Newborn Screening Quality Assurance Program
Quality Control Specimen Certification
Lot 1365–1368 — January 13, 2014

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*
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 + Hydroxybutyrylcarnitine (C3DC + C4OH)	1365	0	1366	1.0	1367	2.5	1368	5.5
Butyrylcarnitine (C4)	1365	0	1366	1.0	1367	2.5	1368	5.0
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	3.0	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

Newborn Screening Quality Assurance Program
Quality Control Specimen Certification
Lot 1365 – 1368 — January 13, 2014

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

ANALYTICAL INFORMATION *Lot Numbers, Mean Values (*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	$\bar{x}$ = 15.7 CL = 12.8–18.6	1366	$\bar{x}$ = 18.3 CL = 13.8–22.7	1367	$\bar{x}$ = 30.8 CL = 24.3–37.3	1368	$\bar{x}$ = 41.7 CL = 32.9–50.5
C2	1365	$\bar{x}$ = 10.5 CL = 9.2–11.8	1366	$\bar{x}$ = 20.3 CL = 16.8–23.8	1367	$\bar{x}$ = 29.6 CL = 25.0–34.3	1368	$\bar{x}$ = 40.6 CL = 32.6–48.5
C3	1365	$\bar{x}$ = 1.3 CL = 0.9–1.6	1366	$\bar{x}$ = 4.0 CL = 3.1–4.9	1367	$\bar{x}$ = 8.0 CL = 4.9–11.0	1368	$\bar{x}$ = 12.1 CL = 9.3–15.0
C3DC + C4OH	1365	$\bar{x}$ = 0.3 CL = 0.1–0.5	1366	$\bar{x}$ = 1.3 CL = 0.5–2.0	1367	$\bar{x}$ = 2.2 CL = 1.2–3.2	1368	$\bar{x}$ = 5.1 CL = 2.6–7.5
C4	1365	$\bar{x}$ = 0.2 CL = 0.1–0.2	1366	$\bar{x}$ = 1.0 CL = 0.7–1.3	1367	$\bar{x}$ = 2.1 CL = 1.4–2.8	1368	$\bar{x}$ = 4.2 CL = 2.9–5.5
C5	1365	$\bar{x}$ = 0.1 CL = 0.1–0.2	1366	$\bar{x}$ = 0.6 CL = 0.4–0.7	1367	$\bar{x}$ = 1.4 CL = 1.0–1.9	1368	$\bar{x}$ = 2.9 CL = 2.1–3.8
C5DC	1365	$\bar{x}$ = 0.0 CL = 0.0–0.1	1366	$\bar{x}$ = 0.5 CL = 0.3–0.8	1367	$\bar{x}$ = 0.9 CL = 0.5–1.3	1368	$\bar{x}$ = 2.3 CL = 1.1–3.5
C5OH	1365	$\bar{x}$ = 0.7 CL = 0.4–1.0	1366	$\bar{x}$ = 1.1 CL = 0.8–1.4	1367	$\bar{x}$ = 1.8 CL = 1.2–2.4	1368	$\bar{x}$ = 2.8 CL = 1.8–3.9
C6	1365	$\bar{x}$ = 0.0 CL = 0.0–0.1	1366	$\bar{x}$ = 0.5 CL = 0.3–0.6	1367	$\bar{x}$ = 0.8 CL = 0.6–1.1	1368	$\bar{x}$ = 2.2 CL = 1.5–2.9
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 = 0.6–1.2	1368	$\bar{x}$ = 2.3 CL = 1.7–2.8
C10	1365	$\bar{x}$ = 0.0 CL = 0.0–0.1	1366	$\bar{x}$ = 0.5 CL = 0.3–0.6	1367	$\bar{x}$ = 0.8 CL = 0.6–1.1	1368	$\bar{x}$ = 2.2 CL = 1.5–2.9
C12	1365	$\bar{x}$ = 0.0 CL = 0.0–0.0	1366	$\bar{x}$ = 0.4 CL = 0.3–0.6	1367	$\bar{x}$ = 0.8 CL = 0.6–1.1	1368	$\bar{x}$ = 2.5 CL = 1.6–3.3
C14	1365	$\bar{x}$ = 0.1 CL = 0.0–0.1	1366	$\bar{x}$ = 0.5 CL = 0.3–0.7	1367	$\bar{x}$ = 1.4 CL = 1.0–1.8	1368	$\bar{x}$ = 2.8 CL = 1.9–3.8
C16	1365	$\bar{x}$ = 0.8 CL = 0.6–1.0	1366	$\bar{x}$ = 3.3 CL = 2.6–4.1	1367	$\bar{x}$ = 7.3 CL = 5.6–9.0	1368	$\bar{x}$ = 11.1 CL = 9.0–13.2
C16OH	1365	$\bar{x}$ = 0.0 CL = 0.0–0.0	1366	$\bar{x}$ = 0.0 CL = 0.0–0.1	1367	$\bar{x}$ = 0.2 CL = 0.1–0.2	1368	$\bar{x}$ = 0.3 CL = 0.2–0.5
C18	1365	$\bar{x}$ = 0.7 CL = 0.5–0.9	1366	$\bar{x}$ = 1.5 CL = 1.1–1.9	1367	$\bar{x}$ = 2.3 CL = 1.7–3.0	1368	$\bar{x}$ = 5.3 CL = 4.0–6.6
C18OH	1365	$\bar{x}$ = 0.0 CL = 0.0–0.0	1366	$\bar{x}$ = 0.2 CL = 0.1–0.2	1367	$\bar{x}$ = 0.3 CL = 0.2–0.4	1368	$\bar{x}$ = 0.5 CL = 0.3–0.7

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 20 successive, independent measurements.

Reference: *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
Lot 1361-1364— January 13, 2014
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*
Free carnitine (C0)	1361	0	1362	10.0	1363	20.0	1364	30.0
Acetylcarnitine (C2)	1361	0	1362	10.0	1363	20.0	1364	30.0
Propionylcarnitine (C3)	1361	0	1362	3.0	1363	7.5	1364	12.0
Malonylcarnitine + Hydroxybutyrylcarnitine (C3DC + C4OH)	1361	0	1362	1.0	1363	2.5	1364	5.5
Butyrylcarnitine (C4)	1361	0	1362	1.0	1363	2.5	1364	5.0
Isovalerylcarnitine (C5)	1361	0	1362	0.5	1363	1.5	1364	3.0
Glutarylcarnitine (C5DC)	1361	0	1362	0.5	1363	1.0	1364	2.5
Hydroxyisovalerylcarnitine (C5OH)	1361	0	1362	0.5	1363	1.5	1364	2.5
Hexanoylcarnitine (C6)	1361	0	1362	0.5	1363	1.0	1364	2.5
Octanoylcarnitine (C8)	1361	0	1362	0.5	1363	1.0	1364	2.5
Decanoylcarnitine (C10)	1361	0	1362	0.5	1363	1.0	1364	2.5
Dodecanoylcarnitine (C12)	1361	0	1362	0.5	1363	1.0	1364	2.5
Myristoylcarnitine (C14)	1361	0	1362	0.5	1363	1.5	1364	3.0
Palmitoylcarnitine (C16)	1361	0	1362	3.0	1363	8.0	1364	12.0
Hydroxypalmitoylcarnitine (C16OH)	1361	0	1362	0.1	1363	0.5	1364	1.0
Stearoylcarnitine (C18)	1361	0	1362	1.0	1363	2.0	1364	5.0

Newborn Screening Quality Assurance Program
Quality Control Specimen Certification
Lot 1361 – 1364 — January 13, 2014
Previous Lot Transition Materials (parallel testing)
Acylcarnitines Method: MS/MS Non-Derivatized - MS/MS non-kit

ANALYTICAL INFORMATION *Lot Numbers, Mean Values (*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	1361	$\bar{x}$ = 14.6 CL = 12.2 – 17.1	1362	$\bar{x}$ = 23.2 CL = 17.8 – 28.8	1363	$\bar{x}$ = 32.4 CL = 24.6 – 40.2	1364	$\bar{x}$ = 42.5 CL = 32.2 – 52.8
C2	1361	$\bar{x}$ = 11.4 CL = 10.2 – 12.6	1362	$\bar{x}$ = 21.1 CL = 18.9 – 23.3	1363	$\bar{x}$ = 31.7 CL = 27.6 – 35.9	1364	$\bar{x}$ = 42.0 CL = 37.2 – 46.8
C3	1361	$\bar{x}$ = 1.1 CL = 0.9 – 1.4	1362	$\bar{x}$ = 4.1 CL = 3.5 – 4.7	1363	$\bar{x}$ = 8.8 CL = 7.6 – 9.9	1364	$\bar{x}$ = 14.3 CL = 12.0 – 16.6
C3DC + C4OH	1361	$\bar{x}$ = 0.2 CL = 0.1 – 0.3	1362	$\bar{x}$ = 1.1 CL = 0.7 – 1.5	1363	$\bar{x}$ = 2.2 CL = 1.4 – 3.0	1364	$\bar{x}$ = 4.8 CL = 3.6 – 6.0
C4	1361	$\bar{x}$ = 0.1 CL = 0.1 – 0.2	1362	$\bar{x}$ = 1.0 CL = 0.7 – 1.2	1363	$\bar{x}$ = 2.3 CL = 1.9 – 2.6	1364	$\bar{x}$ = 4.5 CL = 3.7 – 5.4
C5	1361	$\bar{x}$ = 0.1 CL = 0.0 – 0.1	1362	$\bar{x}$ = 0.5 CL = 0.4 – 0.6	1363	$\bar{x}$ = 1.5 CL = 1.2 – 1.8	1364	$\bar{x}$ = 2.9 CL = 2.4 – 3.5
C5DC	1361	$\bar{x}$ = 0.1 CL = 0.0 – 0.1	1362	$\bar{x}$ = 0.6 CL = 0.4 – 0.7	1363	$\bar{x}$ = 1.0 CL = 0.8 – 1.2	1364	$\bar{x}$ = 2.4 CL = 1.9 – 2.9
C5OH	1361	$\bar{x}$ = 0.8 CL = 0.6 – 1.0	1362	$\bar{x}$ = 1.2 CL = 1.0 – 1.4	1363	$\bar{x}$ = 2.0 CL = 1.6 – 2.4	1364	$\bar{x}$ = 2.9 CL = 2.5 – 3.2
C6	1361	$\bar{x}$ = 0.0 CL = 0.0 – 0.0	1362	$\bar{x}$ = 0.5 CL = 0.4 – 0.6	1363	$\bar{x}$ = 0.9 CL = 0.7 – 1.2	1364	$\bar{x}$ = 2.2 CL = 1.9 – 2.5
C8	1361	$\bar{x}$ = 0.0 CL = 0.0 – 0.0	1362	$\bar{x}$ = 0.5 CL = 0.4 – 0.6	1363	$\bar{x}$ = 1.0 CL = 0.9 – 1.2	1364	$\bar{x}$ = 2.6 CL = 2.0 – 3.0
C10	1361	$\bar{x}$ = 0.0 CL = 0.0 – 0.0	1362	$\bar{x}$ = 0.5 CL = 0.4 – 0.6	1363	$\bar{x}$ = 1.0 CL = 0.8 – 1.2	1364	$\bar{x}$ = 2.5 CL = 2.1 – 3.0
C12	1361	$\bar{x}$ = 0.0 CL = 0.0 – 0.0	1362	$\bar{x}$ = 0.5 CL = 0.4 – 0.6	1363	$\bar{x}$ = 1.0 CL = 0.8 – 1.1	1364	$\bar{x}$ = 2.4 CL = 1.9 – 2.9
C14	1361	$\bar{x}$ = 0.1 CL = 0.0 – 0.1	1362	$\bar{x}$ = 0.6 CL = 0.4 – 0.7	1363	$\bar{x}$ = 1.6 CL = 1.3 – 1.9	1364	$\bar{x}$ = 3.2 CL = 2.4 – 3.9
C16	1361	$\bar{x}$ = 0.8 CL = 0.7 – 0.9	1362	$\bar{x}$ = 3.5 CL = 3.0 – 4.0	1363	$\bar{x}$ = 7.8 CL = 6.8 – 8.7	1364	$\bar{x}$ = 11.1 CL = 9.8 – 12.3
C16OH	1361	$\bar{x}$ = 0.0 CL = 0.0 – 0.0	1362	$\bar{x}$ = 0.1 CL = 0.0 – 0.1	1363	$\bar{x}$ = 0.2 CL = 0.2 – 0.2	1364	$\bar{x}$ = 0.4 CL = 0.3 – 0.4
C18	1361	$\bar{x}$ = 0.7 CL = 0.6 – 0.8	1362	$\bar{x}$ = 1.6 CL = 1.2 – 1.9	1363	$\bar{x}$ = 2.4 CL = 2.0 – 2.7	1364	$\bar{x}$ = 5.2 CL = 4.4 – 6.0

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 20 successive, independent measurements.

Reference: *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.*