Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 2— July 11, 2011

ENRICHMENT LEVELS (endogenous levels not included)
Acylcarnitines Method: MSMS Derivatized - MS/MS non-kit

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	161	0	162	10.0	163	20.0	164	30.0
Acetylcarnitine (C2)	161	0	162	10.0	163	20.0	164	30.0
Propionylcarnitine (C3)	161	0	162	3.0	163	7.5	164	12.0
Butyrylcarnitine (C4)	161	0	162	1.0	163	2.5	164	5.0
Isovalerylcarnitine (C5)	161	0	162	0.5	163	1.5	164	3.0
Hexanoylcarnitine (C6)	161	0	162	0.5	163	1.0	164	2.5
Octanoylcarnitine (C8)	161	0	162	0.5	163	1.0	164	2.5
Decanoylcarnitine (C10)	161	0	162	0.5	163	1.0	164	2.5
Dodecanoylcarnitine (C12)	161	0	162	0.5	163	1.0	164	2.5
Myristoylcarnitine (C14)	161	0	162	0.5	163	1.5	164	3.0
Palmitoylcarnitine (C16)	161	0	162	4.0	163	8.0	164	12.0
Stearoylcarnitine (C18)	161	0	162	1.0	163	2.0	164	5.0
Malonylcarnitine (C3DC)	161	0	162	0.5	163	1.5	164	3.0
Glutarylcarnitine (C5DC)	161	0	162	0.5	163	1.0	164	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	161	0	162	0.5	163	1.5	164	2.5
3-Hydroxypalmitoylcarnitine (C16OH)	161	0	162	0.5	163	1.0	164	2.5

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ANALYTICAL INFORMATION *Lot Numbers, Mean Values ($\bar{x}$, µmol/L whole blood), and 95% Confidence Limits (CL)*

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
C0	161	$\bar{x}$ = 13.99 CL = 10.51-17.47	162	$\bar{x}$ = 23.31 CL = 16.56-30.06	163	$\bar{x}$ = 32.69 CL = 22.07-43.31	164	$\bar{x}$ = 41.43 CL = 28.79-54.06
C2	161	$\bar{x}$ = 13.42 CL = 11.32-15.51	162	$\bar{x}$ = 22.36 CL = 19.59-25.12	163	$\bar{x}$ = 31.58 CL = 27.84-35.31	164	$\bar{x}$ = 38.18 CL = 32.85-43.51
C3	161	$\bar{x}$ = 1.01 CL = 0.71-1.31	162	$\bar{x}$ = 3.96 CL = 3.27-4.65	163	$\bar{x}$ = 8.18 CL = 6.69-9.66	164	$\bar{x}$ = 11.35 CL = 8.88-13.83
C4	161	$\bar{x}$ =0.11 CL = 0.07-0.16	162	$\bar{x}$ = 0.80 CL = 0.66-0.94	163	$\bar{x}$ = 1.88 CL = 1.46-2.29	164	$\bar{x}$ = 3.36 CL = 2.79-3.92
C5	161	$\bar{x}$ = 0.07 CL = 0.04-0.10	162	$\bar{x}$ = 0.47 CL = 0.38-0.56	163	$\bar{x}$ = 1.27 CL = 1.07-1.46	164	$\bar{x}$ = 2.35 CL = 2.02-2.68
C6	161	$\bar{x}$ = 0.01 CL = 0.02-0.03	162	$\bar{x}$ = 0.38 CL = 0.30-0.45	163	$\bar{x}$ = 0.73 CL = 0.57-0.89	164	$\bar{x}$ = 1.68 CL = 1.34-2.02
C8	161	$\bar{x}$ = 0.03 CL = 0.00-0.05	162	$\bar{x}$ = 0.49 CL = 0.40-0.58	163	$\bar{x}$ = 0.97 CL = 0.80-1.14	164	$\bar{x}$ = 2.35 CL = 1.73-2.97
C10	161	$\bar{x}$ = 0.02 CL = 0.00-0.05	162	$\bar{x}$ = 0.53 CL = 0.40-0.66	163	$\bar{x}$ = 1.08 CL = 0.89-1.26	164	$\bar{x}$ = 2.41 CL = 1.77-3.06
C12	161	$\bar{x}$ = 0.03 CL = 0.00-0.07	162	$\bar{x}$ = 0.51 CL = 0.33-0.70	163	$\bar{x}$ = 0.97 CL = 0.60-1.33	164	$\bar{x}$ = 2.21 CL = 1.52-2.89
C14	161	$\bar{x}$ = 0.06 CL = 0.03-0.10	162	$\bar{x}$ = 0.54 CL = 0.42-0.66	163	$\bar{x}$ = 1.44 CL = 1.12-1.75	164	$\bar{x}$ = 2.67 CL = 2.07-3.27
C16	161	$\bar{x}$ = 0.99 CL = 0.74-1.24	162	$\bar{x}$ = 4.06 CL = 3.51-4.61	163	$\bar{x}$ = 7.46 CL = 6.06-8.86	164	$\bar{x}$ = 10.04 CL = 8.39-11.68
C18	161	$\bar{x}$ = 0.77 CL = 0.63-0.90	162	$\bar{x}$ = 1.63 CL = 1.34-1.92	163	$\bar{x}$ = 2.50 CL = 2.18-2.82	164	$\bar{x}$ = 4.71 CL = 4.14-5.28
C3DC	161	$\bar{x}$ = 0.03 CL = 0.01-0.05	162	$\bar{x}$ = 0.31 CL = 0.20-0.43	163	$\bar{x}$ = 0.80 CL = 0.61-0.98	164	$\bar{x}$ = 1.50 CL = 1.03-1.97
C5DC	161	$\bar{x}$ = 0.02 CL = 0.00-0.05	162	$\bar{x}$ = 0.26 CL = 0.14-0.38	163	$\bar{x}$ = 0.49 CL = 0.37-0.60	164	$\bar{x}$ = 1.10 CL = 0.77-1.43
C5OH	161	$\bar{x}$ = 0.49 CL = 0.34-0.65	162	$\bar{x}$ = 0.89 CL = 0.73-1.05	163	$\bar{x}$ = 1.70 CL = 1.43-1.97	164	$\bar{x}$ = 2.38 CL = 1.91-2.85
C16OH	161	$\bar{x}$ = 0.01 CL = 0.00-0.03	162	$\bar{x}$ = 0.35 CL = 0.27-0.44	163	$\bar{x}$ = 0.70 CL = 0.53-0.87	164	$\bar{x}$ = 1.62 CL = 1.38-1.86

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.*

Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 2 — July 11, 2011
Transition (parallel testing) material

ENRICHMENT LEVELS (endogenous levels not included)
Acylcarnitines Method: MSMS Derivatized - MS/MS non-kit

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	065	0	066	10.0	067	20.0	068	30.0
Acetylcarnitine (C2)	065	0	066	10.0	067	20.6	068	30.0
Propionylcarnitine (C3)	065	0	066	3.0	067	7.5	068	12.0
Butyrylcarnitine (C4)	065	0	066	1.0	067	2.5	068	5.0
Isovalerylcarnitine (C5)	065	0	066	0.5	067	1.5	068	3.0
Hexanoylcarnitine (C6)	065	0	066	0.5	067	1.0	068	2.5
Octanoylcarnitine (C8)	065	0	066	0.5	067	1.0	068	2.5
Decanoylcarnitine (C10)	065	0	066	0.5	067	1.0	068	2.5
Dodecanoylcarnitine (C12)	065	0	066	0.5	067	1.0	068	2.5
Myristoylcarnitine (C14)	065	0	066	0.5	067	1.5	068	3.0
Palmitoylcarnitine (C16)	065	0	066	4.0	067	8.0	068	12.0
Stearoylcarnitine (C18)	065	0	066	1.0	067	2.0	068	5.0
Malonylcarnitine (C3DC)	065	0	066	0.5	067	1.5	068	3.0
Glutarylcarnitine (C5DC)	065	0	066	0.5	067	1.0	068	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	065	0	066	0.5	067	1.5	068	2.5
3-Hydroxypalmitoylcarnitine (C16OH)	065	0	066	0.5	067	1.0	068	2.5

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 2 — July 11, 2011
Transition (parallel testing) material

ANALYTICAL INFORMATION *Lot Numbers, Mean Values ($\bar{x}$, µmol/L whole blood), and 95% Confidence Limits (CL)*

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
C0	065	$\bar{x}$ = 13.09 CL = 7.85-18.32	066	$\bar{x}$ = 24.27 CL = 18.75-29.80	067	$\bar{x}$ = 34.24 CL = 23.70-44.77	068	$\bar{x}$ = 46.41 CL = 31.21-61.60
C2	065	$\bar{x}$ = 10.62 CL = 8.18-13.06	066	$\bar{x}$ = 18.99 CL = 15.23-22.74	067	$\bar{x}$ = 27.29 CL = 23.13-31.44	068	$\bar{x}$ = 37.36 CL = 32.52-42.19
C3	065	$\bar{x}$ = 1.04 CL = 0.73-1.35	066	$\bar{x}$ = 3.56 CL = 2.61-4.51	067	$\bar{x}$ = 6.97 CL = 5.28-8.65	068	$\bar{x}$ = 12.26 CL = 8.74-15.78
C4	065	$\bar{x}$ =0.10 CL = 0.06-0.15	066	$\bar{x}$ = 0.74 CL = 0.49-0.98	067	$\bar{x}$ = 1.82 CL = 1.37-2.27	068	$\bar{x}$ = 3.55 CL = 2.37-4.73
C5	065	$\bar{x}$ = 0.07 CL = 0.04-0.11	066	$\bar{x}$ = 0.44 CL = 0.28-0.60	067	$\bar{x}$ = 1.30 CL = 0.90-1.69	068	$\bar{x}$ = 2.55 CL = 1.94-3.16
C6	065	$\bar{x}$ = 0.02 CL = 0.01-0.03	066	$\bar{x}$ = 0.36 CL = 0.23-0.48	067	$\bar{x}$ = 0.70 CL = 0.46-0.93	068	$\bar{x}$ = 1.71 CL = 1.32-2.11
C8	065	$\bar{x}$ = 0.02 CL = 0.00-0.04	066	$\bar{x}$ = 0.43 CL = 0.25-0.61	067	$\bar{x}$ = 0.85 CL = 0.75-0.96	068	$\bar{x}$ = 2.13 CL = 1.63-2.63
C10	065	$\bar{x}$ = 0.02 CL = 0.00-0.03	066	$\bar{x}$ = 0.42 CL = 0.27-0.57	067	$\bar{x}$ = 0.89 CL = 0.63-1.15	068	$\bar{x}$ = 2.14 CL = 1.54-2.75
C12	065	$\bar{x}$ = 0.02 CL = 0.00-0.05	066	$\bar{x}$ = 0.49 CL = 0.39-0.59	067	$\bar{x}$ = 0.93 CL = 0.71-1.14	068	$\bar{x}$ = 2.07 CL = 1.58-2.57
C14	065	$\bar{x}$ = 0.06 CL = 0.02-0.09	066	$\bar{x}$ = 0.44 CL = 0.28-0.60	067	$\bar{x}$ = 1.24 CL = 0.94-1.54	068	$\bar{x}$ = 2.49 CL = 1.88-3.09
C16	065	$\bar{x}$ = 0.88 CL = 0.60-1.15	066	$\bar{x}$ = 4.02 CL = 3.31-4.73	067	$\bar{x}$ = 7.02 CL = 5.50-8.55	068	$\bar{x}$ = 9.96 CL = 8.47-11.45
C18	065	$\bar{x}$ = 0.67 CL = 0.51-0.82	066	$\bar{x}$ = 1.48 CL = 1.24-1.73	067	$\bar{x}$ = 2.30 CL = 1.78-2.82	068	$\bar{x}$ = 4.71 CL = 3.85-5.58
C3DC	065	$\bar{x}$ = 0.03 CL = 0.00-0.07	066	$\bar{x}$ = 0.34 CL = 0.19-0.49	067	$\bar{x}$ = 0.98 CL = 0.67-1.29	068	$\bar{x}$ = 2.03 CL = 1.10-2.96
C5DC	065	$\bar{x}$ = 0.02 CL = 0.00-0.06	066	$\bar{x}$ = 0.29 CL = 0.12-0.47	067	$\bar{x}$ = 0.60 CL = 0.39-0.80	068	$\bar{x}$ = 1.51 CL = 0.86-2.17
C5OH	065	$\bar{x}$ = 0.45 CL = 0.28-0.61	066	$\bar{x}$ = 0.79 CL = 0.61-0.96	067	$\bar{x}$ = 1.52 CL = 1.06-1.97	068	$\bar{x}$ = 2.18 CL = 1.60-2.76
C16OH	065	$\bar{x}$ = 0.02 CL = 0.00-0.05	066	$\bar{x}$ = 0.37 CL = 0.26-0.47	067	$\bar{x}$ = 0.69 CL = 0.53-0.86	068	$\bar{x}$ = 1.80 CL = 1.16-2.45

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.*