Newborn Screening Quality Assurance Program
Quality Control Specimen Certification
Set 2—July 2015

Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Free carnitine (C0)	1561	0	1562	10.0	1563	20.0	1564	30.0	February 28, 2016
Acetylcarnitine (C2)	1561	0	1562	10.0	1563	20.0	1564	30.0	February 28, 2016
Propionylcarnitine (C3)	1561	0	1562	4.0	1563	8.0	1564	12.0	February 28, 2016
Butyrylcarnitine (C4)	1561	0	1562	1.0	1563	3.0	1564	5.0	February 28, 2016
Malonylcarnitine + Hydroxybutyrylcarnitine (C3DC + C4OH)	1561	0	1562	1.0	1563	2.5	1564	5.5	February 28, 2016
Isovalerylcarnitine (C5)	1561	0	1562	0.5	1563	1.5	1564	3.0	February 28, 2016
Glutarylcarnitine (C5DC)	1561	0	1562	0.5	1563	1.0	1564	2.5	February 28, 2016
Hydroxyisovalerylcarnitine (C5OH)	1561	0	1562	1.0	1563	2.0	1564	3.0	February 28, 2016
Hexanoylcarnitine (C6)	1561	0	1562	0.5	1563	1.0	1564	2.5	February 28, 2016
Octanoylcarnitine (C8)	1561	0	1562	0.5	1563	1.0	1564	2.5	February 28, 2016
Decanoylcarnitine (C10)	1561	0	1562	0.5	1563	1.0	1564	2.5	February 28, 2016
Dodecanoylcarnitine (C12)	1561	0	1562	1.0	1563	2.0	1564	3.0	February 28, 2016
Myristoylcarnitine (C14)	1561	0	1562	0.5	1563	1.5	1564	3.0	February 28, 2016
Palmitoylcarnitine (C16)	1561	0	1562	4.0	1563	8.0	1564	12.0	February 28, 2016
Hydroxypalmitoylcarnitine (C16OH)	1561	0	1562	0.25	1563	1.0	1564	1.5	February 28, 2016
Stearoylcarnitine (C18)	1561	0	1562	1.0	1563	3.0	1564	5.0	February 28, 2016
Hydroxystearoylcarnitine (C18OH)	1561	0	1562	0.25	1563	1.0	1564	1.5	February 28, 2016

ENRICHMENT LEVELS (endogenous levels not included)

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Set 2— July 2015

Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

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*	*Expiration Date*
C0	1561	$\bar{x}$ = 13.3 CL = 11.0-15.6	1562	$\bar{x}$ = 22.9 CL = 18.9-27.0	1563	$\bar{x}$ = 32.6 CL = 26.9-38.3	1564	$\bar{x}$ = 42.2 CL = 35.0–49.3	February 28, 2016
C2	1561	$\bar{x}$ = 9.9 CL = 8.5-11.3	1562	$\bar{x}$ = 19.1 CL = 16.8-21.5	1563	$\bar{x}$ = 28.9 CL = 25.3-32.6	1564	$\bar{x}$ = 40.2 CL = 34.6-45.8	February 28, 2016
C3	1561	$\bar{x}$ = 1.0 CL = 0.9–1.2	1562	$\bar{x}$ = 5.2 CL = 4.5-5.9	1563	$\bar{x}$ = 9.3 CL = 8.0-10.6	1564	$\bar{x}$ = 14.3 CL = 12.4-16.2	February 28, 2016
C4	1561	$\bar{x}$ = 0.1 CL = 0.1–0.1	1562	$\bar{x}$ = 1.0 CL = 0.8–1.1	1563	$\bar{x}$ = 2.8 CL = 2.3-3.2	1564	$\bar{x}$ = 5.0 CL = 4.2-5.8	February 28, 2016
C3DC + C4OH	1561	$\bar{x}$ = 0.0 CL = 0.0–0.1	1562	$\bar{x}$ = 0.4 CL = 0.3-0.4	1563	$\bar{x}$ = 0.7 CL = 0.6-0.8	1564	$\bar{x}$ = 1.7 CL = 1.4-1.9	February 28, 2016
C5	1561	$\bar{x}$ = 0.1 CL = 0.0–0.1	1562	$\bar{x}$ = 0.5 CL = 0.5–0.6	1563	$\bar{x}$ = 1.5 CL = 1.3–1.7	1564	$\bar{x}$ = 2.9 CL = 2.4–3.4	February 28, 2016
C5DC	1561	$\bar{x}$ = 0.0 CL = 0.0–0.0	1562	$\bar{x}$ = 0.4 CL = 0.4–0.5	1563	$\bar{x}$ = 0.8 CL = 0.7–0.9	1564	$\bar{x}$ = 2.0 CL = 1.7–2.4	February 28, 2016
C5OH	1561	$\bar{x}$ = 0.7 CL = 0.6–0.8	1562	$\bar{x}$ = 1.6 CL = 1.4–1.9	1563	$\bar{x}$ = 2.6 CL = 2.3–2.9	1564	$\bar{x}$ = 3.7 CL = 3.1-4.2	February 28, 2016
C6	1561	$\bar{x}$ = 0.0 CL = 0.0–0.0	1562	$\bar{x}$ = 0.5 CL = 0.5–0.6	1563	$\bar{x}$ = 1.0 CL = 0.8–1.1	1564	$\bar{x}$ = 2.5 CL = 2.1–2.9	February 28, 2016
C8	1561	$\bar{x}$ = 0.0 CL = 0.0–0.0	1562	$\bar{x}$ = 0.5 CL = 0.5–0.6	1563	$\bar{x}$ = 1.0 CL = 0.9–1.2	1564	$\bar{x}$ = 2.6 CL = 2.2–2.9	February 28, 2016
C10	1561	$\bar{x}$ = 0.1 CL = 0.0–0.1	1562	$\bar{x}$ = 0.7 CL = 0.5–0.8	1563	$\bar{x}$ = 1.2 CL = 1.0-1.4	1564	$\bar{x}$ = 3.0 CL = 2.6–3.5	February 28, 2016
C12	1561	$\bar{x}$ = 0.0 CL = 0.0–0.0	1562	$\bar{x}$ = 1.0 CL = 0.8–1.1	1563	$\bar{x}$ = 1.9 CL = 1.6-2.2	1564	$\bar{x}$ = 2.9 CL = 2.5-3.4	February 28, 2016
C14	1561	$\bar{x}$ = 0.0 CL = 0.0–0.1	1562	$\bar{x}$ = 0.5 CL = 0.4–0.6	1563	$\bar{x}$ = 1.5 CL = 1.3–1.7	1564	$\bar{x}$ = 3.0 CL = 2.6–3.5	February 28, 2016
C16	1561	$\bar{x}$ = 0.7 CL = 0.6–0.8	1562	$\bar{x}$ = 4.2 CL = 3.6–4.8	1563	$\bar{x}$ = 7.4 CL = 6.4–8.4	1564	$\bar{x}$ = 11.3 CL = 9.6–13.0	February 28, 2016
C16OH	1561	$\bar{x}$ = 0.0 CL = 0.0–0.0	1562	$\bar{x}$ = 0.2 CL = 0.1–0.2	1563	$\bar{x}$ = 0.7 CL = 0.6–0.7	1564	$\bar{x}$ = 1.0 CL = 0.9–1.1	February 28, 2016
C18	1561	$\bar{x}$ = 0.6 CL = 0.5–0.7	1562	$\bar{x}$ = 1.5 CL = 1.3–1.7	1563	$\bar{x}$ =3.2 CL = 2.7–3.6	1564	$\bar{x}$ = 5.1 CL = 4.4–5.8	February 28, 2016
C18OH	1561	$\bar{x}$ = 0.0 CL = 0.0–0.0	1562	$\bar{x}$ = 0.1 CL = 0.1–0.2	1563	$\bar{x}$ = 0.6 CL = 0.5–0.7	1564	$\bar{x}$ = 0.9 CL = 0.7–1.0	February 28, 2016

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 2015 Transition Set
Previous Lot Transition Materials (parallel testing)
Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte (µmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*	*Expiration Date*
Free carnitine (C0)	1465	0	1466	10.0	1467	20.0	1468	30.0	August 31, 2015
Acetylcarnitine (C2)	1465	0	1466	10.0	1467	20.0	1468	30.0	August 31, 2015
Propionylcarnitine (C3)	1465	0	1466	3.0	1467	7.5	1468	12.0	August 31, 2015
Butyrylcarnitine (C4)	1465	0	1466	1.0	1467	2.5	1468	5.0	August 31, 2015
Malonylcarnitine + Hydroxybutyrylcarnitine (C3DC + C4OH)	1465	0	1466	1.0	1467	2.5	1468	5.5	August 31, 2015
Isovalerylcarnitine (C5)	1465	0	1466	0.5	1467	1.5	1468	3.0	August 31, 2015
Glutarylcarnitine (C5DC)	1465	0	1466	0.5	1467	1.0	1468	2.5	August 31, 2015
Hydroxyisovalerylcarnitine (C5OH)	1465	0	1466	0.5	1467	1.5	1468	2.5	August 31, 2015
Hexanoylcarnitine (C6)	1465	0	1466	0.5	1467	1.0	1468	2.5	August 31, 2015
Octanoylcarnitine (C8)	1465	0	1466	0.5	1467	1.0	1468	2.5	August 31, 2015
Decanoylcarnitine (C10)	1465	0	1466	0.5	1467	1.0	1468	2.5	August 31, 2015
Dodecanoylcarnitine (C12)	1465	0	1466	0.5	1467	1.0	1468	2.5	August 31, 2015
Myristoylcarnitine (C14)	1465	0	1466	0.5	1467	1.5	1468	3.0	August 31, 2015
Palmitoylcarnitine (C16)	1465	0	1466	3.0	1467	8.0	1468	12.0	August 31, 2015
Hydroxypalmitoylcarnitine (C16OH)	1465	0	1466	0.25	1467	0.5	1468	1.0	August 31, 2015
Stearoylcarnitine (C18)	1465	0	1466	1.0	1467	2.0	1468	5.0	August 31, 2015
Hydroxystearoylcarnitine (C18OH)	1465	0	1466	0.5	1467	1.0	1468	1.5	August 31, 2015

Set 1— January 2015 Transition Set

Previous Lot Transition Materials (parallel testing)

Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

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*	*Expiration Date*
C0	1465	$\bar{x}$ = 13.6 CL = 11.7–15.4	1466	$\bar{x}$ = 23.0 CL = 20.8–25.3	1467	$\bar{x}$ = 32.9 CL = 29.5–36.4	1468	$\bar{x}$ = 42.5 CL = 37.7–47.4	August 31, 2015
C2	1465	$\bar{x}$ = 7.8 CL = 6.7–8.9	1466	$\bar{x}$ = 16.8 CL = 15.0–18.5	1467	$\bar{x}$ = 25.7 CL = 23.3–28.1	1468	$\bar{x}$ = 34.0 CL = 29.9–38.2	August 31, 2015
C3	1465	$\bar{x}$ = 0.8 CL = 0.6–1.0	1466	$\bar{x}$ = 3.4 CL = 2.5–4.3	1467	$\bar{x}$ = 7.5 CL = 5.6–9.5	1468	$\bar{x}$ = 11.5 CL = 9.0–14.0	August 31, 2015
C4	1465	$\bar{x}$ = 0.1 CL = 0.1–0.2	1466	$\bar{x}$ = 0.9 CL = 0.6–1.1	1467	$\bar{x}$ = 2.0 CL = 1.4–2.6	1468	$\bar{x}$ = 4.0 CL = 3.0–4.9	August 31, 2015
C3DC + C4OH	1465	$\bar{x}$ = 0.1 CL = 0.0–0.1	1466	$\bar{x}$ = 0.3 CL = 0.2–0.4	1467	$\bar{x}$ = 0.6 CL = 0.4–0.8	1468	$\bar{x}$ = 1.4 CL = 1.0–1.9	August 31, 2015
C5	1465	$\bar{x}$ = 0.1 CL = 0.0–0.1	1466	$\bar{x}$ = 0.5 CL = 0.4–0.6	1467	$\bar{x}$ = 1.3 CL = 1.0–1.6	1468	$\bar{x}$ = 2.5 CL = 1.9–3.2	August 31, 2015
C5DC	1465	$\bar{x}$ = 0.1 CL = 0.0–0.1	1466	$\bar{x}$ = 0.6 CL = 0.3–0.8	1467	$\bar{x}$ = 1.0 CL = 0.7–1.4	1468	$\bar{x}$ = 2.5 CL = 1.7–3.2	August 31, 2015
C5OH	1465	$\bar{x}$ = 0.6 CL = 0.4–0.8	1466	$\bar{x}$ = 1.0 CL = 0.8–1.3	1467	$\bar{x}$ = 1.9 CL = 1.4–2.4	1468	$\bar{x}$ = 2.7 CL = 2.1–3.4	August 31, 2015
C6	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.4 CL = 0.3–0.5	1467	$\bar{x}$ = 0.8 CL = 0.6–1.0	1468	$\bar{x}$ = 2.0 CL = 1.4–2.6	August 31, 2015
C8	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.4 CL = 0.4–0.5	1467	$\bar{x}$ = 0.9 CL = 0.7–1.1	1468	$\bar{x}$ = 2.2 CL = 1.8–2.7	August 31, 2015
C10	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.5 CL = 0.4–0.7	1467	$\bar{x}$ = 1.0 CL = 0.8–1.2	1468	$\bar{x}$ = 2.7 CL = 2.0–3.5	August 31, 2015
C12	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.4 CL = 0.3–0.6	1467	$\bar{x}$ = 0.8 CL = 0.6–1.0	1468	$\bar{x}$ = 2.1 CL = 1.6–2.5	August 31, 2015
C14	1465	$\bar{x}$ = 0.0 CL = 0.0–0.1	1466	$\bar{x}$ = 0.5 CL = 0.4–0.5	1467	$\bar{x}$ = 1.4 CL = 1.1–1.6	1468	$\bar{x}$ = 2.7 CL = 2.2–3.3	August 31, 2015
C16	1465	$\bar{x}$ = 0.7 CL = 0.6–0.8	1466	$\bar{x}$ = 3.3 CL = 2.7–3.8	1467	$\bar{x}$ = 7.6 CL = 6.5–8.7	1468	$\bar{x}$ = 10.7 CL = 9.2–12.2	August 31, 2015
C16OH	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.1 CL = 0.1–0.2	1467	$\bar{x}$ = 0.3 CL = 0.2–0.3	1468	$\bar{x}$ = 0.6 CL = 0.4–0.7	August 31, 2015
C18	1465	$\bar{x}$ = 0.6 CL = 0.5–0.7	1466	$\bar{x}$ = 1.5 CL = 1.3–1.6	1467	$\bar{x}$ = 2.4 CL = 2.0–2.8	1468	$\bar{x}$ = 5.0 CL = 4.1–5.9	August 31, 2015
C18OH	1465	$\bar{x}$ = 0.0 CL = 0.0–0.0	1466	$\bar{x}$ = 0.3 CL = 0.2–0.3	1467	$\bar{x}$ = 0.5 CL = 0.4–0.6	1468	$\bar{x}$ = 0.8 CL = 0.6–0.9	August 31, 2015

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.*