Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 2 — July 9, 2012

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)	261	0	262	10.0	263	20.0	264	30.0
Acetylcarnitine (C2)	261	0	262	10.0	263	20.0	264	30.0
Propionylcarnitine (C3)	261	0	262	3.0	263	7.5	264	12.0
Butyrylcarnitine (C4)	261	0	262	1.0	263	2.5	264	5.0
Isovalerylcarnitine (C5)	261	0	262	0.5	263	1.5	264	3.0
Hexanoylcarnitine (C6)	261	0	262	0.5	263	1.0	264	2.5
Octanoylcarnitine (C8)	261	0	262	0.5	263	1.0	264	2.5
Decanoylcarnitine (C10)	261	0	262	0.5	263	1.0	264	2.5
Dodecanoylcarnitine (C12)	261	0	262	0.5	263	1.0	264	2.5
Myristoylcarnitine (C14)	261	0	262	0.5	263	1.5	264	3.0
Palmitoylcarnitine (C16)	261	0	262	4.0	263	8.0	264	12.0
Stearoylcarnitine (C18)	261	0	262	1.0	263	2.0	264	5.0
Malonylcarnitine (C3DC)	261	0	262	0.5	263	1.5	264	3.0
Glutarylcarnitine (C5DC)	261	0	262	0.5	263	1.0	264	2.5
3-Hydroxybutyrylcarnitine (C4OH)	261	0	262	0.5	263	1.0	264	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	261	0	262	0.5	263	1.5	264	2.5
3-Hydroxypalmitoylcarnitine (C16OH)	261	0	262	0.5	263	1.0	264	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	261	$\bar{x}$ = 15.5 CL = 12.3-18.8	262	$\bar{x}$ = 29.3 CL = 23.6-35.1	263	$\bar{x}$ = 43.5 CL = 35.8-51.1	264	$\bar{x}$ = 59.7 CL = 48.8-70.7
C2	261	$\bar{x}$ = 8.9 CL = 7.6-10.3	262	$\bar{x}$ = 17.8 CL = 15.5-20.1	263	$\bar{x}$ = 26.2 CL = 23.1-29.2	264	$\bar{x}$ = 35.4 CL = 31.0-39.9
C3	261	$\bar{x}$ = 1.0 CL = 0.7-1.2	262	$\bar{x}$ = 3.7 CL = 2.9-4.4	263	$\bar{x}$ = 8.1 CL = 6.4-9.9	264	$\bar{x}$ = 12.4 CL = 10.2-14.7
C4	261	$\bar{x}$ =0.1 CL = 0.0-0.1	262	$\bar{x}$ = 0.8 CL = 0.6-1.1	263	$\bar{x}$ = 1.8 CL = 1.4-2.3	264	$\bar{x}$ = 3.8 CL = 3.0-4.7
C5	261	$\bar{x}$ = 0.1 CL = 0.0-0.1	262	$\bar{x}$ = 0.5 CL = 0.3-0.6	263	$\bar{x}$ = 1.2 CL = 1.0-1.4	264	$\bar{x}$ = 2.4 CL = 1.8-3.0
C6	261	$\bar{x}$ = 0.0 CL = 0.0-0.0	262	$\bar{x}$ = 0.4 CL = 0.3-0.5	263	$\bar{x}$ = 0.7 CL = 0.6-0.8	264	$\bar{x}$ = 1.8 CL = 1.4-2.2
C8	261	$\bar{x}$ = 0.0 CL = 0.0-0.0	262	$\bar{x}$ = 0.5 CL = 0.4-0.6	263	$\bar{x}$ = 1.0 CL = 0.8-1.1	264	$\bar{x}$ = 2.4 CL = 1.9-2.9
C10	261	$\bar{x}$ = 0.0 CL = 0.0-0.0	262	$\bar{x}$ = 0.5 CL = 0.4-0.7	263	$\bar{x}$ = 1.1 CL = 0.9-1.3	264	$\bar{x}$ = 2.6 CL = 1.9-3.2
C12	261	$\bar{x}$ = 0.0 CL = 0.0-0.1	262	$\bar{x}$ = 0.6 CL = 0.2-1.0	263	$\bar{x}$ = 1.1 CL = 0.6-1.7	264	$\bar{x}$ = 2.4 CL = 1.5-3.2
C14	261	$\bar{x}$ = 0.1 CL = 0.0-0.1	262	$\bar{x}$ = 0.5 CL = 0.4-0.7	263	$\bar{x}$ = 1.4 CL = 1.0-1.7	264	$\bar{x}$ = 2.6 CL = 2.2-3.1
C16	261	$\bar{x}$ = 0.7 CL = 0.5-0.9	262	$\bar{x}$ = 3.5 CL = 3.0-4.1	263	$\bar{x}$ = 6.4 CL = 5.5-7.4	264	$\bar{x}$ = 9.2 CL = 7.0-11.5
C18	261	$\bar{x}$ = 0.5 CL = 0.4-0.6	262	$\bar{x}$ = 1.2 CL = 1.0-1.5	263	$\bar{x}$ = 2.0 CL = 1.6-2.5	264	$\bar{x}$ = 4.2 CL = 3.4-5.0
C3DC	261	$\bar{x}$ = 0.0 CL = 0.0-0.1	262	$\bar{x}$ = 0.3 CL = 0.2-0.3	263	$\bar{x}$ = 0.7 CL = 0.5-0.8	264	$\bar{x}$ = 1.3 CL = 1.0-1.7
C5DC	261	$\bar{x}$ = 0.0 CL = 0.0-0.0	262	$\bar{x}$ = 0.3 CL = 0.2-0.4	263	$\bar{x}$ = 0.7 CL = 0.5-0.9	264	$\bar{x}$ = 1.5 CL = 1.2-1.8
C4OH	261	$\bar{x}$ = 0.1 CL = 0.0-0.1	262	$\bar{x}$ = 0.5 CL = 0.4-0.6	263	$\bar{x}$ = 1.0 CL = 0.8-1.1	264	$\bar{x}$ = 2.2 CL = 1.8-2.5
C5OH	261	$\bar{x}$ = 0.5 CL = 0.3-0.6	262	$\bar{x}$ = 0.9 CL = 0.7-1.0	263	$\bar{x}$ = 1.7 CL = 1.3-2.1	264	$\bar{x}$ = 2.4 CL = 2.0-2.8
C16OH	261	$\bar{x}$ = 0.0 CL = 0.0-0.0	262	$\bar{x}$ = 0.4 CL = 0.3-0.5	263	$\bar{x}$ = 0.8 CL = 0.6-0.9	264	$\bar{x}$ = 2.0 CL = 1.3-2.6

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 9, 2012
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)	165	0	166	10.0	167	20.0	168	30.0
Acetylcarnitine (C2)	165	0	166	10.0	167	20.0	168	30.0
Propionylcarnitine (C3)	165	0	166	3.0	167	7.5	168	12.0
Butyrylcarnitine (C4)	165	0	166	1.0	167	2.5	168	5.0
Isovalerylcarnitine (C5)	165	0	166	0.5	167	1.5	168	3.0
Hexanoylcarnitine (C6)	165	0	166	0.5	167	1.0	168	2.5
Octanoylcarnitine (C8)	165	0	166	0.5	167	1.0	168	2.5
Decanoylcarnitine (C10)	165	0	166	0.5	167	1.0	168	2.5
Dodecanoylcarnitine (C12)	165	0	166	0.5	167	1.0	168	2.5
Myristoylcarnitine (C14)	165	0	166	0.5	167	1.5	168	3.0
Palmitoylcarnitine (C16)	165	0	166	4.0	167	8.0	168	12.0
Stearoylcarnitine (C18)	165	0	166	1.0	167	2.0	168	5.0
Malonylcarnitine (C3DC)	165	0	166	0.5	167	1.5	168	3.0
Glutarylcarnitine (C5DC)	165	0	166	0.5	167	1.0	168	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	165	0	166	0.5	167	1.5	168	2.5
3-Hydroxypalmitoylcarnitine (C16OH)	165	0	166	0.5	167	1.0	168	2.5

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 2— July 9, 2012
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	165	$\bar{x}$ = 7.5 CL = 4.4-10.6	166	$\bar{x}$ = 16.9 CL = 9.9-23.9	167	$\bar{x}$ = 26.2 CL = 15.9-26.6	168	$\bar{x}$ = 37.8 CL = 24.8-50.8
C2	165	$\bar{x}$ = 8.9 CL = 7.7-10.2	166	$\bar{x}$ = 18.5 CL = 15.9-21.2	167	$\bar{x}$ = 27.6 CL = 23.5-31.6	168	$\bar{x}$ = 37.8 CL = 30.8-44.8
C3	165	$\bar{x}$ = 0.85 CL = 0.63-1.1	166	$\bar{x}$ = 3.7 CL = 2.9-4.5	167	$\bar{x}$ = 7.5 CL = 6.0-9.0	168	$\bar{x}$ = 12.1 CL = 9.1-15.2
C4	165	$\bar{x}$ =0.1 CL = 0.0-0.2	166	$\bar{x}$ = 1.0 CL = 0.8-1.3	167	$\bar{x}$ = 2.3 CL = 1.9-2.8	168	$\bar{x}$ = 4.5 CL = 3.2-5.7
C5	165	$\bar{x}$ = 0.1 CL = 0.0-0.1	166	$\bar{x}$ = 0.4 CL = 0.4-0.6	167	$\bar{x}$ = 1.3 CL = 1.0-1.5	168	$\bar{x}$ = 2.4 CL = 1.8-2.9
C6	165	$\bar{x}$ = 0.0 CL = 0.0-0.0	166	$\bar{x}$ = 0.36 CL = 0.2-0.5	167	$\bar{x}$ = 0.7 CL = 0.5-0.9	168	$\bar{x}$ = 1.6 CL = 1.1-2.2
C8	165	$\bar{x}$ = 0.0 CL = 0.0-0.0	166	$\bar{x}$ = 0.5 CL = 0.4-0.6	167	$\bar{x}$ = 0.9 CL = 0.6-1.2	168	$\bar{x}$ = 2.3 CL = 1.8-2.8
C10	165	$\bar{x}$ = 0.0 CL = 0.0-0.0	166	$\bar{x}$ = 0.5 CL = 0.3-0.6	167	$\bar{x}$ = 1.0 CL = 0.7-1.3	168	$\bar{x}$ = 2.2 CL = 1.7-2.8
C12	165	$\bar{x}$ = 0.0 CL = 0.0-0.1	166	$\bar{x}$ = 0.5 CL = 0.3-0.6	167	$\bar{x}$ = 0.9 CL = 0.6-1.2	168	$\bar{x}$ = 2.1 CL = 1.5-2.6
C14	165	$\bar{x}$ = 0.0 CL = 0.0-0.1	166	$\bar{x}$ = 0.5 CL = 0.3-0.6	167	$\bar{x}$ = 1.3 CL = 1.0-1.7	168	$\bar{x}$ = 3.1 CL = 2.3-3.9
C16	165	$\bar{x}$ = 0.4 CL = 0.3-0.5	166	$\bar{x}$ = 3.3 CL = 2.8-3.8	167	$\bar{x}$ = 6.1 CL = 5.1-7.2	168	$\bar{x}$ = 9.0 CL = 7.0-11.0
C18	165	$\bar{x}$ = 0.4 CL = 0.3-0.5	166	$\bar{x}$ = 1.1 CL = 0.9-1.3	167	$\bar{x}$ = 1.9 CL = 1.5-2.2	168	$\bar{x}$ = 4.0 CL = 2.9-5.2
C3DC	165	$\bar{x}$ = 0.0 CL = 0.0-0.1	166	$\bar{x}$ = 0.2 CL = 0.2-0.3	167	$\bar{x}$ = 0.7 CL = 0.5-0.9	168	$\bar{x}$ = 1.4 CL = 1.1-1.6
C5DC	165	$\bar{x}$ = 0.0 CL = 0.0-0.0	166	$\bar{x}$ = 0.3 CL = 0.2-0.4	167	$\bar{x}$ = 0.6 CL = 0.5-0.8	168	$\bar{x}$ = 1.5 CL = 1.2-1.9
C5OH	165	$\bar{x}$ = 0.4 CL = 0.3-0.5	166	$\bar{x}$ = 0.8 CL = 0.6-1.0	167	$\bar{x}$ = 1.6 CL = 1.3-1.9	168	$\bar{x}$ = 2.4 CL = 2.0-2.8
C16OH	165	$\bar{x}$ = 0.0 CL = 0.0-0.0	166	$\bar{x}$ = 0.3 CL = 0.3-0.4	167	$\bar{x}$ = 0.7 CL = 0.5-0.8	168	$\bar{x}$ = 1.6 CL = 1.3-1.9

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.*