

Newborn Screening Quality Assurance Program

2014 UDOT

May 2014

INTRODUCTION

The UDOT proficiency testing challenge is a unique component of the Newborn Screening Quality Assurance Program (NSQAP) utilizing a panel of dried blood spot (DBS) specimens that enter the testing scheme in a manner similar to actual newborn screening specimens. All analytes on a laboratory's test panel must be assayed for each specimen.

METHODS

On April 7, 2014, a panel of 25, blind-coded DBS specimens was distributed to all active UDOT participants. Specimens were enriched with predetermined levels of the following analytes: 17 α -hydroxyprogesterone (17-OHP), total galactose (Tgal), immunoreactive trypsinogen (IRT), leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), citrulline (Cit), arginine (Arg), succinylacetone (SUAC), C3, C3DC, C4, C4OH, C5, C5:1, C5DC, C5OH, C10:2, C14, C14:1, C16, C16OH, C18, C18:1, C18OH. Specimens deficient in the following analytes were also included in the panel: galactose-1-phosphate uridyltransferase (GALT), biotinidase (Bio) and C0.

Most UDOT pools were prepared from whole blood with the hematocrit adjusted to 50% and were enriched with high-purity analytes. The C0(L) deficient/biotinidase deficient pool was produced by combining washed, packed red blood cells with heat-treated charcoal stripped serum to achieve a 50% hematocrit. The GALT/Tgal pool was made by adding a 50/50 serum/saline mixture to washed, packed red blood cells until the hematocrit was 50% and then the reconstituted blood was heat-treated to decrease the GALT enzyme activity. The blood pool was then enriched with predetermined levels of Tgal (consisting of galactose and galactose-1-phosphate).

All of the blood pools were spotted in 75 μ L aliquots onto lot W112 of Whatman 903 filter paper, dried, and stored according to standard practices. [1]

Note: Specimen 21423 is certified as “outside normal limits” for GALT and Tgal. The process to decrease GALT enzyme activity in this specimen also decreased biotinidase enzyme activity. Therefore, some participants reported abnormal biotinidase for this specimen. However, less than 80% of the participants who test for biotinidase reported biotinidase as “outside normal limits”; consequently biotinidase was not a certified analyte for this specimen.



Direct inquiries to:
Centers for Disease Control and Prevention (CDC)
4770 Buford Highway, NE, MS/F43
Atlanta, GA 30341-3724

Quarterly publications for colleagues and participants of the
Proficiency Testing Program for UDOT in Dried Blood Spots.

Phone: 770-488-4582
FAX: 770-488-4255
E-mail: IWilliams1@cdc.gov

Editors: Sherri D. Zobel
Irene S. Williams



2014 UDOT

REPORTS and RESULTS

We processed data from 68 participants. Laboratories were asked to report only results that were “outside normal limits”. In the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

Not Evaluated: C3DC+C4OH in specimens 21405 and 21416 was not evaluated. In order for a specimen to be evaluated, it must have > 80% consensus among all UDOT participants. Participant consensus of 80% was not achieved for this analyte in either specimen; therefore, it was declared an educational challenge in both specimens.

The GALT, IRT and biotinidase expected values are based on the NSQAP assayed values. The expected value for all other analytes is the sum of the base pool (endogenous) plus the enrichment level. The 2014 UDOT specimen certification of expected values and frequency for outside normal limits is summarized in Table 1. Table 2 contains the summary of participant cutoffs for all 2014 UDOT analytes. Non-certified analytes found by participant laboratories are shown in Table 3. Overall statistics, mean concentrations by methods and Z-score charts are summarized in pages 7 -37. (Note: Z scores are coded for each lab. Find your Z score code in the Reviewer’s Comments box on your laboratory’s evaluation page.)

[1] Mei JV, Alexander JR, Adam BW, Hannon WH. Use of Filter Paper for the Collection and Analysis of Human Whole Blood Specimens. *Nutr.* 2001 May;131(5):1631S-6S.

**Newborn Screening Quality Assurance Program
2014 UDOT Proficiency Testing Panel**

**Data Evaluation
Lab XXX**

For summarized analytical information about the 2014 UDOT PT event, go to
http://www.cdc.gov/labstandards/nsqap_reports.html

A **Z-score** is a calculated value that tells how many standard deviations a laboratory result is from the mean value expected for that specimen. It is calculated by taking the difference between the laboratory result and the overall mean, then dividing by the standard deviation observed for that specimen. For example, if a laboratory result of 38.5 is observed on a specimen having an overall mean of 36.0 and a standard deviation of 1.2, the Z-score is 2.1 $[(38.5-36.0)/1.2]$. A Z-score of 2.1 means that the observed laboratory value is 2.1 standard deviations from the overall mean, therefore this result exceeds a 2s control limit but not a 3s control limit.

NSQAP determines the “Estimate of Laboratory Bias” (ref. ISO 5724-4) where the quantity $(x - X)$ establishes the **Z-score** as a measurement of analytical performance quality:

x = lab value

X = overall mean

SD = standard deviation

$$\text{Z-score} = \frac{\text{lab value} - \text{overall mean}}{\text{overall SD}}$$

Interpretation of Z-Score:

$|z| \leq 2$ = **satisfactory**

$2 < |z| < 3$ = **questionable**

$|z| \geq 3$ = **unsatisfactory**

Z-scores are coded for each lab. Find your **Z-score** code in the Reviewer’s Comments box.

Reviewer’s Comments

***Your Z-score code is “N” and is found as a vertical number
on the x-axis within each analyte chart.***

This evaluation is based on the analytes selected on the data report form.

Each participant received a lab-specific evaluation.

**Newborn Screening Quality Assurance Program
2014 UDOT Proficiency Testing Panel**

Table 1. Specimen Certification Frequency of Outside-Normal-Limits Report

Specimen	Specimen Certification			Labs Reporting ONL *	
	Analyte	Expected Value	Units		Percent (%)**
21401	Decadienoylcarnitine (C10:2)	1.23	µmol/L blood	28 of 31	90.3
21402	Isovalerylcarnitine (C5)	1.61	µmol/L blood	56 of 59	94.9
21403	<i>normal</i>				
21404	Tyrosine (Tyr)	891.9	µmol/L blood	52 of 61	85.2
21404	Succinylacetone (SUAC)	40.5	µmol/L blood	32 of 34	94.1
21405	Hydroxybutyrylcarnitine (C4OH)	1.67	µmol/L blood	24 of 27	88.9
21405	C3DC + C4OH	1.99 ***	µmol/L blood	14 of 18	77.8
21406	Propionylcarnitine (C3)	13.93	µmol/L blood	55 of 57	96.5
21407	<i>normal</i>				
21408	Arginine (Arg)	290.9	µmol/L blood	41 of 43	95.3
21409	Tiglylcarnitine (C5:1)	1.03	µmol/L blood	54 of 56	96.4
21409	Hydroxyisovalerylcarnitine (C5OH)	2.95	µmol/L blood	54 of 56	96.4
21410	Methionine (Met)	190.9	µmol/L blood	53 of 54	98.1
21411	Hydroxypalmitoylcarnitine (C16OH)	1.03	µmol/L blood	57 of 59	96.6
21411	Hydroxystearoylcarnitine (C18OH)	1.28	µmol/L blood	42 of 44	95.5
21412	Biotinidase (Bio)	n/a		48 of 50	96.0
21412	Free Carnitine (C0 Low)	2.69	µmol/L blood	56 of 58	96.6
21413	Immunoreactive Trypsinogen (IRT)	267.1 ^	ng/mL blood	49 of 50	98.0
21414	Butyrylcarnitine (C4)	2.62	µmol/L blood	48 of 51	94.1
21415	<i>normal</i>				
21416	Malonylcarnitine (C3DC)	3.18	µmol/L blood	28 of 30	93.3
21416	C3DC + C4OH	3.21	µmol/L blood	10 of 18	55.5
21417	17 α-Hydroxyprogesterone (17-OHP)	127.2	ng/mL serum	49 of 51	96.1
21418	<i>normal</i>				
21419	Glutaryl carnitine (C5DC)	1.05	µmol/L blood	56 of 58	96.6
21420	Myristoylcarnitine (C14)	1.59	µmol/L blood	48 of 51	94.1
21420	Tetradecenoylcarnitine (C14:1)	1.61	µmol/L blood	56 of 59	94.9
21421	Citrulline (Cit)	189.6	µmol/L blood	53 of 54	98.1
21422	Leucine (Leu)	891.3	µmol/L blood	50 of 55	90.9
21422	Valine (Val)	592.2	µmol/L blood	36 of 40	90.0
21423	Total Galactose (Tgal)	25.6	mg/dL blood	26 of 26	100.0
21423	Galactose-1-Phosphate Uridyltransferase (GALT)	<1.5 ^	U/g Hb	47 of 48	97.9
21424	<i>normal</i>				
21425	Palmitoylcarnitine (C16)	15.33	µmol/L blood	53 of 56	94.6
21425	Stearoylcarnitine (C18)	6.15	µmol/L blood	43 of 48	89.6
21425	Oleoylcarnitine (C18:1)	9.60	µmol/L blood	47 of 51	92.2

*Total number of laboratories reporting data per analyte varies.

**A gradable specimen must have 80% or more agreement among laboratories.

***All certified MS/MS expected values are derivatized except C3DC+C4OH

Expected Value - Sum of endogenous and enrichment values

^ NSQAP assayed value

**Newborn Screening Quality Assurance Program
2014 UDOT Proficiency Testing Panel**

Table 2. Summary of Reported Cutoff Values

Analyte	N	Mean	Median	Min/Max	Units
17-OHP	49	34.0	33.0	7 - 65	ng/ml serum
GALT	20	3.0	3.0	1.5 - 6.0	U/g Hb
GALT	13	50.0	50.0	40 - 60	µmol/L blood
GALT	7	3.5	3.5	2.5 - 4.4	U/dL
Total Galactose	25	11.6	10.0	6 - 38	mg/dL blood
IRT	49	66.0	62.0	36.8 - 118.4	ng/mL blood
Biotinidase	10	46.5	50.0	13 - 60	nmol/min/dL
Biotinidase	10	10.4	10.0	8 - 16	ERU*
Biotinidase	6	26.3	31.0	10 - 36	MRU**
<hr/>					
Arg	41	64.5	50.0	20 - 125	µmol/L blood
Cit	53	54.8	55.0	18 - 100	µmol/L blood
Leu	50	285.4	277.5	175 - 450	µmol/L blood
Met	53	73.6	70.0	34 - 150	µmol/L blood
Tyr	52	326.7	314.5	88 - 600	µmol/L blood
Val	36	289.3	277.0	189 - 530	µmol/L blood
SUAC	32	2.9	2.8	0.5 - 7.0	µmol/L blood
<hr/>					
C0(low)	56	8.90	8.00	3.80 - 33.00	µmol/L blood
C3	55	5.87	6.00	1.90 - 9.00	µmol/L blood
C3DC	28	0.25	0.20	0.11 - 0.45	µmol/L blood
C4	48	1.27	1.30	0.55 - 1.90	µmol/L blood
C4OH	24	0.64	0.65	0.27 - 1.00	µmol/L blood
C3DC+C4OH	14	0.59	0.38	0.25 - 3.03	µmol/L blood
C5	56	0.67	0.61	0.30 - 1.20	µmol/L blood
C5:1	54	0.24	0.18	0.02 - 0.64	µmol/L blood
C5DC	56	0.35	0.31	0.12 - 0.80	µmol/L blood
C5OH	54	0.79	0.80	0.28 - 1.18	µmol/L blood
C10:2	28	0.15	0.13	0.04 - 0.36	µmol/L blood
C14	48	0.77	0.72	0.17 - 1.20	µmol/L blood
C14:1	56	0.63	0.65	0.19 - 0.80	µmol/L blood
C16	53	7.84	7.79	0.41 - 10.00	µmol/L blood
C16OH	57	0.13	0.12	0.07 - 0.25	µmol/L blood
C18	42	2.42	2.27	0.22 - 4.00	µmol/L blood
C18:1	47	3.44	3.00	0.36 - 7.00	µmol/L blood
C18OH	42	0.11	0.10	0.03 - 0.26	µmol/L blood

*ERU - Enzyme Response Units

**MRU - Microplate Response Units

**Newborn Screening Quality Assurance Program
2014 UDOT Proficiency Testing Program
Table 3. Number of Laboratories Reporting Non-Certified Analytes**

Specimen	Certified Analyte	Non-Certified Not Expected Analyte(s)
21401	C10:2	
21402	C5	
21403	<i>normal</i>	C3DC (1), C5OH (6), C10:1 (1), C10:2 (1)
21404	Tyr, SUAC	C5OH (7), C10:1 (1), C10:2 (1), C18OH (1)
21405	C4OH, C3DC+C4OH	C18 (1)
21406	C3	
21407	<i>normal</i>	Leu (1), C5OH (6), C18 (4), C18:1 (1)
21408	Arg	Leu (1), C4OH (1), C5OH (1), C18:1(1)
21409	C5:1, C5OH	C3 (1), C4 (1), C16OH (1)
21410	Met	C5OH (1)
21411	C16OH, C18OH	
21412	Bio, C0 Low	TSH (1), C16 (1)
21413	IRT	T4 (1), C5OH (3), C18 (4)
21414	C4	
21415	<i>normal</i>	C5OH (1)
21416	C3DC, C3DC+C4OH	Cit (1), C4OH (1), C5OH (1)
21417	17-OHP	C5OH (1)
21418	<i>normal</i>	Leu (1), C5OH (1)
21419	C5DC	Cit (1), C5:1 (1), C5OH (6)
21420	C14, C14:1	C10 (1)
21421	Cit	Leu (1), C5OH (1), C10:1 (1), C14:1 (1)
21422	Leu, Val	Arg (3), C5DC (1), C5OH (1), C18 (1)
21423	Tgal, GALT	Bio (39)
21424	<i>normal</i>	C5OH (1), C16 (1)
21425	C16, C18, C18:1	C0 high (1), C5OH (1)

The number in parentheses shows how many labs reported the analyte as outside-normal-limits.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Overall Statistics

Specimen	21401	21402	21404	21404	21405	21405	21406
Analyte	C10:2	C5	Tyr	SUAC	C4OH	C3DC+C4OH	C3
N****	27	53	50	29	22	13	52
Outliers	1	3	2	3	2	1	3
Mean	0.88	1.38	763.4	13.0	1.08	0.80	12.64
SD	0.26	0.16	99.1	5.4	0.22	0.10	1.52
UL (95%)	1.40	1.72	957.5	23.7	1.50	1.00	15.60
LL (95%)	0.38	1.06	569.2	2.4	0.64	0.60	9.68

Specimen	21408	21409	21409	21410	21411	21411	21412
Analyte	Arg	C5:1	C5OH	Met	C16OH	C18OH	Bio ^
N****	41	52	52	51	55	40	7
Outliers	0	2	2	2	2	2	0
Mean	189.5	0.94	2.08	156.1	0.64	0.82	19.8
SD	85.6	0.20	0.44	16.0	0.16	0.20	20.4
UL (95%)	357.2	1.32	2.94	187.5	0.94	1.20	59.7
LL (95%)	21.8	0.56	1.22	124.7	0.32	0.44	0.0

Specimen	21412	21412	21412	21413	21414	21416	21416
Analyte	Bio ^ ^	Bio ^ ^ ^	C0(low)	IRT	C4	C3DC	C3DC+C4OH
N****	10	6	54	49	47	28	10
Outliers	0	0	2	0	1	0	0
Mean	1.7	2.3	3.24	247.9	2.34	2.68	0.54
SD	1.2	2.2	1.36	23.6	0.22	1.40	0.10
UL (95%)	4.0	6.6	5.90	294.2	2.78	5.42	0.72
LL (95%)	0.0	0.0	0.60	201.5	1.90	0.00	0.34

^ Biotinidase measured in nmol/min/dL.

^^ Biotinidase measured in ERU.

^^^ Biotinidase measured in MRU.

*GALT measured in U/g Hb.

**GALT measured in umol/L blood.

***GALT measured in U/dL.

**** Values outside the 99% CI (outliers) were excluded from the calculations. UL = upper limit LL = lower limit

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Overall Statistics

Specimen	21417	21419	21420	21420	21421	21422	21422
Analyte	17 – OHP	C5DC	C14	C14:1	Cit	Leu	Val
N****	48	56	45	55	53	48	36
Outliers	1	0	3	1	0	2	0
Mean	94.4	1.08	1.50	1.24	140.3	756.0	518.4
SD	10.0	0.40	0.18	0.24	28.8	82.0	87.0
UL (95%)	114.0	1.86	1.84	1.72	196.8	916.7	689.0
LL (95%)	74.9	0.28	1.16	0.76	83.8	595.3	347.9

Specimen	21423	21423	21423	21423	21425	21425	21425
Analyte	Tgal	GALT*	GALT**	GALT***	C16	C18	C18:1
N****	25	17	13	4	50	42	45
Outliers	0	2	0	0	3	1	2
Mean	28.1	1.3	24.3	0.1	13.62	6.04	7.12
SD	6.3	0.6	4.9	0.1	1.54	0.88	1.02
UL (95%)	40.4	2.4	33.9	0.4	16.64	7.74	9.12
LL (95%)	15.8	0.2	14.7	0.0	10.60	4.32	5.12

^ Biotinidase measured in nmol/min/dL.

^^ Biotinidase measured in ERU.

^^^ Biotinidase measured in MRU.

*GALT measured in U/g Hb.

**GALT measured in umol/L blood.

***GALT measured in U/dL.

**** Values outside the 99% CI (outliers) were excluded from the calculations. UL = upper limit LL = lower limit

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21401		C10:2		
		Expected Value 1.23 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	16	1.04	0.36
35	Deriv-MS/MS PE NeoGram MS2 Kit	6	0.88	0.10
60	Non-deriv MS/MS PE NeoBase Kit	5	0.64	0.06

Specimen No. 21402		C5		
		Expected Value 1.61 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	22	1.40	0.20
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	1.40	0.20
60	Non-deriv MS/MS PE NeoBase Kit	18	1.30	0.06

Specimen No. 21404		Tyr		
		Expected Value 891.9 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	23	704.8	105.7
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	792.4	79.9
38	Non-deriv MS/MS non-kit	2	692.0	---*
60	Non-deriv MS/MS PE NeoBase Kit	14	819.4	72.4

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21404		SUAC		
		Expected Value 40.5 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	12	25.9	17.7
60	Non-deriv MS/MS PE NeoBase Kit	17	9.5	1.4

Specimen No. 21405		C4OH		
		Expected Value 1.67 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	18	1.02	0.20
35	Deriv-MS/MS PE NeoGram MS2 Kit	5	1.50	0.42

Specimen No. 21405		C3DC+C4OH		
		Expected Value 1.99 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
60	Non-deriv MS/MS PE NeoBase Kit	13	0.80	0.10

Specimen No. 21406		C3		
		Expected Value 13.93 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	22	13.08	2.76
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	12.80	1.32
60	Non-deriv MS/MS PE NeoBase Kit	20	12.02	0.84

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21408		Arg		
		Expected Value 290.9µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	18	118.1	80.6
35	Deriv-MS/MS PE NeoGram MS2 Kit	7	213.8	15.2
60	Non-deriv MS/MS PE NeoBase Kit	16	259.2	22.3

Specimen No. 21409		C5:1		
		Expected Value 1.03µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	22	1.08	0.30
35	Deriv-MS/MS PE NeoGram MS2 Kit	10	0.92	0.18
38	Non-deriv MS/MS non-kit	2	0.78	---*
60	Non-deriv MS/MS PE NeoBase Kit	20	0.88	0.10

Specimen No. 21409		C5OH		
		Expected Value 2.95µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	22	2.40	0.64
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	2.26	0.44
38	Non-deriv MS/MS non-kit	2	2.32	---*
60	Non-deriv MS/MS PE NeoBase Kit	19	1.80	0.24

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21410		Met		
		Expected Value 190.9 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	19	151.9	15.7
35	Deriv-MS/MS PE NeoGram MS2 Kit	10	167.7	13.8
60	Non-deriv MS/MS PE NeoBase Kit	21	154.9	15.7

Specimen No. 21411		C16OH		
		Expected Value 1.03 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	23	0.70	0.16
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	0.72	0.18
38	Non-deriv MS/MS non-kit	2	0.28	---*
60	Non-deriv MS/MS PE NeoBase Kit	19	0.54	0.04

Specimen No. 21411		C18OH		
		Expected Value 1.28 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	16	0.96	0.32
35	Deriv-MS/MS PE NeoGram MS2 Kit	10	0.96	0.20
60	Non-deriv MS/MS PE NeoBase Kit	14	0.76	0.06

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21412		Bio		
		Expected Value N/A nmol/min/dL		
		N	Mean	SD
Method Code	Method Name			
9	PerkinElmer Neonatal Kit	7	19.8	20.4

Specimen No. 21412		Bio		
		Expected Value N/A ERU		
		N	Mean	SD
Method Code	Method Name			
34	Astoria-Pacific 50 Hour Reagent Kit	10	1.7	1.2

Specimen No. 21412		Bio		
		Expected Value N/A MRU		
		N	Mean	SD
Method Code	Method Name			
64	Astoria-Pacific Neonatal Microplate Reagent Kit	6	2.3	2.2

Specimen No. 21412		C0(low)		
		Expected Value 2.69 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	21	3.00	1.04
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	4.56	1.40
38	Non-deriv MS/MS non-kit	2	6.36	---*
60	Non-deriv MS/MS PE NeoBase Kit	19	2.48	0.32

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21413		IRT		
		Expected Value 267.1 ng/mL blood		
		N	Mean	SD
Method Code	Method Name			
21	AutoDelfia	35	243.6	24.5
62	PerkinElmer GSP Neonatal	14	258.7	18.0

Specimen No. 21414		C4		
		Expected Value 2.62 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	20	2.36	0.22
35	Deriv-MS/MS PE NeoGram MS2 Kit	8	2.36	0.28
60	Non-deriv MS/MS PE NeoBase Kit	17	2.24	0.14

Specimen No. 21416		C3DC		
		Expected Value 3.18 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	19	2.02	0.70
35	Deriv-MS/MS PE NeoGram MS2 Kit	8	4.52	0.76

Specimen No. 21416		C3DC+C4OH		
		Expected Value 3.21 µmol/L blood		
		N	Mean	SD
Method Code	Method Name			
60	Non-deriv MS/MS PE NeoBase Kit	10	0.54	0.10

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21417		17-OHP		
		Expected Value 127.2 ng/mL serum		
		N	Mean	SD
Method Code	Method Name			
19	Other	4	92.6	10.0
21	AutoDelfia	12	97.1	12.3
58	AutoDelfia Neonatal 17-OHP (B024)	18	96.5	7.7
62	PerkinElmer GSP Neonatal	14	90.0	9.8

Specimen No. 21419		C5DC		
		Expected Value 1.05 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	23	0.64	0.18
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	1.32	0.14
60	Non-deriv MS/MS PE NeoBase Kit	20	1.38	0.12

Specimen No. 21420		C14		
		Expected Value 1.59 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	19	1.54	0.22
35	Deriv-MS/MS PE NeoGram MS2 Kit	9	1.58	0.10
60	Non-deriv MS/MS PE NeoBase Kit	17	1.42	0.12

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21420		C14:1		
		Expected Value 1.61 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	24	1.30	0.24
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	1.52	0.20
60	Non-deriv MS/MS PE NeoBase Kit	20	1.04	0.10

Specimen No. 21421		Cit		
		Expected Value 189.6 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	20	116.7	31.4
35	Deriv-MS/MS PE NeoGram MS2 Kit	11	156.8	14.7
60	Non-deriv MS/MS PE NeoBase Kit	21	154.3	14.3

Specimen No. 21422		Leu		
		Expected Value 891.3 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	21	748.5	119.2
35	Deriv-MS/MS PE NeoGram MS2 Kit	10	785.3	86.1
60	Non-deriv MS/MS PE NeoBase Kit	18	755.6	75.2

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21422		Val		
		Expected Value 592.2 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	16	493.1	81.9
35	Deriv-MS/MS PE NeoGram MS2 Kit	10	541.2	77.6
60	Non-deriv MS/MS PE NeoBase Kit	9	550.2	96.2

Specimen No. 21423		Tgal		
		Expected Value 25.6 μmg/dL blood		
		N	Mean	SD
Method Code	Method Name			
25	Bio-Rad Quantase	2	24.5	---*
34	Astoria-Pacific 50 Hour Reagent Kit	9	32.0	1.9
47	Fluorometric Manual	5	27.8	5.4
9	PerkinElmer Neonatal Kit	6	21.4	4.3

Specimen No. 21423		GALT		
		Expected Value <1.5 U/g Hb		
		N	Mean	SD
Method Code	Method Name			
64	Astoria-Pacific Neonatal Microplate Reagent Kit	5	1.0	0.2
9	PerkinElmer Neonatal Kit	13	1.6	0.9

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

Mean Concentration by Method

Specimen No. 21423		GALT		
		Expected Value N/A $\mu\text{mol/L}$ blood		
		N	Mean	SD
Method Code	Method Name			
34	Astoria-Pacific 50 Hour Reagent Kit	13	24.3	4.9

Specimen No. 21423		GALT		
		Expected Value N/A U/dL blood		
		N	Mean	SD
Method Code	Method Name			
62	PerkinElmer GSP Neonatal	4	0.1	0.1

Specimen No. 21425		C16		
		Expected Value 15.33 $\mu\text{mol/L}$ blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	22	13.46	2.10
35	Deriv-MS/MS PE NeoGram MS2 Kit	9	14.04	1.40
60	Non-deriv MS/MS PE NeoBase Kit	20	13.32	1.30

Specimen No. 21425		C18		
		Expected Value 6.15 $\mu\text{mol/L}$ blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	17	5.74	0.96
35	Deriv-MS/MS PE NeoGram MS2 Kit	8	6.38	0.94
60	Non-deriv MS/MS PE NeoBase Kit	16	6.18	0.70

Methods with N = 1 are not identified.

* SD was not included for N \leq 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

2014 UDOT Proficiency Testing Panel

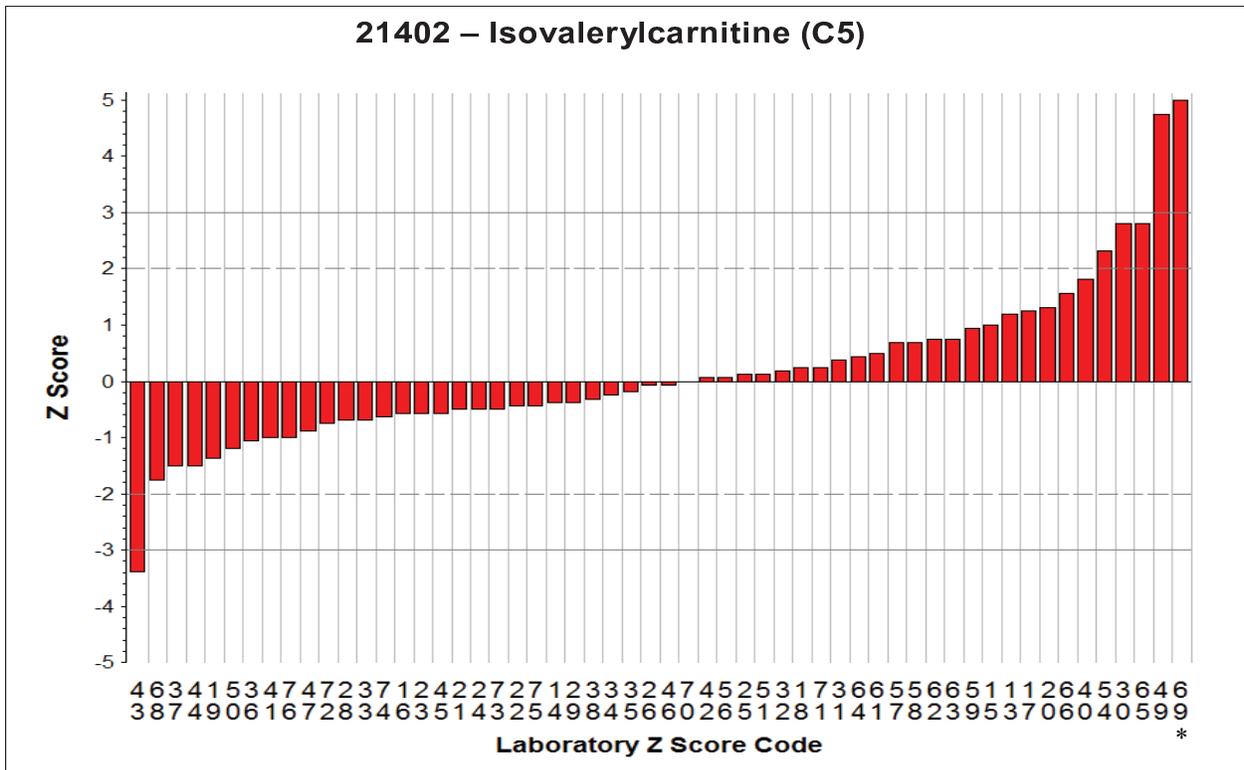
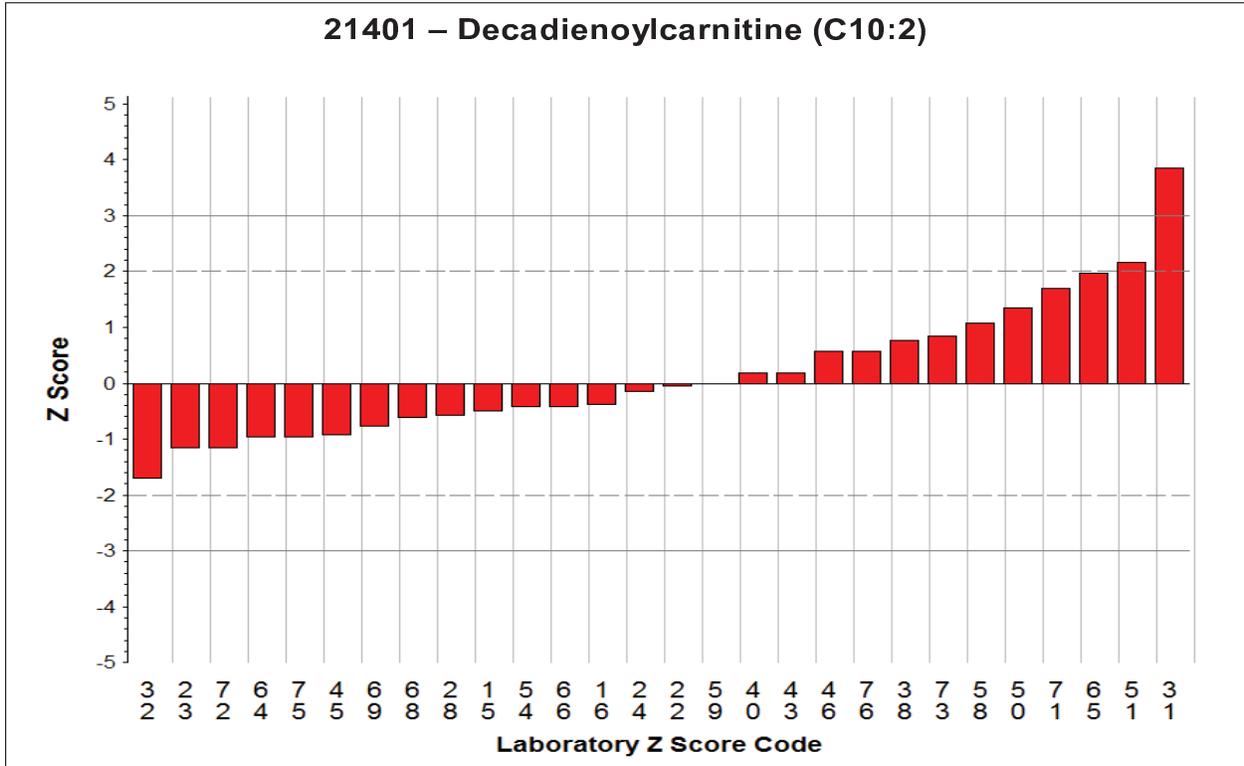
Mean Concentration by Method

Specimen No. 21425		C18:1		
		Expected Value 9.60 μmol/L blood		
		N	Mean	SD
Method Code	Method Name			
22	Deriv-MS/MS non-kit	19	6.46	1.00
35	Deriv-MS/MS PE NeoGram MS2 Kit	8	7.64	1.22
60	Non-deriv MS/MS PE NeoBase Kit	18	7.32	0.84

Methods with N = 1 are not identified.

* SD was not included for N ≤ 3.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
2014 UDOT Proficiency Testing Panel
Z Scores

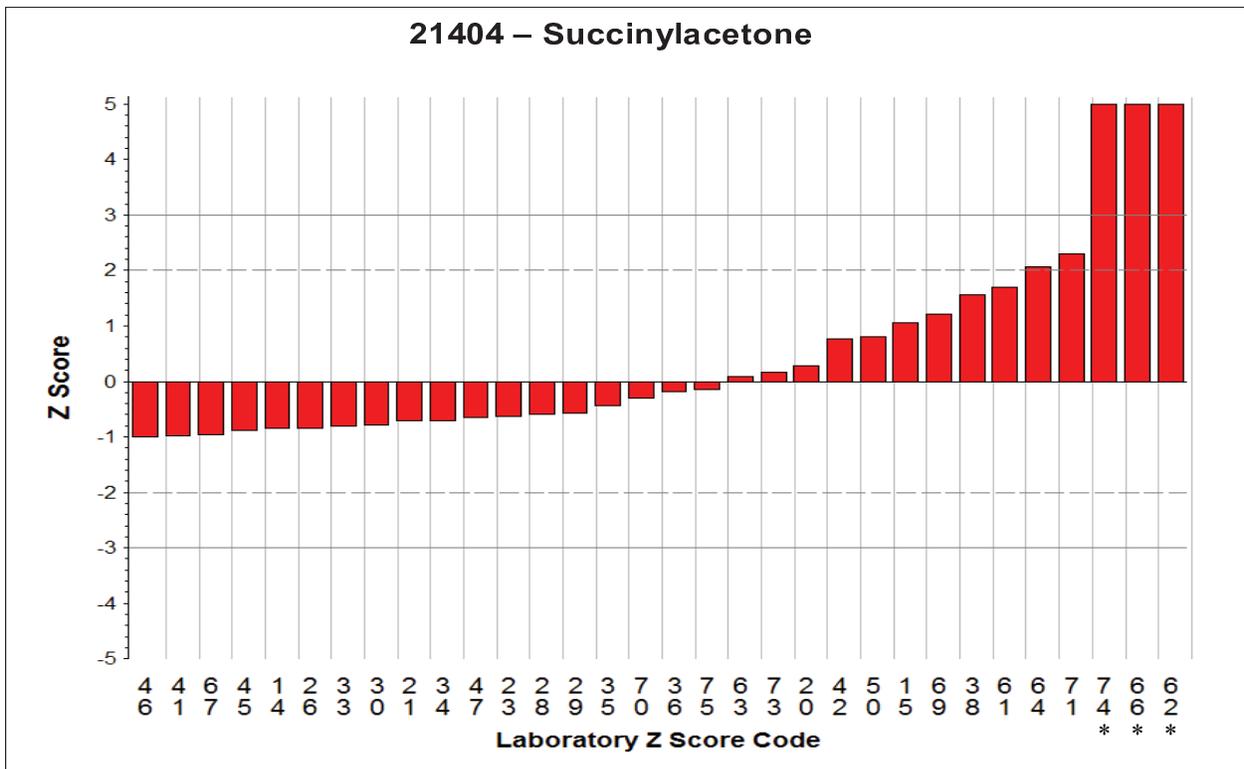
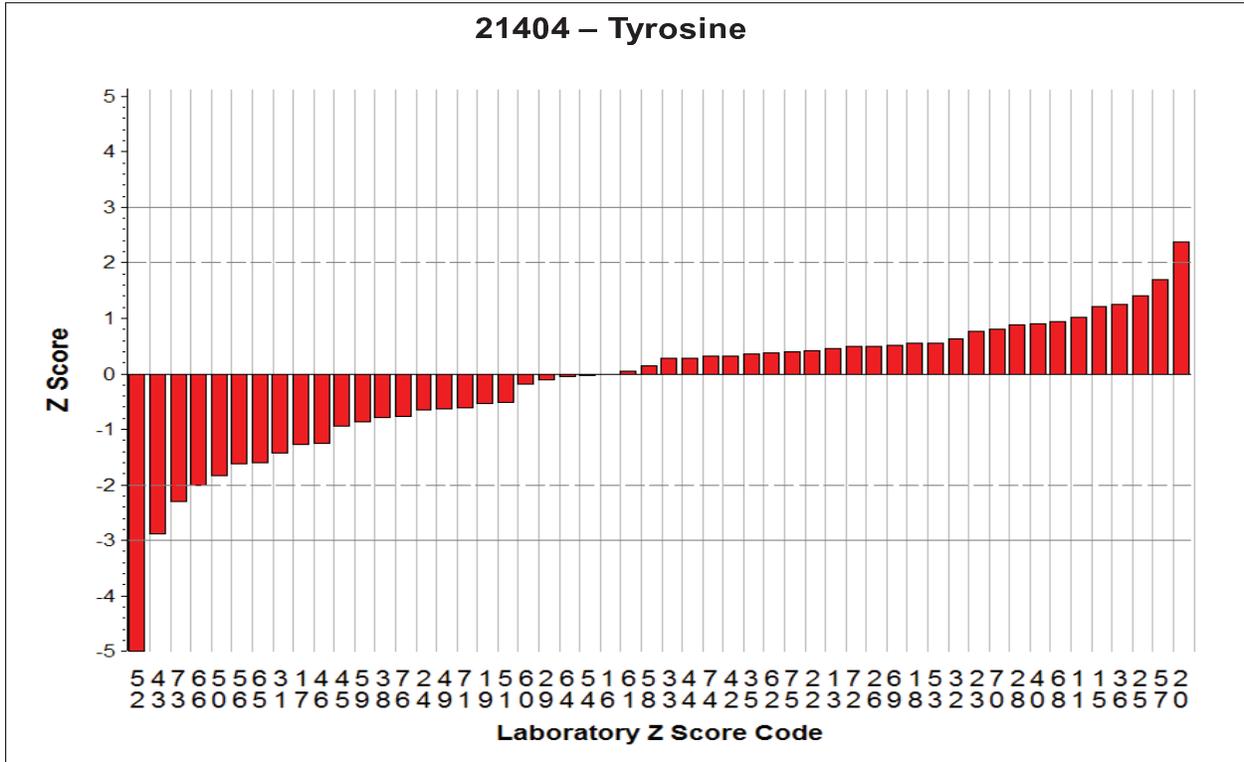


* Z Score >5

|Z| ≤ 2 satisfactory 2 > |Z| < 3 = questionable |Z| ≥ 3 unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores

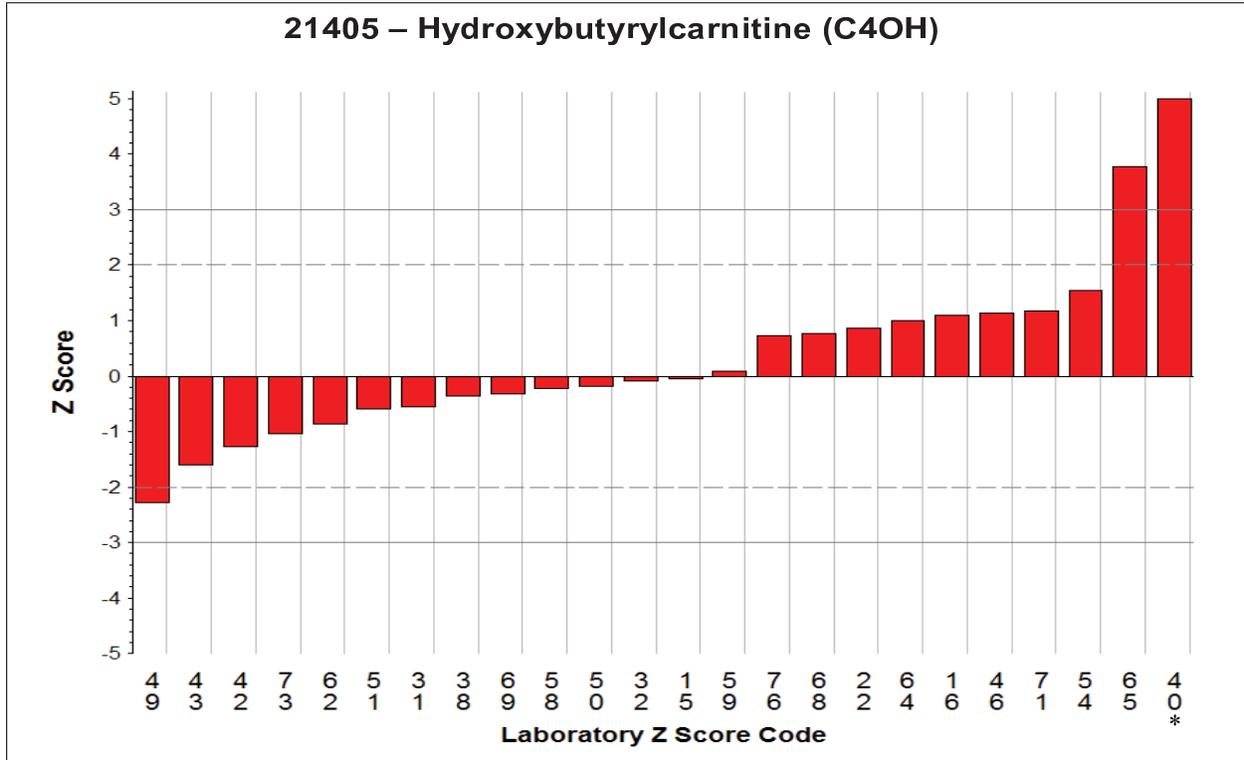


* Z Score >5

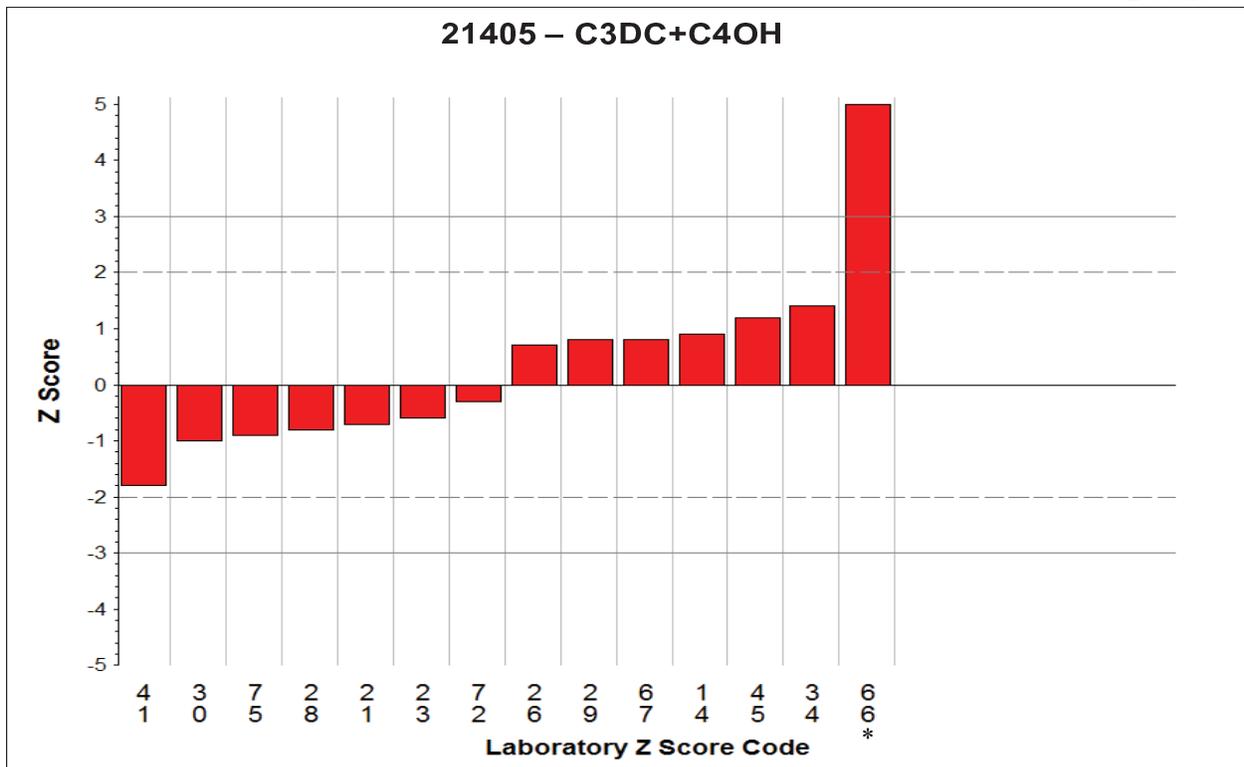
$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



* Z Score >5

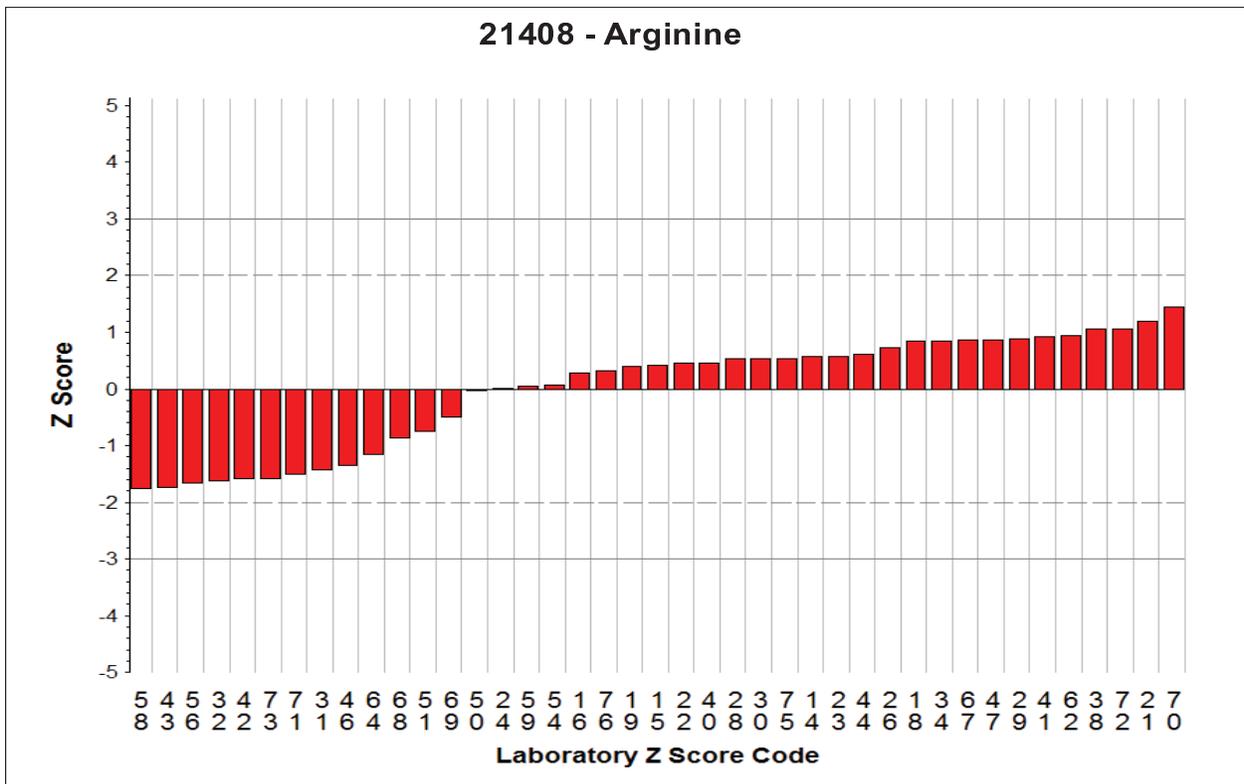
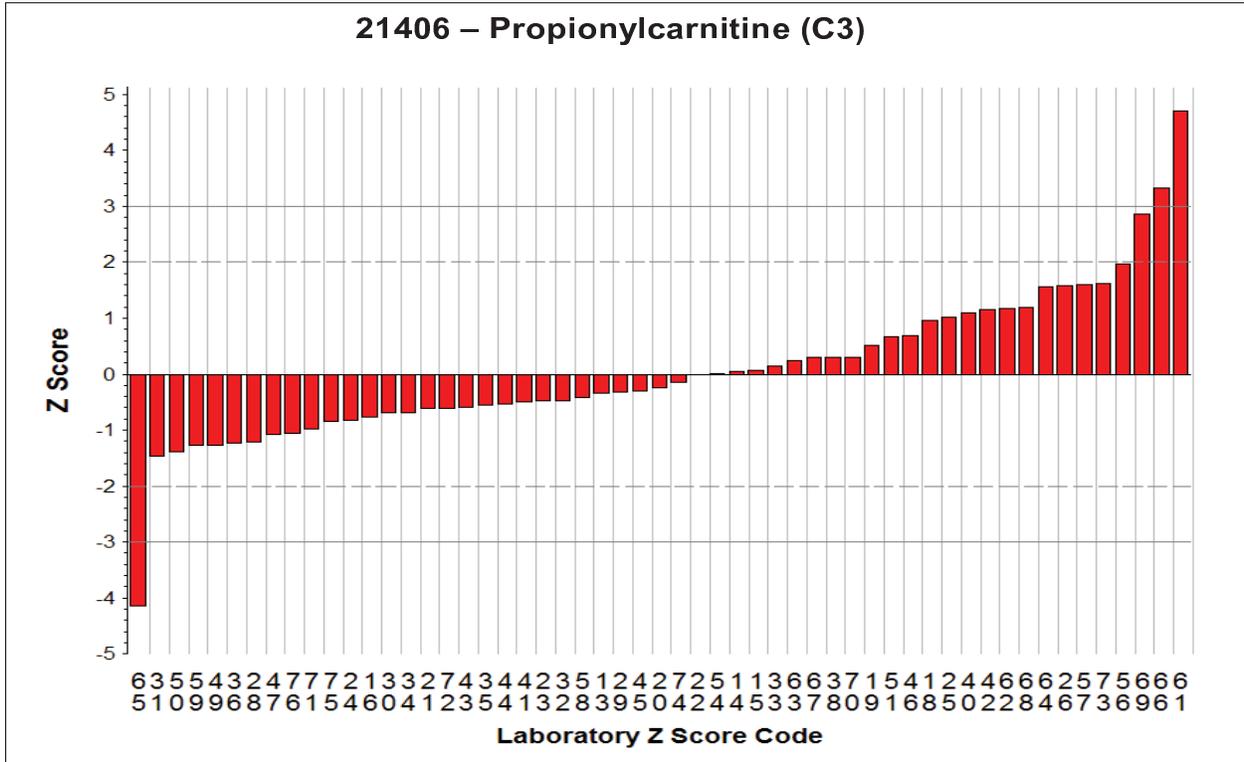


* Z Score >5

$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

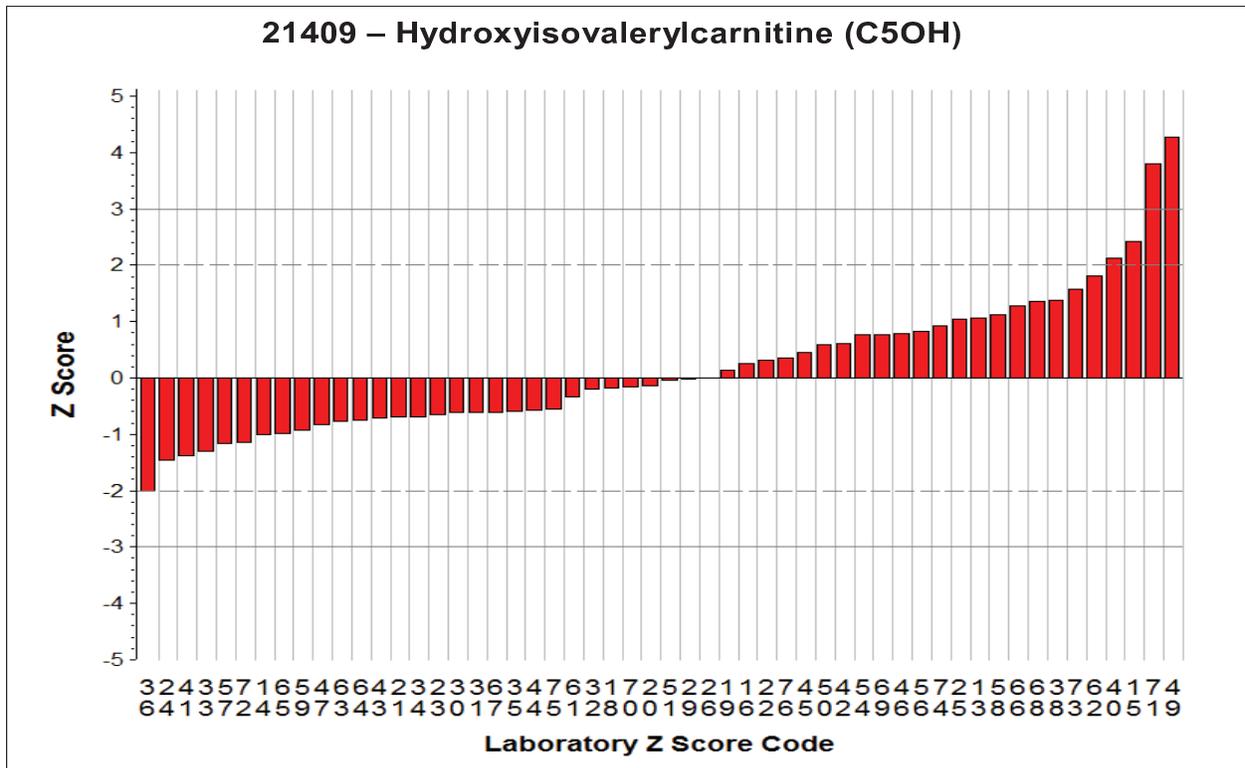
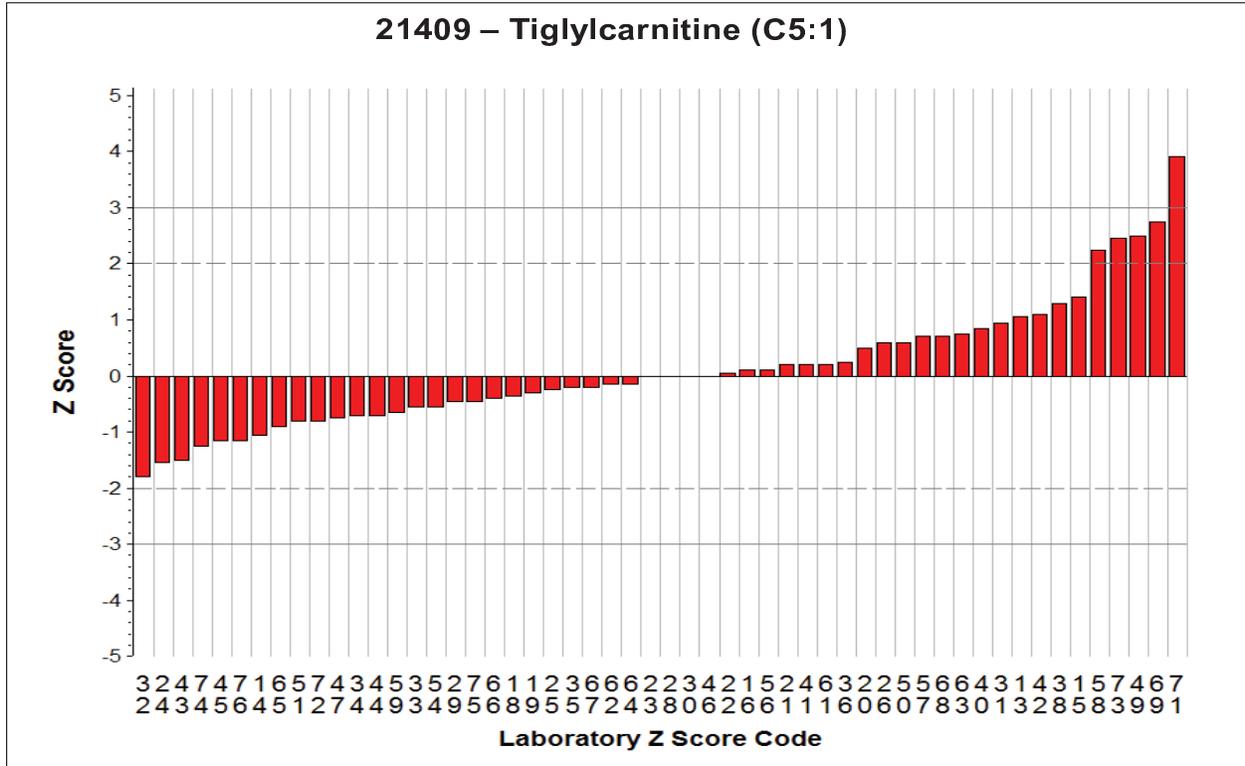
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

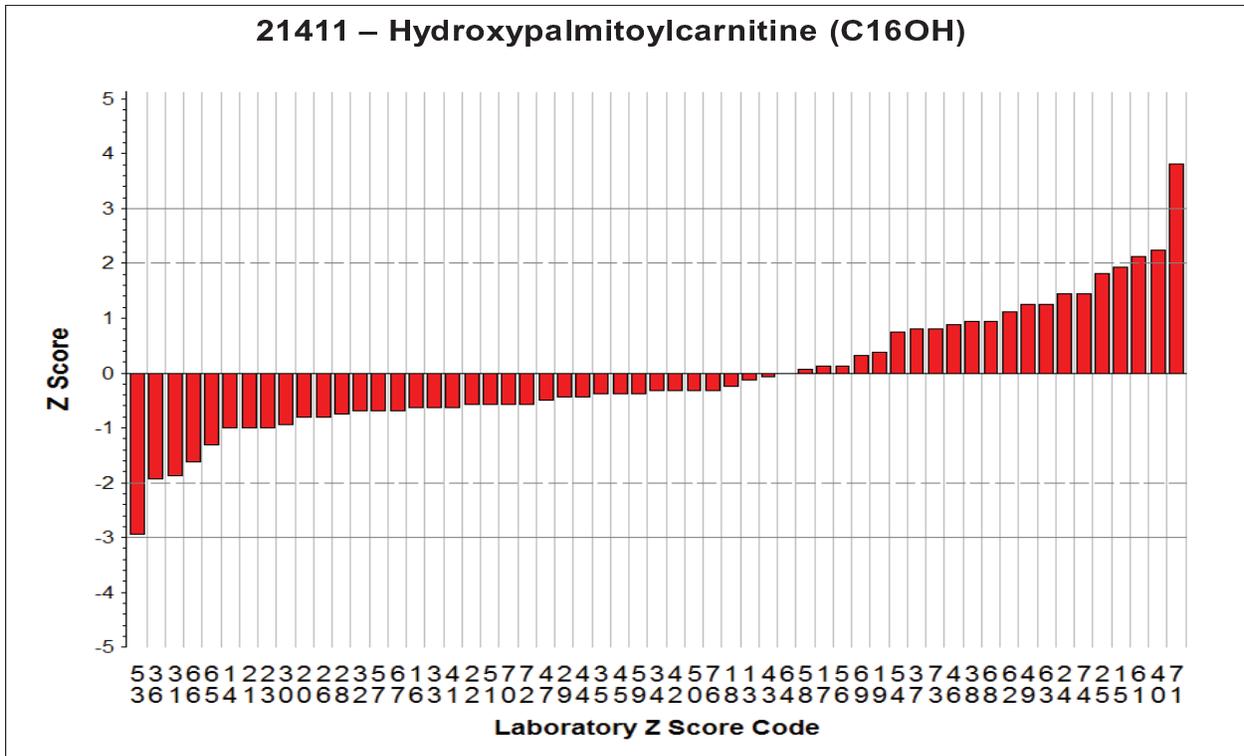
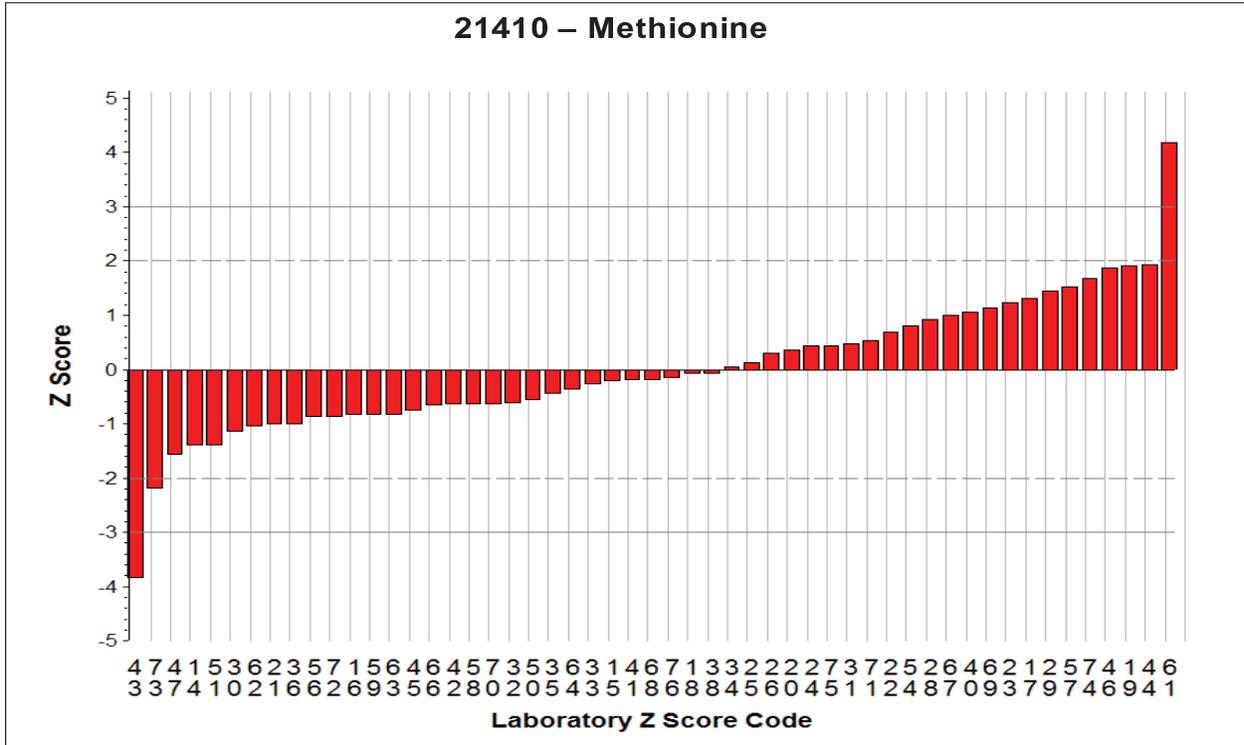
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

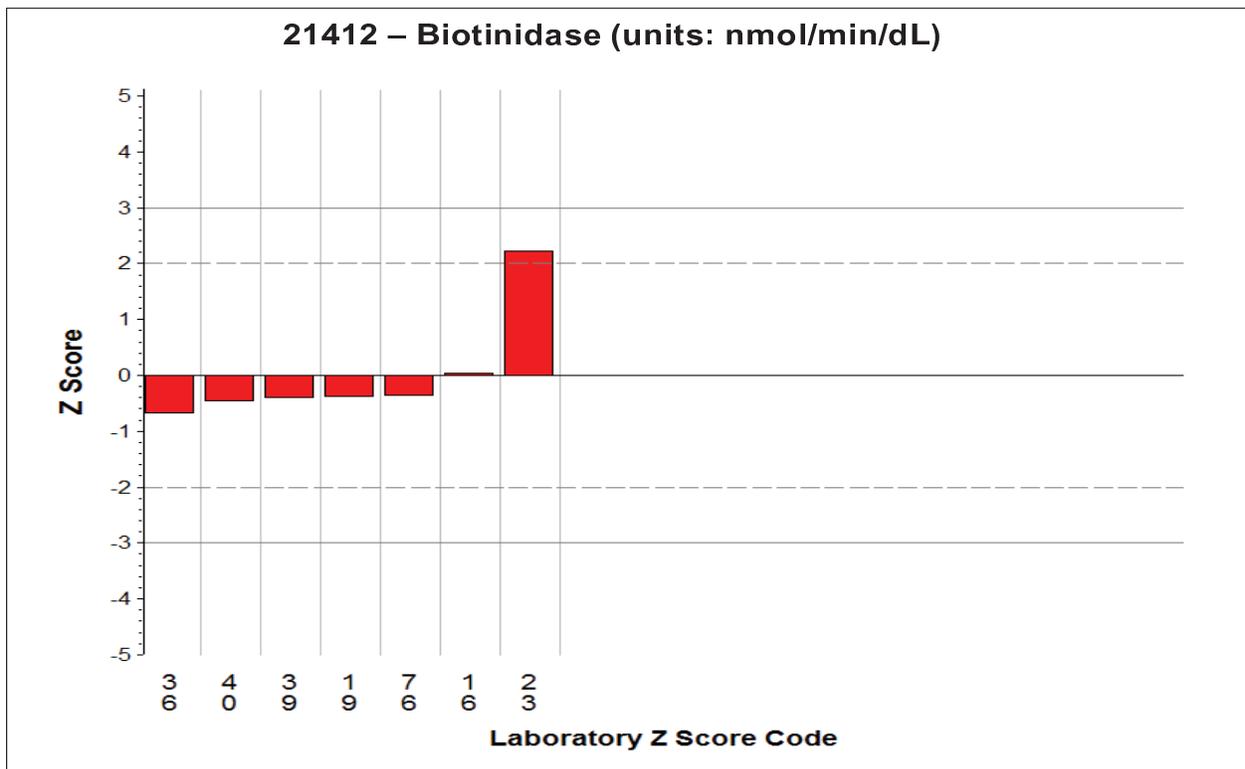
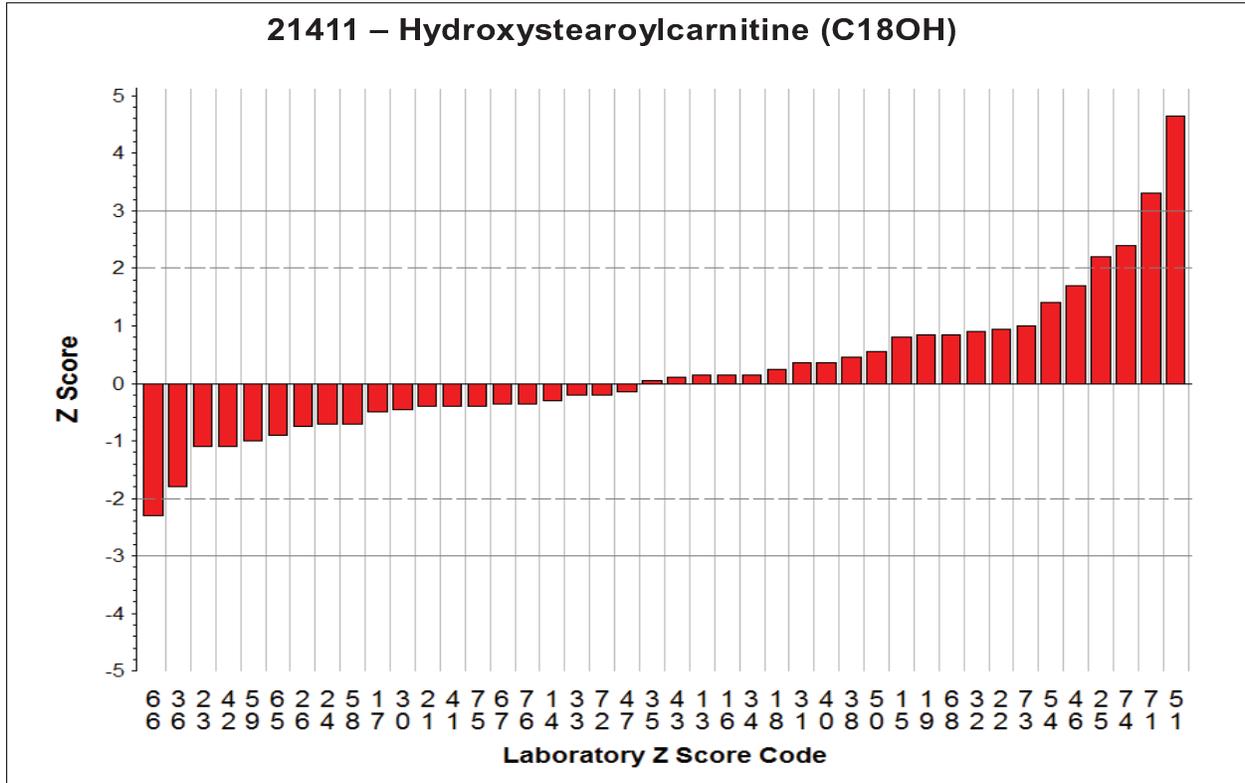
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

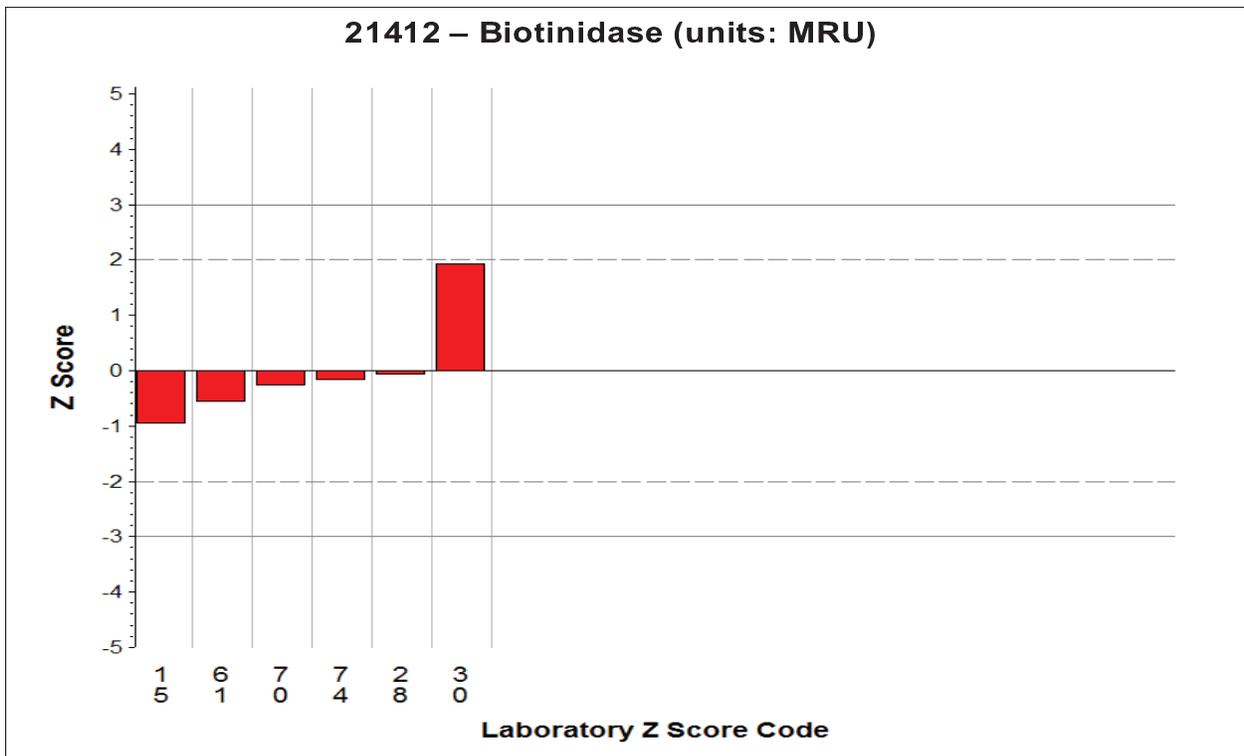
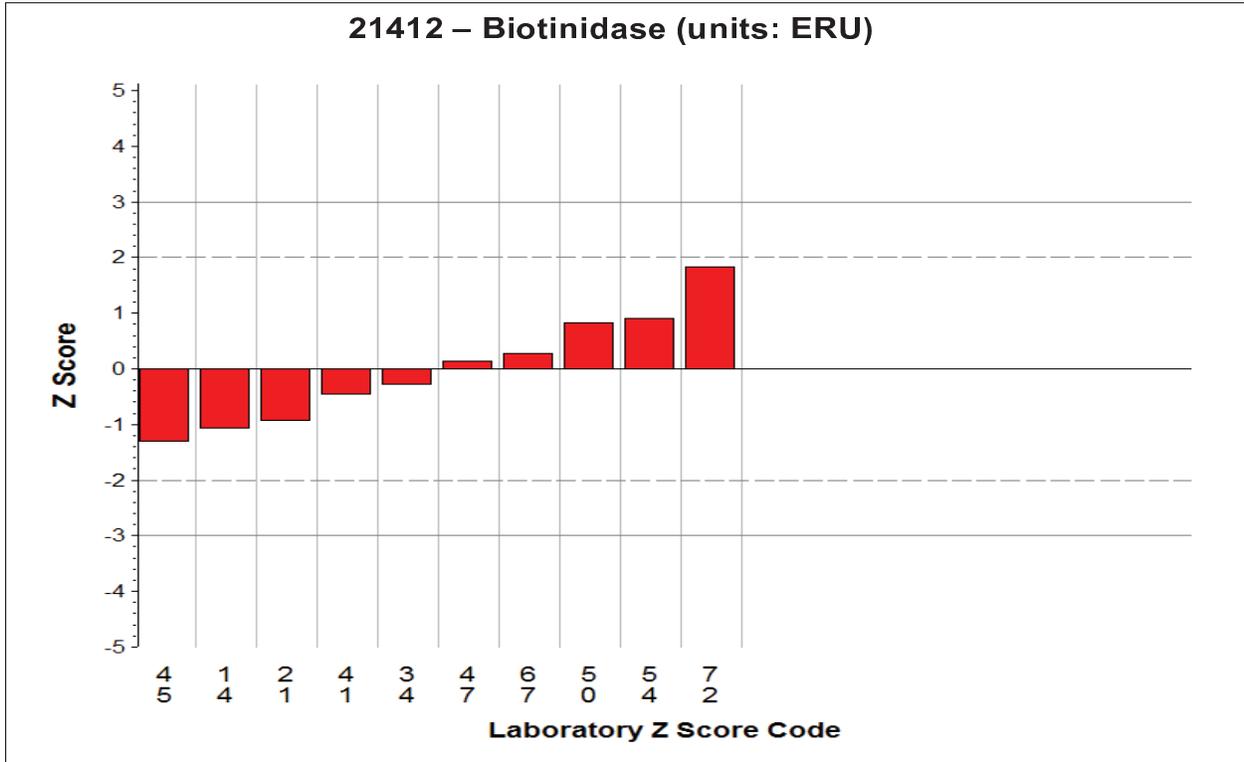
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

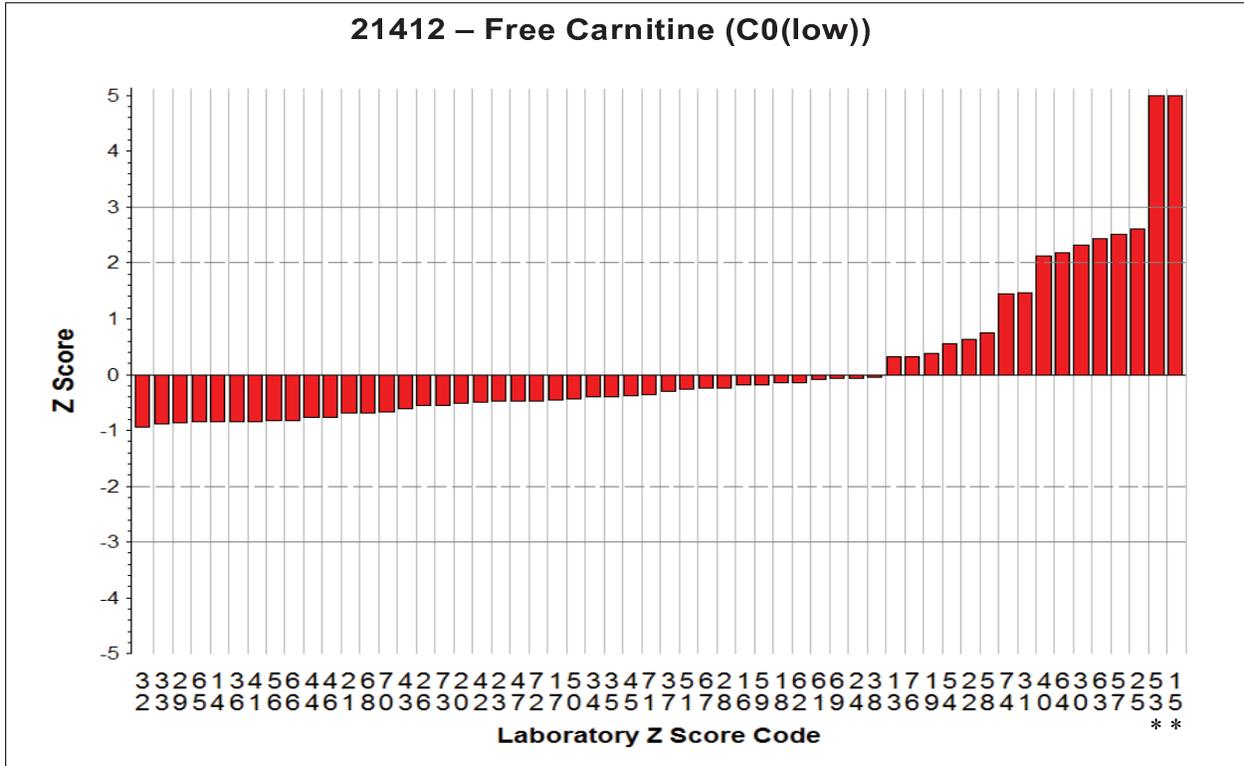
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



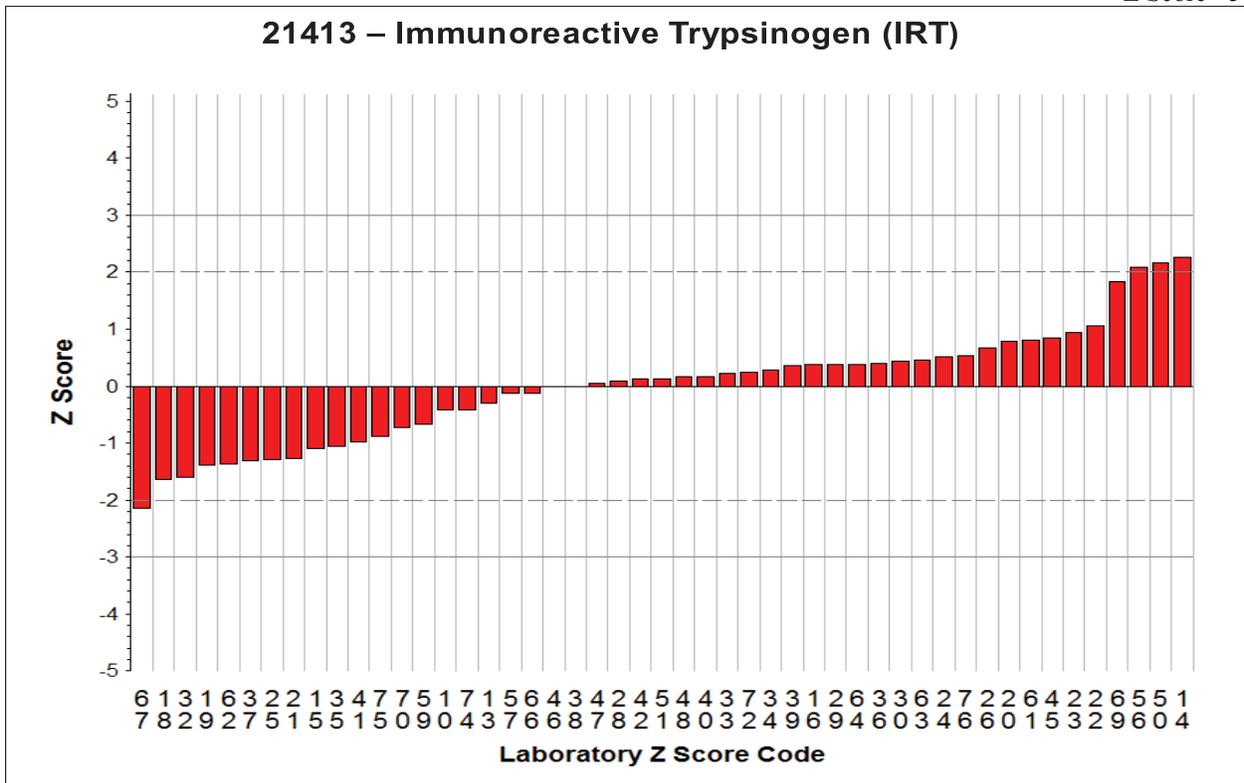
$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



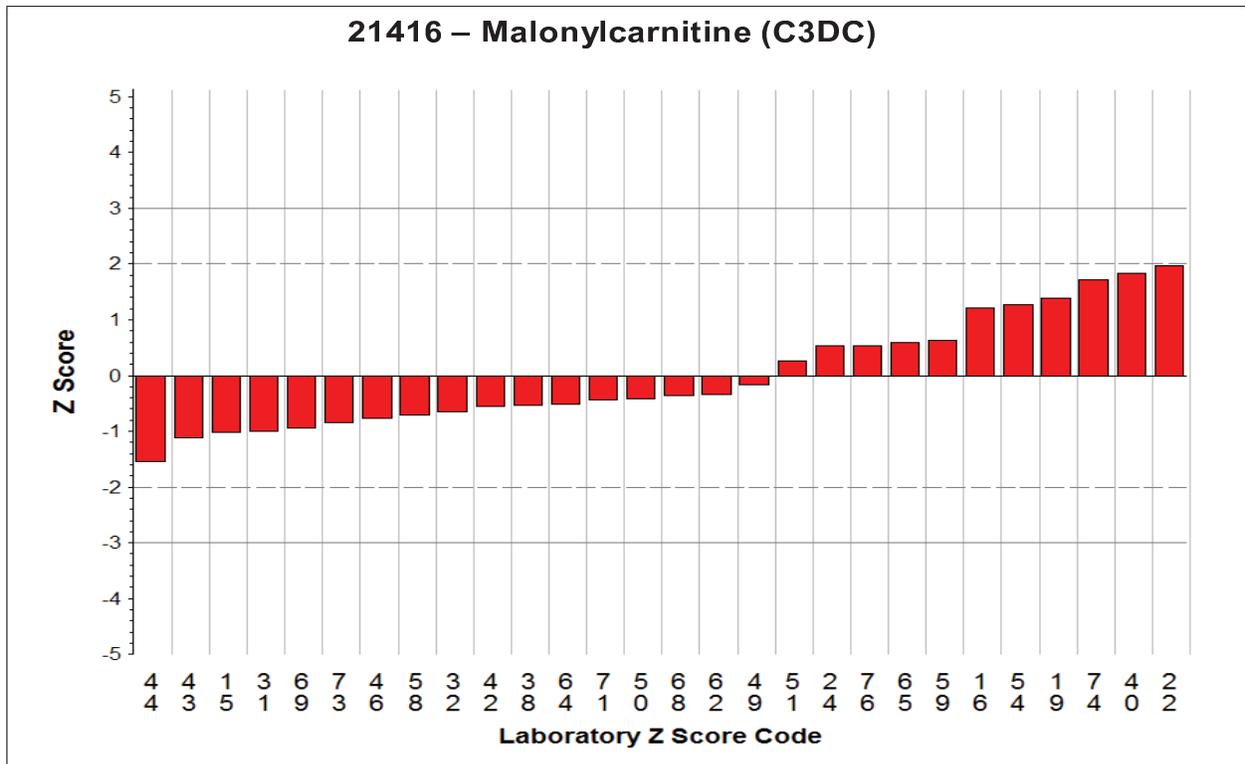
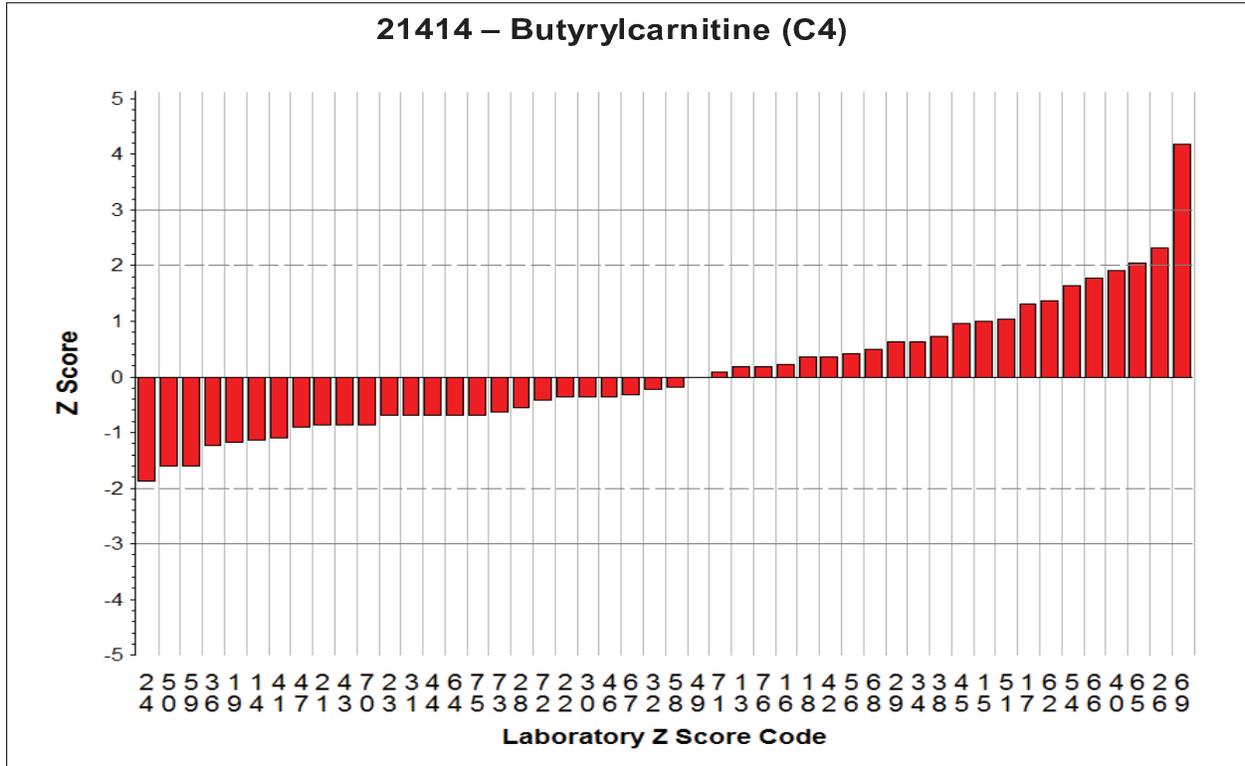
* Z Score >5



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

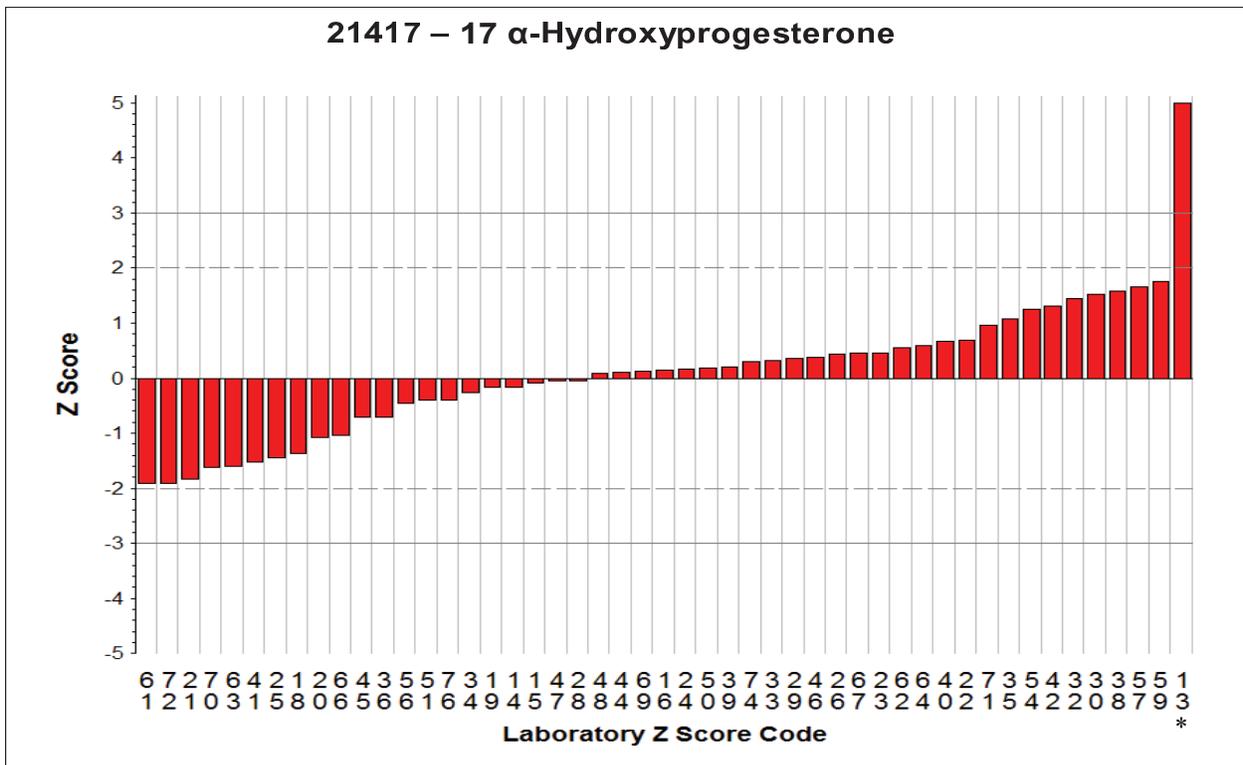
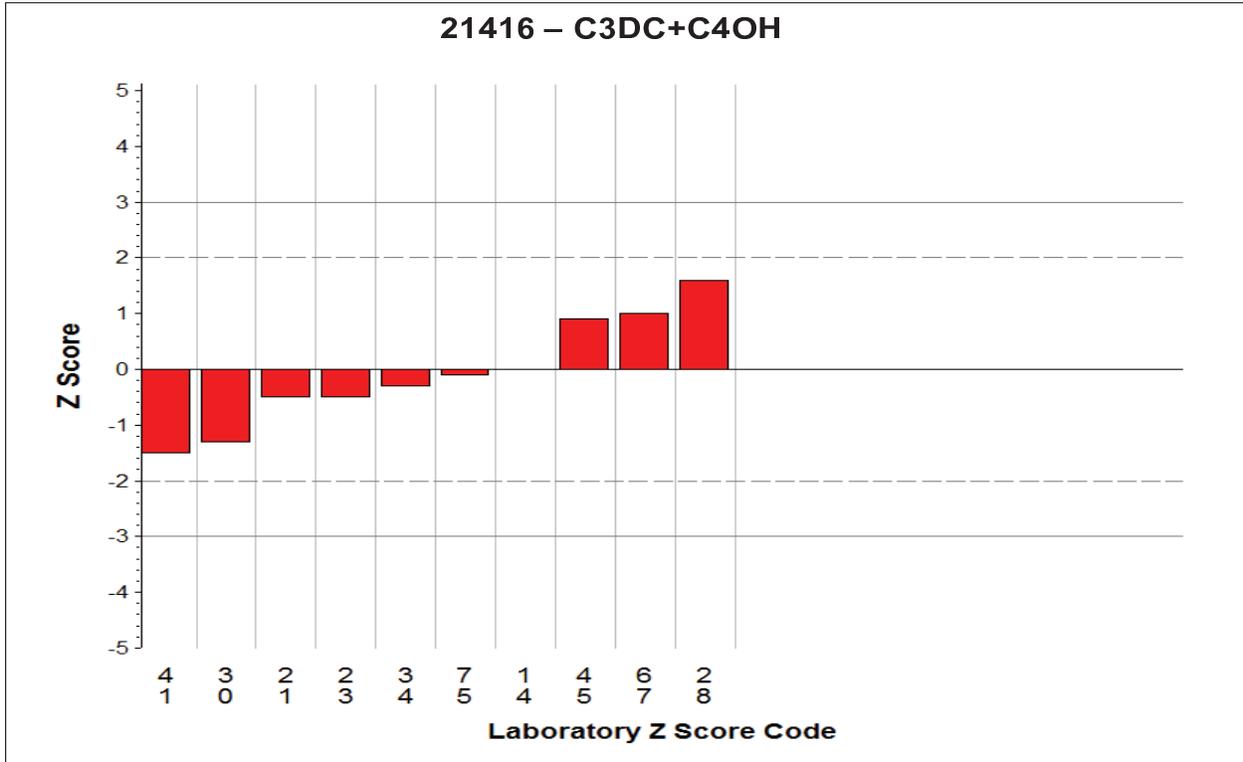
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores

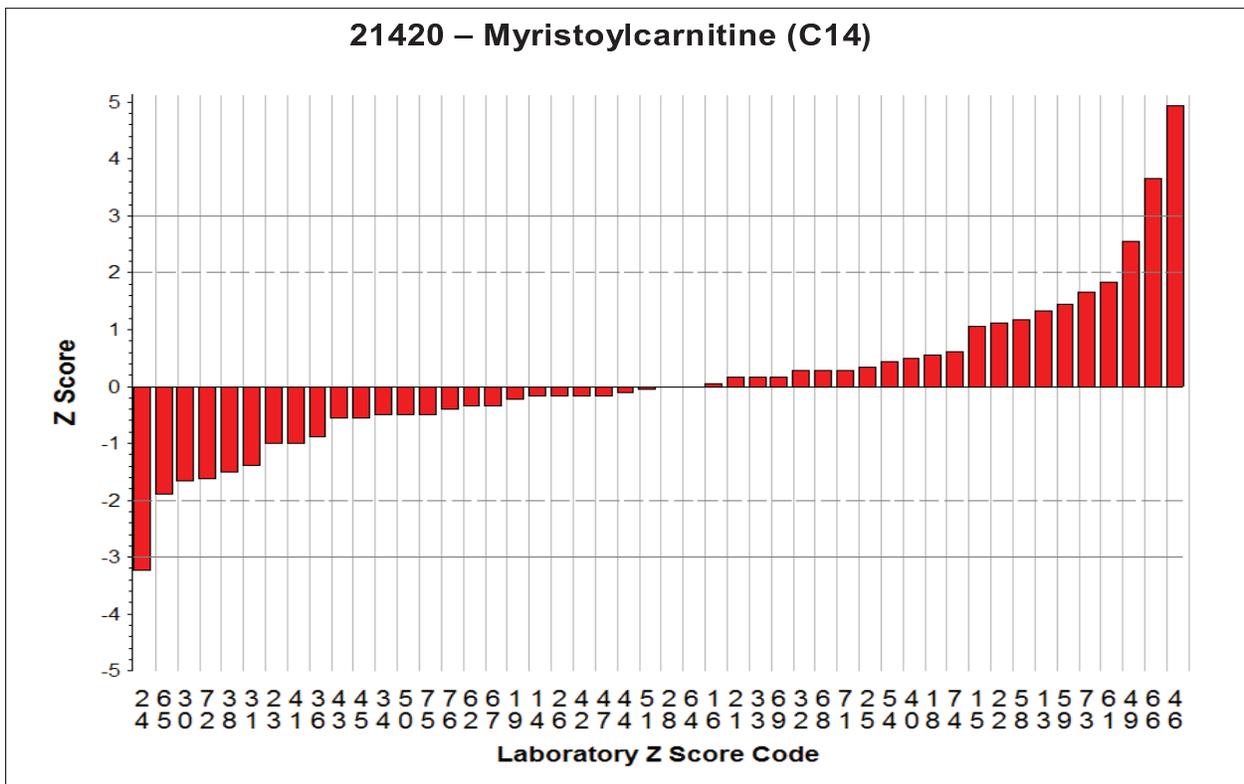
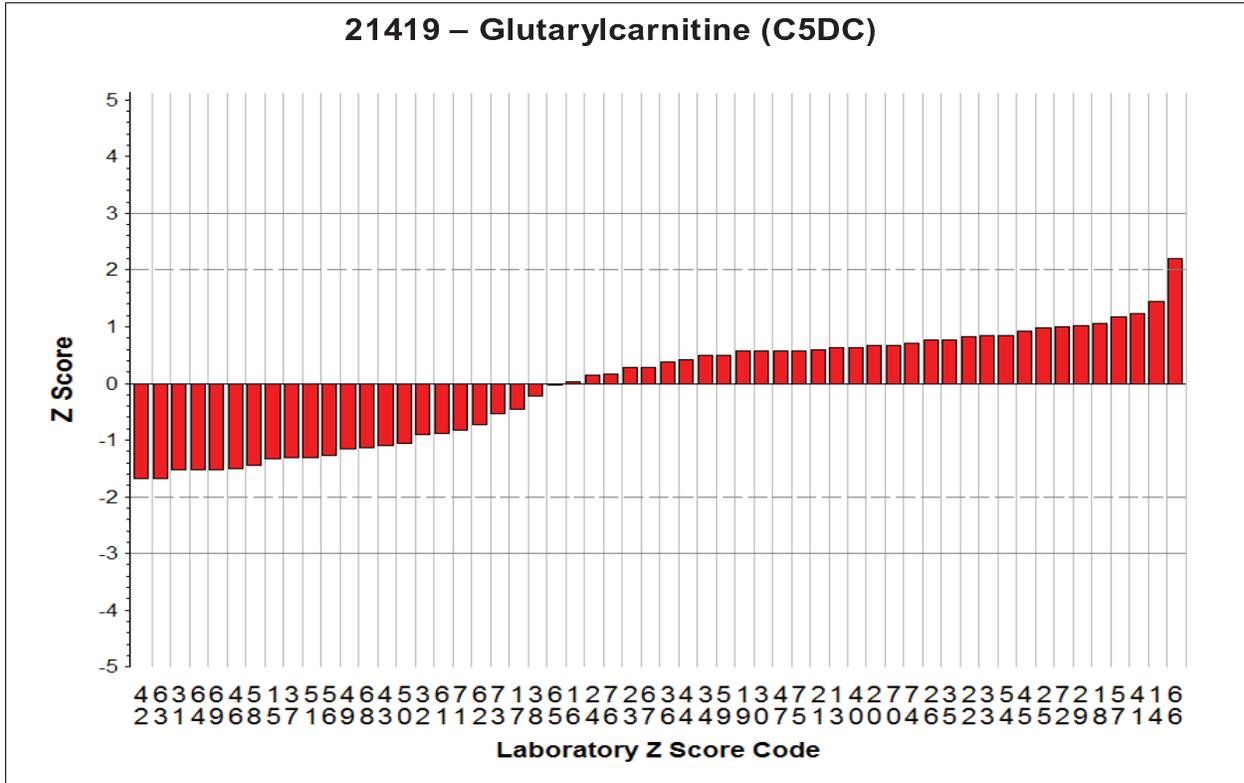


* Z Score >5

$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

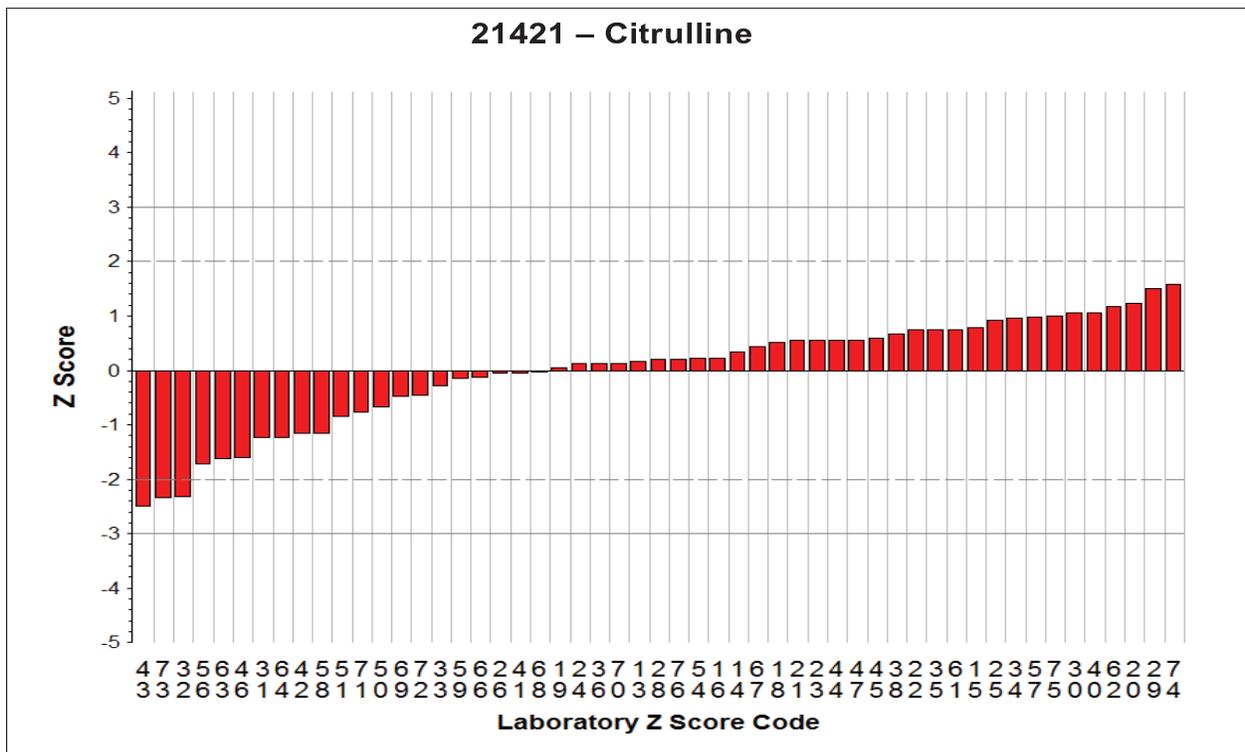
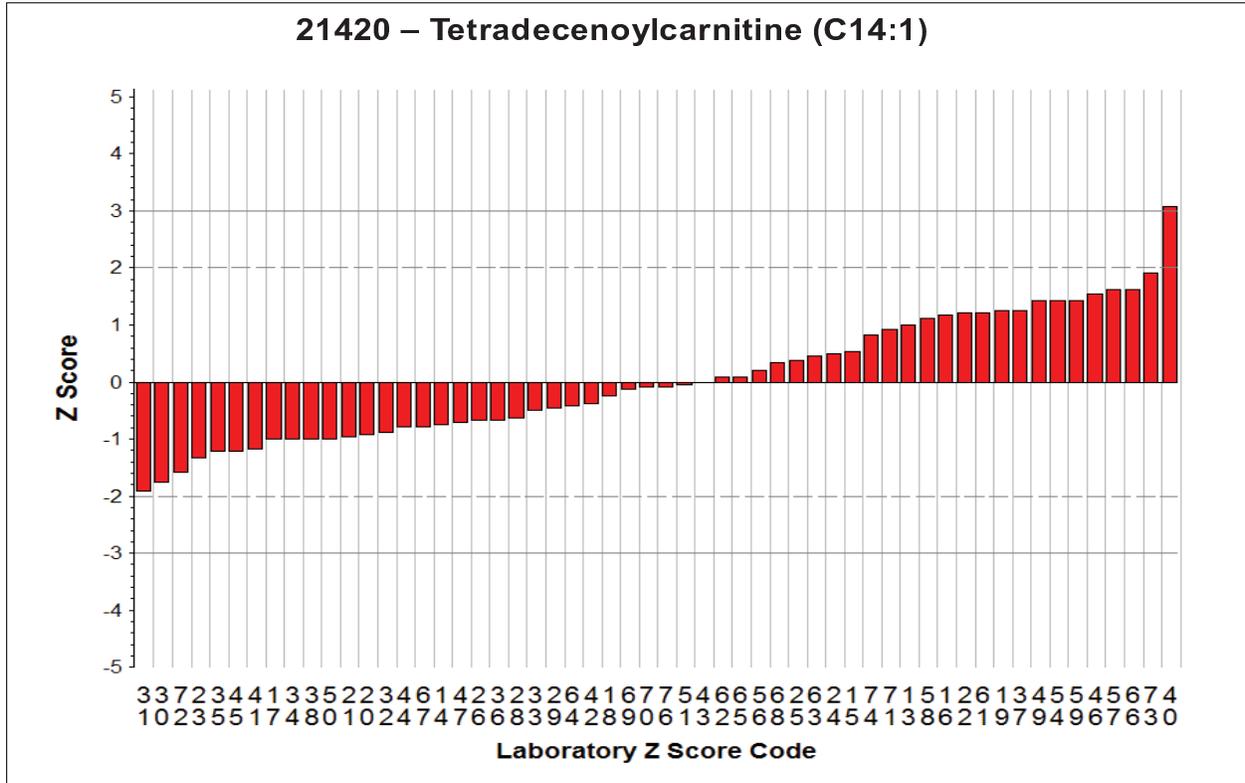
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

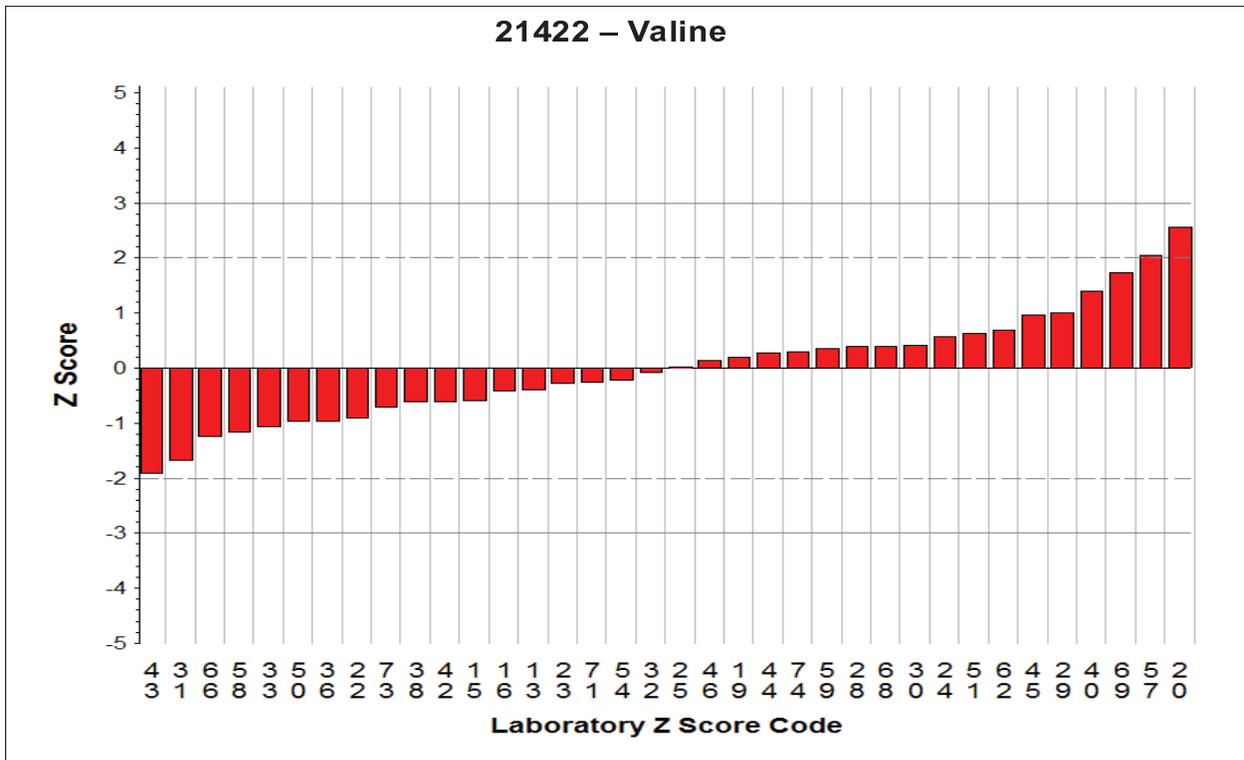
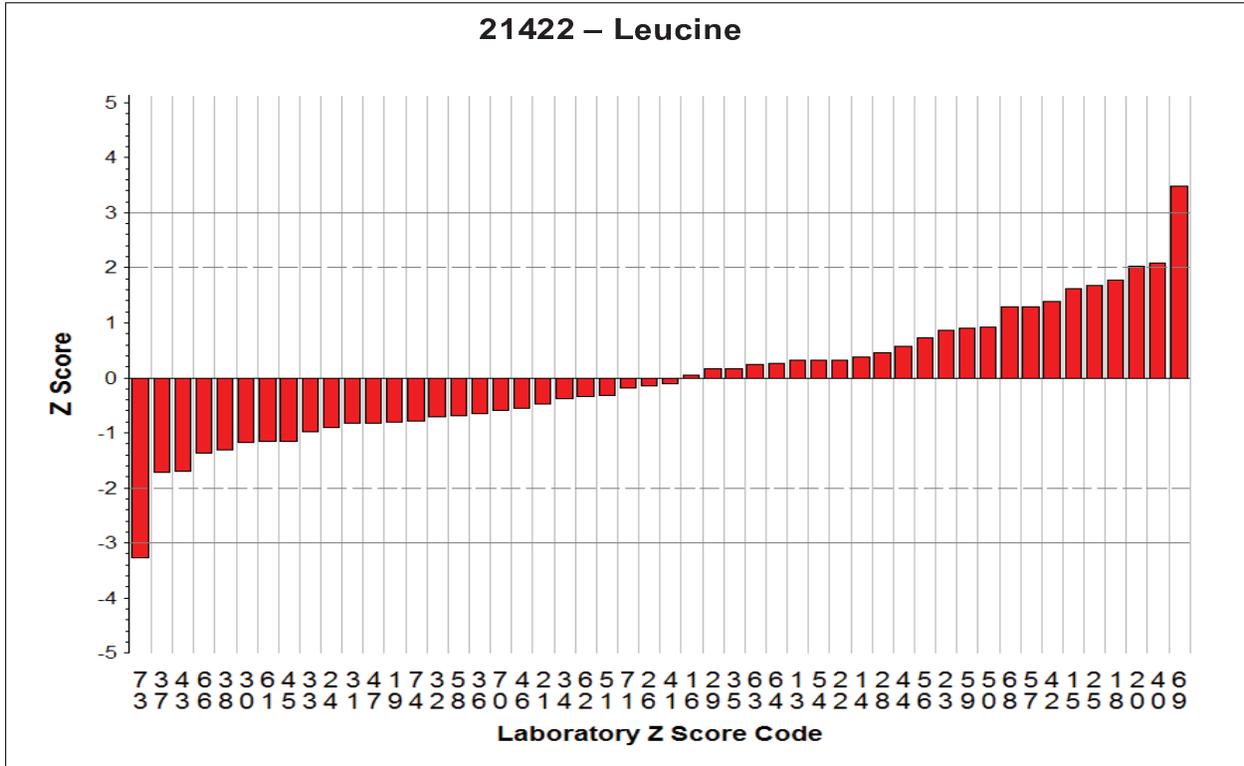
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

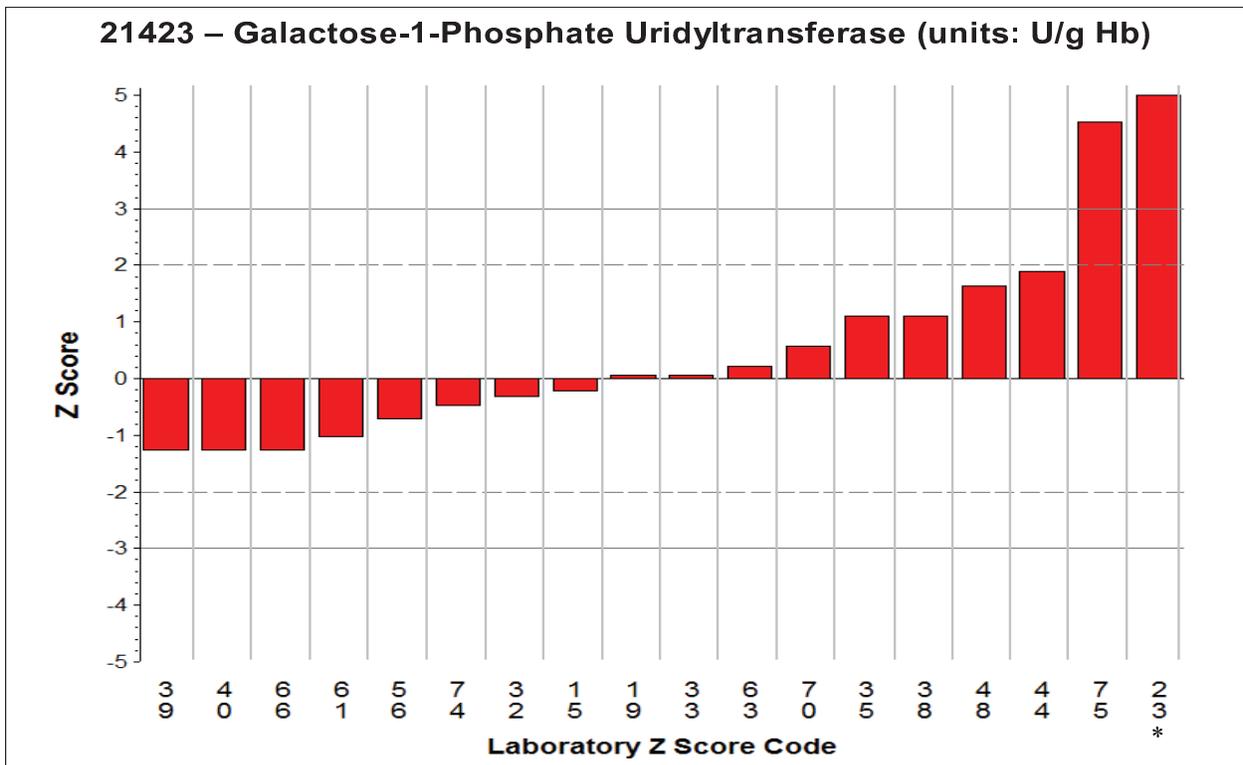
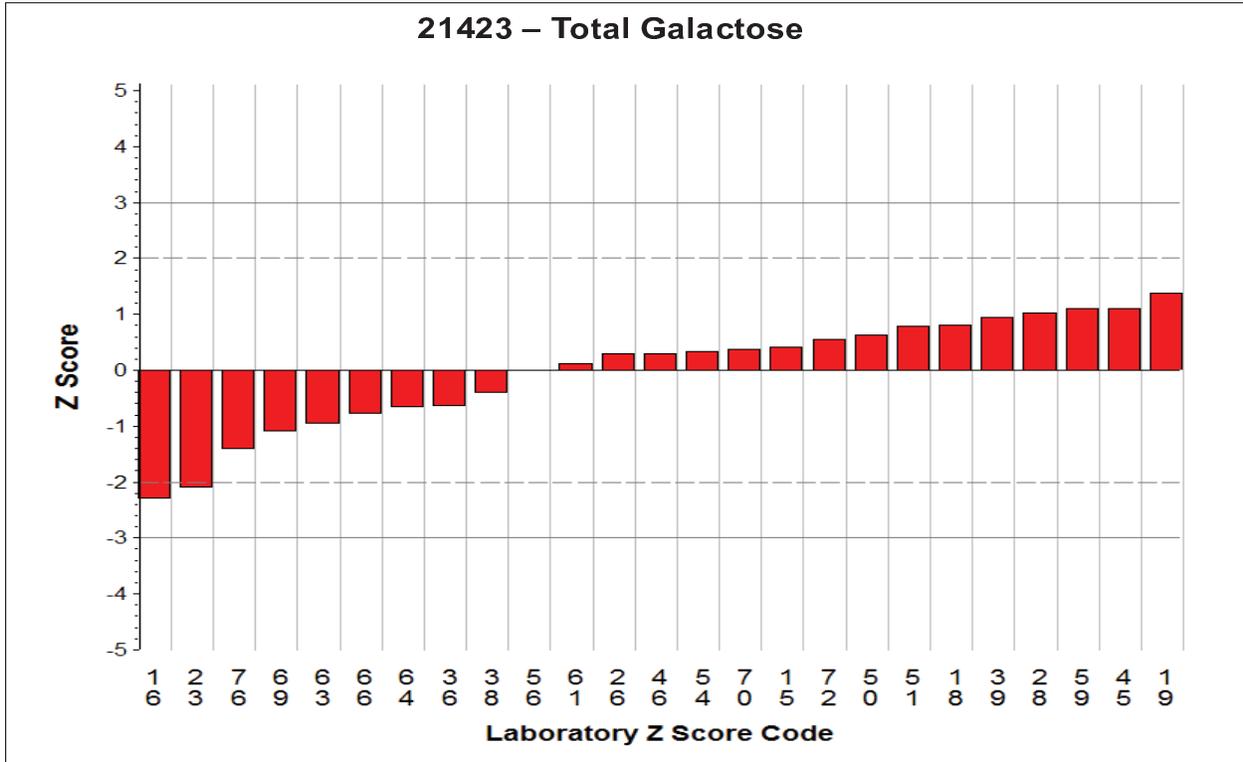
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores

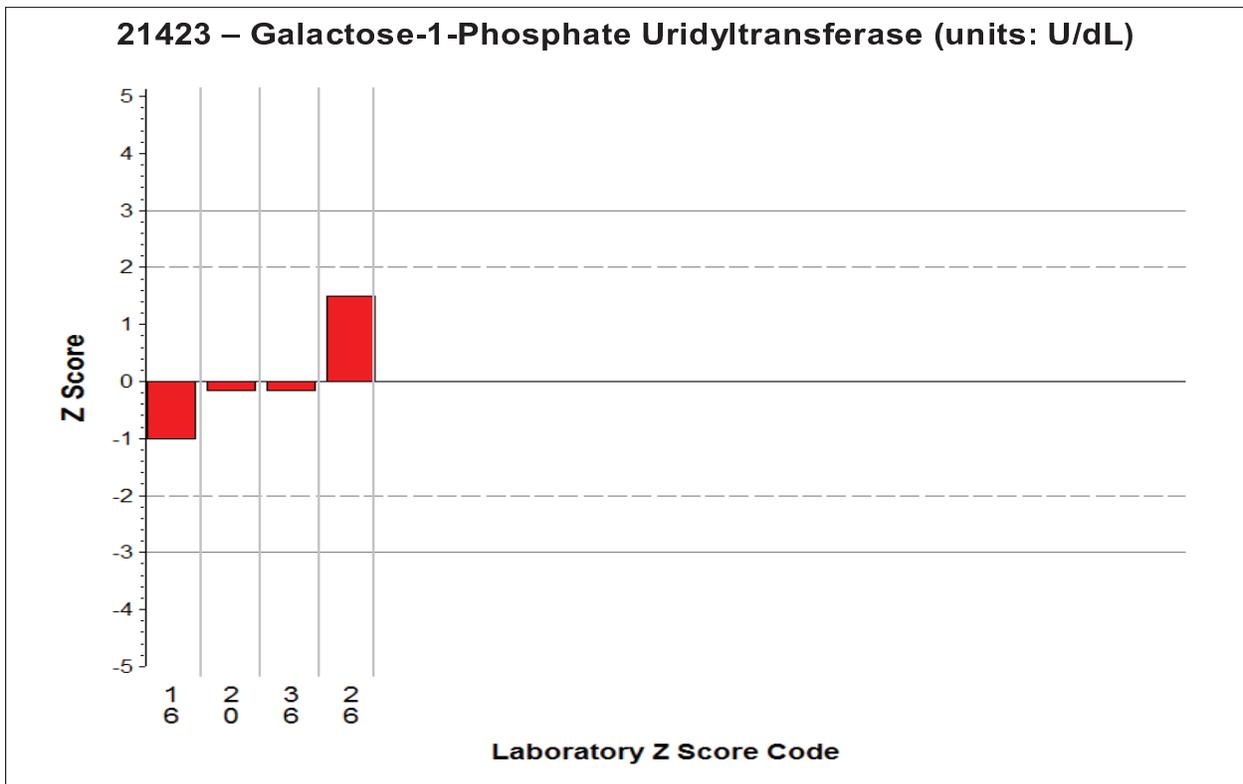
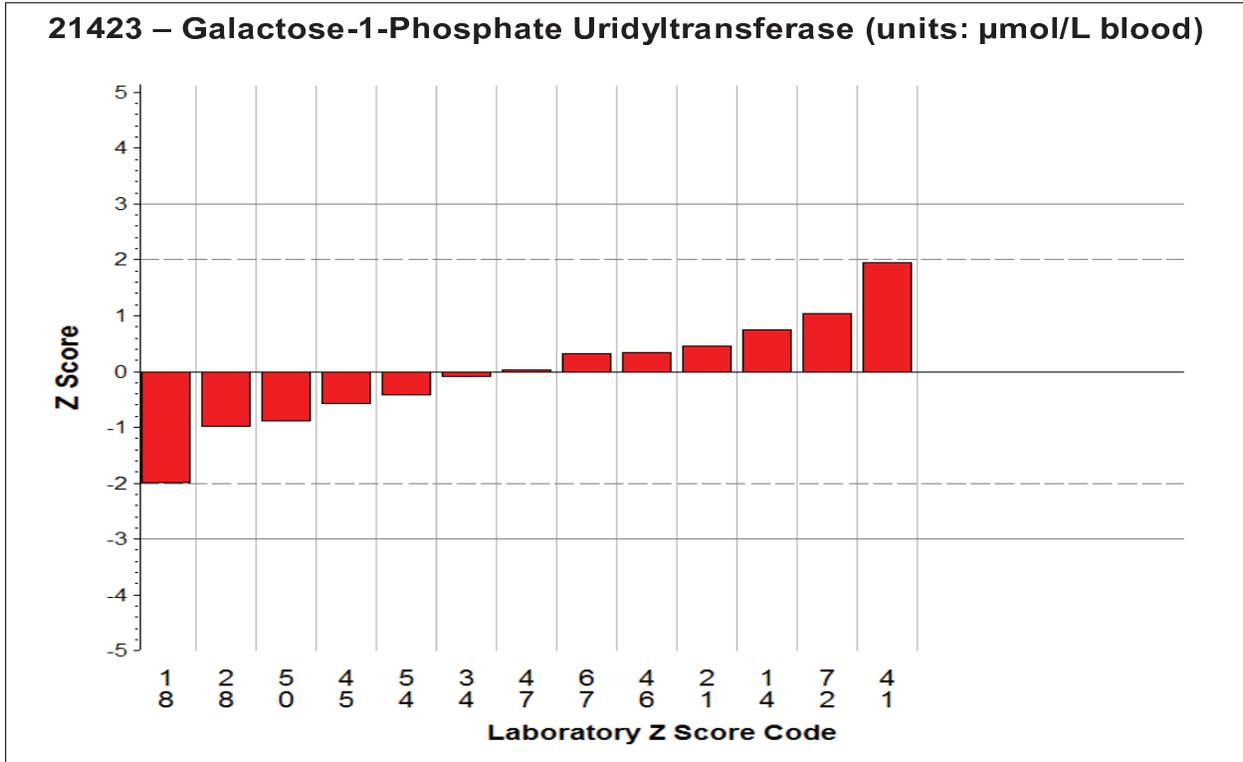


* Z Score >5

$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

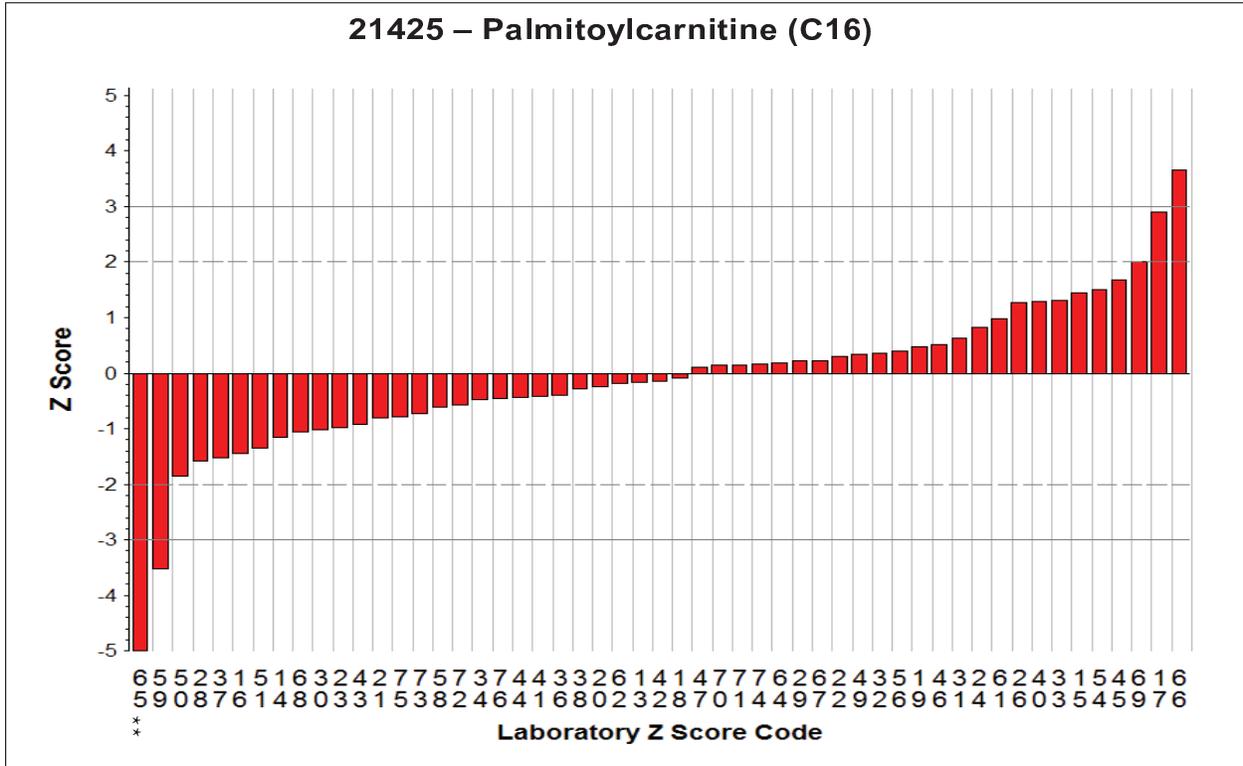
NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



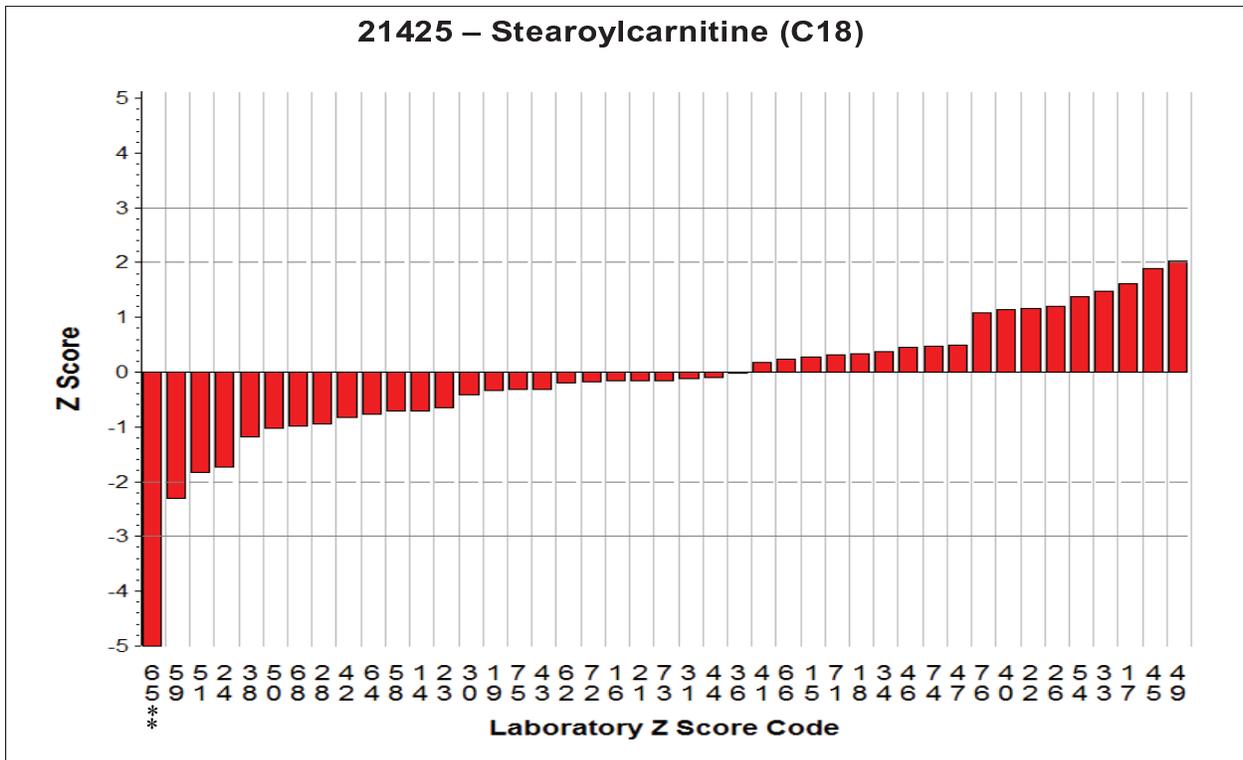
$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



** Z Score < -5

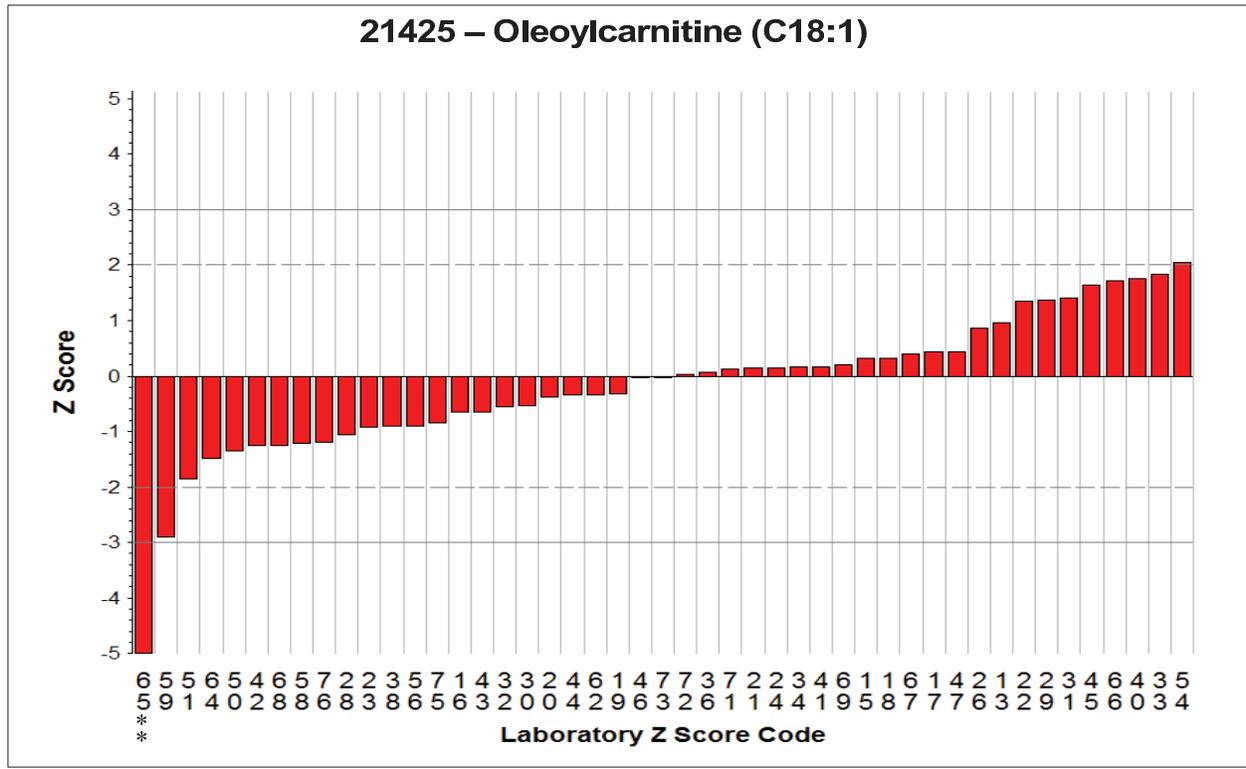


** Z Score < -5

$|Z| \leq 2$ satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ unsatisfactory

Find your Z-score code in the Reviewer's Comment box.

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM
 2014 UDOT Proficiency Testing Panel
 Z Scores



** Z Score < -5

$|Z| \leq 2$ = satisfactory $2 > |Z| < 3$ = questionable $|Z| \geq 3$ = unsatisfactory

 Find your Z-score code in the Reviewer's Comment box.

This **NEWBORN SCREENING QUALITY ASSURANCE PROGRAM** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC)** and the **Association of Public Health Laboratories**.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director

Thomas R. Frieden, M.D., M.P.H.

Acting Director

National Center for Environmental Health

Robin Ikeda, M.D., M.P.H.

Director

Division of Laboratory Sciences

James L. Pirkle, M.D., Ph.D.

Chief

Newborn Screening and Molecular Biology Branch

Carla Cuthbert, Ph.D.



Contributors: Barbara W. Adam
Paul Dantonio
Victor R. De Jesus, Ph.D.
Marie C. Earley, Ph.D.
Sharon Flores
David Foreman
Stephanie Foster
Elizabeth M. Hall
Christopher Haynes, Ph.D.
Sarah Klass
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Daniel Mandel, Ph.D.
Joanne Mei, Ph.D.
Nancy Meredith
Patrick Pickens
Kelsey Sheard
Jennifer Taylor, Ph.D.
Robert Vogt, Ph.D.
Irene Williams
Golriz Yazdanpanah
Hui Zhou, Ph.D.
Sherri Zobel

Production: Sarah Brown
Felicia Manning
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910

President

Christine Bean, Ph.D., M.B.A., MT(ASCP)

Chairman, Newborn Screening and Genetics in Public Health Committee

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patrick Hopkin, B.S.



INQUIRIES TO:

*Sherri Zobel and Irene Williams, Editors • Centers for Disease Control and Prevention (CDC) Newborn Screening Quality Assurance Program • Mailstop F-43
4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: SZobel@cdc.gov*