**Newborn Screening Quality Assurance Program**

**Quality Control Specimen Certification**
**Set 1: January 9, 2012**

## * *Analysis Method: MSMS NON-DERIVATIZED - MSMS NON-KIT*

**Enrichment Levels (endogenous not included)**

| *Analyte* | *Units* | *Lot* | *Base* | *Lot* | *Low* | *Lot* | *Intermediate* | *Lot* | *High* |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| Total Galactose | mg / dL blood | 125 | 5 | 126 | 10 | 127 | 15 | 128 | 30 |
| Phenylalanine | µmol / L blood | 125 | 0 | 126 | 150 | 127 | 400 | 128 | 600 |
| Leucine | µmol / L blood | 125 | 0 | 126 | 200 | 127 | 500 | 128 | 800 |
| Methionine | µmol / L blood | 125 | 0 | 126 | 100 | 127 | 250 | 128 | 500 |
| Tyrosine | µmol / L blood | 125 | 0 | 126 | 250 | 127 | 500 | 128 | 750 |
| Valine | µmol / L blood | 125 | 0 | 126 | 250 | 127 | 600 | 128 | 1000 |
| Citrulline | µmol / L blood | 125 | 0 | 126 | 50 | 127 | 150 | 128 | 300 |
| Arginine | µmol / L blood | 125 | 0 | 126 | 65 | 127 | 130 | 128 | 200 |
| Succinylacetone | µmol / L blood | 125 | 0 | 126 | 2.5 | 127 | 5 | 128 | 10 |

**Analytical Information**

| *Lot Numbers, Mean Values (X) and 95% Confidence Limits (CL)* | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Analyte* | *Lot* | *Mean and 95% CL* | | *Lot* | *Mean and 95% CL* | | *Lot* | *Mean and 95% CL* | | *Lot* | *Mean and 95% CL* |
| | | | | | | | | | | | |
| Total Gal | 125 | $\overline{X}$ = | 4.7 | 126 | $\overline{X}$ = | 9.0 | 127 | $\overline{X}$ = | 14.6 | 128 | $\overline{X}$ = 30.3 |
| | | CL= | 3.5 - 5.9 | | CL= | 7.7 - 10.3 | | CL= | 12.9 - 16.3 | | CL= 25.4 - 35.1 |
| Phe* | 125 | $\overline{X}$ = | 70.2 | 126 | $\overline{X}$ = | 186.9 | 127 | $\overline{X}$ = | 397.5 | 128 | $\overline{X}$ = 560.3 |
| | | CL= | 56.7 - 83.7 | | CL= | 157.6 - 216.1 | | CL= | 316.9 - 478.1 | | CL= 458.5 - 662.1 |
| Leu* | 125 | $\overline{X}$ = | 160.0 | 126 | $\overline{X}$ = | 316.7 | 127 | $\overline{X}$ = | 576.3 | 128 | $\overline{X}$ = 831.1 |
| | | CL= | 136.9 - 183.1 | | CL= | 275.0 - 358.4 | | CL= | 480.8 - 671.8 | | CL= 727.1 - 935.1 |
| Met* | 125 | $\overline{X}$ = | 19.1 | 126 | $\overline{X}$ = | 87.0 | 127 | $\overline{X}$ = | 203.3 | 128 | $\overline{X}$ = 372.3 |
| | | CL= | 9.2 - 29.0 | | CL= | 63.6 - 110.4 | | CL= | 145.7 - 260.9 | | CL= 284.7 - 460.0 |
| Tyr* | 125 | $\overline{X}$ = | 49.2 | 126 | $\overline{X}$ = | 226.6 | 127 | $\overline{X}$ = | 425.5 | 128 | $\overline{X}$ = 559.3 |
| | | CL= | 34.0 - 64.3 | | CL= | 187.0 - 266.2 | | CL= | 297.1 - 553.9 | | CL= 459.9 - 658.8 |
| Val* | 125 | $\overline{X}$ = | 132.6 | 126 | $\overline{X}$ = | 290.8 | 127 | $\overline{X}$ = | 548.7 | 128 | $\overline{X}$ = 829.3 |
| | | CL= | 105.4 - 159.7 | | CL= | 241.1 - 340.6 | | CL= | 467.1 - 630.3 | | CL= 712.4 - 946.3 |
| Cit* | 125 | $\overline{X}$ = | 26.6 | 126 | $\overline{X}$ = | 65.4 | 127 | $\overline{X}$ = | 145.4 | 128 | $\overline{X}$ = 246.6 |
| | | CL= | 19.2 - 34.0 | | CL= | 51.1 - 79.7 | | CL= | 118.4 - 172.4 | | CL= 195.1 - 298.0 |
| Arg* | 125 | $\overline{X}$ = | 8.8 | 126 | $\overline{X}$ = | 16.6 | 127 | $\overline{X}$ = | 36.0 | 128 | $\overline{X}$ = 63.6 |
| | | CL= | 4.7 - 13.0 | | CL= | 10.6 - 22.5 | | CL= | 20.1 - 51.9 | | CL= 48.4 - 78.7 |
| SUAC* | 125 | $\overline{X}$ = | 0.2 | 126 | $\overline{X}$ = | 1.0 | 127 | $\overline{X}$ = | 1.8 | 128 | $\overline{X}$ = 3.3 |
| | | CL= | 0.2 - 0.3 | | CL= | 0.8 - 1.2 | | CL= | 1.5 - 2.1 | | CL= 2.7 - 4.0 |

**Note:** The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 20 successive, independent measurements. *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr., editor. Laboratory methods for neonatal screening, Washington DC, American Public Health Association, 1993, 23-46.*