National Conversation:
Tandem Mass Spectrometry in Newborn Screening

Quality Assurance & Quality Improvement

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February 6, 2015

NJ Health
New Jersey Department of Health

State of New Jersey
NEWBORN SCREENING

- **Quality Assurance (QA)** – all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality. **NOTE**: Quality assurance may be said to comprise internal quality assurance and external quality assurance and is interrelated with quality control.

- **Quality Control (QC)** – the operational techniques and activities that are used to fulfill requirements for quality.

- **Quality Indicators (QI)** - a metric that gives an indication of process or output quality and can be used to make comparisons across different Programs

Rejecting assays is not the purpose of quality control

Materials

- Source
  - In-house
  - Commercial vendor
    - Kit
    - Non-kit
    - CDC NSQAP
- Levels
  - Decision points
    - WNL
    - Abnormal

Method

- Analyte selection
  - *m/z* range
  - Classes
  - Acquisition modes
  - Internal standards
- Establishing laboratory range
  - Replicates ≥ 20 observations
  - Instrument to Instrument
- Frequency
  - ≥ 2 per plate

Sample
C0
C2
C3
C4
C4 SRM
C5
C5 SRM
C5DC
C6
C8
C10
C12
C14
C16
C16 SRM
C18
C18 SRM
CIT
LEU
MET
PHE
TYR
ARG
C3 IS INT
C4 IS INT
C16 IS INT
CIT IS INT
LEU IS INT
PHE IS INT

Method

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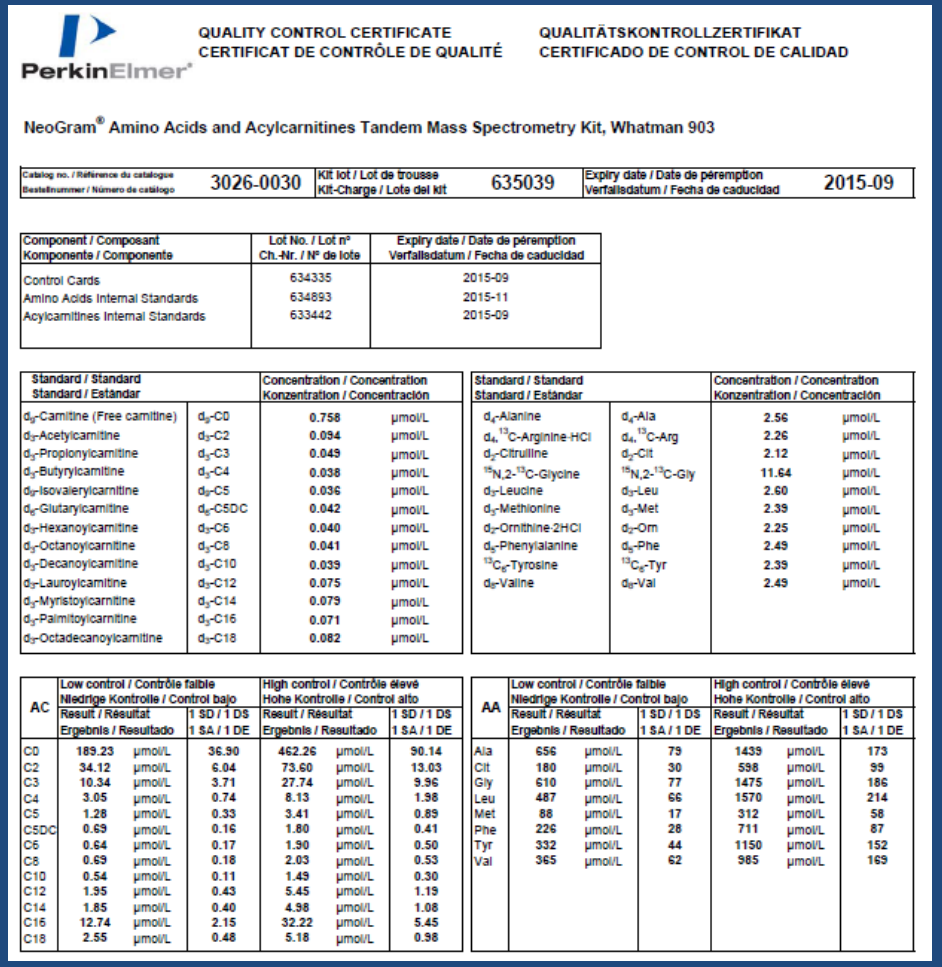

PerkinElmer

QUALITY CONTROL CERTIFICATE
CERTIFICAT DE CONTRÔLE DE QUALITÉ
QUALITÄTSKONTROLLZERTIFIKAT
CERTIFICADO DE CONTROL DE CALIDAD

NeoGram® Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Whatman 903

Catalog no. / Référence du catalogue / Bestellnummer / Número de catálogo	3026-0030	Kit lot / Lot de trousse / Kit-Charge / Lote del kit	635039	Expiry date / Date de péremption / Verfallsdatum / Fecha de caducidad	2015-09

Component / Composant / Komponente / Componente	Lot No. / Lot n° / Ch.-Nr. / N° de lote	Expiry date / Date de péremption / Verfallsdatum / Fecha de caducidad
Control Cards	634335	2015-09
Amino Acids Internal Standards	634893	2015-11
Acylcarnitines Internal Standards	633442	2015-09

Standard / Standard / Standard / Estándar		Concentration / Concentration / Konzentration / Concentración	
d_9-Carnitine (Free carnitine)	d_9-C0	0.758	µmol/L
d_3-Acetylcarnitine	d_3-C2	0.094	µmol/L
d_3-Propionylcarnitine	d_3-C3	0.049	µmol/L
d_3-Butyrylcarnitine	d_3-C4	0.038	µmol/L
d_9-Isovalerylcarnitine	d_9-C5	0.036	µmol/L
d_6-Glutarylcarnitine	d_6-C5DC	0.042	µmol/L
d_3-Hexanoylcarnitine	d_3-C6	0.040	µmol/L
d_3-Octanoylcarnitine	d_3-C8	0.041	µmol/L
d_3-Decanoylcarnitine	d_3-C10	0.039	µmol/L
d_3-Lauroylcarnitine	d_3-C12	0.075	µmol/L
d_3-Myristoylcarnitine	d_3-C14	0.079	µmol/L
d_3-Palmitoylcarnitine	d_3-C16	0.071	µmol/L
d_3-Octadecanoylcarnitine	d_3-C18	0.082	µmol/L

Standard / Standard / Standard / Estándar		Concentration / Concentration / Konzentration / Concentración	
d_4-Alanine	d_4-Ala	2.56	µmol/L
d_4,^{13}C-Arginine·HCl	d_4,^{13}C-Arg	2.26	µmol/L
d_2-Citrulline	d_2-Cit	2.12	µmol/L
^{15}N,2-^{13}C-Glycine	^{15}N,2-^{13}C-Gly	11.64	µmol/L
d_3-Leucine	d_3-Leu	2.60	µmol/L
d_3-Methionine	d_3-Met	2.39	µmol/L
d_2-Ornithine·2HCl	d_2-Orn	2.25	µmol/L
d_5-Phenylalanine	d_5-Phe	2.49	µmol/L
$^{13}C_6$-Tyrosine	$^{13}C_6$-Tyr	2.39	µmol/L
d_8-Valine	d_8-Val	2.49	µmol/L

AC	Low control / Contrôle faible / Niedrige Kontrolle / Control bajo			High control / Contrôle élevé / Hohe Kontrolle / Control alto		
	Result / Résultat / Ergebnis / Resultado		1 SD / 1 DS / 1 SA / 1 DE	Result / Résultat / Ergebnis / Resultado		1 SD / 1 DS / 1 SA / 1 DE
C0	189.23	µmol/L	36.90	462.26	µmol/L	90.14
C2	34.12	µmol/L	6.04	73.60	µmol/L	13.03
C3	10.34	µmol/L	3.71	27.74	µmol/L	9.96
C4	3.05	µmol/L	0.74	8.13	µmol/L	1.98
C5	1.28	µmol/L	0.33	3.41	µmol/L	0.89
C5DC	0.69	µmol/L	0.16	1.80	µmol/L	0.41
C6	0.64	µmol/L	0.17	1.90	µmol/L	0.50
C8	0.69	µmol/L	0.18	2.03	µmol/L	0.53
C10	0.54	µmol/L	0.11	1.49	µmol/L	0.30
C12	1.95	µmol/L	0.43	5.45	µmol/L	1.19
C14	1.85	µmol/L	0.40	4.98	µmol/L	1.08
C16	12.74	µmol/L	2.15	32.22	µmol/L	5.45
C18	2.55	µmol/L	0.48	5.18	µmol/L	0.98

AA	Low control / Contrôle faible / Niedrige Kontrolle / Control bajo			High control / Contrôle élevé / Hohe Kontrolle / Control alto		
	Result / Résultat / Ergebnis / Resultado		1 SD / 1 DS / 1 SA / 1 DE	Result / Résultat / Ergebnis / Resultado		1 SD / 1 DS / 1 SA / 1 DE
Ala	656	µmol/L	79	1439	µmol/L	173
Cit	180	µmol/L	30	598	µmol/L	99
Gly	610	µmol/L	77	1475	µmol/L	186
Leu	487	µmol/L	66	1570	µmol/L	214
Met	88	µmol/L	17	312	µmol/L	58
Phe	226	µmol/L	28	711	µmol/L	87
Tyr	332	µmol/L	44	1150	µmol/L	152
Val	365	µmol/L	62	985	µmol/L	169

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  - Replicates ≥ 20 observations
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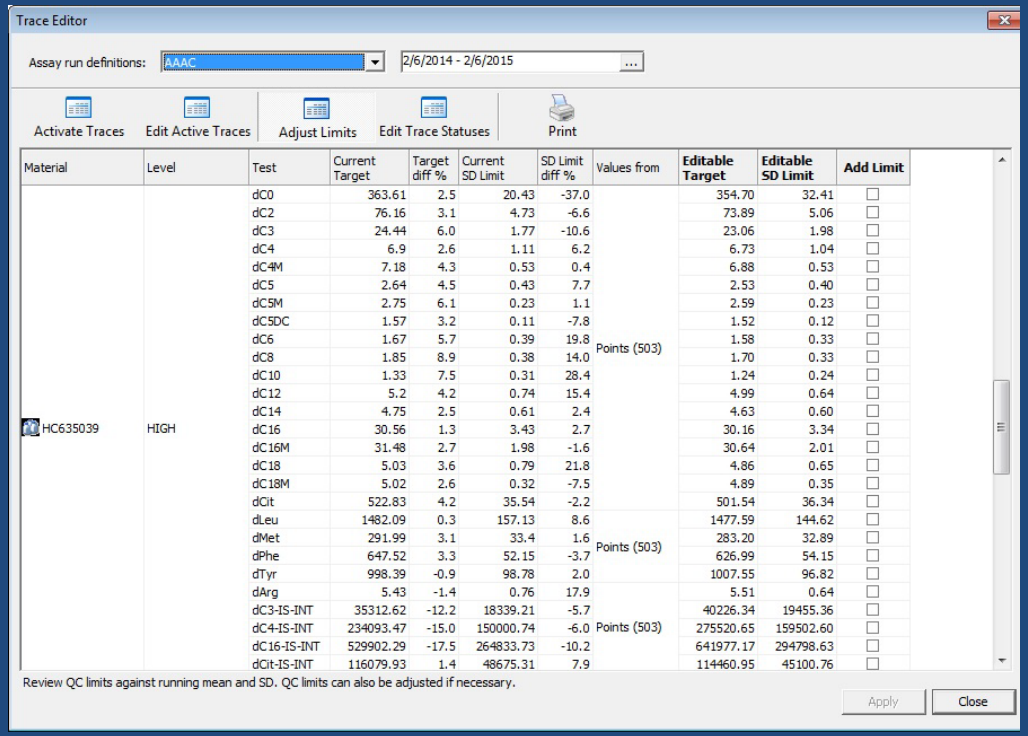
  - ≥ 2 per plate



Material	Level	Test	Current Target	Target diff %	Current SD Limit	SD Limit diff %	Values from	Editable Target	Editable SD Limit	Add Limit
		dC0	363.61	2.5	20.43	-37.0		354.70	32.41	
		dC2	76.16	3.1	4.73	-6.6		73.89	5.06	
		dC3	24.44	6.0	1.77	-10.6		23.06	1.98	
		dC4	6.9	2.6	1.11	6.2		6.73	1.04	
		dC4M	7.18	4.3	0.53	0.4		6.88	0.53	
		dC5	2.64	4.5	0.43	7.7		2.53	0.40	
		dC5M	2.75	6.1	0.23	1.1		2.59	0.23	
		dC5DC	1.57	3.2	0.11	-7.8		1.52	0.12	
		dC6	1.67	5.7	0.39	19.8	Points (503)	1.58	0.33	
		dC8	1.85	8.9	0.38	14.0		1.70	0.33	
		dC10	1.33	7.5	0.31	28.4		1.24	0.24	
		dC12	5.2	4.2	0.74	15.4		4.99	0.64	
		dC14	4.75	2.5	0.61	2.4		4.63	0.60	
HC635039	HIGH	dC16	30.56	1.3	3.43	2.7		30.16	3.34	
		dC16M	31.48	2.7	1.98	-1.6		30.64	2.01	
		dC18	5.03	3.6	0.79	21.8		4.86	0.65	
		dC18M	5.02	2.6	0.32	-7.5		4.89	0.35	
		dCit	522.83	4.2	35.54	-2.2		501.54	36.34	
		dLeu	1482.09	0.3	157.13	8.6		1477.59	144.62	
		dMet	291.99	3.1	33.4	1.6	Points (503)	283.20	32.89	
		dPhe	647.52	3.3	52.15	-3.7		626.99	54.15	
		dTyr	998.39	-0.9	98.78	2.0		1007.55	96.82	
		dArg	5.43	-1.4	0.76	17.9		5.51	0.64	
		dC3-IS-INT	35312.62	-12.2	18339.21	-5.7		40226.34	19455.36	
		dC4-IS-INT	234093.47	-15.0	150000.74	-6.0	Points (503)	275520.65	159502.60	
		dC16-IS-INT	529902.29	-17.5	264833.73	-10.2		641977.17	294798.63	
		dCit-IS-INT	116079.93	1.4	48675.31	7.9		114460.95	45100.76	

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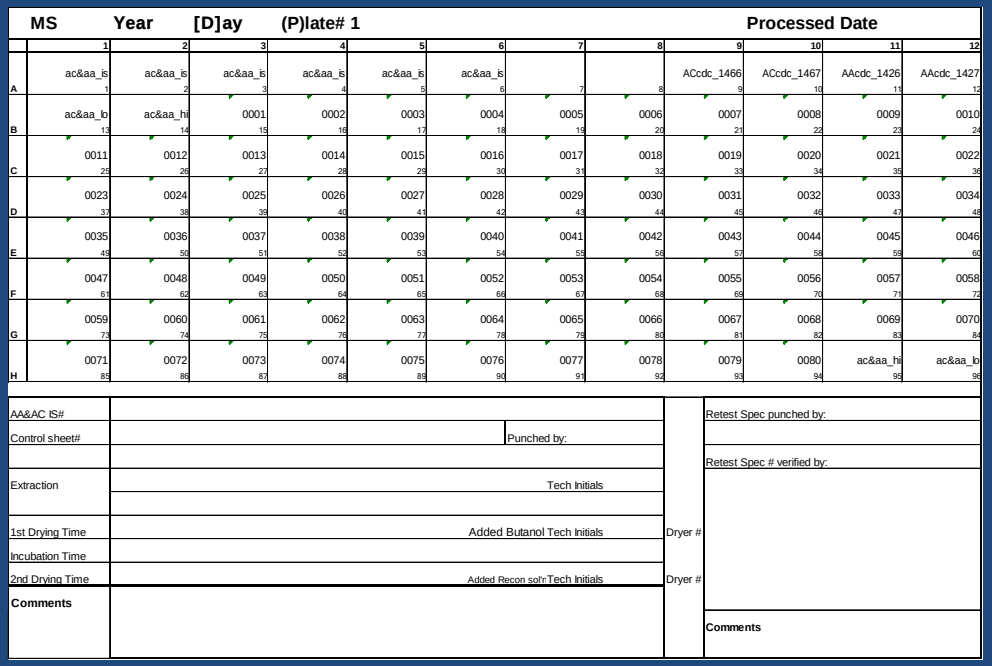

MS	Year	[D]ay	(P)late# 1					Processed Date			
1	2	3	4	5	6	7	8	9	10	11	12
A	ac&aa_is 1	ac&aa_is 2	ac&aa_is 3	ac&aa_is 4	ac&aa_is 5	ac&aa_is 6	7	8	ACcdc_1466 9	ACcdc_1467 10	AAcdc_1426 11	AAcdc_1427 12
B	ac&aa_lo 13	ac&aa_hi 14	0001 15	0002 16	0003 17	0004 18	0005 19	0006 20	0007 21	0008 22	0009 23	0010 24
C	0011 25	0012 26	0013 27	0014 28	0015 29	0016 30	0017 31	0018 32	0019 33	0020 34	0021 35	0022 36
D	0023 37	0024 38	0025 39	0026 40	0027 41	0028 42	0029 43	0030 44	0031 45	0032 46	0033 47	0034 48
E	0035 49	0036 50	0037 51	0038 52	0039 53	0040 54	0041 55	0042 56	0043 57	0044 58	0045 59	0046 60
F	0047 61	0048 62	0049 63	0050 64	0051 65	0052 66	0053 67	0054 68	0055 69	0056 70	0057 71	0058 72
G	0059 73	0060 74	0061 75	0062 76	0063 77	0064 78	0065 79	0066 80	0067 81	0068 82	0069 83	0070 84
H	0071 85	0072 86	0073 87	0074 88	0075 89	0076 90	0077 91	0078 92	0079 93	0080 94	ac&aa_hi 95	ac&aa_lo 96

AA&AC IS#				Retest Spec punched by:
Control sheet#		Punched by:		
				Retest Spec # verified by:
Extraction		Tech Initials		
1st Drying Time		Added Butanol Tech Initials	Dryer #	
Incubation Time				
2nd Drying Time		Added Recon sol'n Tech Initials	Dryer #	
Comments				Comments

Monitor & Corrective Action

- Acceptance Criteria
  - Modified Westgard
  - Controls
    - Individual vs. Multiple analytes
    - Individual vs. Multiple Controls
  - Patients
    - Mean
    - Median
- Frequency
- Trends
- Shifts

Sample	2015035P1-LOW1	2015035P1-LOW2	Range	2015035P1-HIGH1	2015035P1-HIGH2	Range
C0	139.46	157.12	(123.52 - 181.60)	358.85	342.54	(302.32 - 424.90)
C2	32.49	35.83	(29.79 - 42.99)	73.68	73.62	(61.97 - 90.35)
C3	8.33	9.44	(7.46 - 11.60)	23.56	22.56	(19.13 - 29.75)
C4	1.68	2.65	(1.39 - 4.09)	7.73	5.95	(3.57 - 10.23)
C4 MRM	2.31	2.63	(2.21 - 3.35)	6.68	6.27	(5.59 - 8.77)
C5	1.23	1.06	(0.50 - 1.58)	2.29	2.26	(1.35 - 3.93)
C5 MRM	0.94	1.05	(0.87 - 1.23)	2.49	2.55	(2.06 - 3.44)
C5DC	0.63	0.67	(0.48 - 0.72)	1.53	1.48	(1.24 - 1.90)
C6	0.42	0.63	(0.17 - 1.07)	2.19	1.46	(0.50 - 2.84)
C8	0.8	0.62	(0.24 - 1.08)	1.79	1.4	(0.71 - 2.99)
C10	0.55	0.49	(0.14 - 0.86)	1.28	0.61	(0.40 - 2.26)
C12	2.11	1.9	(1.08 - 2.82)	4.1	5.22	(2.98 - 7.42)
C14	1.99	2.19	(1.06 - 2.62)	3.65	5.43	(2.92 - 6.58)
C16	10.86	10.86	(8.09 - 17.09)	24.34	27.81	(20.27 - 40.85)
C16 MRM	11.7	13.62	(10.62 - 14.70)	31.59	29.63	(25.54 - 37.42)
C18	2.26	2.35	(1.59 - 3.33)	5.2	5.98	(2.66 - 7.40)
C18 MRM	2.36	2.56	(2.02 - 2.98)	4.87	4.67	(4.06 - 5.98)
CIT	161.82	174.12	(128.98 - 191.02)	526.25	509.94	(416.21 - 629.45)
LEU	379.78	575.87	(363.63 - 613.17)	1614.49	1485.48	(1010.70 - 1953.48)
MET	94.2	109.52	(54.32 - 112.76)	321.77	253.68	(191.79 - 392.19)
PHE	192.89	227.81	(167.78 - 254.48)	539.97	656.16	(491.07 - 803.97)
TYR	281.85	391.81	(215.61 - 389.97)	1107.64	999.54	(702.05 - 1294.73)
ARG	6.88	6.33	(3.36 - 7.08)	5.61	5.1	(3.15 - 7.71)

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State of New Jersey NEWBORN SCREENING

Monitor & Corrective Action

- Acceptance Criteria
  - Modified Westgard
  - Controls
    - Individual vs. Multiple analytes
    - Individual vs. Multiple Controls
  - Patients
    - Mean
    - Median
- Frequency
- Trends
- Shifts

Sample	2015035P1-LOW1	2015035P1-LOW2	Range	2015035P1-HIGH1	2015035P1-HIGH2	Range
C0	139.46	157.12	(123.52 - 181.60)	358.85	342.54	(302.32 - 424.90)
C2	32.49	35.83	(29.79 - 42.99)	73.68	73.62	(61.97 - 90.35)
C3	8.33	9.44	(7.46 - 11.60)	23.56	22.56	(19.13 - 29.75)
C4	1.68	2.65	(1.39 - 4.09)	7.73	5.95	(3.57 - 10.23)
C4 MRM	2.31	2.63	(2.21 - 3.35)	6.68	6.27	(5.59 - 8.77)
C5	1.23	1.06	(0.50 - 1.58)	2.29	2.26	(1.35 - 3.93)
C5 MRM	0.94	1.05	(0.87 - 1.23)	2.49	2.55	(2.06 - 3.44)
C5DC	0.63	0.67	(0.48 - 0.72)	1.53	1.48	(1.24 - 1.90)
C6	0.42	0.63	(0.17 - 1.07)	2.19	1.46	(0.50 - 2.84)
C8	0.8	0.62	(0.24 - 1.08)	1.79	1.4	(0.71 - 2.99)
C10	0.55	0.49	(0.14 - 0.86)	1.28	0.61	(0.40 - 2.26)
C12	2.11	1.9	(1.08 - 2.82)	4.1	5.22	(2.98 - 7.42)
C14	1.99	2.19	(1.06 - 2.62)	3.65	5.43	(2.92 - 6.58)
C16	10.86	10.86	(8.09 - 17.09)	24.34	27.81	(20.27 - 40.85)
C16 MRM	11.7	13.62	(10.62 - 14.70)	31.59	29.63	(25.54 - 37.42)
C18	2.26	2.35	(1.59 - 3.33)	5.2	5.98	(2.66 - 7.40)
C18 MRM	2.36	2.56	(2.02 - 2.98)	4.87	4.67	(4.06 - 5.98)
CIT	161.82	174.12	(128.98 - 191.02)	526.25	509.94	(416.21 - 629.45)
LEU	379.78	575.87	(363.63 - 613.17)	1614.49	1485.48	(1010.70 - 1953.48)
MET	94.2	109.52	(54.32 - 112.76)	321.77	253.68	(191.79 - 392.19)
PHE	192.89	227.81	(167.78 - 254.48)	539.97	656.16	(491.07 - 803.97)
TYR	281.85	389.96	(215.61 - 389.97)	1107.64	999.54	(702.05 - 1294.73)
ARG	6.88	6.33	(3.36 - 7.08)	5.61	5.1	(3.15 - 7.71)

Monitor & Corrective Action

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Sample	2015035P1-LOW1	2015035P1-LOW2	Range	2015035P1-HIGH1	2015035P1-HIGH2	Range
C0	139.46	157.12	(123.52 - 181.60)	358.85	342.54	(302.32 - 424.90)
C2	32.49	35.83	(29.79 - 42.99)	73.68	73.62	(61.97 - 90.35)
C3	8.33	9.44	(7.46 - 11.60)	23.56	22.56	(19.13 - 29.75)
C4	1.68	2.65	(1.39 - 4.09)	7.73	5.95	(3.57 - 10.23)
C4 MRM	2.31	2.63	(2.21 - 3.35)	6.68	6.27	(5.59 - 8.77)
C5	1.23	1.06	(0.50 - 1.58)	2.29	2.26	(1.35 - 3.93)
C5 MRM	0.94	1.05	(0.87 - 1.23)	2.49	2.55	(2.06 - 3.44)
C5DC	0.63	0.67	(0.48 - 0.72)	1.53	1.48	(1.24 - 1.90)
C6	0.42	0.63	(0.17 - 1.07)	2.19	1.46	(0.50 - 2.84)
C8	0.8	0.62	(0.24 - 1.08)	1.79	1.4	(0.71 - 2.99)
C10	0.55	0.49	(0.14 - 0.86)	1.28	0.61	(0.40 - 2.26)
C12	2.11	1.9	(1.08 - 2.82)	4.1	5.22	(2.98 - 7.42)
C14	1.99	2.19	(1.06 - 2.62)	3.65	5.43	(2.92 - 6.58)
C16	10.86	10.86	(8.09 - 17.09)	24.34	27.81	(20.27 - 40.85)
C16 MRM	11.7	13.62	(10.62 - 14.70)	31.59	29.63	(25.54 - 37.42)
C18	2.26	2.35	(1.59 - 3.33)	5.2	5.98	(2.66 - 7.40)
C18 MRM	2.36	2.56	(2.02 - 2.98)	4.87	4.67	(4.06 - 5.98)
CIT	161.82	174.12	(128.98 - 191.02)	526.25	509.94	(416.21 - 629.45)
LEU	379.78	575.87	(363.63 - 613.17)	1614.49	1485.48	(1010.70 - 1953.48)
MET	94.2	109.52	(54.32 - 112.76)	321.77	253.68	(191.79 - 392.19)
PHE	192.89	227.81	(167.78 - 254.48)	539.97	656.16	(491.07 - 803.97)
TYR	281.85	389.96	(215.61 - 389.97)	1107.64	999.54	(702.05 - 1294.73)
ARG	6.88	6.33	(3.36 - 7.08)	5.61	5.1	(3.15 - 7.71)

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DAILY QC CHECK
TEST RANGE -
TEST DATE -

Date MS#	Control	C0	C3	C4	C5DC	C8	C14	C16	CIT	LEU	MET	PHE	TYR	ARG	Comments
Plate ID	LOW-1														
	LOW-2														
RT	HIGH-1														
	HIGH-2														
MS#	LOW-1														
Plate ID	LOW-2														
	HIGH-1														
	HIGH-2														
	ACcdc 1466														
P1	ACcdc 1467														
	Aacdc 1426														
	Aacdc 1427														
	NB Median														
MS#	LOW-1														
Plate ID	LOW-2														
	HIGH-1														
	HIGH-2														
	NB Median														
MS#	LOW-1														
Plate ID	LOW-2														
	HIGH-1														
	HIGH-2														
	NB Median														
MS#	LOW-1														
Plate ID	LOW-2														
	HIGH-1														
	HIGH-2														
	NB Median														
MS#	LOW-1														
Plate ID	LOW-2														
	HIGH-1														
	HIGH-2														
	NB Median														

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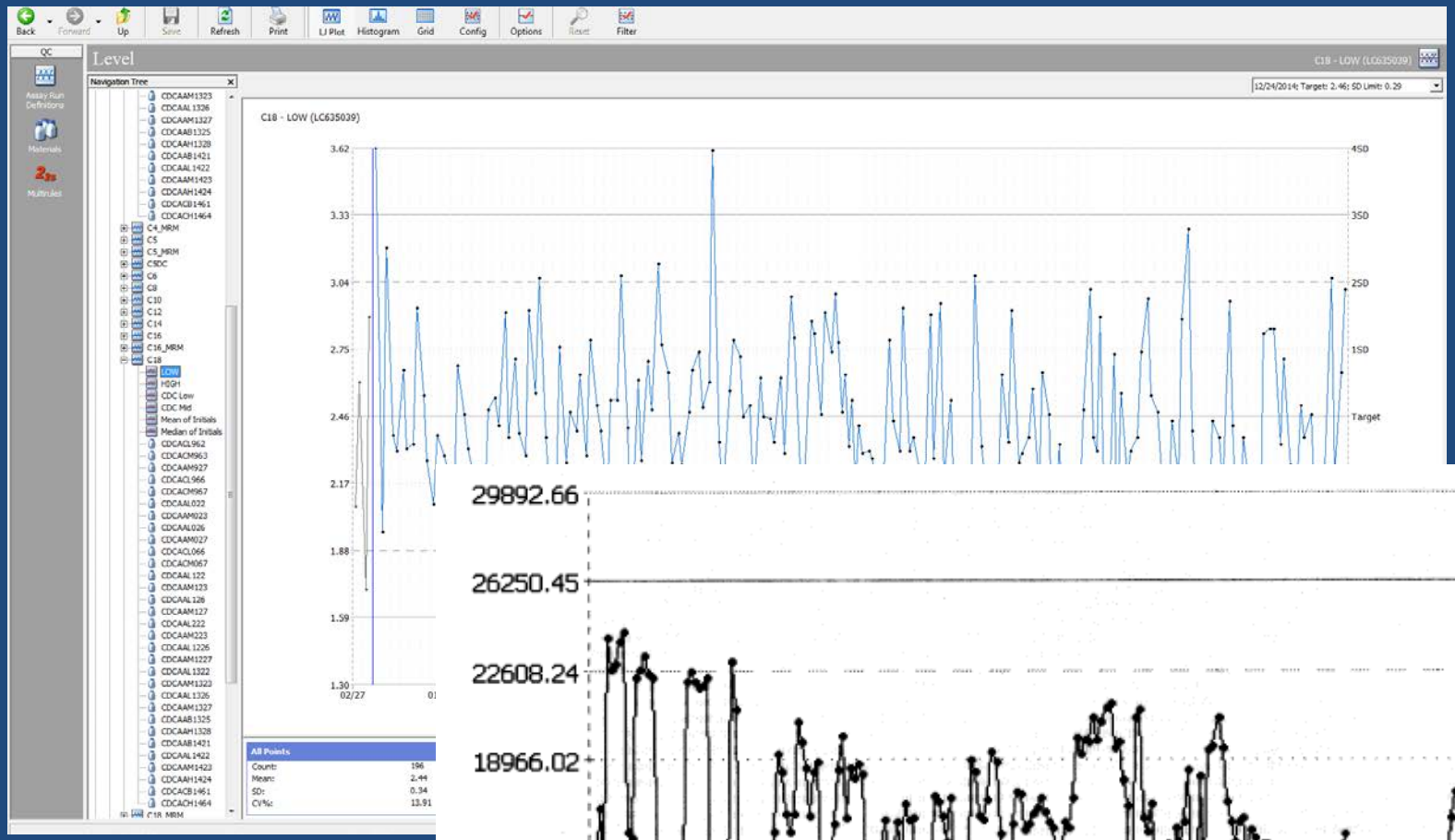
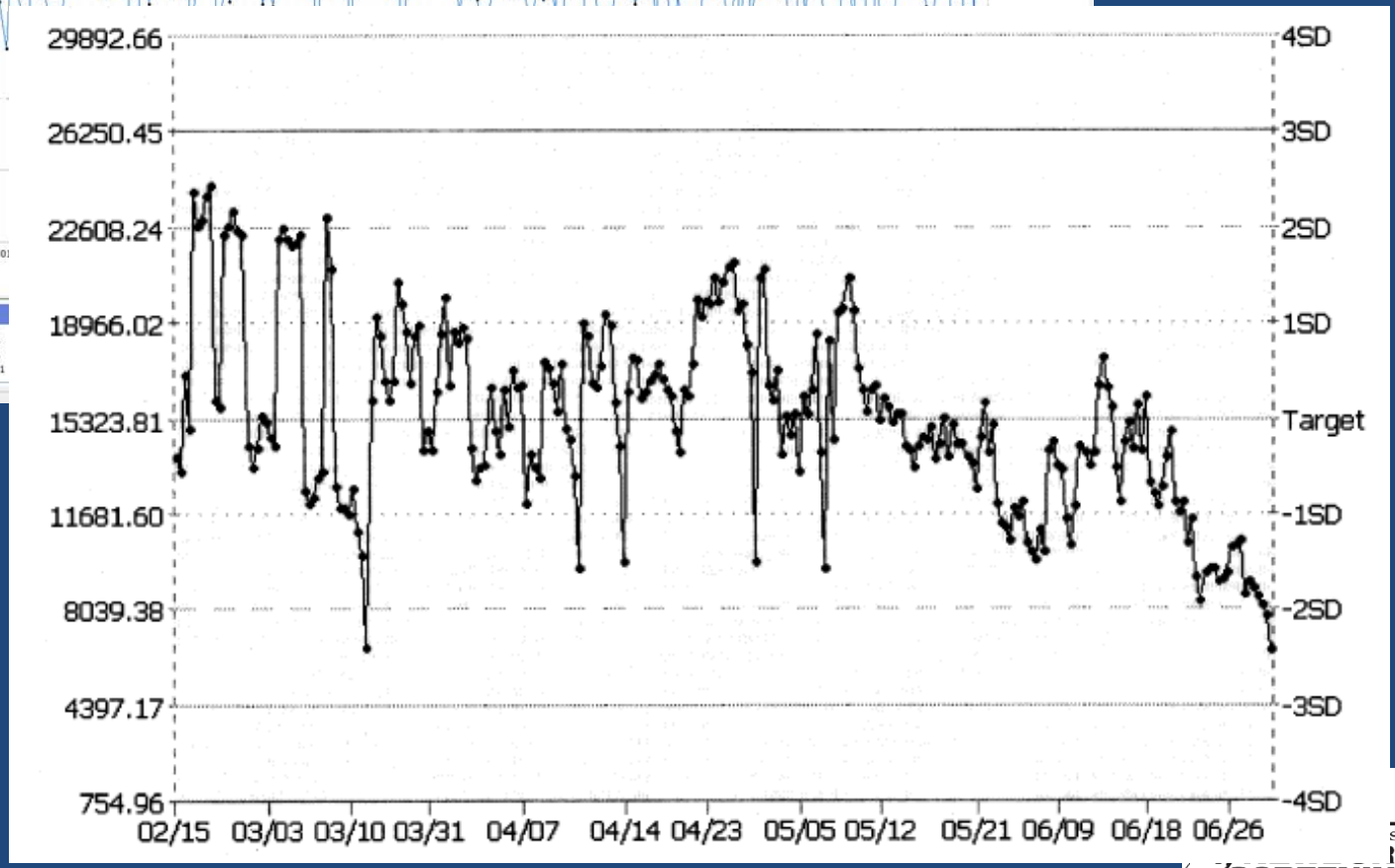
State of New Jersey NEWBORN SCREENING





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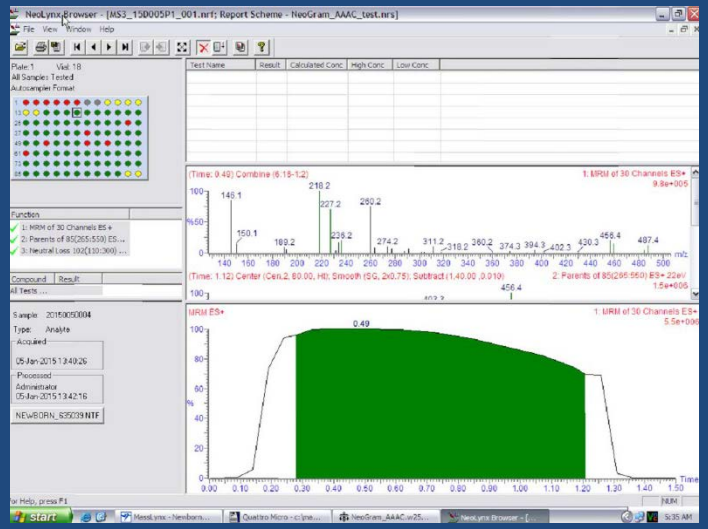
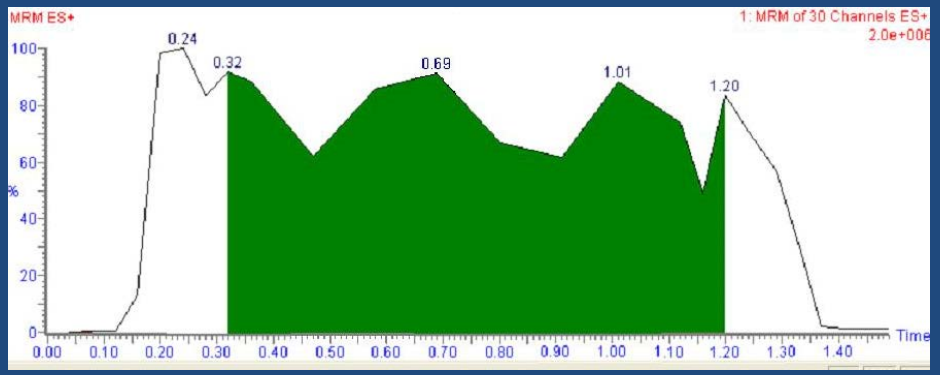
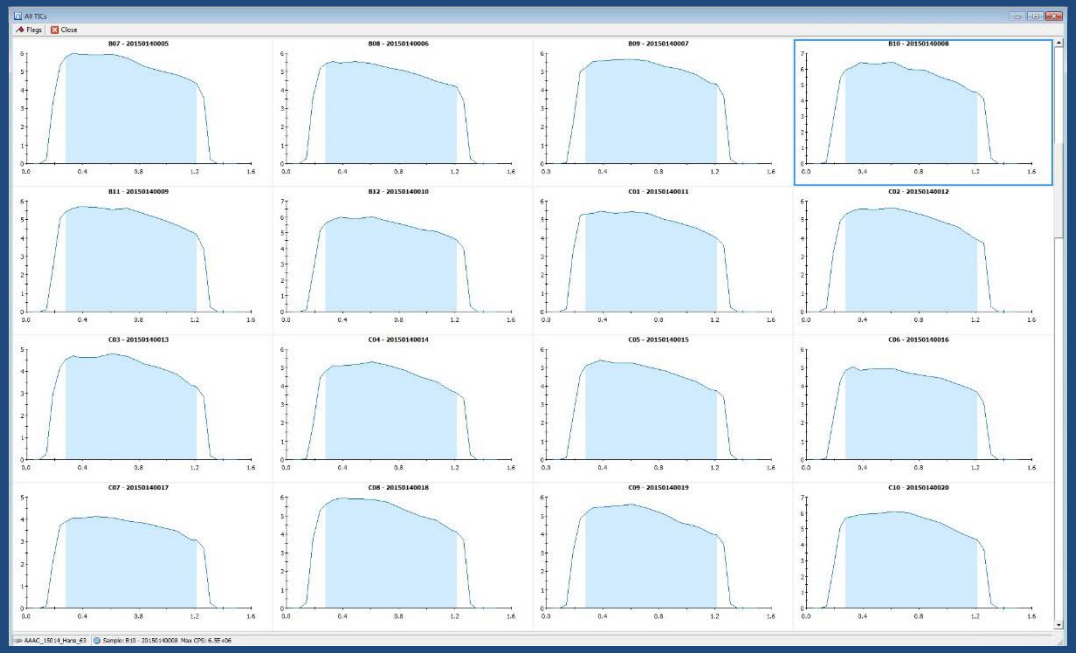
SCREENING

Total Ion Chromatograms







Cutoffs

- Frequency
- Percentiles
- Individual vs. Pattern

Analyte	Mean	SD	Median	UWL	UCL
C0 (low)	30.83	10.90	28.83		
C0 (high)				107.00	137.00
C0/(C16+C18)high	9.28	3.91	8.59	37.97	53.42
C0/(C16+C18)low					
C3	1.65	0.72	1.51	6.86	9.00
C3/C16 (R)	0.65	0.34	0.57	2.43	2.73
C3/C2 (R)	0.06	0.07	0.06	0.20	0.26
C3DC	0.08	0.03	0.08	0.22	0.30
C4	0.45	0.30	0.38	1.10	1.30
C4/C2 (R)	0.0110	0.0040	0.0100	0.04	0.07
C4/C3 (R)	0.16	0.08	0.14	0.76	0.94
C4OH	0.20	0.09	0.02	0.65	0.75
C4OH/C16	0.076	0.070	0.072	0.200	0.298
C5	0.14	0.08	0.12	0.70	0.90

Analyte	Previous Median	7/09 to 12/09 Median	Current Bord Value	Calculate Bord Value	Current Bord %ile	Calculate Bord %ile	Current Pre Value	Calculate Pre Value	Current Pre %ile	Calculate Pre %ile
Arg		9.87	100.00			0.9991	200.00			0.9998
C0 (low)		34.40	10.46		0.0007	0.0010	5.23		0.0005	0.0008
C0 (high)	35.30		107.00	103.09	0.9986	0.9989	137.00	128.02	0.9997	0.9998
C0/C16	12.59	12.12	32.87	38.02	0.9884	0.9838	66.84	76.99	0.9986	0.9975
C0/C18	43.97	43.99	100.00	106.45	0.9909	0.9878	170.00	182.18	0.9990	0.9987
C10:1	0.07	0.06	0.30	0.24	0.9988	0.9990	0.62	0.75	0.9995	0.9994

Accession Number	Baby Last Name	Birth Date	Birth Time	Birth Wt	Gender	Birth Order	Age collected	Mom Last Name	Mom First Name	Zip Code	Specimen Type	Cit	Phe	Phe/Tyr	Leu	Leu/Ala	Leu/Phe	Val	Met	Met/Phe	Tyr	C5	C5/C2	C5/C3	C5DC	C5DO/C16	C5OH	C6DC	C3MRM	C3/C2	C3/C16	C8DC	C5:1	C8	C10:1	C6	C8/C10	C8/C16	C14:1	C14	C14:2	C16:1	C14:1/C16	C14:1/C12:1	C4	C4/C2	C4/C3	C16OH	C16:1OH	C18OH
20111810001	MONDAY	6/28/2011	157	3420	1		24	MONDAY	LISA	8527	1	16.34	51.23	0.8	89.4	0.23	1.75	121.89	27.63	0.54	64.38	0.06	0	0.06	0.09	0.06	0.14	0.06	0.99	0.05	0.61	0.05	0.04	0.07	0.06	0.08	0.61	0.04	0.16	0.18	0.05	0.1	0.09	3.42	0.19	0.01	0.15	0.03	0.06	0.04
20111810002	MARTIN	6/28/2011	525	2075	2	1	25	MARTIN	DANIELLE	8022	1	25.45	68.42	0.64	122.39	0.28	1.8	143.96	49.35	0.72	106.9	0.15	0	0.1	0.13	0.06	0.16	0.09	1.36	0.05	0.65	0.13	0.02	0.07	0.07	0.06	0.95	0.04	0.22	0.22	0.09	0.16	0.13	3.54	0.28	0.01	0.15	0.04	0.08	0.04
20111810003	MARTIN	6/28/2011	526	2505	2	2	25	MARTIN	DANIELLE	8022	1	18.25	76.75	0.74	112.76	0.39	1.47	119.09	34.34	0.45	104.9	0.13	0	0.05	0.13	0.05	0.26	0.09	2.19	0.06	0.89	0.14	0.02	0.09	0.06	0.06	0.93	0.04	0.19	0.29	0.05	0.17	0.09	1.83	0.37	0.01	0.1	0.03	0.07	0.06
20111810004	DAVIS	6/27/2011	2307	2595	2		24	DAVIS	SHERI	8618	1	9.55	69.73	1.18	133.96	0.35	1.93	135.59	35.6	0.51	59.4	0.16	0.01	0.14	0.15	0.05	0.14	0.06	1.07	0.04	0.34	0.08	0.04	0.1	0.1	0.03	1.96	0.03	0.2	0.24	0.04	0.34	0.06	2.22	0.19	0.01	0.19	0.03	0.09	0.05
20111810005	JOHNSON	6/27/2011	1900	3705	1		29	JOHNSON	HILLARY	8505	1	13.46	55.49	1.14	133.58	0.48	2.42	121.81	35.74	0.65	48.8	0.1	0.01	0.13	0.08	0.05	0.16	0.04	0.89	0.05	0.51	0.06	0.01	0.08	0.06	0.12	1.12	0.05	0.1	0.14	0.06	0.08	0.06	4.49	0.33	0.01	0.21	0.01	0.05	0.02
20111810006	GRAY	6/27/2011	1532	3965	1		29	GRAY	SAMARA	19020	1	36.48	69.67	0.6	89.43	0.27	1.29	120.91	30.45	0.44	117.58	0.09	0	0.09	0.14	0.05	0.06	0.11	1.01	0.05	0.37	0.09	0.05	0.12	0.08	0.06	1.06	0.04	0.19	0.22	0.03	0.29	0.07	0.84	0.32	0.01	0.26	0.06	0.07	0.06
20111810007	BROWN	6/27/2011	916	3220	1		25	BROWN	CHARDAE	8619	1	17.27	52.28	0.61	64.51	0.27	1.24	64.98	29.4	0.56	86.6	0.09	0	0.11	0.1	0.06	0.21	0.06	0.73	0.05	0.44	0.08	0.03	0.05	0.03	0.07	0.44	0.02	0.11	0.23	0.04	0.19	0.05	1.17	0.17	0.01	0.19	0.05	0.06	0.03
20111810008	RYNESS	6/21/2011	1556	3674	1		141	RYNESS	MEREDITH	8540	1	12.77	45.47	0.25	149.25	0.6	3.29	147.04	20.84	0.46	183.47	0.14	0.01	0.13	0.03	0.02	0.11	0.04	0.85	0.06	0.58	0.04	0.02	0.03	0.05	0.05	0.61	0.02	0.1	0.24	0.03	0.09	0.07	3.44	0.3	0.01	0.19	0.02	0.08	0.02
20111810009	AMES	6/29/2011	18	3277	1		2	AMES	ANDREA	8232	1	20.25	79.13	1.1	134.43	0.21	1.71	151.29	38.28	0.49	71.97	0.18	0.01	0.11	0.12	0.05	0.51	0.07	1.36	0.06	0.54	0.08	0.03	0.07	0.01	0.05	0.7	0.03	0.13	0.23	0.11	0.22	0.05	1.57	0.3	0.01	0.23	0.08	0.17	0
20111810010	JONES	6/27/2011	1241	3733	2		41	JONES	MILKAMARY	8226	1	19.62	54.44	0.33	109.29	0.42	2.02	110.17	22.27	0.41	164.52	0.1	0	0.08	0.15	0.05	0.15	0.13	1.83	0.05	0.58	0.1	0.04	0.04	0.06	0.12	0.43	0.01	0.28	0.5	0.08	0.3	0.07	3.15	0.48	0.01	0.19	0.11	0.06	0.05
20111810011	WARD	6/27/2011	1048	3767	1		44	WARD	RACHEL	8210	1	17.7	48.07	0.64	86.83	0.42	1.81	81.12	13.78	0.29	75.97	0.07	0	0.08	0.17	0.05	0.09	0.15	1.07	0.04	0.34	0.09	0.02	0.07	0.11	0.13	0.5	0.02	0.34	0.32	0.07	0.28	0.1	2.01	0.14	0.01	0.15	0.04	0.02	0.02
20111810012	PAUL	6/27/2011	1503	3020	1		39	PAUL	DANIELLE A	8094	1	17.72	55.87	0.75	116.88	0.54	2.1	131.49	22.98	0.41	75.12	0.18	0	0.06	0.17	0.04	0.12	0.11	2.09	0.06	0.48	0.09	0.02	0.12	0.09	0.08	1.28	0.03	0.33	0.35	0.05	0.4	0.07	1.64	0.24	0.01	0.15	0.05	0.12	0.04
20111810013	TOTARO	6/27/2011	1748	3925	2		34	TOTARO	CARRIE	8822	1	20.03	47.56	0.53	90.18	0.41	1.9	101.49	21.34	0.45	90.68	0.15	0.01	0.07	0.1	0.03	0.11	0.09	1.67	0.08	0.57	0.06	0.02	0.03	0.01	0.04	0.54	0.01	0.1	0.26	0.04	0.21	0.04	1.53	0.23	0.01	0.14	0.05	0.06	0.01
20111810014	BRUNO	6/27/2011	2006	2470	1		31	BRUNO	KERRI	8844	1	9.76	58.35	0.61	86.5	0.29	1.49	92.61	36.29	0.62	96.29	0.09	0	0.13	0.2	0.07	0.09	0.1	0.87	0.04	0.3	0.08	0.03	0.17	0.12	0.08	0.75	0.06	0.25	0.38	0.09	0.31	0.09	1.09	0.2	0.01	0.21	0.06	0.08	0.03
20111810015	GALEK	6/27/2011	2316	2320	2		28	GALEK	MICHELE	7090	1	10.57	39.64	0.31	79.37	0.4	2.01	67.45	21	0.53	129.34	0.17	0	0.07	0.17	0.05	0.16	0.12	1.61	0.06	0.52	0.13	0.08	0.1	0.13	0.04	0.79	0.04	0.32	0.29	0.03	0.25	0.12	1.27	0.29	0.01	0.2	0.07	0.08	0.07
20111810016	CABRERA	6/27/2011	2356	3385	2		28	CABRERA	JULIA	7924	1	24.62	69.7	0.54	108.62	0.28	1.56	97.74	40.39	0.58	130.48	0.22	0.01	0.13	0.16	0.06	0.18	0.08	1.57	0.06	0.59	0.08	0.06	0.09	0.06	0.11	1.29	0.04	0.14	0.18	0.04	0.19	0.06	1.39	0.2	0.01	0.13	0.02	0.06	0.01
20111810017	CHARD	6/27/2011	1419	4105	1		35	CHARD	LAURA	8069	1	12.61	53.84	1.1	94.21	0.42	1.76	92.58	26.28	0.49	49	0.09	0	0.04	0.13	0.05	0.1	0.1	1.83	0.08	0.69	0.1	0.03	0.1	0.07	0.05	2.1	0.05	0.14	0.28	0.04	0.17	0.07	1.48	0.3	0.01	0.1	0.06	0.03	0.03
20111810018	LOSI	6/27/2011	2300	3600	1		30	LOSI-PETERSON	TINA	8722	1	16.54	51.79	1.14	60.16	0.24	1.17	79.33	23.7	0.46	45.51	0.09	0	0.06	0.1	0.02	0.07	0.06	1.3	0.05	0.34	0.05	0.06	0.06	0.08	0.08	1.56	0.01	0.09	0.19	0.05	0.25	0.02	2.11	0.27	0.01	0.15	0.06	0.09	0.02
20111810019	MAGNUSON	6/27/2011	1226	2833	2		41	MAGNUSON	MINDY	8741	1	18.52	45.08	0.72	98.18	0.33	2.19	76.2	31.85	0.71	62.78	0.08	0	0.07	0.12	0.04	0.18	0.11	1.5	0.04	0.44	0.08	0.01	0.11	0.06	0.07	1.58	0.03	0.16	0.34	0.04	0.47	0.04	4.87	0.18	0	0.11	0.03	0.05	0.03
20111810020	CRANE	6/27/2011	832	4692	2		45	CRANE	MARIA	8753	1	11.28	47.98	0.74	93.52	0.33	1.96	124.27	28.92	0.6	65.09	0.08	0	0.07	0.07	0.03	0.17	0.08	1.43	0.04	0.51	0.07	0.06	0.13	0.04	0.06	1.83	0.04	0.11	0.19	0.04	0.28	0.04	0.8	0.16	0.01	0.12	0	0.1	0.03
20111810021	DUBLIN	6/27/2011	2323	832	1		2	DUBLIN	SONIA	7305	1	10.6	69.33	0.84	153.72	0.48	2.23	209.99	28.07	0.41	83.29	0.37	0.01	0.17	0.09	0.07	0.2	0.04	1.74	0.08	1.39	0.05	0.04	0.05	0.03	0.05	1.09	0.03	0.08	0.15	0.02	0.12	0.05	1.82	0.56	0.03	0.37	0.05	0.05	0
20111810022	GALAN	6/26/2011	1438	3290	2		41	GALAN	DAMARIS	7307	1	14.99	59.86	0.76	122.55	0.34	2.06	127.58	25.25	0.42	78.69	0.19	0	0.05	0.08	0.06	0.21	0.06	1.5	0.08	1.07	0.03	0.01	0.03	0.05	0.14	0.51	0.02	0.13	0.21	0.02	0.06	0.1	12.93	0.23	0.01	0.14	0.02	0.05	0.01
20111810023	RILEY	6/27/2011	1355	3445	2		42	RILEY	ROCHELLE	8070	1	18.93	51.81	0.48	83.99	0.31	1.63	99	20.99	0.41	108.64	0.07	0	0.06	0.1	0.05	0.08	0.15	1.17	0.05	0.55	0.1	0.02	0.06	0.08	0.01	0.77	0.03	0.08	0.21	0.02	0.21	0.04	2.95	0.21	0	0.1	0.02	0.02	0.02
20111810024	SEKKAH	6/27/2011	2207	3125	1		4	SEKKAH	ZOUBIDA	7050	1	30.49	75.39	1.09	125.57	0.17	1.67	148.23	34.45	0.46	69.38	0.17	0	0.05	0.12	0.03	0.2	0.05	3.2	0.08	0.72	0.07	0.02	0.05	0.04	0.1	0.53	0.01	0.16	0.39	0.06	0.21	0.04	2.72	0.5	0.01	0.14	0.07	0.13	0.05
20111810025	HALL	6/27/2011	1419	3400	1		24	HALL	ALISHA	7103	1	18.69	66.17	0.86	94.94	0.39	1.44	85.98	31.03	0.47	77.51	0.1	0	0.14	0.17	0.04	0.51	0.08	0.92	0.03	0.2	0.16	0.04	0.09	0.1	0.05	0.68	0.02	0.18	0.54	0.05	0.3	0.03	1.2	0.25	0.01	0.3	0.11	0.1	0.06
20111810026	MARTINEZ	6/27/2011	800	3225	2		24	MARTINEZ	REINA	7105	1	18.73	66.95	0.49	110.2	0.2	1.65	141.01	51.36	0.77	136.94	0.23	0	0.04	0.13	0.03	0.25	0.08	4.15	0.11	0.91	0.09	0.04	0.05	0.1	0.08	0.89	0.01	0.2	0.29	0.06	0.35	0.05	1.79	0.42	0.01	0.07	0.04	0.1	0.01
20111810027	CRANK	6/27/2011	733	3155	1		24	CRANK	PORSCHA	7103	1	19.58	76.23	0.77	123.12	0.34	1.62	128.49	40.88	0.54	99.76	0.45	0.01	0.3	0.1	0.02	0.2	0.09	1.06	0.04	0.25	0.12	0.05	0.11	0.04	0.13	1	0.02	0.13	0.5	0.06	0.16	0.03	1.22	0.24	0.01	0.24	0.05	0.08	0.02
20111810028	FROST	6/27/2011	1442	3466	2		27	FROST	SJOKIAH	7102	1	15.03	58.59	1.01	92.1	0.24	1.58	92.16	26.78	0.46	58.1	0.11	0.01	0.1	0.11	0.03	0.33	0.07	1.57	0.06	0.48	0.08	0.02	0.09	0.04	0.08	0.76	0.03	0.19	0.21	0.07	0.24	0.06	1.44	0.44	0.01	0.24	0.02	0.02	0
20111810029	BONILLA	6/27/2011	1554	3180	2		24	BONILLA-RIVAS	MAYRA	7104	1	21.08	58.58	0.66	106.47	0.24	1.82	122.57	32.14	0.55	89.6	0.1	0	0.04	0.12	0.04	0.19	0.08	2.69	0.09	0.98	0.07	0.03	0.07	0.06	0.1	1.71	0.03	0.14	0.3	0.06	0.2	0.05	2.1	0.27	0.01	0.08	0.05	0.04	0.04
20111810030	PACHECO	6/27/2011	1957	3080	2		36	PACHECO	ENRIQUETA	8753	1	23.14	53.9	0.85	120.62	0.29	2.25	88.77	29.82	0.56	63.89	0.08	0	0.07	0.06	0.02	0.25	0.1	1.26	0.04	0.38	0.06	0.05	0.14	0.06	0.07	2.31	0.05	0.07	0.24	0.04	0.29	0.03	1.59	0.23	0	0.14	0.06	0.05	0.01
20111810031	OSORIO	6/28/2011	114	3080	2		30	OSORIO	LUISA	8701	1	14.42	47.61	0.68	56.83	0.27	1.2	56.48	27.66	0.58	70.81	0.1	0	0.05	0.06	0.03	0.11	0.05	0.68	0.05	0.34	0.05	0.05	0.04	0.02	0.02	1.02	0.02	0.08	0.17	0.03	0.18	0.04	1.43	0.09	0.01	0.16	0.11	0.02	0.07
20111810032	NUSSBAUM	6/27/2011	1443	3160	1		29	NUSSBAUM	RATZEL	8701	1	20.91	41.45	0.62	75.57	0.31	1.83	70.11	32.84	0.79	67.04	0.12	0	0.05	0.12	0.03	0.13	0.09	1.45	0.06	0.35	0.09	0.01	0.14	0.13	0.07	1.3	0.03	0.28	0.42	0.08	0.31	0.07	1.64	0.23	0.01	0.12	0.06	0.09	0.05
20111810033	MORALES	6/27/2011	902	3250	1		37	MORALES	ANA	8701	1	17.96	52.21	1.15	115.66	0.4	2.22	98.42	23.15	0.44	45.6	0.14	0	0.07	0.08	0.02	0.17	0.1	1.75	0.06	0.5	0.08	0.03	0.09	0.09	0.05	1.34	0.03	0.23	0.33	0.07	0.25	0.07	2.43	0.41	0.01	0.21	0.06	0.09	0.01
20111810034	BERGER	6/27/2011	2005	4000	1		36	BERGER	JACQUELINE	8701	1	13.56	48.94	0.69	94.47	0.36	1.94	76.95	27.57	0.57	71.23	0.13	0	0.07	0.08	0.02	0.16	0.08	1.81	0.06	0.48	0.08	0.04	0.07	0.06	0.05	1.32	0.02	0.1	0.28	0.03	0.23	0.03	1.63	0.31	0.01	0.17	0.07	0.05	0.02

Specimen Type	Cit	Phe	Phe/Tyr	Leu	Leu/Ala	Leu/Phe	Val	Met	Met/Phe	Tyr	C5
1	16.34	51.23	0.8	89.4	0.23	1.75	121.89	27.63	0.54	64.38	0.06
1	25.45	68.42	0.64	122.39	0.28	1.8	143.96	49.35	0.72	106.9	0.15
1	18.25	76.75	0.74	112.76	0.39	1.47	119.09	34.34	0.45	104.9	0.13
1	9.55	69.73	1.18	133.96	0.35	1.93	135.59	35.6	0.51	59.4	0.16
1	13.46	55.49	1.14	133.58	0.48	2.42	121.81	35.74	0.65	48.8	0.1
1	36.48	69.67	0.6	89.43	0.27	1.29	120.91	30.45	0.44	117.58	0.09
1	17.27	52.28	0.61	64.51	0.27	1.24	64.98	29.4	0.56	86.6	0.09
1	12.77	45.47	0.25	149.25	0.6	3.29	147.04	20.84	0.46	183.47	0.14
1	20.25	79.13	1.1	134.43	0.21	1.71	151.29	38.28	0.49	71.97	0.18
1	19.62	54.44	0.33	109.29	0.42	2.02	110.17	22.27	0.41	164.52	0.1

NJ Health
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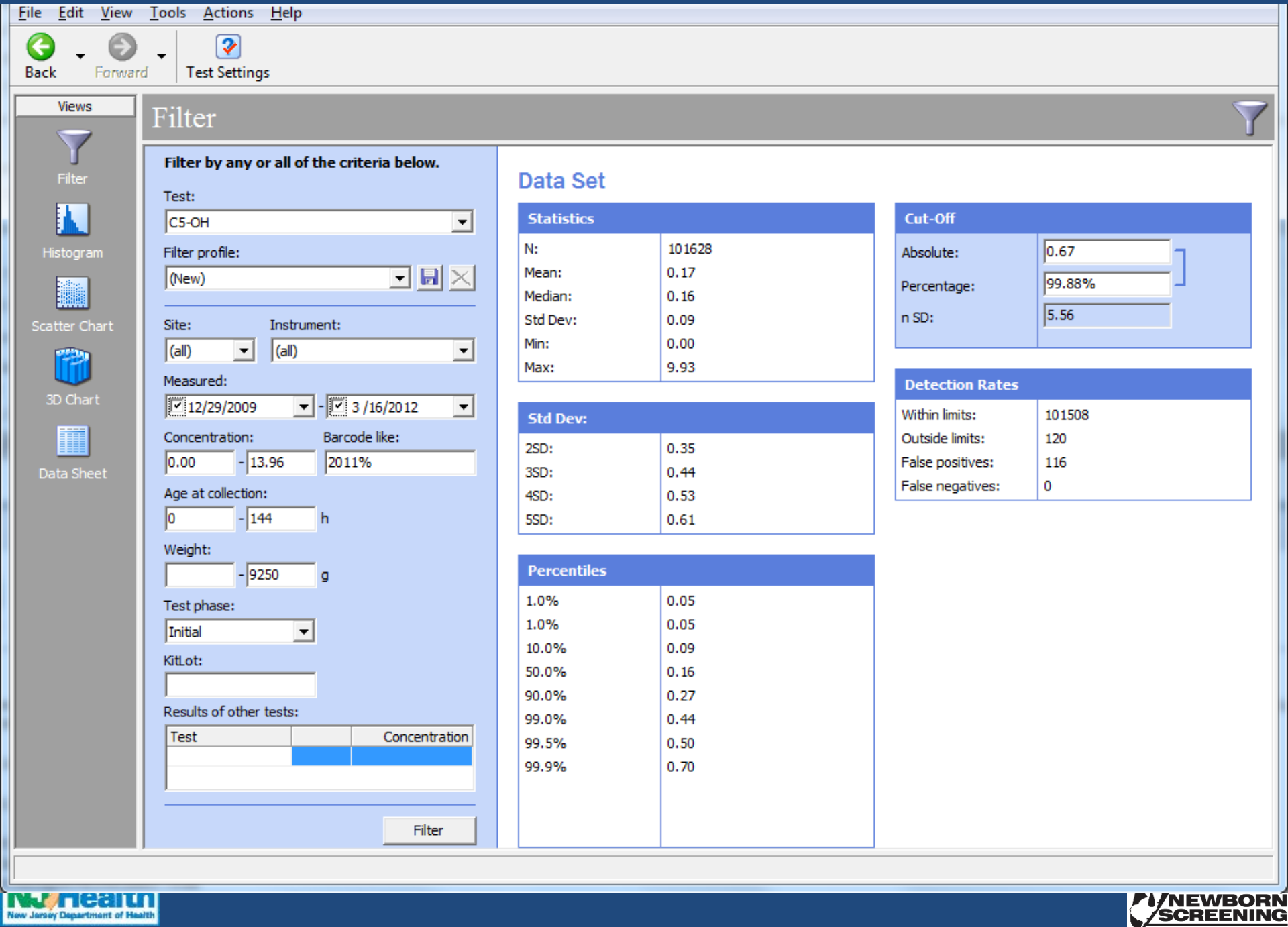
State of New Jersey
NEWBORN SCREENING


File Edit View Tools Actions Help
Back
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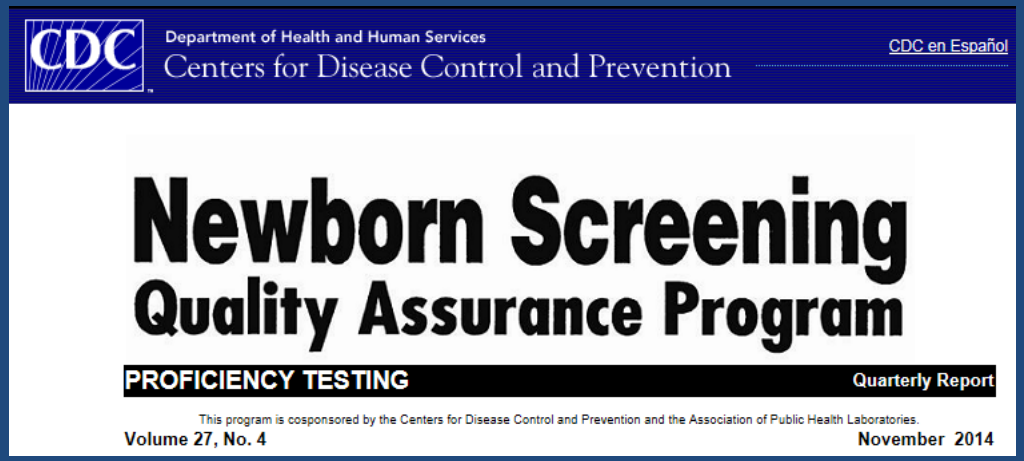
Test Settings
Views
Filter
Histogram
Scatter Chart
3D Chart
Data Sheet
Filter
Filter by any or all of the criteria below.
Test:
C5-OH
Filter profile:
(New)
Site:
(all)
Instrument:
(all)
Measured:
12/29/2009
3 /16/2012
Concentration:
0.00
13.96
Barcode like:
2011%
Age at collection:
0
144
h
Weight:
9250
g
Test phase:
Initial
KitLot:
Results of other tests:
Test
Concentration
Filter
Data Set
Statistics
N: 101628
Mean: 0.17
Median: 0.16
Std Dev: 0.09
Min: 0.00
Max: 9.93
Std Dev:
2SD: 0.35
3SD: 0.44
4SD: 0.53
5SD: 0.61
Percentiles
1.0% 0.05
1.0% 0.05
10.0% 0.09
50.0% 0.16
90.0% 0.27
99.0% 0.44
99.5% 0.50
99.9% 0.70
Cut-Off
Absolute: 0.67
Percentage: 99.88%
n SD: 5.56
Detection Rates
Within limits: 101508
Outside limits: 120
False positives: 116
False negatives: 0

Proficiency Testing

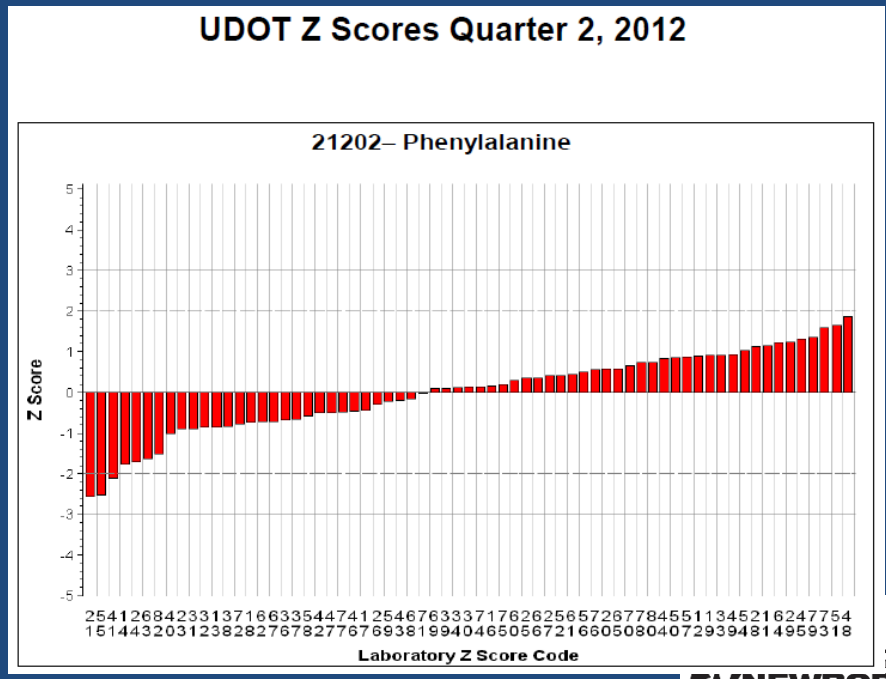
- External
- Internal
- Specimen exchange



Newborn Screening Quality Assurance Program
UDOT Statistics - Mean Concentration by Method
Year: 2012 Quarter: 2

Specimen No. 21206		C16OH		
		Expected Value 0.80 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	23	0.55	0.12
35	Deriv-MS/MS PE NeoGram MS2 Kit	12	0.50	0.05
60	Non-deriv MS/MS PE NeoBase Kit	19	0.41	0.04

Specimen No. 21207		Cit		
		Expected Value 165.16 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	22	106.49	29.40
35	Deriv-MS/MS PE NeoGram MS2 Kit	13	156.36	15.43
60	Non-deriv MS/MS PE NeoBase Kit	21	143.20	14.22



Overall Statistics

(Calculations based on All Labs, All Methods)

Year: 2014 Quarter: 4

Acylcarnitines

Specimen 41461	C0(L)	C3	C3DC	C3DC+ C4OH	C4	C4OH	C5	C5:1	C5DC	C5OH	C6
N*	272	255	131	85	243	115	267	231	273	246	243
Outliers	7	18	2	7	12	4	15	17	4	8	18
Mean	45.36	2.35	2.64	0.75	0.39	0.21	0.18	0.03	1.47	0.49	0.05
UL (95%)	62.18	3.03	5.16	1.62	0.55	0.42	0.26	0.07	2.65	0.75	0.09
LL (95%)	28.54	1.66	0.12	0.00	0.23	0.00	0.11	0.00	0.29	0.22	0.00

Specimen 41462	C0(L)	C3	C3DC	C3DC+ C4OH	C4	C4OH	C5	C5:1	C5DC	C5OH	C6
N*	267	255	125	85	240	112	266	235	264	249	245
Outliers	12	18	8	7	15	7	16	13	13	5	16
Mean	45.57	2.34	0.07	0.13	0.38	0.14	0.18	0.03	0.11	0.50	0.05
UL (95%)	60.87	3.00	0.15	0.28	0.51	0.26	0.24	0.07	0.22	0.75	0.10
LL (95%)	30.27	1.68	0.00	0.00	0.25	0.03	0.12	0.00	0.00	0.25	0.00

	31351						31352					
	Mean	LL	UL	SD	Rep Value	SDI	Mean	LL	UL	SD	Rep Value	SDI
PHE	43.90	24.81	62.98	9.54	38.34	-1	71.19	38.06	104.32	16.57	63.37	0
LEU	115.99	73.68	158.31	21.16	84.73	-1	167.53	103.85	231.22	31.85	130.22	-1
MET	20.53	13.37	27.69	3.58	20.80	0	247.10	166.82	327.38	40.14	238.32	0
TYR	49.52	34.55	64.49	7.49	53.35	1	720.81	533.62	908.00	93.60	671.14	-1
CIT	153.75	102.46	205.05	25.65	164.09	0	20.31	12.53	28.09	3.89	21.30	0
ARG	199.57	38.35	360.79	80.61	295.07	1	9.08	0.39	17.77	4.35	9.19	0

	31361						31362					
	Mean	LL	UL	SD	Rep Value	SDI	Mean	LL	UL	SD	Rep Value	SDI
C0	22.35	13.94	30.76	4.21	31.93	2	36.92	10.79	23.79	-6.57	46.61	-1
C3	1.79	1.20	2.37	0.29	1.48	-1	1.64	0.93	1.86	0.11	1.26	-3
C3DC	0.07	0.00	0.15	0.04	0.06	0	0.08	0.00	0.09	0.01	0.07	-2
C4	0.14	0.02	0.26	0.06	0.00	-2	0.15	0.02	0.37	0.11	0.07	-1
C4OH	0.08	0.01	0.15	0.04	0.07	0	0.09	0.04	0.18	0.05	0.08	0
C5	0.08	0.03	0.13	0.03	0.03	-2	0.11	0.03	0.14	0.02	0.11	0
C5:1	0.02	0.00	0.07	0.03	0.02	0	0.03	0.00	0.06	0.02	0.10	5
C5DC	0.09	0.00	0.19	0.05	0.06	-1	0.09	0.00	0.10	0.01	0.07	-4
C5OH	0.38	0.18	0.58	0.10	0.32	-1	0.72	0.23	0.74	0.01	0.63	-9

MS/MS COLLABORATIVE PROJECT

Region4 Genetics Collaborative

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MS/MS **Welcome: Scott Shone**

EDUCATIONAL PRESENTATIONS

Hot Topics **NEW!** — A 2013 series of 7 presentations recorded by Mayo Medical Laboratories describing the products and clinical tools of the R4S collaborative project

POST-ANALYTICAL INTERPRETIVE TOOLS

Post-Analytical Tools — Calculate a condition-specific score for a case based on all clinically significant analytes and ratios

CURRENT DATA POSTED BY YOUR LABORATORY

Cutoff Values | Normal Percentiles

True Positives | Performance Metrics

Last Update

COMPARE YOUR LABORATORY DATA WITH OTHER PARTICIPANTS

Cutoff Values Comparison | Percentiles Comparison

Performance Metrics Comparison | Disease Range | Disease Range (MoM)

Analyte Comparison | Profile Comparison

CUMULATIVE PROJECT DATA

Participant Profile — Participant profile summary of all responses

Score Cards — Tabular summary of all data (sorted by analyte type)

Plots by Target Range — Display of evidence-based and actual cutoff distribution for one analyte

NJ Health New Jersey Department of Health

State of New Jersey NEWBORN SCREENING

NewSTEPs
A Program of the Association of Public Health Laboratories™

QUALITY INDICATORS

The eight newborn screening Quality Indicators have been developed by representatives from state newborn screening programs and have undergone careful evaluation by stakeholders to assure agreement on definitions. These will be used to provide longitudinal comparisons within a program as well as comparisons to aggregate data across programs.

Quality Indicator 6	Percent of out of range results.
Quality Indicator 7	Frequency of condition detected by newborn screening for each disorder.
Quality Indicator 8	Percent of missed cases (false negatives), reported by disorder.

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State of New Jersey
NEWBORN SCREENING


QUALITY
CONTORL
a.bacall