Newborn Screening Quality Assurance Program
Acylcarnitines Quality Control Specimen Certification
Set 2— July 14, 2014
Acylcarnitines Method: MSMS Derivatized - MS/MS non-kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	1461	0	1462	10.0	1463	20.0	1464	30.0
Acetylcarnitine (C2)	1461	0	1462	10.0	1463	20.0	1464	30.0
Propionylcarnitine (C3)	1461	0	1462	3.0	1463	7.5	1464	12.0
Malonylcarnitine (C3DC)	1461	0	1462	0.5	1463	1.5	1464	3.0
Butyrylcarnitine (C4)	1461	0	1462	1.0	1463	2.5	1464	5.0
Hydroxybutyrylcarnitine (C4OH)	1461	0	1462	0.5	1463	1.0	1464	2.5
Isovalerylcarnitine (C5)	1461	0	1462	0.5	1463	1.5	1464	3.0
Glutarylcarnitine (C5DC)	1461	0	1462	0.5	1463	1.0	1464	2.5
Hydroxyisovalerylcarnitine (C5OH)	1461	0	1462	0.5	1463	1.5	1464	2.5
Hexanoylcarnitine (C6)	1461	0	1462	0.5	1463	1.0	1464	2.5
Octanoylcarnitine (C8)	1461	0	1462	0.5	1463	1.0	1464	2.5
Decanoylcarnitine (C10)	1461	0	1462	0.5	1463	1.0	1464	2.5
Dodecanoylcarnitine (C12)	1461	0	1462	0.5	1463	1.0	1464	2.5
Myristoylcarnitine (C14)	1461	0	1462	0.5	1463	1.5	1464	3.0
Palmitoylcarnitine (C16)	1461	0	1462	4.0	1463	8.0	1464	12.0
Hydroxypalmitoylcarnitine (C16OH)	1461	0	1462	0.1	1463	0.5	1464	1.0
Stearoylcarnitine (C18)	1461	0	1462	1.0	1463	2.0	1464	5.0
Hydroxystearoylcarnitine (C18OH)	1461	0	1462	0.5	1463	1.0	1464	1.5

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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	1461	$\bar{x}$ = 25.9 CL = 15.7-36.2	1462	$\bar{x}$ = 41.8 CL = 35.3-48.4	1463	$\bar{x}$ = 60.0 CL = 49.6-70.3	1464	$\bar{x}$ = 79.0 CL = 60.6-97.3
C2	1461	$\bar{x}$ = 12.9 CL = 10.8-15.1	1462	$\bar{x}$ = 21.3 CL = 18.0-24.7	1463	$\bar{x}$ = 30.8 CL = 22.7-38.9	1464	$\bar{x}$ = 39.4 CL = 27.3-51.5
C3	1461	$\bar{x}$ = 1.3 CL = 1.0-1.6	1462	$\bar{x}$ = 3.9 CL = 2.5-5.4	1463	$\bar{x}$ = 8.2 CL = 4.7-11.6	1464	$\bar{x}$ = 12.4 CL = 6.8-18.0
C3DC	1461	$\bar{x}$ = 0.1 CL = 0.0-0.1	1462	$\bar{x}$ = 0.4 CL = 0.2-0.6	1463	$\bar{x}$ = 1.0 CL = 0.5-1.5	1464	$\bar{x}$ = 1.9 CL = 1.0-2.9
C4	1461	$\bar{x}$ =0.2 CL = 0.1-0.2	1462	$\bar{x}$ = 1.0 CL = 0.5-1.4	1463	$\bar{x}$ = 2.4 CL = 1.2-3.5	1464	$\bar{x}$ = 4.4 CL = 2.3-6.5
C4OH	1461	$\bar{x}$ = 0.1 CL = 0.1-0.1	1462	$\bar{x}$ = 0.4 CL = 0.2-0.6	1463	$\bar{x}$ = 0.7 CL = 0.4-1.1	1464	$\bar{x}$ = 1.7 CL = 0.9-2.5
C5	1461	$\bar{x}$ = 0.1 CL = 0.0-0.1	1462	$\bar{x}$ = 0.5 CL = 0.3-0.7	1463	$\bar{x}$ = 1.2 CL = 0.6-1.8	1464	$\bar{x}$ = 2.4 CL = 1.2-3.5
C5DC	1461	$\bar{x}$ = 0.0 CL = 0.0-0.1	1462	$\bar{x}$ = 0.6 CL = 0.3-1.0	1463	$\bar{x}$ = 1.2 CL = 0.6-1.8	1464	$\bar{x}$ = 2.9 CL = 1.4-4.4
C5OH	1461	$\bar{x}$ = 0.5 CL = 0.3-0.6	1462	$\bar{x}$ = 0.9 CL = 0.6-1.2	1463	$\bar{x}$ = 1.7 CL = 1.0-2.3	1464	$\bar{x}$ = 2.5 CL = 1.4-3.6
C6	1461	$\bar{x}$ = 0.0 CL = 0.0-0.1	1462	$\bar{x}$ = 0.5 CL = 0.2-0.7	1463	$\bar{x}$ = 0.9 CL = 0.4-1.4	1464	$\bar{x}$ = 2.2 CL = 1.0-3.3
C8	1461	$\bar{x}$ = 0.0 CL = 0.0-0.1	1462	$\bar{x}$ = 0.5 CL = 0.3-0.7	1463	$\bar{x}$ = 1.0 CL = 0.5-1.5	1464	$\bar{x}$ = 2.3 CL = 1.0-3.6
C10	1461	$\bar{x}$ = 0.0 CL = 0.0-0.0	1462	$\bar{x}$ = 0.5 CL = 0.4-0.7	1463	$\bar{x}$ = 1.0 CL = 0.7-1.3	1464	$\bar{x}$ = 2.5 CL = 1.8-3.2
C12	1461	$\bar{x}$ = 0.0 CL = 0.0-0.1	1462	$\bar{x}$ = 0.5 CL = 0.2-0.7	1463	$\bar{x}$ = 0.9 CL = 0.5-1.4	1464	$\bar{x}$ = 2.1 CL = 1.0-3.1
C14	1461	$\bar{x}$ = 0.1 CL = 0.0-0.1	1462	$\bar{x}$ = 0.5 CL = 0.3-0.8	1463	$\bar{x}$ = 1.3 CL = 0.7-2.0	1464	$\bar{x}$ = 2.6 CL = 1.3-3.9
C16	1461	$\bar{x}$ = 0.9 CL = 0.7-1.1	1462	$\bar{x}$ = 2.9 CL = 1.9-4.0	1463	$\bar{x}$ = 6.6 CL = 3.7-9.4	1464	$\bar{x}$ = 9.2 CL = 5.0-13.4
C16OH	1461	$\bar{x}$ = 0.0 CL = 0.0-0.0	1462	$\bar{x}$ = 0.1 CL = 0.0-0.1	1463	$\bar{x}$ = 0.3 CL = 0.2-0.5	1464	$\bar{x}$ = 0.6 CL = 0.3-0.9
C18	1461	$\bar{x}$ = 0.7 CL = 0.5-0.8	1462	$\bar{x}$ = 1.3 CL = 1.0-1.7	1463	$\bar{x}$ = 2.1 CL = 1.4-2.9	1464	$\bar{x}$ = 4.3 CL = 2.4-6.3
C18OH	1461	$\bar{x}$ = 0.0 CL = 0.0-0.0	1462	$\bar{x}$ = 0.3 CL = 0.1-0.4	1463	$\bar{x}$ = 0.5 CL = 0.3-0.8	1464	$\bar{x}$ = 0.8 CL = 0.4-1.2

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
Acylcarnitines Quality Control Specimen Certification
Set 1— January 13, 2014
Previous Lot Transition Materials (parallel testing)
Acylcarnitines Method: MSMS Derivatized - MS/MS non-kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	1365	0	1366	10.0	1367	20.0	1368	30.0
Acetylcarnitine (C2)	1365	0	1366	10.0	1367	20.0	1368	30.0
Propionylcarnitine (C3)	1365	0	1366	3.0	1367	7.5	1368	12.0
Malonylcarnitine (C3DC)	1365	0	1366	0.5	1367	1.5	1368	3.0
Butyrylcarnitine (C4)	1365	0	1366	1.0	1367	2.5	1368	5.0
Hydroxybutyrylcarnitine (C4OH)	1365	0	1366	0.5	1367	1.0	1368	2.5
Isovalerylcarnitine (C5)	1365	0	1366	0.5	1367	1.5	1368	3.0
Glutarylcarnitine (C5DC)	1365	0	1366	0.5	1367	1.0	1368	2.5
Hydroxyisovalerylcarnitine (C5OH)	1365	0	1366	0.5	1367	1.5	1368	2.5
Hexanoylcarnitine (C6)	1365	0	1366	0.5	1367	1.0	1368	2.5
Octanoylcarnitine (C8)	1365	0	1366	0.5	1367	1.0	1368	2.5
Decanoylcarnitine (C10)	1365	0	1366	0.5	1367	1.0	1368	2.5
Dodecanoylcarnitine (C12)	1365	0	1366	0.5	1367	1.0	1368	2.5
Myristoylcarnitine (C14)	1365	0	1366	0.5	1367	1.5	1368	3.0
Palmitoylcarnitine (C16)	1365	0	1366	4.0	1367	8.0	1368	12.0
Hydroxypalmitoylcarnitine (C16OH)	1365	0	1366	0.1	1367	0.5	1368	1.0
Stearoylcarnitine (C18)	1365	0	1366	1.0	1367	2.0	1368	5.0
Hydroxystearoylcarnitine (C18OH)	1365	0	1366	0.1	1367	0.5	1368	1.0

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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	1365	$\bar{x}$ = 20.4 CL = 16.6-24.2	1366	$\bar{x}$ = 27.7 CL = 22.7-32.7	1367	$\bar{x}$ = 44.9 CL = 37.3-52.5	1368	$\bar{x}$ = 63.9 CL = 52.1-75.6
C2	1365	$\bar{x}$ = 11.4 CL = 9.9-12.8	1366	$\bar{x}$ = 21.7 CL = 19.4-24.0	1367	$\bar{x}$ = 30.6 CL = 27.2-34.0	1368	$\bar{x}$ = 42.7 CL = 37.2-48.1
C3	1365	$\bar{x}$ = 1.3 CL = 0..7-1.8	1366	$\bar{x}$ = 3.9 CL = 2.7-5.1	1367	$\bar{x}$ = 7.6 CL = 5.1-10.1	1368	$\bar{x}$ = 12.4 CL = 8.7-16.1
C3DC	1365	$\bar{x}$ = 0.0 CL = 0.0-0.1	1366	$\bar{x}$ = 0.4 CL = 0.2-0.5	1367	$\bar{x}$ = 0.9 CL = 0.6-1.2	1368	$\bar{x}$ = 1.8 CL = 1.2-2.5
C4	1365	$\bar{x}$ =0.2 CL = 0.1-0.2	1366	$\bar{x}$ = 1.0 CL = 0.7-1.3	1367	$\bar{x}$ = 2.0 CL = 1.4-2.6	1368	$\bar{x}$ = 4.6 CL = 3.0-6.1
C4OH	1365	$\bar{x}$ = 0.1 CL = 0.0-0.2	1366	$\bar{x}$ = 0.4 CL = 0.2-0.6	1367	$\bar{x}$ = 0.7 CL = 0.5-0.9	1368	$\bar{x}$ = 1.6 CL = 1.0-2.1
C5	1365	$\bar{x}$ = 0.1 CL = 0.0-0.2	1366	$\bar{x}$ = 0.5 CL = 0.4-0.7	1367	$\bar{x}$ = 1.3 CL = 1.0-1.7	1368	$\bar{x}$ = 2.6 CL = 1.7-3.6
C5DC	1365	$\bar{x}$ = 0.0 CL = 0.0-0.1	1366	$\bar{x}$ = 0.5 CL = 0.3-0.7	1367	$\bar{x}$ = 0.9 CL = 0.6-1.2	1368	$\bar{x}$ = 2.3 CL = 1.4-3.3
C5OH	1365	$\bar{x}$ = 0.5 CL = 0.3-0.6	1366	$\bar{x}$ = 0.9 CL = 0.6-1.2	1367	$\bar{x}$ = 1.7 CL = 1.3-2.1	1368	$\bar{x}$ = 2.6 CL = 1.9-3.3
C6	1365	$\bar{x}$ = 0.0 CL = 0.0-0.1	1366	$\bar{x}$ = 0.4 CL = 0.3-0.6	1367	$\bar{x}$ = 0.7 CL = 0.5-1.0	1368	$\bar{x}$ = 1.9 CL = 1.1-2.8
C8	1365	$\bar{x}$ = 0.0 CL = 0.0-0.1	1366	$\bar{x}$ = 0.5 CL = 0.3-0.7	1367	$\bar{x}$ = 0.9 CL = 0.7-1.2	1368	$\bar{x}$ = 2.3 CL = 1.5-3.1
C10	1365	$\bar{x}$ = 0.0 CL = 0.0-0.0	1366	$\bar{x}$ = 0.5 CL = 0.3-0.6	1367	$\bar{x}$ = 0.9 CL = 0.6-1.2	1368	$\bar{x}$ = 2.3 CL = 1.4-3.1
C12	1365	$\bar{x}$ = 0.0 CL = 0.0-0.1	1366	$\bar{x}$ = 0.4 CL = 0.3-0.5	1367	$\bar{x}$ = 0.8 CL = 0.4-1.1	1368	$\bar{x}$ = 2.2 CL = 1.3-3.0
C14	1365	$\bar{x}$ = 0.1 CL = 0.0-0.1	1366	$\bar{x}$ = 0.5 CL = 0.3-0.6	1367	$\bar{x}$ = 1.2 CL = 0.8-1.5	1368	$\bar{x}$ = 2.5 CL = 1.7-3.4
C16	1365	$\bar{x}$ = 0.7 CL = 0.6-0.9	1366	$\bar{x}$ = 3.2 CL = 2.6-3.8	1367	$\bar{x}$ = 7.1 CL = 5.3-8.9	1368	$\bar{x}$ = 10.9 CL = 8.8-13.1
C16OH	1365	$\bar{x}$ = 0.0 CL = 0.0-0.0	1366	$\bar{x}$ = 0.1 CL = 0.0-0.1	1367	$\bar{x}$ = 0.4 CL = 0.2-0.5	1368	$\bar{x}$ = 0.7 CL = 0.5-0.9
C18	1365	$\bar{x}$ = 0.6 CL = 0.5-0.8	1366	$\bar{x}$ = 1.4 CL = 1.1-1.7	1367	$\bar{x}$ = 2.1 CL = 1.8-2.5	1368	$\bar{x}$ = 4.8 CL = 3.6-6.1
C18OH	1365	$\bar{x}$ = 0.0 CL = 0.0-0.0	1366	$\bar{x}$ = 0.3 CL = 0.2-0.4	1367	$\bar{x}$ = 0.6 CL = 0.4-0.7	1368	$\bar{x}$ = 1.0 CL = 0.7-1.2

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.*