 | 0.6 | 1.2 |
| Mg (u) | mg/dL | 5.0 | 1.5 | 1.6 | 12.2 | 1.6 | 1.6 | 4.3 | 1.0 | 1.9 | 107.9 | 1.0 | 1.9 |
| Na (u) | mmol/L | 80.4 | 1.0 | 1.1 | 174.2 | 0.5 | 0.7 | 80.4 | 0.8 | 1.0 | 122.7 | 0.4 | 0.7 |
| P (u) | mg/dL | 26.2 | 2.2 | 3.2 | 51.4 | 2.2 | 2.6 | 26.9 | 1.2 | 4.3 | 181.0 | 1.0 | 2.5 |
| TP (u) | mg/dL | 20.8 | 2.6 | 3.3 | 64.3 | 1.6 | 2.4 | 20.4 | 2.0 | 3.0 | 29.2 | 1.0 | 1.6 |
| UA (u) | mg/dL | 10.2 | 1.8 | 1.8 | 21.9 | 1.9 | 1.9 | 9.6 | 0.7 | 1.0 | 254.4 | 0.7 | 1.1 |
| Urea (u) | mg/dL | 415.7 | 2.4 | 2.7 | 717.0 | 2.7 | 2.9 | 433.0 | 0.8 | 1.6 | 287.1 | 0.8 | 1.7 |

Abbreviations: Sr, repeatability; SWRL, within-laboratory imprecision; otherwise see Table 1.

**Supplementary Table S3.** Repeatability and within-laboratory imprecision of immunochemistry tests.

| Analyte | Unit | Lab A | | | | | | Lab B | | | | | | Lab C | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Decision level 1 | | | Decision level 2 | | | Decision level 1 | | | Decision level 2 | | | Decision level 1 | | | Decision level 2 | | |
| Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) | Mean | Sr (%) | SWRL (%) |
| ACTH | pg/mL | 44.4 | 1.1 | 1.1 | 905.6 | 0.6 | 0.6 | 51.2 | 1.2 | 1.9 | 950.8 | 0.6 | 1.4 | 50.6 | 1.1 | 3.3 | 918.5 | 0.7 | 1.9 |
| AFP | ng/mL | 10.5 | 1.2 | 1.7 | 111.9 | 1.6 | 2.0 | 11.5 | 2.1 | 4.2 | 134.1 | 2.0 | 5.3 | 10.8 | 2.2 | 2.5 | 127.5 | 1.5 | 2.2 |
| Anti-Tg | IU/mL | 53.2 | 2.3 | 2.9 | 177.6 | 1.9 | 2.3 | 62.4 | 3.9 | 4.9 | 163.1 | 2.4 | 4.1 | 65.5 | 3.0 | 3.6 | 164.0 | 3.0 | 3.5 |
| Anti-TPO | IU/mL | 22.5 | 4.1 | 4.6 | 98.1 | 3.8 | 4.0 | 22.1 | 7.0 | 9.4 | 105.5 | 3.2 | 5.1 | 24.0 | 5.2 | 6.6 | 108.4 | 3.3 | 4.2 |
| CA 125 | U/mL | 29.5 | 1.6 | 1.6 | 85.3 | 1.4 | 1.4 | 32.8 | 1.2 | 3.1 | 94.0 | 1.2 | 2.7 | 30.6 | 2.3 | 2.7 | 99.8 | 1.6 | 2.6 |
| CA 15-3 | U/mL | 19.6 | 1.5 | 2.9 | 101.2 | 1.7 | 1.9 | 20.9 | 2.2 | 4.0 | 92.9 | 2.3 | 3.8 | 18.1 | 3.0 | 3.3 | 91.9 | 2.5 | 3.1 |
| CA 19-9 | U/mL | 21.3 | 1.8 | 1.8 | 82.4 | 1.6 | 1.8 | 25.0 | 1.6 | 3.4 | 99.3 | 1.6 | 3.2 | 20.3 | 2.0 | 2.2 | 94.5 | 1.5 | 2.2 |
| CEA | ng/mL | 5.9 | 1.5 | 1.8 | 51.6 | 1.1 | 1.5 | 5.6 | 1.9 | 3.5 | 54.3 | 2.4 | 3.5 | 5.3 | 1.7 | 3.1 | 52.3 | 1.4 | 2.4 |
| CK-MB | ng/mL | 5.1 | 2.7 | 4.6 | 46.0 | 2.1 | 4.6 | 5.2 | 2.0 | 3.1 | 55.8 | 2.1 | 3.2 | 5.1 | 1.6 | 3.0 | 55.0 | 1.4 | 2.7 |
| Cortisol | µg/dL | 9.9 | 2.7 | 3.8 | 23.2 | 6.9 | 8.8 | 11.7 | 2.4 | 3.2 | 25.7 | 1.7 | 3.3 | 11.7 | 1.9 | 2.8 | 25.5 | 1.8 | 2.9 |
| C-pep | ng/mL | 2.0 | 0.9 | 1.0 | 9.9 | 1.1 | 1.6 | 2.0 | 1.4 | 2.4 | 9.9 | 1.5 | 2.0 | 1.9 | 1.5 | 1.6 | 9.5 | 1.4 | 1.8 |
| Cyfra | ng/mL | 2.7 | 1.9 | 2.3 | 26.3 | 1.2 | 1.3 | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT |
| DHEAS | ng/mL | 2.7 | 1.7 | 2.0 | 442.2 | 2.0 | 4.3 | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT |
| E2 | pg/mL | 86.7 | 3.5 | 4.0 | 469.1 | 2.1 | 3.3 | 94.5 | 2.2 | 3.7 | 520.6 | 1.3 | 2.3 | 99.4 | 1.7 | 2.6 | 532.6 | 1.5 | 1.8 |
| Ferritin | ng/mL | 24.9 | 1.4 | 1.5 | 206.7 | 1.3 | 1.5 | 25.9 | 2.3 | 3.1 | 210.8 | 2.7 | 3.6 | 23.4 | 2.0 | 2.9 | 192.2 | 1.5 | 2.2 |
| Folate | ng/mL | 3.9 | 3.6 | 4.0 | 9.6 | 3.3 | 3.7 | 4.7 | 3.3 | 8.8 | 12.7 | 3.3 | 5.7 | 4.5 | 3.6 | 3.7 | 11.9 | 5.0 | 6.9 |
| fPSA | ng/mL | 1.1 | 2.7 | 3.4 | 9.6 | 1.4 | 1.4 | 1.1 | 2.2 | 3.4 | 11.1 | 1.9 | 2.9 | 1.0 | 2.1 | 2.5 | 9.2 | 1.4 | 2.3 |
| FSH | mlU/mL | 14.9 | 2.2 | 2.3 | 44.6 | 4.1 | 4.8 | 5.1 | 1.0 | 1.9 | 15.1 | 1.2 | 1.8 | 18.5 | 2.4 | 2.5 | 44.4 | 2.0 | 2.1 |
| fT4 | ng/dL | 1.2 | 1.8 | 2.0 | 3.3 | 2.6 | 3.0 | 1.2 | 1.9 | 2.6 | 3.5 | 2.0 | 2.5 | 1.3 | 1.2 | 2.2 | 3.4 | 1.3 | 2.5 |
| hCG | ng/mL | 10.7 | 1.0 | 1.2 | 1210.2 | 1.0 | 1.5 | 5.8 | 2.5 | 3.0 | 44.1 | 1.8 | 2.6 | 5.2 | 2.2 | 2.4 | 40.0 | 1.9 | 2.0 |
| Hcy | µmol/L | 11.8 | 2.6 | 3.2 | 27.9 | 2.1 | 3.9 | 12.9 | 1.8 | 3.1 | 38.7 | 2.2 | 2.9 | 12.4 | 2.7 | 3.6 | 25.5 | 1.0 | 2.6 |
| HE4 | pmol/L | NT | NT | NT | NT | NT | NT | 51.3 | 2.2 | 2.8 | 356.7 | 1.7 | 4.0 | 49.7 | 2.5 | 4.6 | 332.5 | 2.2 | 4.9 |
| hsTnI | ng/L | 1.9 | 3.1 | 5 | 15546.7 | 1.2 | 1.8 | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT |
| hsTnT | ng/L | NT | NT | NT | NT | NT | NT | 27.3 | 1.9 | 2.0 | 2110.0 | 0.6 | 1.0 | 27.6 | 1.5 | 2.0 | 2123.0 | 0.6 | 1.4 |
| IgE | IU/mL | 128.0 | 2.6 | 3.3 | 280.6 | 5.7 | 7.5 | 120.9 | 3.3 | 5.2 | 320.3 | 3.0 | 5.0 | 109.5 | 1.6 | 2.2 | 291.1 | 1.3 | 2.2 |
| Insulin | uIU/mL | 22.1 | 1.3 | 2.3 | 68.6 | 1.3 | 2.6 | 21.7 | 1.2 | 2.4 | 70.7 | 1.4 | 1.7 | 23.3 | 1.5 | 3.2 | 71.7 | 1.7 | 3.1 |
| LH | mlU/mL | 10.5 | 2.4 | 2.5 | 53.1 | 3.6 | 3.6 | 6.4 | 1.8 | 2.7 | 29.8 | 1.5 | 2.5 | 10.6 | 2.2 | 2.2 | 51.3 | 1.7 | 1.8 |
| NSE | ng/mL | NT | NT | NT | NT | NT | NT | 12.8 | 1.6 | 3.1 | 90.3 | 1.6 | 2.6 | 11.4 | 1.3 | 2.4 | 89.9 | 1.7 | 2.3 |
| NT-pBNP | pg/mL | 138.0 | 2.1 | 2.2 | 4351.3 | 1.9 | 1.9 | 136.3 | 1.4 | 2.8 | 4236.2 | 1.7 | 3.0 | 133.0 | 1.3 | 1.8 | 4080.3 | 0.9 | 1.5 |
| PIVKA | mAU/mL | 49.8 | 3.6 | 4.5 | 9994.5 | 2.0 | 2.9 | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT | NT |
| Procal | ng/mL | 0.2 | 2 | 3.8 | 66.3 | 2.2 | 2.9 | 0.5 | 1.9 | 2.2 | 9.6 | 1.9 | 2.0 | 0.5 | 1.6 | 2.2 | 9.4 | 1.0 | 1.5 |
| Prolac | ng/mL | 10.5 | 4.7 | 4.7 | 36.5 | 4.5 | 4.9 | 4.6 | 1.8 | 2.2 | 14.5 | 1.6 | 1.9 | 10.4 | 1.9 | 2.5 | 37.1 | 2.0 | 2.3 |
| PSA | ng/mL | 4.7 | 1.5 | 1.6 | 40.0 | 1.6 | 1.6 | 4.3 | 1.5 | 3.3 | 40.9 | 1.5 | 3.0 | 3.9 | 1.8 | 2.1 | 37.9 | 1.5 | 2.0 |
| PTH | pg/mL | 52.8 | 2.4 | 2.4 | 182.3 | 1.1 | 1.4 | 64.3 | 1.5 | 2.0 | 198.2 | 1.5 | 1.9 | 61.8 | 2.0 | 3.9 | 188.3 | 2.5 | 4.7 |
| T3 | nmol/L | 2.7 | 3.9 | 4.3 | 6.5 | 2.5 | 3.5 | 2.3 | 1.8 | 2.5 | 5.3 | 1.6 | 2.1 | 2.5 | 1.9 | 2.5 | 5.8 | 1.4 | 1.9 |
| T4 | µg/dL | 7.4 | 1.5 | 3.7 | 11.4 | 4.4 | 6.2 | 6.9 | 2.3 | 2.7 | 11.1 | 1.7 | 2.5 | 7.0 | 1.2 | 3.5 | 11.1 | 1.8 | 3.2 |
| Testo | ng/mL | 5.8 | 2.6 | 2.8 | 2.6 | 3.8 | 4.8 | 0.2 | 3.5 | 5.5 | 5.0 | 1.6 | 1.9 | 6.0 | 1.8 | 2.7 | 2.5 | 1.3 | 2.6 |
| Tg | ng/mL | 24.1 | 1.9 | 2.0 | 98.4 | 4.0 | 4.4 | 25.1 | 2.2 | 3.1 | 89.9 | 1.3 | 3.2 | 25.7 | 1.9 | 2.8 | 88.3 | 1.3 | 2.7 |
| TSH | uIU/mL | 1.4 | 4.1 | 4.1 | 8.5 | 6.5 | 7.2 | 1.4 | 2.2 | 2.9 | 8.8 | 1.7 | 3.0 | 1.4 | 0.8 | 1.5 | 8.4 | 0.9 | 1.6 |
| TSHR | IU/L | 3.8 | 5.3 | 5.3 | 16.6 | 3.5 | 3.5 | 3.9 | 3.6 | 5.7 | 16.3 | 1.7 | 2.9 | 3.7 | 4.0 | 6.3 | 16.0 | 2.0 | 2.9 |
| Vit B12 | pg/mL | 473.6 | 2.6 | 2.8 | 887.6 | 2.2 | 2.3 | 444.2 | 2.3 | 3.5 | 857.7 | 2.7 | 3.1 | 463.8 | 2.4 | 2.9 | 866.1 | 3.7 | 4.2 |
| Vit D | ng/mL | 11.0 | 3.6 | 3.7 | 30.3 | 3.3 | 4.7 | 12.1 | 4.5 | 5.9 | 26.3 | 4.2 | 5.1 | 11.1 | 4.4 | 5.8 | 25.5 | 2.7 | 3.7 |

Abbreviations: NT, not tested; Sr, repeatability; SWRL, within-laboratory imprecision; otherwise see Table 1.

**Supplementary Table S4.** Sample size and rejection limit to detect between-reagent lot variation of general chemistry tests depending on critical difference

| Analyte | CD source | Roche platform | | | | | | | | | | | | | | Beckman Coulter platform | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Decision level 1 | | | | | | | | Decision level 2 | | | | | | Decision level 1 | | | | | | | | Decision level 2 | | | | | |
| Lab A | | | | Lab B | | | | Lab A | | | Lab B | | | Lab A | | | | | Lab C | | | Lab A | | | Lab C | | |
| Sample size | | RL (%) | | Sample size | | RL (%) | | Sample size | RL (%) | | Sample size | | RL (%) | Sample size | | RL (%) | | | Sample size | | RL (%) | Sample size | | RL (%) | Sample size | | RL (%) |
| ***With intended statistical power ≥ 0.9 and false rejection rate ≤2.5%*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alb | RCV | 2 | | 5.2 | | 5 | | 6.4 | | 1 | 4.6 | | 1 | | 5.0 | 1 | | 4.6 | | | 1 | | 4.8 | 1 | | 4.5 | 1 | | 4.8 |
|  | TE | NA | | NA | | NA | | NA | | 4 | 1.6 | | NA | | NA | 2 | | 1.6 | | | NA | | NA | 4 | | 1.6 | NA | | NA |
|  | EQA | 2 | | 4.8 | | NA | | NA | | 1 | 4.8 | | 2 | | 4.8 | 1 | | 4.8 | | | 1 | | 4.8 | 1 | | 4.8 | 1 | | 4.8 |
| ALP | RCV | 1 | | 9.6 | | NA | | NA | | 1 | 9.2 | | 1 | | 10.4 | 2 | | 11.1 | | | NA | | NA | 1 | | 9.7 | 1 | | 9.6 |
|  | TE | 4 | | 4.8 | | NA | | NA | | 1 | 4.8 | | NA | | NA | NA | | NA | | | NA | | NA | 9 | | 4.8 | NA | | NA |
|  | EQA | 2 | | 6.6 | | NA | | NA | | 1 | 6.6 | | NA | | NA | NA | | NA | | | NA | | NA | 2 | | 6.6 | 1 | | 6.6 |
| ALT | RCV | 1 | | 18.7 | | 1 | | 18.1 | | 1 | 17.5 | | 1 | | 17.8 | 1 | | 17.9 | | | 1 | | 18.4 | 1 | | 17.4 | 1 | | 17.4 |
|  | TE | 5 | | 7.3 | | 4 | | 7.3 | | 1 | 7.3 | | 2 | | 8.6 | 5 | | 7.3 | | | NA | | NA | 1 | | 7.3 | 1 | | 7.3 |
|  | EQA | 5 | | 6.9 | | 4 | | 6.9 | | 1 | 6.9 | | 2 | | 8.1 | 5 | | 6.9 | | | NA | | NA | 1 | | 6.9 | 1 | | 6.9 |
| Amyl | RCV | 1 | | 11.2 | | 1 | | 11.3 | | 1 | 11.1 | | 1 | | 11.1 | 1 | | 11.4 | | | 1 | | 11.3 | 1 | | 11.3 | 1 | | 11.1 |
|  | TE | 1 | | 5.9 | | 1 | | 5.9 | | 1 | 5.9 | | 1 | | 5.9 | 2 | | 5.9 | | | 1 | | 5.9 | 1 | | 5.9 | 1 | | 5.9 |
|  | EQA | 1 | | 6.0 | | 1 | | 6.0 | | 1 | 6.0 | | 1 | | 6.0 | 2 | | 6.0 | | | 1 | | 6.0 | 1 | | 6.0 | 1 | | 6.0 |
| AST | RCV | 1 | | 16.4 | | 1 | | 16.1 | | 1 | 15.9 | | 1 | | 16.0 | 1 | | 16.3 | | | 1 | | 16.1 | 1 | | 16.0 | NA | | NA |
|  | TE | 3 | | 6.1 | | 1 | | 6.1 | | 1 | 6.1 | | 1 | | 6.1 | 2 | | 6.1 | | | 1 | | 6.1 | 1 | | 6.1 | NA | | NA |
|  | EQA | 2 | | 6.9 | | 1 | | 6.9 | | 1 | 6.9 | | 1 | | 6.9 | 2 | | 6.9 | | | 1 | | 6.9 | 1 | | 6.9 | NA | | NA |
| BUN | RCV | 1 | | 23.2 | | 1 | | 23.6 | | 1 | 23.2 | | 1 | | 23.4 | 1 | | 23.5 | | | 1 | | 23.2 | 1 | | 23.3 | NA | | NA |
|  | TE | 1 | | 7.9 | | 2 | | 7.9 | | 1 | 7.9 | | 1 | | 7.9 | 2 | | 7.9 | | | 1 | | 7.9 | 1 | | 7.9 | NA | | NA |
|  | EQA | 1 | | 5.4 | | 7 | | 5.4 | | 1 | 5.4 | | NA | |  | 4 | | 5.4 | | | 1 | | 5.4 | 2 | | 5.4 | NA | | NA |
| Ca | RCV | 5 | | 4.7 | | 3 | | 4.8 | | NA | NA | | 1 | | 3.9 | 2 | | 4.1 | | | 1 | | 3.8 | 1 | | 3.7 | 1 | | 3.7 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | NA | | NA | NA | | NA | | | NA | | NA | NA | | NA | NA | | NA |
|  | EQA | NA | | NA | | 17 | | 3.6 | | NA | NA | | 2 | | 3.6 | 2 | | 3.6 | | | 1 | | 3.6 | 1 | | 3.6 | 1 | | 3.6 |
| Chol | RCV | 1 | | 9.1 | | 1 | | 9.4 | | 1 | 8.9 | | 1 | | 9.0 | 1 | | 9.0 | | | 1 | | 9.0 | 1 | | 8.9 | 1 | | 8.9 |
|  | TE | 2 | | 4.0 | | 401 | | 4.0 | | 1 | 4.0 | | 1 | | 4.0 | 1 | | 4.0 | | | 1 | | 4.0 | 1 | | 4.0 | 1 | | 4.0 |
|  | EQA | 2 | | 4.2 | | 401 | | 4.2 | | 1 | 4.2 | | 1 | | 4.2 | 1 | | 4.2 | | | 1 | | 4.2 | 1 | | 4.2 | 1 | | 4.2 |
| CK | RCV | 1 | | 26.7 | | 1 | | 26.8 | | 1 | 26.6 | | 1 | | 26.7 | 1 | | 26.9 | | | 1 | | 26.8 | 1 | | 26.7 | 1 | | 26.7 |
|  | TE | 1 | | 9.9 | | 1 | | 9.9 | | 1 | 9.9 | | 1 | | 9.9 | 1 | | 9.9 | | | 1 | | 9.9 | 1 | | 9.9 | 1 | | 9.9 |
|  | EQA | 1 | | 6.6 | | 1 | | 6.6 | | 1 | 6.6 | | 1 | | 6.6 | 2 | | 6.6 | | | 1 | | 6.6 | 1 | | 6.6 | 1 | | 6.6 |
| Cl | RCV | NA | | NA | | 5 | | 2.4 | | NA | NA | | 2 | | 2.2 | 2 | | 2.4 | | | 2 | | 2.2 | 1 | | 2.1 | 2 | | 2.2 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | NA | | NA | 28 | | 0.6 | | | NA | | NA | 13 | | 0.6 | NA | | NA |
|  | EQA | NA | | NA | | 2 | | 2.7 | | NA | NA | | 1 | | 2.7 | 2 | | 2.7 | | | 1 | | 2.7 | 1 | | 2.7 | 1 | | 2.7 |
| Cr | RCV | 2 | | 10.2 | | NA | | NA | | 1 | 8.3 | | NA | | NA | 1 | | 8.6 | | | 1 | | 8.5 | 1 | | 8.2 | 1 | | 8.1 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | NA | | NA | 7 | | 3.4 | | | NA | | NA | 8 | | 3.4 | NA | | NA |
|  | EQA | 20 | | 6.0 | | NA | | NA | | 2 | 6.0 | | NA | | NA | 3 | | 6.0 | | | NA | | NA | 2 | | 6.0 | NA | | NA |
| Dbil | RCV | 1 | | 62.0 | | 1 | | 61.4 | | 1 | 61.3 | | 1 | | 61.3 | 1 | | 61.7 | | | 1 | | 61.4 | 1 | | 61.6 | 1 | | 61.3 |
|  | TE | NA | | NA | | 1 | | 13.4 | | 1 | 13.4 | | 1 | | 13.4 | 2 | | 13.4 | | | 1 | | 13.4 | 2 | | 13.4 | 1 | | 13.4 |
|  | EQA | NA | | NA | | NA | | NA | | 1 | 6.0 | | 1 | | 6.0 | NA | | NA | | | NA | | NA | NA | | NA | 1 | | 6.0 |
| GGT | RCV | 1 | | 14.8 | | 1 | | 15.1 | | 1 | 14.7 | | 1 | | 14.8 | 1 | | 15.1 | | | 1 | | 15.0 | 1 | | 14.8 | 1 | | 14.7 |
|  | TE | 1 | | 8.0 | | 1 | | 8.0 | | 1 | 8.0 | | 1 | | 8.0 | 1 | | 8.0 | | | 1 | | 8.0 | 1 | | 8.0 | 1 | | 8.0 |
|  | EQA | 1 | | 6.9 | | 2 | | 6.9 | | 1 | 6.9 | | 1 | | 6.9 | 2 | | 6.9 | | | 1 | | 6.9 | 1 | | 6.9 | 1 | | 6.9 |
| Gluc | RCV | 1 | | 8.5 | | 1 | | 8.5 | | 1 | 8.4 | | 1 | | 8.5 | 1 | | 8.6 | | | 1 | | 9.0 | 1 | | 8.4 | 1 | | 8.6 |
|  | TE | 4 | | 2.9 | | 4 | | 2.9 | | 1 | 2.9 | | 2 | | 2.9 | 2 | | 2.9 | | | NA | | NA | 2 | | 2.9 | 5 | | 2.9 |
|  | EQA | 1 | | 4.8 | | 1 | | 4.8 | | 1 | 4.8 | | 1 | | 4.8 | 1 | | 4.8 | | | NA | | NA | 1 | | 4.8 | 1 | | 4.8 |
| HDL | RCV | 1 | | 9.5 | | 1 | | 10.2 | | 1 | 10.0 | | 1 | | 9.9 | 1 | | 9.9 | | | 1 | | 9.9 | 1 | | 9.8 | 1 | | 9.8 |
|  | TE | 1 | | 5.0 | | NA | | NA | | 2 | 5.0 | | NA | | NA | 5 | | 5.0 | | | NA | | NA | 1 | | 5.0 | 3 | | 5.0 |
|  | EQA | 1 | | 12.0 | | 1 | | 12.0 | | 1 | 12.0 | | 1 | | 12.0 | 1 | | 12.0 | | | 1 | | 12.0 | 1 | | 12.0 | 1 | | 12.0 |
| Iron | RCV | 1 | | 44.2 | | 1 | | 44.1 | | 1 | 44.1 | | 1 | | 44.1 | 1 | | 44.1 | | | 1 | | 44.2 | 1 | | 44.1 | 1 | | 44.1 |
|  | TE | 1 | | 9.2 | | 1 | | 9.2 | | 1 | 9.2 | | 1 | | 9.2 | 1 | | 9.2 | | | 1 | | 9.2 | 1 | | 9.2 | 1 | | 9.2 |
|  | EQA | 1 | | 9.0 | | 1 | | 9.0 | | 1 | 9.0 | | 1 | | 9.0 | 1 | | 9.0 | | | 1 | | 9.0 | 1 | | 9.0 | 1 | | 9.0 |
| K | RCV | 1 | | 7.0 | | 1 | | 7.8 | | 1 | 7.1 | | 1 | | 6.9 | 1 | | 7.1 | | | 1 | | 6.9 | 1 | | 7.0 | 1 | | 6.9 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | 2 | | 2.2 | 4 | | 2.2 | | | 1 | | 2.2 | 2 | | 2.2 | 1 | | 2.2 |
|  | EQA | 2 | | 2.7 | | NA | | NA | | NA | NA | | 1 | | 2.7 | 3 | | 2.7 | | | 1 | | 2.7 | 2 | | 2.7 | 1 | | 2.7 |
| LDH | RCV | 1 | | 8.8 | | 1 | | 9.1 | | 1 | 8.7 | | 1 | | 8.9 | 2 | | 10.1 | | | 1 | | 9.3 | 1 | | 10.0 | 1 | | 9.4 |
|  | TE | 1 | | 3.5 | | NA | | NA | | 1 | 3.5 | | NA | | NA | NA | | NA | | | NA | | NA | NA | | NA | NA | | NA |
|  | EQA | 1 | | 5.4 | | 2 | | 5.4 | | 1 | 5.4 | | 1 | | 5.4 | 24 | | 5.4 | | | NA | | NA | NA | | NA | NA | | NA |
| LDL | RCV | 1 | | 13.9 | | 1 | | 13.9 | | 1 | 14.0 | | 1 | | 14.0 | 1 | | 14.4 | | | 1 | | 14.1 | 1 | | 14.0 | 1 | | 14.1 |
|  | TE | 1 | | 6.2 | | 1 | | 6.2 | | 1 | 6.2 | | 1 | | 6.2 | 5 | | 6.2 | | | 1 | | 6.2 | 1 | | 6.2 | 1 | | 6.2 |
|  | EQA | 1 | | 12.0 | | 1 | | 12.0 | | 1 | 12.0 | | 1 | | 12.0 | 1 | | 12.0 | | | 1 | | 12.0 | 1 | | 12.0 | 1 | | 12.0 |
| Lipa | RCV | 1 | | 15.3 | | 1 | | 15.8 | | 1 | 15.4 | | 1 | | 15.5 | 1 | | 16.3 | | | 1 | | 16.4 | 1 | | 15.6 | NA | | NA |
|  | TE | 1 | | 6.4 | | 3 | | 6.4 | | 1 | 6.4 | | 1 | | 6.4 | NA | | NA | | | NA | | NA | 1 | | 6.4 | NA | | NA |
|  | EQA | 1 | | 6.0 | | 3 | | 6.0 | | 1 | 6.0 | | 1 | | 6.0 | NA | | NA | | | NA | | NA | 1 | | 6.0 | NA | | NA |
| Mg | RCV | 1 | | 6.8 | | NA | | NA | | 1 | 6.4 | | 3 | | 7.1 | 401 | | 9.3 | | | 2 | | 7.3 | 1 | | 6.4 | 1 | | 6.3 |
|  | TE | NA | | NA | | NA | | NA | | 13 | 1.4 | | NA | | NA | NA | | NA | | | NA | | NA | NA | | NA | NA | | NA |
|  | EQA | NA | | NA | | NA | | NA | | 2 | 4.5 | | NA | | NA | NA | | NA | | | NA | | NA | 1 | | 4.5 | 1 | | 4.5 |
| Na | RCV | NA | | NA | | 3 | | 1.3 | | NA | NA | | 2 | | 1.1 | 17 | | 1.6 | | | NA | | NA | 3 | | 1.3 | 17 | | 1.4 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | 28 | | 0.3 | NA | | NA | | | NA | | NA | NA | | NA | NA | | NA |
|  | EQA | NA | | NA | | 2 | | 1.8 | | NA | NA | | 1 | | 1.8 | 5 | | 1.8 | | | 8 | | 1.8 | 2 | | 1.8 | 3 | | 1.8 |
| P | RCV | 1 | | 14.3 | | 1 | | 15.2 | | 1 | 13.7 | | 1 | | 13.9 | 1 | | 14.1 | | | 1 | | 14.2 | 1 | | 13.8 | 1 | | 13.8 |
|  | TE | NA | | NA | | NA | | NA | | 2 | 3.1 | | NA | | NA | 7 | | 3.1 | | | NA | | NA | 2 | | 3.6 | 5 | | 3.1 |
|  | EQA | NA | | NA | | NA | | NA | | 1 | 5.4 | | 1 | | 5.4 | 2 | | 5.4 | | | NA | | NA | 1 | | 5.4 | 1 | | 5.4 |
| Tbil | RCV | 1 | | 37.4 | | 1 | | 36.5 | | 1 | 36.3 | | 1 | | 36.3 | 1 | | 36.7 | | | 1 | | 36.3 | 1 | | 36.4 | 1 | | 36.3 |
|  | TE | NA | | NA | | 2 | | 8.1 | | 1 | 8.1 | | 1 | | 8.1 | 3 | | 8.1 | | | 1 | | 8.1 | 1 | | 8.1 | 1 | | 8.1 |
|  | EQA | 5 | | 12.0 | | 1 | | 12.0 | | 1 | 12.0 | | 1 | | 12.0 | 1 | | 12.0 | | | 1 | | 12.0 | 1 | | 12.0 | 1 | | 12.0 |
| TCO2 | RCV | 4 | | 13.0 | | NA | | NA | | 4 | 14.9 | | NA | | NA | 3 | | 9.4 | | | NA | | NA | 3 | | 8.6 | 2 | | 7.8 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | NA | | NA | NA | | NA | | | NA | | NA | NA | | NA | NA | | NA |
|  | EQA | 5 | | 12.0 | | NA | | NA | | 5 | 12.0 | | NA | | NA | 2 | | 12.0 | | | 1 | | 12.0 | 1 | | 12.0 | 1 | | 12.0 |
| TG | RCV | 1 | | 33.0 | | 1 | | 33.1 | | 1 | 33.0 | | 1 | | 33.0 | 1 | | 33.0 | | | 1 | | 33.6 | 1 | | 33.0 | NA | | NA |
|  | TE | 1 | | 12.0 | | 1 | | 12.0 | | 1 | 12.0 | | 1 | | 12.0 | 1 | | 12.0 | | | NA | | NA | 1 | | 12.0 | NA | | NA |
|  | EQA | 1 | | 5.4 | | NA | | NA | | 1 | 5.4 | | 1 | | 5.4 | 1 | | 5.4 | | | NA | | NA | 1 | | 5.4 | NA | | NA |
| TP | RCV | 1 | | 4.5 | | NA | | NA | | 1 | 4.5 | | NA | | NA | 1 | | 4.8 | | | 1 | | 4.9 | 1 | | 4.7 | 1 | | 4.6 |
|  | TE | 17 | | 1.6 | | NA | | NA | | 3 | 1.6 | | NA | | NA | NA | | NA | | | NA | | NA | NA | | NA | NA | | NA |
|  | EQA | 1 | | 3.6 | | NA | | NA | | 1 | 3.6 | | NA | | NA | 2 | | 3.6 | | | NA | | NA | 2 | | 3.6 | 1 | | 3.6 |
| UA | RCV | 1 | | 14.4 | | 1 | | 14.6 | | 1 | 14.4 | | 1 | | 14.4 | 1 | | 14.5 | | | 1 | | 14.4 | 1 | | 14.4 | 1 | | 14.4 |
|  | TE | 2 | | 3.6 | | 5 | | 3.6 | | 2 | 3.6 | | 2 | | 3.6 | 8 | | 3.6 | | | 1 | | 3.6 | 1 | | 3.6 | 1 | | 3.6 |
|  | EQA | 1 | | 4.2 | | 3 | | 4.2 | | 1 | 4.2 | | 1 | | 4.2 | 3 | | 4.2 | | | 1 | | 4.2 | 1 | | 4.2 | 1 | | 4.2 |
| UIBC | RCV | 2 | | 19.6 | | 1 | | 18.7 | | 1 | 18.4 | | 2 | | 20.2 | 1 | | 16.9 | | | 1 | | 18.0 | 1 | | 17.1 | 1 | | 17.9 |
|  | TE | NA | | NA | | NA | | NA | | NA | NA | | NA | | NA | 2 | | 6.0 | | | NA | | NA | 2 | | 6.0 | NA | | NA |
|  | EQA | NA | | NA | | NA | | NA | | 3 | 12.0 | | NA | | NA | 1 | | 12.0 | | | NA | | NA | 1 | | 12.0 | NA | | NA |
|  |  |  | |  | |  | |  | |  |  | |  | |  |  | |  | | |  | |  |  | |  |  | |  |
|  |  |  | |  | |  | |  | |  |  | |  | |  |  | |  | | |  | |  |  | |  |  | |  |
| ***With statistical power ≥ 0.8 and false rejection rate ≤2.5%*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alb | RCV | | 1 | | 6.0 | | 3 | | 7.4 | 1 | | 6.1 | 1 | 5.8 | | | 1 | | 6.1 | 1 | | 6.4 | | | 1 | 6.0 | | 1 | 5.6 |
|  | TE | | NA | | NA | | NA | | NA | 3 | | 1.9 | NA | NA | | | 401 | | 1.9 | NA | | NA | | | 3 | 1.9 | | NA | NA |
|  | EQA | | 2 | | 5.6 | | 27 | | 5.6 | 1 | | 6.4 | 1 | 5.6 | | | 1 | | 6.4 | 1 | | 6.4 | | | 1 | 6.4 | | 1 | 6.4 |
| ALP | RCV | | 1 | | 12.8 | | NA | | NA | 1 | | 12.3 | 1 | 12.1 | | | 2 | | 12.9 | 2 | | 12.9 | | | 1 | 12.9 | | 1 | 12.8 |
|  | TE | | 2 | | 5.5 | | NA | | NA | 1 | | 6.3 | NA | NA | | | NA | | NA | NA | | NA | | | 3 | 5.5 | | NA | NA |
|  | EQA | | 1 | | 7.7 | | NA | | NA | 1 | | 8.8 | NA | NA | | | NA | | NA | NA | | NA | | | 1 | 7.7 | | 1 | 7.7 |
| ALT | RCV | | 1 | | 24.9 | | 1 | | 24.1 | 1 | | 23.3 | 1 | 23.7 | | | 1 | | 23.9 | 1 | | 24.6 | | | 1 | 23.2 | | 1 | 23.2 |
|  | TE | | 4 | | 8.6 | | 2 | | 8.6 | 1 | | 9.8 | NA | NA | | | 2 | | 8.6 | NA | | NA | | | 1 | 9.8 | | 1 | 9.8 |
|  | EQA | | 4 | | 8.1 | | 2 | | 8.1 | 1 | | 9.2 | NA | NA | | | 2 | | 8.1 | NA | | NA | | | 1 | 9.2 | | 1 | 9.2 |
| Amyl | RCV | | 1 | | 15.0 | | 1 | | 15.0 | 1 | | 14.7 | 1 | 14.8 | | | 1 | | 15.2 | 1 | | 15.1 | | | 1 | 15.1 | | 1 | 14.8 |
|  | TE | | 1 | | 7.9 | | 1 | | 7.9 | 1 | | 7.9 | 1 | 7.9 | | | 1 | | 6.9 | 1 | | 7.9 | | | 1 | 7.9 | | 1 | 7.9 |
|  | EQA | | 1 | | 8.0 | | 1 | | 8.0 | 1 | | 8.0 | 1 | 8.0 | | | 1 | | 7.0 | 1 | | 8.0 | | | 1 | 8.0 | | 1 | 8.0 |
| AST | RCV | | 1 | | 21.9 | | 1 | | 21.4 | 1 | | 21.1 | 1 | 21.4 | | | 1 | | 21.7 | 1 | | 21.4 | | | 1 | 21.3 | | NA | NA |
|  | TE | | 2 | | 7.1 | | 1 | | 7.1 | 1 | | 8.1 | 1 | 8.1 | | | 2 | | 7.1 | 1 | | 7.1 | | | 1 | 8.1 | | NA | NA |
|  | EQA | | 2 | | 8.1 | | 1 | | 9.2 | 1 | | 9.2 | 1 | 9.2 | | | 2 | | 8.1 | 1 | | 9.2 | | | 1 | 9.2 | | NA | NA |
| BUN | RCV | | 1 | | 30.9 | | 1 | | 31.4 | 1 | | 30.9 | 1 | 31.2 | | | 1 | | 31.4 | 1 | | 31.0 | | | 1 | 31.1 | | NA | NA |
|  | TE | | 1 | | 10.6 | | 2 | | 9.2 | 1 | | 10.6 | 1 | 10.6 | | | 1 | | 9.2 | 1 | | 10.6 | | | 1 | 10.6 | | NA | NA |
|  | EQA | | 1 | | 7.2 | | 4 | | 6.3 | 1 | | 7.2 | 3 | 6.3 | | | 3 | | 6.3 | 1 | | 7.2 | | | 1 | 6.3 | | NA | NA |
| Ca | RCV | | 2 | | 5.5 | | 2 | | 5.6 | 2 | | 5.1 | 1 | 4.6 | | | 1 | | 4.8 | 1 | | 4.4 | | | 1 | 5.0 | | 1 | 4.9 |
|  | TE | | NA | | NA | | NA | | NA | NA | | NA | NA | NA | | | NA | | NA | NA | | NA | | | NA | NA | | NA | NA |
|  | EQA | | 401 | | 4.2 | | 5 | | 4.2 | NA | | NA | 1 | 4.2 | | | 2 | | 4.2 | 1 | | 4.8 | | | 1 | 4.8 | | 1 | 4.8 |
| Chol | RCV | | 1 | | 12.1 | | 1 | | 12.5 | 1 | | 11.9 | 1 | 12.0 | | | 1 | | 12.0 | 1 | | 12.0 | | | 1 | 11.9 | | 1 | 11.9 |
|  | TE | | 1 | | 4.7 | | 4 | | 4.7 | 1 | | 5.4 | 1 | 5.4 | | | 1 | | 5.4 | 1 | | 5.4 | | | 1 | 5.4 | | 1 | 5.4 |
|  | EQA | | 1 | | 4.9 | | 4 | | 4.9 | 1 | | 5.6 | 1 | 5.6 | | | 1 | | 5.6 | 1 | | 5.6 | | | 1 | 5.6 | | 1 | 5.6 |
| CK | RCV | | 1 | | 35.6 | | 1 | | 35.7 | 1 | | 35.5 | 1 | 35.5 | | | 1 | | 35.8 | 1 | | 35.7 | | | 1 | 35.6 | | 1 | 35.6 |
|  | TE | | 1 | | 13.3 | | 1 | | 13.3 | 1 | | 13.3 | 1 | 13.3 | | | 1 | | 13.3 | 1 | | 13.3 | | | 1 | 13.3 | | 1 | 13.3 |
|  | EQA | | 1 | | 8.8 | | 1 | | 8.8 | 1 | | 8.8 | 1 | 8.8 | | | 1 | | 7.7 | 1 | | 8.8 | | | 1 | 8.8 | | 1 | 8.8 |
| Cl | RCV | | NA | | NA | | 2 | | 2.8 | NA | | NA | 1 | 2.5 | | | 2 | | 2.8 | 1 | | 2.5 | | | 1 | 2.4 | | 1 | 2.5 |
|  | TE | | NA | | NA | | NA | | NA | NA | | NA | NA | NA | | | 21 | | 0.7 | NA | | NA | | | 10 | 0.7 | | NA | NA |
|  | EQA | | NA | | NA | | 1 | | 3.2 | NA | | NA | 1 | 3.6 | | | 1 | | 3.2 | 1 | | 3.6 | | | 1 | 3.6 | | 1 | 3.6 |
| Cr | RCV | | 2 | | 11.9 | | NA | | NA | 1 | | 11.1 | 2 | 10.6 | | | 1 | | 10.1 | 1 | | 9.9 | | | 1 | 9.6 | | 1 | 10.8 |
|  | TE | | NA | | NA | | NA | | NA | NA | | NA | NA | NA | | | 6 | | 3.9 | NA | | NA | | | 5 | 3.9 | | 2 | 3.9 |
|  | EQA | | 10 | | 7.0 | | NA | | NA | 2 | | 7.0 | NA | NA | | | 2 | | 7.0 | 9 | | 7.0 | | | 1 | 7.0 | | 1 | 7.0 |
| Dbil | RCV | | 1 | | 82.7 | | 1 | | 81.9 | 1 | | 81.7 | 1 | 81.7 | | | 1 | | 82.2 | 1 | | 81.9 | | | 1 | 82.2 | | 1 | 81.7 |
|  | TE | | NA | | NA | | 1 | | 17.8 | 1 | | 17.8 | 1 | 17.8 | | | 2 | | 15.6 | 1 | | 17.8 | | | 1 | 15.6 | | 1 | 17.8 |
|  | EQA | | NA | | NA | | NA | | NA | 1 | | 7.0 | 1 | 8.0 | | | 160 | | 7.0 | NA | | NA | | | NA | NA | | 1 | 7.0 |
| GGT | RCV | | 1 | | 19.7 | | 1 | | 20.1 | 1 | | 19.6 | 1 | 19.7 | | | 1 | | 20.1 | 1 | | 20.0 | | | 1 | 19.7 | | 1 | 19.6 |
|  | TE | | 1 | | 10.7 | | 1 | | 10.7 | 1 | | 10.7 | 1 | 10.7 | | | 1 | | 10.7 | 1 | | 10.7 | | | 1 | 10.7 | | 1 | 10.7 |
|  | EQA | | 1 | | 9.2 | | 1 | | 8.1 | 1 | | 9.2 | 1 | 9.2 | | | 1 | | 8.1 | 1 | | 8.1 | | | 1 | 9.2 | | 1 | 9.2 |
| Gluc | RCV | | 1 | | 11.4 | | 1 | | 11.4 | 1 | | 11.3 | 1 | 11.3 | | | 1 | | 11.4 | 1 | | 11.9 | | | 1 | 11.3 | | 1 | 11.4 |
|  | TE | | 2 | | 3.4 | | 2 | | 3.4 | 1 | | 3.4 | 2 | 3.4 | | | 2 | | 3.4 | NA | | NA | | | 1 | 3.4 | | 2 | 3.4 |
|  | EQA | | 1 | | 6.4 | | 1 | | 6.4 | 1 | | 6.4 | 1 | 6.4 | | | 1 | | 6.4 | 9 | | 5.6 | | | 1 | 6.4 | | 1 | 6.4 |
| HDL | RCV | | 1 | | 12.7 | | 1 | | 13.5 | 1 | | 13.3 | 1 | 13.2 | | | 1 | | 13.3 | 1 | | 13.2 | | | 1 | 13.1 | | 1 | 13.1 |
|  | TE | | 1 | | 6.6 | | NA | | NA | 2 | | 5.8 | 2 | 5.8 | | | 2 | | 5.8 | 2 | | 5.8 | | | 1 | 5.8 | | 1 | 5.8 |
|  | EQA | | 1 | | 16.0 | | 1 | | 16.0 | 1 | | 16.0 | 1 | 16.0 | | | 1 | | 16.0 | 1 | | 16.0 | | | 1 | 16.0 | | 1 | 16.0 |
| Iron | RCV | | 1 | | 58.9 | | 1 | | 58.8 | 1 | | 58.8 | 1 | 58.8 | | | 1 | | 58.8 | 1 | | 58.9 | | | 1 | 58.8 | | 1 | 58.8 |
|  | TE | | 1 | | 12.3 | | 1 | | 12.3 | 1 | | 12.3 | 1 | 12.3 | | | 1 | | 12.3 | 1 | | 12.3 | | | 1 | 12.3 | | 1 | 12.3 |
|  | EQA | | 1 | | 12.0 | | 1 | | 12.0 | 1 | | 12.0 | 1 | 12.0 | | | 1 | | 12.0 | 1 | | 12.0 | | | 1 | 12.0 | | 1 | 12.0 |
| K | RCV | | 1 | | 9.3 | | 1 | | 9.1 | 1 | | 9.4 | 1 | 9.2 | | | 1 | | 9.5 | 1 | | 9.2 | | | 1 | 9.3 | | 1 | 9.2 |
|  | TE | | 9 | | 2.5 | | NA | | NA | NA | | NA | 1 | 2.5 | | | 3 | | 2.5 | 1 | | 2.9 | | | 2 | 2.5 | | 1 | 2.9 |
|  | EQA | | 1 | | 3.2 | | 74 | | 3.2 | 9 | | 3.2 | 1 | 3.6 | | | 2 | | 3.2 | 1 | | 3.6 | | | 1 | 3.2 | | 1 | 3.6 |
| LDH | RCV | | 1 | | 11.7 | | 1 | | 12.1 | 1 | | 11.6 | 1 | 11.9 | | | 1 | | 11.7 | 1 | | 12.4 | | | 1 | 11.6 | | 1 | 11.0 |
|  | TE | | 1 | | 4.6 | | NA | | NA | 1 | | 4.6 | 3 | 4.0 | | | NA | | NA | NA | | NA | | | NA | NA | | NA | NA |
|  | EQA | | 1 | | 7.2 | | 1 | | 6.3 | 1 | | 7.2 | 1 | 7.2 | | | 8 | | 6.3 | 9 | | 6.3 | | | NA | NA | | 9 | 6.3 |
| LDL | RCV | | 1 | | 18.6 | | 1 | | 18.5 | 1 | | 18.7 | 1 | 18.6 | | | 1 | | 19.2 | 1 | | 18.8 | | | 1 | 18.7 | | 1 | 18.8 |
|  | TE | | 1 | | 8.2 | | 1 | | 8.2 | 1 | | 8.2 | 1 | 8.2 | | | 2 | | 7.2 | 1 | | 7.2 | | | 1 | 8.2 | | 1 | 8.2 |
|  | EQA | | 1 | | 16.0 | | 1 | | 16.0 | 1 | | 16.0 | 1 | 16.0 | | | 1 | | 16.0 | 1 | | 16.0 | | | 1 | 16.0 | | 1 | 16.0 |
| Lipa | RCV | | 1 | | 20.4 | | 1 | | 21.1 | 1 | | 20.5 | 1 | 20.6 | | | 1 | | 21.7 | 1 | | 21.8 | | | 1 | 20.8 | | NA | NA |
|  | TE | | 1 | | 8.5 | | 2 | | 7.5 | 1 | | 8.5 | 1 | 8.5 | | | NA | | NA | NA | | NA | | | 1 | 7.5 | | NA | NA |
|  | EQA | | 1 | | 8.0 | | 2 | | 7.0 | 1 | | 8.0 | 1 | 8.0 | | | NA | | NA | NA | | NA | | | 1 | 7.0 | | NA | NA |
| Mg | RCV | | 1 | | 8.0 | | NA | | NA | 1 | | 8.6 | 1 | 9.5 | | | 4 | | 10.9 | 2 | | 8.5 | | | 1 | 8.5 | | 1 | 8.4 |
|  | TE | | NA | | NA | | NA | | NA | 10 | | 1.7 | NA | NA | | | NA | | NA | NA | | NA | | | NA | NA | | 3 | 1.7 |
|  | EQA | | 6 | | 5.3 | | NA | | NA | 1 | | 5.3 | NA | NA | | | NA | | NA | 9 | | 5.3 | | | 1 | 5.3 | | 1 | 6.0 |
| Na | RCV | | NA | | NA | | 2 | | 1.5 | NA | | NA | 2 | 1.2 | | | 5 | | 1.8 | NA | | NA | | | 2 | 1.5 | | 5 | 1.7 |
|  | TE | | NA | | NA | | NA | | NA | NA | | NA | 21 | 0.4 | | | NA | | NA | NA | | NA | | | NA | NA | | NA | NA |
|  | EQA | | NA | | NA | | 1 | | 2.1 | NA | | NA | 1 | 2.4 | | | 3 | | 2.1 | 2 | | 2.1 | | | 1 | 2.1 | | 2 | 2.1 |
| P | RCV | | 1 | | 19.0 | | 1 | | 20.3 | 1 | | 18.3 | 1 | 18.5 | | | 1 | | 18.8 | 1 | | 18.9 | | | 1 | 18.3 | | 1 | 18.3 |
|  | TE | | NA | | NA | | NA | | NA | 1 | | 3.6 | 9 | 3.6 | | | 6 | | 3.6 | NA | | NA | | | NA | NA | | 2 | 3.6 |
|  | EQA | | NA | | NA | | NA | | NA | 1 | | 7.2 | 1 | 6.3 | | | 2 | | 6.3 | NA | | NA | | | 1 | 7.2 | | 1 | 7.2 |
| Tbil | RCV | | 1 | | 49.8 | | 1 | | 48.7 | 1 | | 48.4 | 1 | 48.5 | | | 1 | | 49.0 | 1 | | 48.5 | | | 1 | 48.5 | | 1 | 48.4 |
|  | TE | | 27 | | 9.5 | | 1 | | 9.5 | 1 | | 10.8 | 1 | 10.8 | | | 2 | | 9.5 | 1 | | 10.8 | | | 1 | 10.8 | | 1 | 10.8 |
|  | EQA | | 3 | | 14.0 | | 1 | | 16.0 | 1 | | 16.0 | 1 | 16.0 | | | 1 | | 14.0 | 1 | | 16.0 | | | 1 | 16.0 | | 1 | 16.0 |
| TCO2 | RCV | | 3 | | 15.1 | | NA | | NA | 3 | | 17.4 | NA | NA | | | 2 | | 11.0 | 2 | | 9.7 | | | 2 | 10.1 | | 1 | 9.1 |
|  | TE | | NA | | NA | | NA | | NA | NA | | NA | NA | NA | | | NA | | NA | NA | | NA | | | NA | NA | | NA | NA |
|  | EQA | | 4 | | 14.0 | | NA | | NA | 4 | | 14.0 | NA | NA | | | 1 | | 14.0 | 1 | | 16.0 | | | 1 | 16.0 | | 1 | 16.0 |
| TG | RCV | | 1 | | 44.0 | | 1 | | 44.1 | 1 | | 44.0 | 1 | 44.0 | | | 1 | | 44.0 | 1 | | 44.8 | | | 1 | 44.0 | | NA | NA |
|  | TE | | 1 | | 15.9 | | 1 | | 15.9 | 1 | | 15.9 | 1 | 15.9 | | | 1 | | 15.9 | NA | | NA | | | 1 | 15.9 | | NA | NA |
|  | EQA | | 1 | | 7.2 | | 2 | | 6.3 | 1 | | 7.2 | 1 | 7.2 | | | 1 | | 7.2 | NA | | NA | | | 1 | 7.2 | | NA | NA |
| TP | RCV | | 1 | | 6.0 | | 6 | | 7.0 | 1 | | 6.0 | 9 | 6.5 | | | 1 | | 6.4 | 1 | | 5.7 | | | 1 | 5.5 | | 1 | 6.1 |
|  | TE | | 5 | | 1.8 | | NA | | NA | 2 | | 1.8 | NA | NA | | | 160 | | 1.8 | NA | | NA | | | NA | NA | | NA | NA |
|  | EQA | | 1 | | 4.8 | | NA | | NA | 1 | | 4.8 | NA | NA | | | 2 | | 4.2 | 9 | | 4.2 | | | 1 | 4.2 | | 1 | 4.8 |
| UA | RCV | | 1 | | 19.3 | | 1 | | 19.4 | 1 | | 19.3 | 1 | 19.3 | | | 1 | | 19.4 | 1 | | 19.2 | | | 1 | 19.2 | | 1 | 19.2 |
|  | TE | | 1 | | 4.2 | | 3 | | 4.2 | 1 | | 4.2 | 1 | 4.2 | | | 2 | | 4.2 | 1 | | 4.8 | | | 1 | 4.8 | | 1 | 4.8 |
|  | EQA | | 1 | | 4.9 | | 2 | | 4.9 | 1 | | 4.9 | 1 | 4.9 | | | 2 | | 4.9 | 1 | | 5.6 | | | 1 | 5.6 | | 1 | 5.6 |
| UIBC | RCV | | 1 | | 22.8 | | 1 | | 25.0 | 1 | | 21.4 | 2 | 23.6 | | | 1 | | 22.6 | 1 | | 24.0 | | | 1 | 22.8 | | 1 | 23.9 |
|  | TE | | NA | | NA | | NA | | NA | NA | | NA | NA | NA | | | 1 | | 7.0 | NA | | NA | | | 2 | 7.0 | | NA | NA |
|  | EQA | | NA | | NA | | 6 | | 14.0 | 2 | | 14.0 | NA | NA | | | 1 | | 16.0 | 2 | | 14.0 | | | 1 | 16.0 | | 1 | 14.0 |

Abbreviations: EQA, external quality assessment; NA, not applicable; RCV, reference change value; RL, rejection limit; TE, total error; otherwise see Table 1

**Supplementary Table S5.** Sample size and rejection limit to detect between-reagent lot variation of urine chemistry tests depending on critical difference

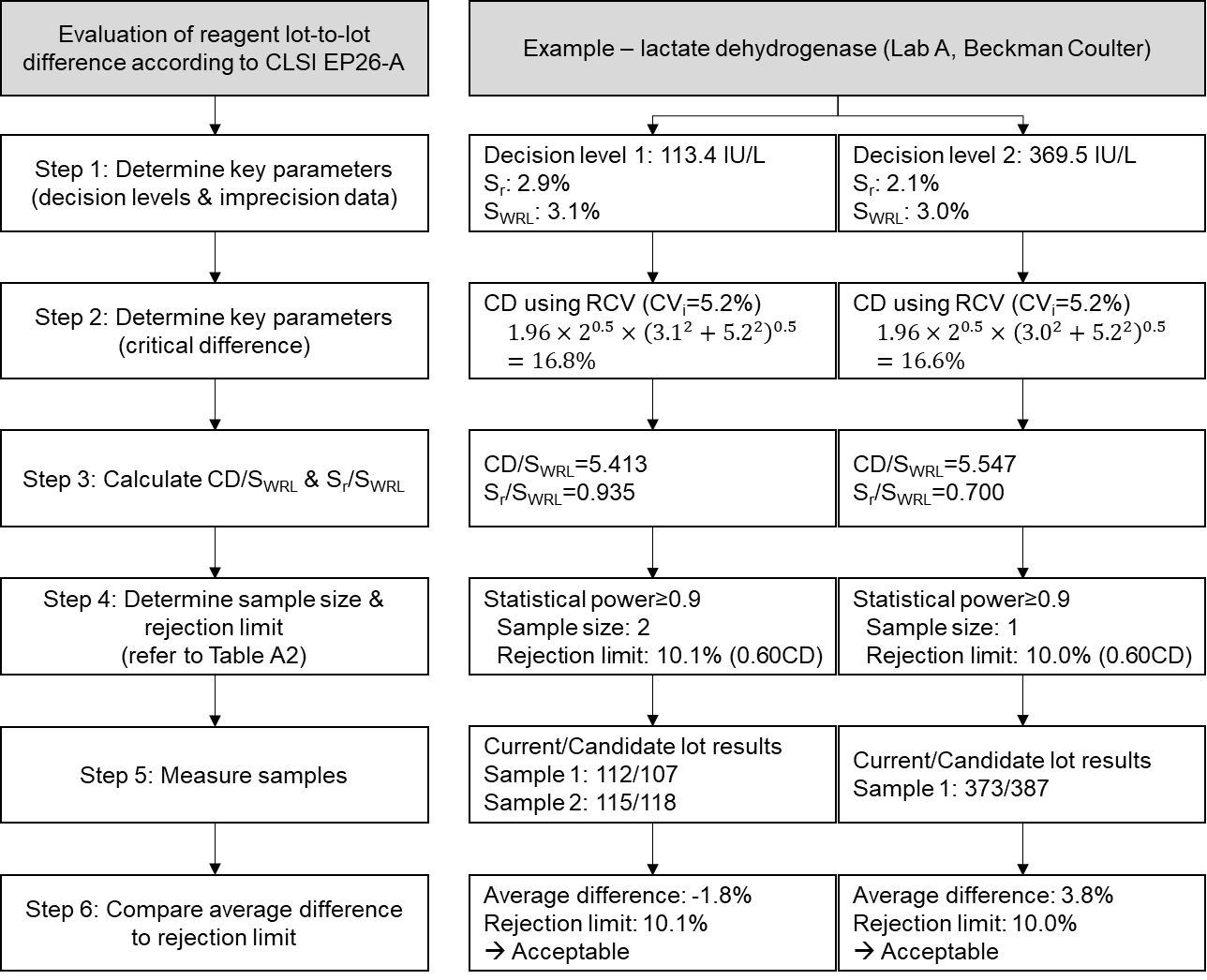
| Analyte | CD source | | Roche platform | | | | | | | | | | | | | | Beckman Coulter platform | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Level 1 | | | | | | | | Level 2 | | | | | | Level 1 | | | | Level 2 | | | |
| Lab A | | | | Lab B | | | | Lab A | | | | Lab B | | Lab A | | Lab C | | Lab A | | Lab C | |
| Sample size | | RL (%) | | Sample size | | RL (%) | | Sample size | | RL (%) | | Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) |
| ***With intended statistical power ≥ 0.9 and false rejection rate ≤2.5%*** | | | | | | | | | | | | | | | | | | | | | | | | |
| Alb (u) | RCV | 1 | | 17.2 | | 1 | | 17.0 | | 1 | | 16.9 | | 1 | | 16.8 | 2 | 19.8 | 1 | 17.6 | 1 | 17.1 | 1 | 16.9 |
|  | TE | 5 | | 6.0 | | 5 | | 6.0 | | 1 | | 6.0 | | 1 | | 6.0 | 13 | 6.0 | NA | NA | 2 | 6.0 | 2 | 6.0 |
|  | EQA | 1 | | 9.0 | | 1 | | 9.0 | | 1 | | 9.0 | | 1 | | 9.0 | 7 | 9.0 | NA | NA | 1 | 9.0 | 1 | 9.0 |
| Ca (u) | RCV | NA | | NA | | 1 | | 16.9 | | NA | | NA | | 1 | | 16.8 | 1 | 17.5 | 1 | 16.7 | 1 | 17.1 | 1 | 16.7 |
|  | TE | NA | | NA | | 1 | | 6.0 | | NA | | NA | | 1 | | 6.0 | NA | NA | 1 | 6.0 | 2 | 6.0 | 1 | 6.0 |
|  | EQA | NA | | NA | | 2 | | 5.1 | | NA | | NA | | 1 | | 5.1 | NA | NA | 1 | 5.1 | 3 | 5.1 | 1 | 5.1 |
| Cl (u) | RCV | NA | | NA | | 1 | | 16.7 | | 1 | | 16.9 | | 1 | | 16.7 | 1 | 16.7 | 1 | 16.7 | 1 | 16.7 | 1 | 16.7 |
|  | TE | NA | | NA | | 1 | | 6.0 | | 1 | | 6.0 | | 1 | | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 |
|  | EQA | NA | | NA | | 1 | | 6.0 | | 1 | | 6.0 | | 1 | | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 |
| Cr (u) | RCV | NA | | NA | | 1 | | 17.5 | | NA | | NA | | 1 | | 17.3 | 1 | 17.1 | 1 | 16.8 | 1 | 17.1 | 1 | 16.8 |
|  | TE | NA | | NA | | NA | | NA | | NA | | NA | | NA | | NA | 2 | 6.0 | 1 | 6.0 | 2 | 6.0 | 1 | 6.0 |
|  | EQA | NA | | NA | | NA | | NA | | NA | | NA | | NA | | NA | 2 | 7.2 | 1 | 7.2 | 2 | 7.2 | 1 | 7.2 |
| Gluc (u) | RCV | 1 | | 17.9 | | 1 | | 16.8 | | 1 | | 16.9 | | 1 | | 16.7 | 1 | 16.9 | 1 | 17.4 | 1 | 16.8 | 1 | 16.7 |
|  | TE | NA | | NA | | 1 | | 6.0 | | 1 | | 6.0 | | 1 | | 6.0 | 1 | 6.0 | NA | NA | 1 | 6.0 | 1 | 6.0 |
|  | EQA | NA | | NA | | 1 | | 6.6 | | 1 | | 6.6 | | 1 | | 6.6 | 1 | 6.6 | NA | NA | 1 | 6.6 | 1 | 6.6 |
| K (u) | RCV | 1 | | 16.7 | | 1 | | 16.7 | | 1 | | 16.7 | | 1 | | 16.8 | 1 | 16.8 | 1 | 16.7 | 1 | 16.9 | 1 | 16.8 |
|  | TE | 1 | | 6.0 | | 1 | | 6.0 | | 1 | | 6.0 | | 1 | | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 |
|  | EQA | 1 | | 5.1 | | 1 | | 5.1 | | 1 | | 5.1 | | 1 | | 5.1 | 1 | 5.1 | 1 | 5.1 | 2 | 5.1 | 1 | 5.1 |
| Mg (u) | RCV | 1 | | 17.0 | | NT | | NT | | NA | | NA | | NT | | NT | 1 | 16.8 | 1 | 16.9 | 1 | 16.8 | 1 | 16.9 |
|  | TE | 2 | | 6.0 | | NT | | NT | | NA | | NA | | NT | | NT | 1 | 6.0 | 2 | 6.0 | 1 | 6.0 | 2 | 6.0 |
|  | EQA | 2 | | 6.0 | | NT | | NT | | NA | | NA | | NT | | NT | 1 | 6.0 | 2 | 6.0 | 1 | 6.0 | 2 | 6.0 |
| Na (u) | RCV | NA | | NA | | 1 | | 16.8 | | NA | | NA | | 1 | | 16.7 | 1 | 16.7 | 1 | 16.7 | 1 | 16.7 | 1 | 16.7 |
|  | TE | NA | | NA | | 1 | | 6.0 | | NA | | NA | | 1 | | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 | 1 | 6.0 |
|  | EQA | NA | | NA | | 2 | | 3.9 | | NA | | NA | | 1 | | 3.9 | 1 | 3.9 | 1 | 3.9 | 1 | 3.9 | 1 | 3.9 |
| P (u) | RCV | 1 | | 16.8 | | 1 | | 17.5 | | NA | | NA | | 1 | | 17.0 | 1 | 17.5 | NA | NA | 1 | 17.2 | 1 | 17.1 |
|  | TE | 1 | | 6.0 | | NA | | NA | | NA | | NA | | 5 | | 6.0 | NA | NA | NA | NA | 9 | 6.0 | NA | NA |
|  | EQA | 1 | | 6.9 | | NA | | NA | | NA | | NA | | 1 | | 6.9 | NA | NA | NA | NA | 4 | 6.9 | NA | NA |
| TP (u) | RCV | 1 | | 17.0 | | 1 | | 17.1 | | 1 | | 17.7 | | 1 | | 16.8 | 1 | 17.5 | 1 | 17.4 | 1 | 17.1 | 1 | 16.8 |
|  | TE | 2 | | 6.0 | | 2 | | 6.0 | | NA | | NA | | 1 | | 6.0 | NA | NA | NA | NA | NA | NA | 1 | 6.0 |
|  | EQA | 1 | | 6.9 | | 2 | | 8.1 | | NA | | NA | | 1 | | 6.9 | NA | NA | NA | NA | 5 | 6.9 | 1 | 6.9 |
| UA (u) | RCV | 1 | | 17.4 | | 1 | | 17.0 | | NA | | NA | | 1 | | 16.9 | 1 | 16.9 | 1 | 16.7 | 1 | 16.9 | 1 | 16.7 |
|  | TE | NA | | NA | | 2 | | 6.0 | | NA | | NA | | 2 | | 6.0 | 1 | 6.0 | 1 | 6.0 | 2 | 6.0 | 1 | 6.0 |
|  | EQA | NA | | NA | | 1 | | 8.1 | | NA | | NA | | 1 | | 8.1 | 1 | 8.1 | 1 | 8.1 | 1 | 8.1 | 1 | 8.1 |
| Urea (u) | RCV | 1 | | 16.9 | | 1 | | 17.2 | | 1 | | 17.0 | | 1 | | 17.3 | 1 | 17.2 | 1 | 16.8 | 1 | 17.3 | 1 | 16.9 |
|  | TE | 1 | | 6.0 | | NA | | NA | | 2 | | 6.0 | | 9 | | 6.0 | 5 | 6.0 | 1 | 6.0 | 7 | 6.0 | 1 | 6.0 |
|  | EQA | 1 | | 8.1 | | 2 | | 8.1 | | 1 | | 8.1 | | 2 | | 8.1 | 2 | 8.1 | 1 | 8.1 | 2 | 8.1 | 1 | 8.1 |
| ***With statistical power ≥ 0.8 and false rejection rate ≤2.5%*** | | | | | | | | | | | | | | | | | | | | | | | | |
| Alb (u) | RCV | | 1 | | 22.9 | | 1 | | 22.7 | | 1 | | 22.5 | | 1 | 22.3 | 1 | 23.1 | 1 | 23.5 | 1 | 22.8 | 1 | 22.6 |
|  | TE | | 3 | | 7.0 | | 2 | | 70.0 | | 1 | | 7.0 | | 1 | 8.0 | 10 | 7.0 | NA | NA | 2 | 7.0 | 1 | 7.0 |
|  | EQA | | 1 | | 10.5 | | 1 | | 12.0 | | 1 | | 12.0 | | 1 | 12.0 | 6 | 10.5 | 9 | 10.5 | 1 | 12.0 | 1 | 12.0 |
| Ca (u) | RCV | | NA | | NA | | 1 | | 22.5 | | NA | | NA | | 1 | 22.4 | 1 | 23.4 | 1 | 22.3 | 1 | 22.8 | 1 | 22.3 |
|  | TE | | NA | | NA | | 1 | | 7.0 | | NA | | NA | | 1 | 8.0 | 401 | 7.0 | 1 | 8.0 | 2 | 7.0 | 1 | 8.0 |
|  | EQA | | NA | | NA | | 2 | | 6.0 | | NA | | NA | | 1 | 6.0 | NA | NA | 1 | 6.8 | 2 | 6.0 | 1 | 6.8 |
| Cl (u) | RCV | | NA | | NA | | 1 | | 22.3 | | 1 | | 22.5 | | 1 | 22.2 | 1 | 22.2 | 1 | 22.2 | 1 | 22.2 | 1 | 22.2 |
|  | TE | | NA | | NA | | 1 | | 8.0 | | 1 | | 7.0 | | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 |
|  | EQA | | NA | | NA | | 1 | | 8.0 | | 1 | | 7.0 | | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 |
| Cr (u) | RCV | | NA | | NA | | 1 | | 23.4 | | NA | | NA | | 1 | 23.1 | 1 | 22.8 | 1 | 22.5 | 1 | 22.8 | 1 | 22.3 |
|  | TE | | NA | | NA | | NA | | NA | | NA | | NA | | NA | NA | 2 | 7.0 | 1 | 8.0 | 2 | 7.0 | 1 | 8.0 |
|  | EQA | | NA | | NA | | NA | | NA | | NA | | NA | | 3 | 8.4 | 1 | 8.4 | 1 | 9.6 | 1 | 8.4 | 1 | 9.6 |
| Gluc (u) | RCV | | 1 | | 23.8 | | 1 | | 22.5 | | 1 | | 22.5 | | 1 | 22.3 | 1 | 22.5 | 1 | 23.2 | 1 | 22.4 | 1 | 22.3 |
|  | TE | | NA | | NA | | 1 | | 8.0 | | 1 | | 7.0 | | 1 | 8.0 | 1 | 7.0 | NA | NA | 1 | 8.0 | 1 | 8.0 |
|  | EQA | | NA | | NA | | 1 | | 8.8 | | 1 | | 8.8 | | 1 | 8.8 | 1 | 8.8 | NA | NA | 1 | 8.8 | 1 | 8.8 |
| K (u) | RCV | | 1 | | 22.3 | | 1 | | 22.3 | | 1 | | 22.3 | | 1 | 22.4 | 1 | 22.4 | 1 | 22.3 | 1 | 22.5 | 1 | 22.3 |
|  | TE | | 1 | | 8.0 | | 1 | | 8.0 | | 1 | | 8.0 | | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 7.0 | 1 | 8.0 |
|  | EQA | | 1 | | 6.8 | | 1 | | 6.8 | | 1 | | 6.8 | | 1 | 6.0 | 1 | 6.8 | 1 | 6.8 | 1 | 6.0 | 1 | 6.8 |
| Mg (u) | RCV | | 1 | | 22.7 | | NT | | NT | | NA | | NA | | NT | NT | 1 | 22.5 | 1 | 22.6 | 1 | 22.5 | 1 | 22.6 |
|  | TE | | 2 | | 7.0 | | NT | | NT | | NA | | NA | | NT | NT | 1 | 8.0 | 1 | 7.0 | 1 | 8.0 | 1 | 7.0 |
|  | EQA | | 2 | | 7.0 | | NT | | NT | | NA | | NA | | NT | NT | 1 | 8.0 | 1 | 7.0 | 1 | 8.0 | 1 | 7.0 |
| Na (u) | RCV | | NA | | NA | | 1 | | 22.3 | | NA | | NA | | 1 | 22.2 | 1 | 22.3 | 1 | 22.3 | 1 | 22.2 | 1 | 22.2 |
|  | TE | | NA | | NA | | 1 | | 8.0 | | NA | | NA | | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 | 1 | 8.0 |
|  | EQA | | NA | | NA | | 1 | | 4.6 | | NA | | NA | | 1 | 5.2 | 1 | 4.6 | 1 | 5.2 | 1 | 5.2 | 1 | 5.2 |
| P (u) | RCV | | 1 | | 22.4 | | 1 | | 23.4 | | NA | | NA | | 1 | 22.7 | 1 | 23.3 | NA | NA | 1 | 22.9 | 1 | 22.9 |
|  | TE | | 1 | | 8.0 | | NA | | NA | | NA | | NA | | 2 | 7.0 | NA | NA | NA | NA | 3 | 7.0 | 2 | 7.0 |
|  | EQA | | 1 | | 9.2 | | NA | | NA | | NA | | NA | | 2 | 8.1 | NA | NA | NA | NA | 2 | 8.1 | 2 | 8.1 |
| TP (u) | RCV | | 1 | | 22.6 | | 1 | | 22.9 | | 1 | | 23.6 | | 1 | 22.3 | 1 | 23.4 | 1 | 23.2 | 1 | 22.8 | 1 | 22.5 |
|  | TE | | 1 | | 7.0 | | 2 | | 7.0 | | NA | | NA | | 1 | 8.0 | 401 | 7.0 | NA | NA | 3 | 7.0 | 1 | 8.0 |
|  | EQA | | 1 | | 8.1 | | NA | | NA | | NA | | NA | | 1 | 9.2 | 401 | 8.1 | NA | NA | 2 | 8.1 | 1 | 9.2 |
| UA (u) | RCV | | 1 | | 23.2 | | 1 | | 22.7 | | NA | | NA | | 1 | 22.6 | 1 | 22.5 | 1 | 22.3 | 1 | 22.6 | 1 | 22.3 |
|  | TE | | NA | | NA | | 2 | | 7.0 | | NA | | NA | | 1 | 7.0 | 1 | 7.0 | 1 | 8.0 | 1 | 7.0 | 1 | 8.0 |
|  | EQA | | 9 | | 9.5 | | 1 | | 10.8 | | NA | | NA | | 1 | 10.8 | 1 | 10.8 | 1 | 10.8 | 1 | 10.8 | 1 | 10.8 |
| Urea (u) | RCV | | 1 | | 22.5 | | 1 | | 23.0 | | 1 | | 22.6 | | 1 | 23.0 | 1 | 23.0 | 1 | 22.5 | 1 | 23.1 | 1 | 22.5 |
|  | TE | | 1 | | 7.0 | | 6 | | 7.0 | | 1 | | 7.0 | | 3 | 7.0 | 3 | 7.0 | 1 | 8.0 | 4 | 7.0 | 1 | 7.0 |
|  | EQA | | 1 | | 10.8 | | 1 | | 9.5 | | 1 | | 10.8 | | 2 | 9.5 | 1 | 9.5 | 1 | 10.8 | 2 | 9.5 | 1 | 10.8 |

Abbreviations: EQA, external quality assessment; NA, not applicable; NT, not tested; RCV, reference change value; RL, rejection limits; TE, total error; otherwise see Table 1

**Supplementary Table S6.** Sample size and rejection limit to detect between-reagent lot variation of immunochemistry tests depending on critical difference

| Analyte | CD source | Decision level 1 | | | | | | Decision level 2 | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lab A | | Lab B | | Lab C | | Lab A | | Lab B | | Lab C | |
| Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) | Sample size | RL (%) |
| ***With intended statistical power ≥0.9 and false rejection rate ≤2.5%*** | | | | | | | | | | | | | |
| ACTH | RCV | 1 | 16.7 | 1 | 16.9 | 1 | 17.5 | 1 | 16.7 | 1 | 16.8 | 1 | 16.9 |
|  | TE | 1 | 6.0 | 2 | 6.0 | NA | NA | 1 | 6.0 | 1 | 6.0 | NA | NA |
|  | EQA | 1 | 6.0 | 2 | 6.0 | NA | NA | 1 | 6.0 | 1 | 6.0 | NA | NA |
| AFP | RCV | 1 | 44.5 | 1 | 45.0 | 1 | 44.6 | 1 | 44.5 | 1 | 45.3 | 1 | 44.6 |
|  | TE | 1 | 15.7 | 1 | 15.7 | 1 | 15.7 | 1 | 15.7 | NA | NA | 1 | 15.7 |
|  | EQA | 1 | 10.2 | NA | NA | 1 | 10.2 | 1 | 10.2 | NA | NA | 1 | 10.2 |
| Anti-Tg | RCV | 1 | 14.9 | 1 | 16.3 | 1 | 15.4 | 1 | 14.6 | 1 | 15.7 | 1 | 15.3 |
|  | TE | 2 | 8.3 | NA | NA | 9 | 8.3 | 1 | 8.3 | NA | NA | 5 | 8.3 |
|  | EQA | NA | NA | NA | NA | NA | NA | 4 | 6.0 | NA | NA | NA | NA |
| Anti-TPO | RCV | 1 | 20.3 | 3 | 24.4 | 2 | 21.8 | 1 | 19.9 | 1 | 20.6 | 1 | 20.0 |
|  | TE | 2 | 13.9 | NA | NA | 401 | 13.9 | 1 | 13.9 | 5 | 13.9 | 1 | 13.9 |
|  | EQA | NA | NA | NA | NA | NA | NA | 8 | 6.0 | NA | NA | NA | NA |
| CA 125 | RCV | 1 | 22.3 | 1 | 22.7 | 1 | 22.6 | 1 | 22.2 | 1 | 22.6 | 1 | 22.5 |
|  | TE | 1 | 7.3 | NA | NA | 3 | 7.3 | 1 | 7.3 | NA | NA | 5 | 7.3 |
|  | EQA | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 |
| CA 15-3 | RCV | 1 | 11.2 | 2 | 12.1 | 1 | 11.5 | 1 | 10.6 | 2 | 12.0 | 1 | 11.4 |
|  | TE | NA | NA | NA | NA | 7 | 6.2 | 2 | 6.2 | NA | NA | NA | NA |
|  | EQA | 1 | 9.6 | NA | NA | 2 | 9.6 | 1 | 9.6 | NA | NA | 2 | 9.6 |
| CA 19-9 | RCV | 1 | 37.5 | 1 | 37.8 | 1 | 37.6 | 1 | 37.5 | 1 | 37.8 | 1 | 37.6 |
|  | TE | 1 | 17.1 | 1 | 17.1 | 1 | 17.1 | 1 | 17.1 | 1 | 17.1 | 1 | 17.1 |
|  | EQA | 1 | 6.0 | NA | NA | 2 | 6.0 | 1 | 6.0 | NA | NA | 5 | 6.0 |
| CEA | RCV | 1 | 29.9 | 1 | 30.3 | 1 | 30.2 | 1 | 29.9 | 1 | 30.3 | 1 | 30.0 |
|  | TE | 1 | 12.1 | 1 | 12.1 | 1 | 12.1 | 1 | 12.1 | 1 | 12.1 | 1 | 12.1 |
|  | EQA | 1 | 8.4 | NA | NA | NA | NA | 1 | 8.4 | NA | NA | 1 | 8.4 |
| CK-MB | RCV | 1 | 31.5 | 1 | 31.0 | 1 | 31.0 | 1 | 31.5 | 1 | 31.1 | 1 | 30.9 |
|  | TE | NA | NA | 5 | 9.0 | 2 | 9.0 | NA | NA | 5 | 9.0 | 1 | 9.0 |
|  | EQA | 2 | 15.0 | 1 | 15.0 | 1 | 15.0 | 3 | 15.0 | 1 | 15.0 | 1 | 15.0 |
| Cortisol | RCV | 1 | 38.9 | 1 | 38.8 | 1 | 38.7 | 1 | 41.1 | 1 | 38.8 | 1 | 38.7 |
|  | TE | 1 | 14.6 | 1 | 14.6 | 1 | 14.6 | NA | NA | 1 | 14.6 | 1 | 14.6 |
|  | EQA | 3 | 11.1 | 1 | 11.1 | 1 | 11.1 | NA | NA | 1 | 11.1 | 1 | 11.1 |
| C-pep | RCV | 1 | 27.7 | 1 | 27.9 | 1 | 27.7 | 1 | 27.7 | 1 | 27.8 | 1 | 27.8 |
|  | TE | 1 | 6.2 | NA | NA | 1 | 6.2 | 1 | 6.2 | 2 | 6.2 | 1 | 6.2 |
|  | EQA | 1 | 6.0 | NA | NA | 1 | 6.0 | 1 | 6.0 | 2 | 6.0 | 1 | 6.0 |
| Cyfra | RCV | 1 | 37.1 | NT | NT | NT | NT | 1 | 37.0 | NT | NT | NT | NT |
|  | TE | 1 | 8.4 | NT | NT | NT | NT | 1 | 8.4 | NT | NT | NT | NT |
|  | EQA | 4 | 6.0 | NT | NT | NT | NT | 1 | 6.0 | NT | NT | NT | NT |
| DHEAS | RCV | 1 | 10.5 | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
|  | TE | 5 | 4.7 | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
|  | EQA | 2 | 6.0 | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
| E2 | RCV | 1 | 25.8 | 1 | 25.7 | 1 | 25.3 | 1 | 25.5 | 1 | 25.2 | 1 | 25.1 |
|  | TE | 17 | 7.8 | NA | NA | 2 | 7.8 | NA | NA | 1 | 7.8 | 1 | 7.8 |
|  | EQA | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 |
| Ferritin | RCV | 1 | 28.9 | 1 | 29.2 | 1 | 29.2 | 1 | 28.9 | 1 | 29.4 | 1 | 29.0 |
|  | TE | 1 | 5.1 | NA | NA | NA | NA | 1 | 5.1 | NA | NA | NA | NA |
|  | EQA | 1 | 8.1 | 8 | 8.1 | 5 | 8.1 | 1 | 8.1 | 401 | 8.1 | 1 | 8.1 |
| Folate | RCV | 1 | 40.5 | 1 | 42.5 | 1 | 40.4 | 1 | 40.4 | 1 | 41.0 | 1 | 41.5 |
|  | TE | 2 | 11.7 | NA | NA | 2 | 11.7 | 2 | 11.7 | NA | NA | NA | NA |
|  | EQA | 1 | 18.0 | NA | NA | 1 | 18.0 | 1 | 18.0 | 2 | 18.0 | 8 | 18.0 |
| fPSA | RCV | 1 | 13.1 | 1 | 13.1 | 1 | 12.5 | 1 | 12.0 | 1 | 12.8 | 1 | 12.4 |
|  | TE | 401 | 7.9 | NA | NA | 2 | 7.9 | 1 | 7.9 | 5 | 7.9 | 1 | 7.9 |
|  | EQA | NA | NA | NA | NA | 4 | 6.0 | 1 | 6.0 | NA | NA | NA | NA |
| FSH | RCV | 1 | 21.0 | 1 | 20.9 | 1 | 21.0 | 1 | 22.1 | 1 | 20.8 | 1 | 20.9 |
|  | TE | 1 | 9.5 | 1 | 9.5 | 1 | 9.5 | 17 | 9.5 | 1 | 9.5 | 1 | 9.5 |
|  | EQA | 1 | 8.4 | 1 | 8.4 | 1 | 8.4 | NA | NA | 1 | 8.4 | 1 | 8.4 |
| fT4 | RCV | 1 | 13.2 | 1 | 13.5 | 1 | 13.3 | 1 | 13.7 | 1 | 13.5 | 1 | 13.5 |
|  | TE | 4 | 4.5 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | 1 | 7.8 | 2 | 7.8 | 1 | 7.8 | 3 | 7.8 | 2 | 7.8 | 2 | 7.8 |
| hCG | RCV | 1 | 16.8 | 1 | 17.4 | 1 | 17.1 | 1 | 16.8 | 1 | 17.2 | 1 | 17.0 |
|  | TE | 1 | 6.0 | NA | NA | 3 | 6.0 | 1 | 6.0 | NA | NA | 2 | 6.0 |
|  | EQA | 1 | 10.2 | 1 | 10.2 | 1 | 10.2 | 1 | 10.2 | 1 | 10.2 | 1 | 10.2 |
| Hcy | RCV | 1 | 14.8 | 1 | 14.7 | 1 | 15.0 | 1 | 15.3 | 1 | 14.6 | 1 | 14.5 |
|  | TE | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| HE4 | RCV | NT | NT | 1 | 16.8 | 1 | 17.9 | NT | NT | 1 | 17.5 | 1 | 18.1 |
|  | TE | NT | NT | NA | NA | NA | NA | NT | NT | NA | NA | NA | NA |
|  | EQA | NT | NT | 401 | 6.0 | NA | NA | NT | NT | NA | NA | NA | NA |
| hsTnI | RCV | 1 | 24.9 | NT | NT | NT | NT | 1 | 23.6 | NT | NT | NT | NT |
|  | TE | NA | NA | NT | NT | NT | NT | 1 | 8.4 | NT | NT | NT | NT |
|  | EQA | NA | NA | NT | NT | NT | NT | 1 | 12.0 | NT | NT | NT | NT |
| hsTnT | RCV | NT | NT | 1 | 50.8 | 1 | 50.8 | NT | NT | 1 | 50.8 | 1 | 50.8 |
|  | TE | NT | NT | 1 | 14.7 | 1 | 14.7 | NT | NT | 1 | 14.7 | 1 | 14.7 |
|  | EQA | NT | NT | 1 | 12.6 | 1 | 12.6 | NT | NT | 1 | 12.6 | 1 | 12.6 |
| IgE | RCV | 1 | 17.5 | 1 | 18.7 | 1 | 17.0 | 401 | 20.8 | 1 | 18.6 | 1 | 17.0 |
|  | TE | NA | NA | NA | NA | 3 | 6.0 | NA | NA | NA | NA | NA | NA |
|  | EQA | 1 | 12.0 | NA | NA | 1 | 12.0 | NA | NA | NA | NA | 1 | 12.0 |
| Insulin | RCV | 1 | 35.3 | 1 | 35.3 | 1 | 35.5 | 1 | 35.4 | 1 | 35.2 | 1 | 35.5 |
|  | TE | 1 | 13.5 | 1 | 13.5 | 1 | 13.5 | 1 | 13.5 | 1 | 13.5 | 1 | 13.5 |
|  | EQA | NA | NA | NA | NA | NA | NA | NA | NA | 1 | 6.0 | NA | NA |
| LH | RCV | 1 | 38.1 | 1 | 38.2 | 1 | 38.1 | 1 | 38.4 | 1 | 38.1 | 1 | 38.0 |
|  | TE | 1 | 12.8 | 1 | 12.8 | 1 | 12.8 | 1 | 12.8 | 1 | 12.8 | 1 | 12.8 |
|  | EQA | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 | 1 | 12.0 |
| NSE | RCV | NT | NT | 1 | 18.8 | 1 | 18.6 | NT | NT | 1 | 18.6 | 1 | 18.5 |
|  | TE | NT | NT | NA | NA | NA | NA | NT | NT | NA | NA | 3 | 6.3 |
|  | EQA | NT | NT | NA | NA | NA | NA | NT | NT | NA | NA | 8 | 6.0 |
| NT-pBNP | RCV | 1 | 17.0 | 1 | 17.3 | 1 | 16.9 | 1 | 16.9 | 1 | 17.4 | 1 | 16.8 |
|  | TE | 8 | 3.9 | NA | NA | NA | NA | 4 | 3.9 | NA | NA | NA | NA |
|  | EQA | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 |
| PIVKA | RCV | 1 | 18.2 | NT | NT | NT | NT | 1 | 17.3 | NT | NT | NT | NT |
|  | TE | NA | NA | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
|  | EQA | NA | NA | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
| Procal | RCV | 1 | 17.8 | 1 | 17.0 | 1 | 17.0 | 1 | 17.3 | 1 | 17.0 | 1 | 16.8 |
|  | TE | NA | NA | 2 | 6.0 | 3 | 6.0 | NA | NA | 2 | 6.0 | 1 | 6.0 |
|  | EQA | NA | NA | 2 | 6.0 | 3 | 6.0 | NA | NA | 2 | 6.0 | 1 | 6.0 |
| Prolac | RCV | 1 | 34.0 | 1 | 33.3 | 1 | 33.4 | 1 | 34.1 | 1 | 33.2 | 1 | 33.3 |
|  | TE | 3 | 11.2 | 1 | 11.2 | 1 | 11.2 | 4 | 11.2 | 1 | 11.2 | 1 | 11.2 |
|  | EQA | 2 | 12.0 | 1 | 12.0 | 1 | 12.0 | 3 | 12.0 | 1 | 12.0 | 1 | 12.0 |
| PSA | RCV | 1 | 11.6 | 1 | 12.6 | 1 | 11.8 | 1 | 11.6 | 1 | 12.4 | 1 | 11.8 |
|  | TE | 1 | 7.3 | NA | NA | 1 | 7.3 | 1 | 7.3 | NA | NA | 1 | 7.3 |
|  | EQA | 1 | 9.3 | NA | NA | 1 | 9.3 | 1 | 9.3 | 2 | 9.3 | 1 | 9.3 |
| PTH | RCV | 1 | 40.4 | 1 | 40.4 | 1 | 40.8 | 1 | 40.3 | 1 | 40.4 | 1 | 41.0 |
|  | TE | 1 | 12.8 | 1 | 12.8 | 2 | 12.8 | 1 | 12.8 | 1 | 12.8 | NA | NA |
|  | EQA | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 |
| T3 | RCV | 2 | 13.5 | 1 | 12.2 | 1 | 12.2 | 1 | 12.9 | 1 | 12.0 | 1 | 11.9 |
|  | TE | NA | NA | NA | NA | NA | NA | NA | NA | 5 | 5.1 | 8 | 5.1 |
|  | EQA | 4 | 9.6 | 1 | 9.6 | 1 | 9.6 | 3 | 9.6 | 1 | 9.6 | 1 | 9.6 |
| T4 | RCV | 1 | 12.3 | 1 | 1.0 | 1 | 12.1 | NA | NA | 1 | 11.4 | 1 | 11.9 |
|  | TE | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | NA | NA | 2 | 7.5 | NA | NA | NA | NA | 2 | 7.5 | NA | NA |
| Testo | RCV | 1 | 20.5 | 1 | 22.0 | 1 | 20.5 | 1 | 21.5 | 1 | 20.2 | 1 | 20.4 |
|  | TE | 3 | 7.0 | NA | NA | NA | NA | NA | NA | 1 | 7.0 | NA | NA |
|  | EQA | 1 | 12.3 | NA | NA | 1 | 12.3 | 5 | 12.3 | 1 | 12.3 | 1 | 12.3 |
| Tg | RCV | 1 | 21.5 | 1 | 21.9 | 1 | 21.8 | 1 | 22.5 | 1 | 21.9 | 1 | 21.8 |
|  | TE | 1 | 8.3 | 8 | 8.3 | 5 | 8.3 | 7 | 8.3 | NA | NA | 3 | 8.3 |
|  | EQA | 2 | 6.0 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| TSH | RCV | 1 | 27.3 | 1 | 26.9 | 1 | 26.6 | 1 | 29.0 | 1 | 26.9 | 1 | 26.6 |
|  | TE | 2 | 9.9 | 1 | 9.9 | 1 | 9.9 | NA | NA | 1 | 9.9 | 1 | 9.9 |
|  | EQA | 4 | 8.1 | 2 | 8.1 | 1 | 8.1 | NA | NA | NA | NA | 1 | 8.1 |
| TSHR | RCV | 3 | 11.9 | NA | NA | NA | NA | 2 | 11.5 | 2 | 9.3 | 2 | 9.3 |
|  | TE | 13 | 6.0 | NA | NA | NA | NA | 5 | 6.0 | NA | NA | NA | NA |
|  | EQA | 13 | 6.0 | NA | NA | NA | NA | 5 | 6.0 | NA | NA | NA | NA |
| Vit B12 | RCV | 1 | 17.3 | 1 | 17.6 | 1 | 17.3 | 1 | 17.1 | 1 | 17.4 | 1 | 18.0 |
|  | TE | 4 | 6.0 | NA | NA | NA | NA | 2 | 6.0 | 17 | 6.0 | NA | NA |
|  | EQA | 1 | 15.0 | 1 | 15.0 | 1 | 15.0 | 1 | 15.0 | 1 | 15.0 | 1 | 15.0 |
| Vit D | RCV | 1 | 17.7 | 2 | 19.3 | 1 | 19.2 | 1 | 18.4 | 1 | 18.7 | 1 | 17.7 |
|  | TE | 8 | 6.0 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | 8 | 6.0 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| ***With intended power ≥0.8 and false rejection rate ≤2.5%)*** | | | | | | | | | | | | | |
| ACTH | RCV | 1 | 22.3 | 1 | 22.6 | 1 | 23.4 | 1 | 22.2 | 1 | 22.4 | 1 | 22.6 |
|  | TE | 1 | 8.0 | 1 | 7.0 | NA | NA | 1 | 8.0 | 1 | 8.0 | 1 | 7.0 |
|  | EQA | 1 | 8.0 | 1 | 7.0 | NA | NA | 1 | 8.0 | 1 | 8.0 | 1 | 7.0 |
| AFP | RCV | 1 | 59.3 | 1 | 59.9 | 1 | 59.5 | 1 | 59.4 | 1 | 60.4 | 1 | 59.4 |
|  | TE | 1 | 20.9 | 1 | 20.9 | 1 | 20.9 | 1 | 20.9 | 2 | 18.3 | 1 | 20.9 |
|  | EQA | 1 | 13.6 | 9 | 11.9 | 1 | 13.6 | 1 | 13.6 | NA | NA | 1 | 13.6 |
| Anti-Tg | RCV | 1 | 19.9 | 1 | 19.0 | 1 | 17.9 | 1 | 19.5 | 1 | 20.9 | 1 | 20.4 |
|  | TE | 2 | 9.7 | NA | NA | 3 | 9.7 | 1 | 11.0 | NA | NA | 3 | 9.7 |
|  | EQA | 401 | 7.0 | NA | NA | NA | NA | 2 | 7.0 | NA | NA | 27 | 7.0 |
| Anti-TPO | RCV | 1 | 27.1 | 2 | 28.5 | 1 | 25.4 | 1 | 26.6 | 1 | 27.5 | 1 | 26.7 |
|  | TE | 1 | 16.2 | NA | NA | 4 | 16.2 | 1 | 16.2 | 2 | 16.2 | 1 | 16.2 |
|  | EQA | NA | NA | NA | NA | NA | NA | 5 | 7.0 | NA | NA | NA | NA |
| CA 125 | RCV | 1 | 29.7 | 1 | 30.3 | 1 | 30.1 | 1 | 29.7 | 1 | 30.1 | 1 | 30.1 |
|  | TE | 1 | 9.7 | NA | NA | 2 | 8.5 | 1 | 9.7 | NA | NA | 2 | 8.5 |
|  | EQA | 1 | 16.0 | 1 | 16.0 | 1 | 16.0 | 1 | 16.0 | 1 | 16.0 | 1 | 16.0 |
| CA 15-3 | RCV | 1 | 15.0 | 1 | 14.2 | 1 | 13.5 | 1 | 14.2 | 1 | 13.9 | 1 | 13.3 |
|  | TE | NA | NA | NA | NA | 4 | 0.8 | 1 | 7.3 | NA | NA | 9 | 7.3 |
|  | EQA | 1 | 11.2 | 9 | 11.2 | 2 | 11.2 | 1 | 12.8 | 3 | 11.2 | 1 | 11.2 |
| CA 19-9 | RCV | 1 | 50.1 | 1 | 50.5 | 1 | 50.1 | 1 | 50.1 | 1 | 50.4 | 1 | 50.1 |
|  | TE | 1 | 22.7 | 1 | 22.7 | 1 | 22.7 | 1 | 22.7 | 1 | 22.7 | 1 | 22.7 |
|  | EQA | 1 | 7.0 | NA | NA | 2 | 7.0 | 1 | 7.0 | NA | NA | 2 | 7.0 |
| CEA | RCV | 1 | 39.9 | 1 | 40.4 | 1 | 40.3 | 1 | 39.8 | 1 | 40.4 | 1 | 40.0 |
|  | TE | 1 | 16.2 | 1 | 14.1 | 1 | 16.2 | 1 | 16.2 | 1 | 16.2 | 1 | 16.2 |
|  | EQA | 1 | 11.2 | 9 | 9.8 | 2 | 9.8 | 1 | 11.2 | 3 | 9.8 | 1 | 9.8 |
| CK-MB | RCV | 1 | 42.1 | 1 | 41.4 | 1 | 41.3 | 1 | 42.1 | 1 | 41.4 | 1 | 41.2 |
|  | TE | NA | NA | 2 | 10.5 | 1 | 10.5 | NA | NA | 2 | 10.5 | 1 | 10.5 |
|  | EQA | 1 | 17.5 | 1 | 20.0 | 1 | 20.0 | 1 | 17.5 | 1 | 20.0 | 1 | 20.0 |
| Cortisol | RCV | 1 | 51.9 | 1 | 51.7 | 1 | 51.6 | 1 | 54.8 | 1 | 51.7 | 1 | 51.6 |
|  | TE | 1 | 19.5 | 1 | 19.5 | 1 | 19.5 | NA | NA | 1 | 19.5 | 1 | 19.5 |
|  | EQA | 2 | 13.0 | 1 | 13.0 | 1 | 14.8 | NA | NA | 1 | 13.0 | 1 | 14.8 |
| C-pep | RCV | 1 | 36.9 | 1 | 37.2 | 1 | 37.0 | 1 | 37.0 | 1 | 37.1 | 1 | 37.0 |
|  | TE | 1 | 8.3 | 9 | 7.3 | 1 | 8.3 | 1 | 8.3 | 1 | 7.3 | 1 | 7.3 |
|  | EQA | 1 | 8.0 | 9 | 7.0 | 1 | 8.0 | 1 | 8.0 | 1 | 7.0 | 1 | 7.0 |
| Cyfra | RCV | 1 | 49.5 | NT | NT | NT | NT | 1 | 49.3 | NT | NT | NT | NT |
|  | TE | 1 | 11.2 | NT | NT | NT | NT | 1 | 11.2 | NT | NT | NT | NT |
|  | EQA | 2 | 7.0 | NT | NT | NT | NT | 1 | 8.0 | NT | NT | NT | NT |
| DHEAS | RCV | 1 | 14.0 | NT | NT | NT | NT | 2 | 14.3 | NT | NT | NT | NT |
|  | TE | 3 | 5.5 | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
|  | EQA | 1 | 7.0 | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
| E2 | RCV | 1 | 34.4 | 1 | 34.3 | 1 | 33.8 | 1 | 34.1 | 1 | 33.7 | 1 | 33.5 |
|  | TE | 5 | 9.1 | NA | NA | 1 | 9.1 | NA | NA | 1 | 10.4 | 1 | 10.4 |
|  | EQA | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 |
| Ferritin | RCV | 1 | 38.5 | 1 | 39.0 | 1 | 38.9 | 1 | 38.5 | 1 | 39.2 | 1 | 38.7 |
|  | TE | 1 | 5.9 | NA | NA | NA | NA | 1 | 5.9 | NA | NA | NA | NA |
|  | EQA | 1 | 10.8 | 2 | 9.5 | 2 | 9.5 | 1 | 10.8 | 4 | 9.5 | 1 | 10.8 |
| Folate | RCV | 1 | 54.0 | 1 | 56.7 | 1 | 53.8 | 1 | 53.8 | 1 | 54.7 | 1 | 55.4 |
|  | TE | 2 | 13.7 | NA | NA | 1 | 13.7 | 1 | 13.7 | NA | NA | NA | NA |
|  | EQA | 1 | 24.0 | NA | NA | 1 | 24.0 | 1 | 24.0 | 1 | 21.0 | 2 | 21.0 |
| fPSA | RCV | 1 | 17.5 | 1 | 17.5 | 1 | 16.7 | 1 | 16.0 | 1 | 17.0 | 1 | 16.5 |
|  | TE | 4 | 9.2 | NA | NA | 1 | 9.2 | 1 | 10.5 | 2 | 9.2 | 1 | 9.2 |
|  | EQA | NA | NA | NA | NA | 2 | 7.0 | 1 | 8.0 | NA | NA | 3 | 7.0 |
| FSH | RCV | 1 | 28.0 | 1 | 27.8 | 1 | 28.1 | 1 | 29.5 | 1 | 27.8 | 1 | 27.9 |
|  | TE | 1 | 12.7 | 1 | 12.7 | 1 | 12.7 | 5 | 11.1 | 1 | 12.7 | 1 | 12.7 |
|  | EQA | 1 | 11.2 | 1 | 11.2 | 1 | 9.8 | 27 | 9.8 | 1 | 11.2 | 1 | 11.2 |
| fT4 | RCV | 1 | 17.6 | 1 | 18.0 | 1 | 17.8 | 1 | 18.3 | 1 | 18.0 | 1 | 18.0 |
|  | TE | 2 | 5.2 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | 1 | 10.4 | 1 | 9.1 | 1 | 9.1 | 2 | 9.1 | 1 | 9.1 | 1 | 9.1 |
| hCG | RCV | 1 | 22.3 | 1 | 23.2 | 1 | 22.8 | 1 | 22.4 | 1 | 22.9 | 1 | 22.6 |
|  | TE | 1 | 8.0 | 9 | 7.0 | 2 | 7.0 | 1 | 8.0 | NA | NA | 1 | 7.0 |
|  | EQA | 1 | 13.6 | 1 | 11.9 | 1 | 13.6 | 1 | 13.6 | 1 | 13.6 | 1 | 13.6 |
| Hcy | RCV | 1 | 19.7 | 1 | 19.6 | 1 | 17.6 | 1 | 20.3 | 1 | 19.5 | 1 | 19.3 |
|  | TE | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | 9 | 7.0 | NA | NA | NA | NA | NA | NA | 401 | 7.0 | NA | NA |
| HE4 | RCV | NT | NT | 1 | 22.4 | 1 | 20.8 | NT | NT | 1 | 23.3 | 1 | 24.1 |
|  | TE | NT | NT | 401 | 6.7 | NA | NA | NT | NT | NA | NA | NA | NA |
|  | EQA | NT | NT | 4 | 7.0 | NA | NA | NT | NT | NA | NA | NA | NA |
| hsTnI | RCV | 1 | 33.2 | NT | NT | NT | NT | 1 | 31.5 | NT | NT | NT | NT |
|  | TE | NA | NA | NT | NT | NT | NT | 1 | 11.2 | NT | NT | NT | NT |
|  | EQA | 3 | 14.0 | NT | NT | NT | NT | 1 | 16.0 | NT | NT | NT | NT |
| hsTnT | RCV | NT | NT | 1 | 67.8 | 1 | 67.8 | NT | NT | 1 | 67.7 | 1 | 67.7 |
|  | TE | NT | NT | 1 | 19.6 | 1 | 19.6 | NT | NT | 1 | 19.6 | 1 | 19.6 |
|  | EQA | NT | NT | 1 | 16.8 | 1 | 16.8 | NT | NT | 1 | 16.8 | 1 | 16.8 |
| IgE | RCV | 1 | 23.4 | 1 | 25.0 | 1 | 22.7 | 4 | 24.3 | 1 | 24.8 | 1 | 22.7 |
|  | TE | 401 | 7.0 | NA | NA | 2 | 7.0 | NA | NA | NA | NA | 2 | 7.0 |
|  | EQA | 1 | 16.0 | NA | NA | 1 | 16.0 | NA | NA | 3 | 14.0 | 1 | 16.0 |
| Insulin | RCV | 1 | 47.1 | 1 | 47.1 | 1 | 47.3 | 1 | 47.1 | 1 | 46.9 | 1 | 47.3 |
|  | TE | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 | 1 | 18.0 |
|  | EQA | 9 | 7.0 | 9 | 7.0 | NA | NA | NA | NA | 1 | 7.0 | NA | NA |
| LH | RCV | 1 | 50.9 | 1 | 50.9 | 1 | 50.8 | 1 | 51.2 | 1 | 50.9 | 1 | 50.7 |
|  | TE | 1 | 17.0 | 1 | 17.0 | 1 | 17.0 | 1 | 14.9 | 1 | 17.0 | 1 | 17.0 |
|  | EQA | 1 | 16.0 | 1 | 16.0 | 1 | 16.0 | 1 | 14.0 | 1 | 16.0 | 1 | 16.0 |
| NSE | RCV | NT | NT | 1 | 25.1 | 1 | 24.7 | NT | NT | 1 | 24.8 | 1 | 24.7 |
|  | TE | NT | NT | NA | NA | 9 | 7.3 | NT | NT | 3 | 7.3 | 2 | 7.3 |
|  | EQA | NT | NT | NA | NA | 9 | 7.0 | NT | NT | NA | NA | 2 | 7.0 |
| NT-pBNP | RCV | 1 | 22.7 | 1 | 23.0 | 1 | 22.5 | 1 | 22.6 | 1 | 23.2 | 1 | 22.4 |
|  | TE | 5 | 4.6 | NA | NA | 6 | 4.6 | 3 | 4.6 | NA | NA | 3 | 4.6 |
|  | EQA | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 |
| PIVKA | RCV | 1 | 21.3 | NT | NT | NT | NT | 1 | 23.1 | NT | NT | NT | NT |
|  | TE | NA | NA | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
|  | EQA | NA | NA | NT | NT | NT | NT | NA | NA | NT | NT | NT | NT |
| Procal | RCV | 1 | 23.7 | 1 | 22.7 | 1 | 22.7 | 1 | 23.1 | 1 | 22.6 | 1 | 22.4 |
|  | TE | NA | NA | 2 | 7.0 | 2 | 7.0 | 401 | 7.0 | 1 | 7.0 | 1 | 8.0 |
|  | EQA | NA | NA | 2 | 7.0 | 2 | 7.0 | 401 | 7.0 | 1 | 7.0 | 1 | 8.0 |
| Prolac | RCV | 1 | 45.3 | 1 | 44.4 | 1 | 44.5 | 1 | 45.4 | 1 | 44.3 | 1 | 44.4 |
|  | TE | 2 | 13.0 | 1 | 14.9 | 1 | 14.9 | 2 | 13.0 | 1 | 14.9 | 1 | 14.9 |
|  | EQA | 2 | 14.0 | 1 | 16.0 | 1 | 16.0 | 2 | 14.0 | 1 | 16.0 | 1 | 16.0 |
| PSA | RCV | 1 | 15.5 | 1 | 16.8 | 1 | 15.8 | 1 | 15.5 | 1 | 16.5 | 1 | 15.7 |
|  | TE | 1 | 9.7 | NA | NA | 1 | 8.5 | 1 | 9.7 | 9 | 8.5 | 1 | 9.7 |
|  | EQA | 1 | 12.4 | 2 | 10.9 | 1 | 12.4 | 1 | 12.4 | 1 | 10.9 | 1 | 12.4 |
| PTH | RCV | 1 | 53.9 | 1 | 53.8 | 1 | 54.4 | 1 | 53.8 | 1 | 53.8 | 1 | 54.7 |
|  | TE | 1 | 17.0 | 1 | 17.0 | 1 | 14.9 | 1 | 17.0 | 1 | 17.0 | 2 | 14.9 |
|  | EQA | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 | 1 | 24.0 |
| T3 | RCV | 1 | 15.8 | 1 | 16.3 | 1 | 16.3 | 1 | 17.2 | 1 | 16.0 | 1 | 15.9 |
|  | TE | NA | NA | NA | NA | 401 | 6.0 | NA | NA | 2 | 6.0 | 2 | 6.0 |
|  | EQA | 2 | 11.2 | 1 | 12.8 | 1 | 12.8 | 2 | 11.2 | 1 | 12.8 | 1 | 12.8 |
| T4 | RCV | 1 | 14.3 | 1 | 15.4 | 1 | 14.2 | NA | NA | 1 | 15.2 | 1 | 15.9 |
|  | TE | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | NA | NA | 2 | 8.8 | NA | NA | NA | NA | 1 | 8.8 | NA | NA |
| Testo | RCV | 1 | 27.3 | 1 | 25.6 | 1 | 27.3 | 1 | 28.7 | 1 | 26.9 | 1 | 27.2 |
|  | TE | 2 | 8.1 | NA | NA | 3 | 8.1 | NA | NA | 1 | 9.3 | 9 | 8.1 |
|  | EQA | 1 | 16.4 | NA | NA | 1 | 16.4 | 2 | 14.4 | 1 | 16.4 | 1 | 16.4 |
| Tg | RCV | 1 | 28.7 | 1 | 29.2 | 1 | 29.1 | 1 | 30.0 | 1 | 29.3 | 1 | 29.0 |
|  | TE | 1 | 11.1 | 2 | 9.7 | 2 | 9.7 | 4 | 9.7 | NA | NA | 1 | 9.7 |
|  | EQA | 1 | 7.0 | NA | NA | NA | NA | 160 | 7.0 | NA | NA | NA | NA |
| TSH | RCV | 1 | 36.4 | 1 | 35.8 | 1 | 35.4 | 1 | 33.9 | 1 | 35.9 | 1 | 35.4 |
|  | TE | 2 | 11.6 | 1 | 11.6 | 1 | 13.2 | 160 | 11.6 | 1 | 13.2 | 1 | 13.2 |
|  | EQA | 3 | 9.5 | 2 | 9.5 | 1 | 10.8 | NA | NA | 2 | 9.5 | 1 | 10.8 |
| TSHR | RCV | 2 | 13.9 | NA | NA | NA | NA | NA | NA | 1 | 10.9 | 1 | 10.9 |
|  | TE | 10 | 7.0 | NA | NA | NA | NA | 4 | 7.0 | NA | NA | NA | NA |
|  | EQA | 10 | 7.0 | NA | NA | NA | NA | 4 | 7.0 | NA | NA | NA | NA |
| Vit B12 | RCV | 1 | 23.0 | 1 | 23.5 | 1 | 23.1 | 1 | 22.8 | 1 | 23.2 | 1 | 24.1 |
|  | TE | 2 | 7.0 | NA | NA | 9 | 7.0 | 2 | 7.0 | 5 | 7.0 | NA | NA |
|  | EQA | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | 1 | 17.5 |
| Vit D | RCV | 1 | 23.6 | 1 | 22.5 | 1 | 22.4 | 1 | 24.5 | 1 | 24.9 | 1 | 23.6 |
|  | TE | 5 | 7.0 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
|  | EQA | 5 | 7.0 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |

Abbreviations: EQA, external quality assessment; NA, not applicable; NT, not tested; RCV, reference change value; RL, rejection limit; TE, total error; otherwise see Table 1



**Supplementary Figure S1**. Examples of evaluating reagent lot-to-lot differences of lactate dehydrogenase. Abbreviations: CD, critical difference; CVi, within-subject biologic variation; RCV, reference change value; Sr, repeatability; SWRL, within-laboratory imprecision.