

Newborn Screening Quality Assurance Program
Quality Control Specimen Certification

Second-Tier Maple Syrup Urine Disease and Phenylketonuria by LC-MS/MS
EXPIRATION: November 2017

Method: LC-MS/MS

ENRICHMENT LEVELS (endogenous levels not included)

Lot	<i>Enrichment levels. Units are $\mu\text{mol/liter}$ whole blood.</i>					
	<i>Allo-Isoleucine</i>	<i>Isoleucine</i>	<i>Leucine</i>	<i>Phenylalanine</i>	<i>Tyrosine</i>	<i>Valine</i>
A1513	0	0	0	0	0	0
B1513	100	100	100	100	100	100
C1513	200	200	200	200	200	200
D1513	400	400	400	400	400	400
E1513	800	800	800	800	800	800

ANALYTICAL INFORMATION

<i>Lot Numbers, Mean Values (x), and 95% Confidence Limits (CL). Units are $\mu\text{mol/L}$ whole blood.</i>						
	<i>Allo-Isoleucine</i>	<i>Isoleucine</i>	<i>Leucine</i>	<i>Phenylalanine</i>	<i>Tyrosine</i>	<i>Valine</i>
Lot	<i>Mean/ 95% CL</i>					
A1513	$\bar{x} = 1.7$ CL = 0.2 – 3.2	$\bar{x} = 2.3$ CL = 0.7 – 3.8	$\bar{x} = 18.8$ CL = 0.0 – 42.3	$\bar{x} = 8.4$ CL = 0.0 – 21.8	$\bar{x} = 22.7$ CL = 10.4 – 35.0	$\bar{x} = 47.4$ CL = 25.8 – 69.0
B1513	$\bar{x} = 83.7$ CL = 70.9 – 96.5	$\bar{x} = 31.4$ CL = 11.6 – 51.3	$\bar{x} = 94.0$ CL = 56.4 – 131.7	$\bar{x} = 66.7$ CL = 36.7 – 96.6	$\bar{x} = 86.8$ CL = 73.6 – 99.9	$\bar{x} = 113.5$ CL = 89.8 – 137.2
C1513	$\bar{x} = 179.6$ CL = 153.9 – 205.2	$\bar{x} = 113.1$ CL = 90.1 – 136.1	$\bar{x} = 178.7$ CL = 150.0 – 207.5	$\bar{x} = 142.5$ CL = 110.8 – 174.2	$\bar{x} = 165.2$ CL = 133.4 – 196.9	$\bar{x} = 180.8$ CL = 148.6 – 213.0
D1513	$\bar{x} = 330.6$ CL = 282.0 – 379.3	$\bar{x} = 206.0$ CL = 124.3 – 287.8	$\bar{x} = 289.0$ CL = 186.7 – 391.4	$\bar{x} = 236.2$ CL = 128.2 – 344.2	$\bar{x} = 263.7$ CL = 200.4 – 327.0	$\bar{x} = 266.2$ CL = 197.9 – 334.4
E1513	$\bar{x} = 684.9$ CL = 539.5 – 830.3	$\bar{x} = 580.1$ CL = 448.9 – 711.3	$\bar{x} = 684.2$ CL = 544.8 – 823.6	$\bar{x} = 597.2$ CL = 448.9 – 745.5	$\bar{x} = 557.2$ CL = 430.0 – 684.4	$\bar{x} = 579.4$ CL = 480.8 – 678.0

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 10 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.*