Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 1 — January 7, 2013

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)	1265	0	1266	10.0	1267	20.0	1268	30.0
Acetylcarnitine (C2)	1265	0	1266	10.0	1267	20.0	1268	30.0
Propionylcarnitine (C3)	1265	0	1266	3.0	1267	7.5	1268	12.0
Butyrylcarnitine (C4)	1265	0	1266	1.0	1267	2.5	1268	5.0
Isovalerylcarnitine (C5)	1265	0	1266	0.5	1267	1.5	1268	3.0
Hexanoylcarnitine (C6)	1265	0	1266	0.5	1267	1.0	1268	2.5
Octanoylcarnitine (C8)	1265	0	1266	0.5	1267	1.0	1268	2.5
Decanoylcarnitine (C10)	1265	0	1266	0.5	1267	1.0	1268	2.5
Dodecanoylcarnitine (C12)	1265	0	1266	0.5	1267	1.0	1268	2.5
Myristoylcarnitine (C14)	1265	0	1266	0.5	1267	1.5	1268	3.0
Palmitoylcarnitine (C16)	1265	0	1266	3.0	1267	8.0	1268	12.0
Stearoylcarnitine (C18)	1265	0	1266	1.0	1267	2.0	1268	5.0
Malonylcarnitine (C3DC)	1265	0	1266	0.5	1267	1.5	1268	3.0
Glutarylcarnitine (C5DC)	1265	0	1266	0.5	1267	1.0	1268	2.5
3-Hydroxybutyrylcarnitine (C4OH)	1265	0	1266	0.5	1267	1.0	1268	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	1265	0	1266	0.5	1267	1.5	1268	2.5
3-Hydroxypalmitoylcarnitine (C16OH)	1265	0	1266	0.1	1267	0.5	1268	1.0

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Quality Control Specimen Certification, Acylcarnitines Set 1 — January 7, 2013

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	1265	$\bar{x}$ = 16.2 CL = 13.6-18.9	1266	$\bar{x}$ = 31.5 CL = 24.3-38.8	1267	$\bar{x}$ = 47.8 CL = 38.4-57.1	1268	$\bar{x}$ = 65.6 CL = 52.0-79.1
C2	1265	$\bar{x}$ = 8.1 CL = 7.2-9.0	1266	$\bar{x}$ = 16.3 CL = 14.0-18.7	1267	$\bar{x}$ = 25.3 CL = 22.9-27.8	1268	$\bar{x}$ = 33.8 CL = 30.4-37.3
C3	1265	$\bar{x}$ = 0.7 CL = 0.5-0.9	1266	$\bar{x}$ = 3.3 CL = 2.6-3.9	1267	$\bar{x}$ = 7.1 CL = 6.3-7.9	1268	$\bar{x}$ = 11.2 CL = 8.5-13.9
C4	1265	$\bar{x}$ =0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.8 CL = 0.7-1.0	1267	$\bar{x}$ = 2.0 CL = 1.6-2.4	1268	$\bar{x}$ = 4.1 CL = 3.4-4.8
C5	1265	$\bar{x}$ = 0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.4 CL = 0.3-0.5	1267	$\bar{x}$ = 1.2 CL = 1.0-1.4	1268	$\bar{x}$ = 2.6 CL = 2.1-3.1
C6	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.4 CL = 0.3-0.5	1267	$\bar{x}$ = 0.7 CL = 0.6-0.9	1268	$\bar{x}$ = 2.0 CL = 1.6-2.4
C8	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.4 CL = 0.3-0.5	1267	$\bar{x}$ = 0.8 CL = 0.7-1.0	1268	$\bar{x}$ = 2.2 CL = 1.8-2.5
C10	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.4 CL = 0.3-0.6	1267	$\bar{x}$ = 0.8 CL = 0.7-1.0	1268	$\bar{x}$ = 2.1 CL = 1.8-2.3
C12	1265	$\bar{x}$ = 0.0 CL = 0.0-0.1	1266	$\bar{x}$ = 0.4 CL = 0.3-0.6	1267	$\bar{x}$ = 0.9 CL = 0.7-1.0	1268	$\bar{x}$ = 2.0 CL = 1.7-2.4
C14	1265	$\bar{x}$ = 0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.5 CL = 0.4-0.6	1267	$\bar{x}$ = 1.3 CL = 1.1-1.4	1268	$\bar{x}$ = 2.5 CL = 2.2-2.9
C16	1265	$\bar{x}$ = 0.5 CL = 0.4-0.6	1266	$\bar{x}$ = 2.3 CL = 1.8-2.7	1267	$\bar{x}$ = 5.5 CL = 5.0-6.1	1268	$\bar{x}$ = 8.3 CL = 7.1-9.5
C18	1265	$\bar{x}$ = 0.4 CL = 0.4-0.5	1266	$\bar{x}$ = 1.1 CL = 0.9-1.3	1267	$\bar{x}$ = 1.7 CL = 1.5-2.0	1268	$\bar{x}$ = 4.1 CL = 3.4-4.9
C3DC	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.3 CL = 0.2-0.3	1267	$\bar{x}$ = 0.7 CL = 0.6-0.8	1268	$\bar{x}$ = 1.4 CL = 1.1-1.7
C5DC	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.3 CL = 0.2-0.4	1267	$\bar{x}$ = 0.7 CL = 0.5-0.8	1268	$\bar{x}$ = 1.8 CL = 1.5-2.2
C4OH	1265	$\bar{x}$ = 0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.4 CL = 0.2-0.5	1267	$\bar{x}$ = 0.7 CL = 0.6-0.8	1268	$\bar{x}$ = 1.8 CL = 1.3-2.2
C5OH	1265	$\bar{x}$ = 0.4 CL = 0.4-0.5	1266	$\bar{x}$ = 0.8 CL = 0.6-0.9	1267	$\bar{x}$ = 1.5 CL = 1.3-1.7	1268	$\bar{x}$ = 2.4 CL = 1.8-3.0
C16OH	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.1 CL = 0.0-0.1	1267	$\bar{x}$ = 0.3 CL = 0.3-0.4	1268	$\bar{x}$ = 0.7 CL = 0.5-0.8

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 1— January 7, 2013
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)	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

Newborn Screening
Quality Assurance Program

Quality Control Specimen Certification, Acylcarnitines Set 1— January 7, 2013
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	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.*