# Sannova achieves single-digit CV's for most analyses:

Small Molecules: Summary of all calibration curves for the **validation** of **Dextroamphetamine**

| Batch ID | Date of batch Injected | STD A | STD B | STD C | STD D | STD E | STD F | STD G | STD H |
|---|---|---|---|---|---|---|---|---|---|
| | | 0.366 | 0.732 | 1.464 | 2.440 | 4.880 | 9.761 | 19.522 | 39.043 |
| | | ng/mL | ng/mL | ng/mL | ng/mL | ng/mL | ng/mL | ng/mL | ng/mL |
| 003-005 | 16-Jan-12 | 0.368 | 0.720 | 1.498 | 2.411 | 4.773 | 10.098 | 19.304 | 38.994 |
| 003-008 | 20-Jan-12 | 0.379 | 0.678 | 1.485 | 2.370 | 4.945 | 9.932 | 20.272 | 38.386 |
| 003-007 | 17-Jan-12 | 0.369 | 0.712 | 1.495 | 2.439 | 4.755 | 10.194 | 19.261 | 38.723 |
| 003-009 | 17-Jan-12 | 0.360 | 0.733 | 1.529 | 2.567 | 4.734 | 10.081 | 18.417 | 38.012 |
| 003-012 | 20-Jan-12 | 0.377 | 0.715 | 1.336 | 2.459 | 4.988 | 9.874 | 19.312 | 41.005 |
| 003-013 | 20-Jan-12 | 0.366 | 0.721 | 1.482 | 2.537 | 4.801 | 10.292 | 18.383 | 38.434 |
| Mean | | 0.370 | 0.713 | 1.471 | 2.464 | 4.833 | 10.079 | 19.158 | 38.926 |
| SD | | 0.007 | 0.019 | 0.068 | 0.075 | 0.107 | 0.157 | 0.699 | 1.071 |
| %CV | | **1.9** | **2.7** | **4.6** | **3.0** | **2.2** | **1.6** | **3.6** | **2.8** |
| % ACCURACY | | **101.1** | **97.4** | **100.5** | **101.0** | **99.0** | **103.3** | **98.1** | **99.7** |
| n | | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |

Large Molecules: Summary of all calibration standard concentrations in **Rat Plasma for Protein by digestion**

| Batch ID | Date of batch Injected | STD A | STD A' | STD B | STD C | STD D | STD E | STD F | STD G | STD H | STD H' |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 2.904 | 2.904 | 5.186 | 8.644 | 14.406 | 20.580 | 29.400 | 42.000 | 60.000 | 60.000 |
| | | µg/mL | µg/mL | µg/mL | µg/mL | µg/mL | µg/mL | µg/mL | µg/mL | µg/mL | µg/mL |
| 012-001 | 18-Sep-15 | 2.895 | 2.902 | 5.192 | 8.859 | 13.986 | 20.726 | 29.327 | 42.008 | 61.445 | 58.704 |
| 013-001 | 22-Sep-15 | 2.956 | 2.877 | 5.180 | 8.378 | 14.033 | 21.342 | 30.087 | 42.700 | 56.912 | 61.383 |
| 008-001 | 24-Sep-15 | 2.871 | 2.858 | 5.493 | 8.636 | 13.887 | 21.665 | 27.258 | 42.315 | 61.409 | 59.650 |
| 006-001 | 25-Sep-15 | 2.849 | 2.897 | 5.444 | 8.571 | 14.158 | 20.967 | 28.418 | 41.951 | 62.467 | 58.327 |
| 014-001 | 29-Sep-15 | 2.726 | 3.018 | 5.398 | 8.736 | 14.326 | 20.373 | 27.108 | 40.605 | 64.752 | 57.025 |
| 013-002 | 29-Sep-15 | 2.829 | 2.932 | 5.315 | 8.944 | 13.882 | 19.898 | 30.175 | 41.827 | 57.512 | 62.724 |
| 006-003 | 01-Oct-15 | 2.818 | 2.961 | 5.400 | 8.304 | 14.211 | 20.669 | 30.255 | 41.826 | 58.506 | 61.034 |
| 014-006 | 07-Oct-15 | 2.898 | 2.870 | 5.300 | 8.875 | 13.473 | 20.833 | 29.459 | 41.326 | 60.166 | 60.588 |
| Mean | | 2.855 | 2.914 | 5.340 | 8.663 | 13.995 | 20.809 | 29.011 | 41.820 | 60.396 | 59.929 |
| SD | | 0.068 | 0.054 | 0.114 | 0.235 | 0.262 | 0.546 | 1.277 | 0.632 | 2.658 | 1.858 |
| %CV | | **2.4** | **1.9** | **2.1** | **2.7** | **1.9** | **2.6** | **4.4** | **1.5** | **4.4** | **3.1** |
| % ACCURACY | | **98.3** | **100.3** | **103.0** | **100.2** | **97.1** | **101.1** | **98.7** | **99.6** | **100.7** | **99.9** |
| n | | **8** | **8** | **8** | **8** | **8** | **8** | **8** | **8** | **8** | **8** |

In CMC: Summary of all Aminocaproic Acid Residual Solvents

| Solvent | System Precision | | Limit of Quantitation | | | | Linearity | | Stability of sample at room temperature | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Spec | Result (%) | Spec | Result (%) | Spec | Result | Spec | Result | Spec (%) | Result (%) |
| Methanol | % RSD must be NMT 15.0 | 0.7 | % RSD must be NMT 25.0 | 2.0 | S/N must be NLT 10 | 28 | The correlation coefficient value must be ≥ 0.98 | 1.00 | The recovery of stability sample must be 80.0 to 140.0 | 97.1 |
| Acetone | | 0.5 | | 1.6 | | 210 | | 1.00 | | 99.2 |
| Isopropyl Alcohol | | 0.3 | | 1.7 | | 82 | | 1.00 | | 102 |
| Dichloromethane | | 0.9 | | 2.0 | | 26 | | 1.00 | | 90.2 |
| n-Hexane | | 1.0 | | 2.1 | | 69 | | 0.99 | | 96.7 |
| Cyclohexanone | | 0.6 | | 2.9 | | 48 | | 1.00 | | 91.5 |

…Continued

| Solvent | Accuracy | | | Method Precision | | Intermediate Precision | | Ruggedness | |
|---|---|---|---|---|---|---|---|---|---|
| | Spec (%) | Result (%) | Result (%) (LOQ) | Spec | Result | Spec | Result | Spec | Result |
| Methanol | Recovery 80.0 - 140.0<br>Recovery 70.0 - 140.0 at LOQ | 94.7 - 100 | 96.0 - 103.6 | % RSD must be NMT 15.0 | 3.1% | % RSD must be NMT 15.0 | 2.0% | % RSD must be NMT 20.0 | 3.63% |
| Acetone | | 96.3 - 98 | 98.4 - 107.3 | | 2.6% | | 3.3% | | 2.1% |
| Isopropyl Alcohol | | 103.1 - 105.4 | 98.0 - 105.3 | | 1.9% | | 2.0% | | 2.5% |
| Dichloromethane | | 93.2 - 96.6 | 92.4 - 100.9 | | 2.2% | | 4.0% | | 3.5% |
| n-Hexane | | 110.1 - 115.0 | 111.4 - 122.4 | | 2.1% | | 4.4% | | 15.0% |
| Cyclohexanone | | 89.5 - 92.8 | 93.8 - 101.9 | | 2.6% | | 2.6% | | 3.2% |