

Survey: **NBS2/19**
month: **May 2019**
Participant-No: **9900667**
date of issue: **04.05.19**



Referenzinstitut für Bioanalytik



Tijen Tanyalcin MD,PH
Tanyalcin Tip laboratuvari
Kizilkanat Sag lik Sitisi B Blok kat 1
1359 sokak no 4/3
35220 ALSANCAK, IZMIR
TURKEY

Survey directors

Prof. Dr. C. Knabbe
Prof. Dr. Dr. K.P. Kohse
Prof. Dr. M. Neumaier

Head of RfB

Dr. W. J. Geilenkeuser
Dr. A. Kessler

Bonn, 24. May 2019

Participation certificate

We confirm that you have participated in the survey for neonatal screening.

The analytes determined by you are as follows:

TSH (2) | 17-OH-progesterone (2) | IRT (2)

The number in parentheses characterizes the analytical method used.

The assignment of the number to the respective method and/or the respective instrument is to be taken from the total evaluation.

Survey: **NBS2/19**
 month: **May 2019**
 Participant-No: **9900667**



Listing and Evaluation of all your results

Explanations

Certificate

A certificate is issued (given) for an analyte only if the basis for an evaluation of the accuracy is given by the guidelines of the German Medical Association and/or if an evaluation is possible in analogy to these guidelines (see comments on the evaluation) and, if both results for an analyte are within the given acceptance limits. (marked as '+' below C)

Certificate of participation

In the participation certificate all analytes which are included in the list on this page are listed.
 If all analytes are listed on the certificate no participation certificate is printed.

Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL UL = lower resp. upper limit	Certification: + = fulfilled (quotient D/Dmax <= 1.0) - = not fulfilled (quotient D/Dmax > 1.0) ± = certification cancelled because of technical and/or analytical reasons
---------	--	---

	C	M	R	D/Dmax	T	LL	UL							
TSH [mU/l]	±	2	A 11.9 B 13.9	2.51 -1.18	6.77 21.6	4.73 15.1	8.81 28.1							
17-OH-progesterone [nmol/l]	±	2	A 24.3 B 79.9	1.45 1.18	16.9 59.0	11.8 41.3	22.0 76.7							
IRT [µg/l]	±	2	A 51.1 B 16.4	-1.14 2.03	77.6 10.1	54.3 7.07	101 13.2							

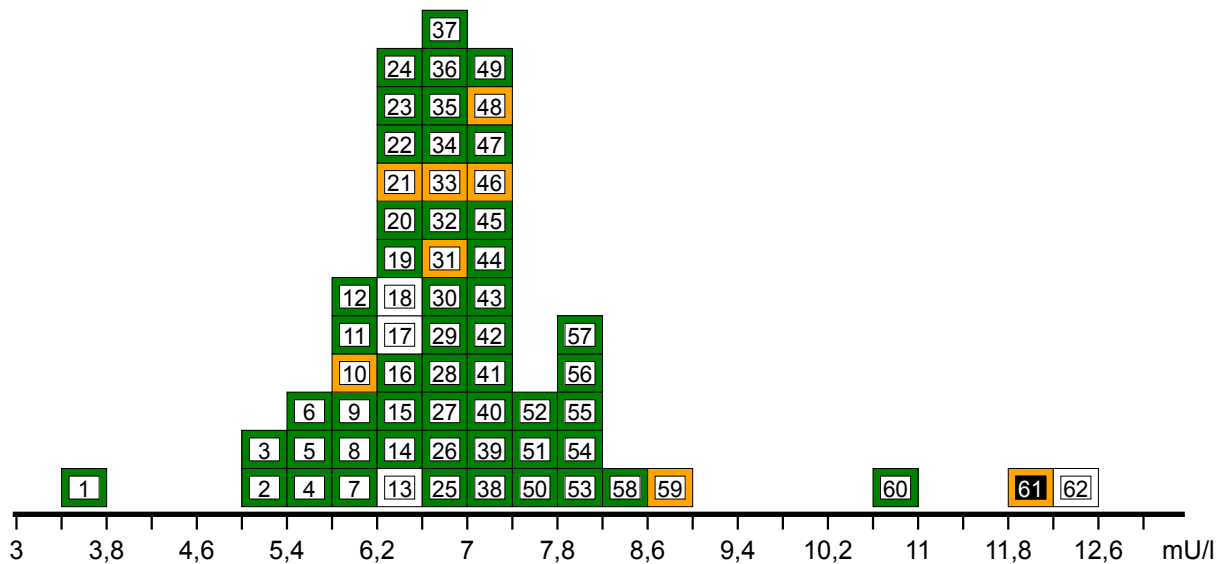
Findings NBS2/19 -May 2019-
Neonatal - Screening, TSH, Sample A
Participant No 9900667



Legend: N = number of results
XM = mean value
SD = standard deviation
CV = coefficient of variation
M = method number

r n = result box/result code no.
r n r n = normal | CH/AGS/CF possible
r n r n = CH/AGS/CF evident | other

—+— = 16. bis 84. percentile with median
 CH = congenital hypothyroidism
 AGS = adrenogen. syndrome
 CF = cystic fibrosis
r n = marks your result box



Descriptive Statistics

N = 62
 XM= 6,9 mU/l
 SD= 1,3 mU/l
 CV= 19,7 %

Statistics of classifications

■ normal 50
 ■ CH/AGS/CF possible 8
 ■ CH/AGS/CF evident
 other

Statistics of Implications, related to Classifications

none	new card	plasma sample	other
49	8		

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	Percentiles				Kit Classifications					
								2	4	6	8	10	12	■	■	■	■
All Kits		62	3.50	6.00	6.77	7.81	12.4			—+—				50	8	0	0
2	9	2	5.33		5.81		6.28							1	0	0	0
3	350	3	6.40		6.45		7.60							2	0	0	0
4	245	18	5.70	5.92	6.91	7.82	8.10		—+—					15	3	0	0
4	246	6	5.00		6.42		7.00							5	1	0	0
4	247	19	6.00	6.20	6.80	7.72	8.65		—+—					16	3	0	0
5	77	8	3.50	4.38	6.54	7.27	7.60		—+—					8	0	0	0
5	111	2	10.9		11.7		12.4							1	0	0	0

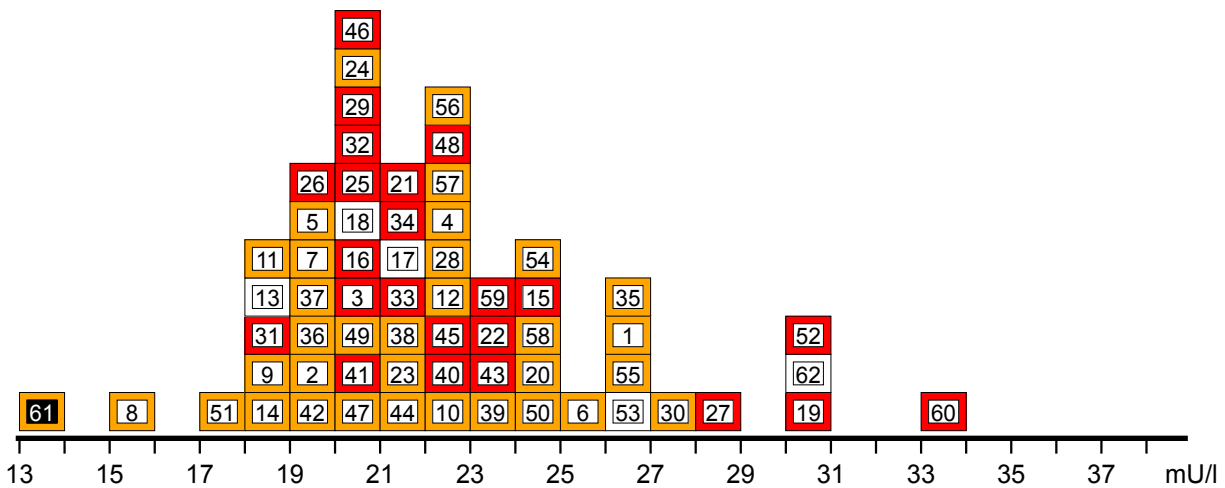
Other Kits: 1 77(1), 2 99(1), 4 91(1), 4 99(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

Findings NBS2/19 -May 2019-
Neonatal - Screening, TSH, Sample B
Participant No 9900667



Legend:	N = number of results	r n = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value	r n r n = normal CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	r n r n = CH/AGS/CF evident other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		r n = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 62	■ normal				
XM= 22,2 mU/l	■ CH/AGS/CF possible 34		28	6	
SD= 3,7 mU/l	■ CH/AGS/CF evident 23			22	
CV= 16,6 %	other 1		1		

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications							
								10	20	30	■	■	■	■	
All Kits		62	13.9	19.1	21.6	26.1	33.9	—+—				0	34	23	1
2	9	2	18.8		19.5		20.2					0	0	1	0
3	350	3	17.7		20.2		24.2					0	2	0	0
4	245	18	18.6	19.6	21.3	23.0	24.9	—+—				0	11	7	0
4	246	6	15.2		20.1		21.9					0	3	3	0
4	247	19	18.3	19.0	21.6	24.3	26.9	—+—				0	11	8	0
5	77	8	22.3	23.8	27.2	30.6	30.8	—+—				0	5	3	0
5	111	2	30.5		32.2		33.9					0	0	1	0

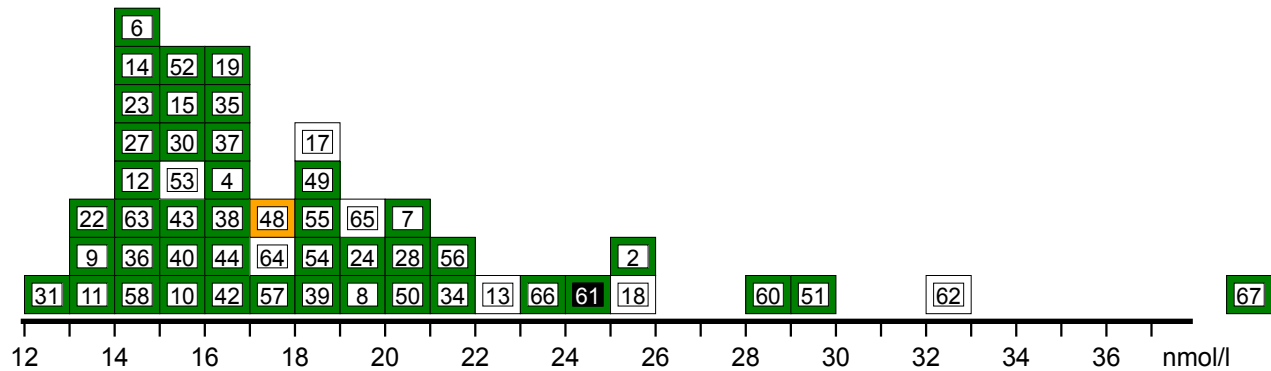
Other Kits: 1 77(1),2 99(1),4 91(1),4 99(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

Findings NBS2/19 -May 2019-
Neonatal - Screening, 17-OHP, Sample A
Participant No 9900667



Legend: N = number of results [r n] = result box/result code no. —+— = 16. bis 84. percentile with median
 XM = mean value [r n] [r n] = normal | CH/AGS/CF possible CH = congenital hypothyroidism
 SD = standard deviation [r n] [r n] = CH/AGS/CF evident | other AGS = adrenogen. syndrome
 CV = coefficient of variation [r n] [r n] = CH/AGS/CF evident | other CF = cystic fibrosis
 M = method number [r n] [r n] = CH/AGS/CF evident | other [r n] = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 51	■ normal 43	42			
XM= 18,5 nmol/l	■ CH/AGS/CF possible 1		1		
SD= 5,1 nmol/l	■ CH/AGS/CF evident				
CV= 28,0 %	■ other				

Kit Evaluation for Sample A

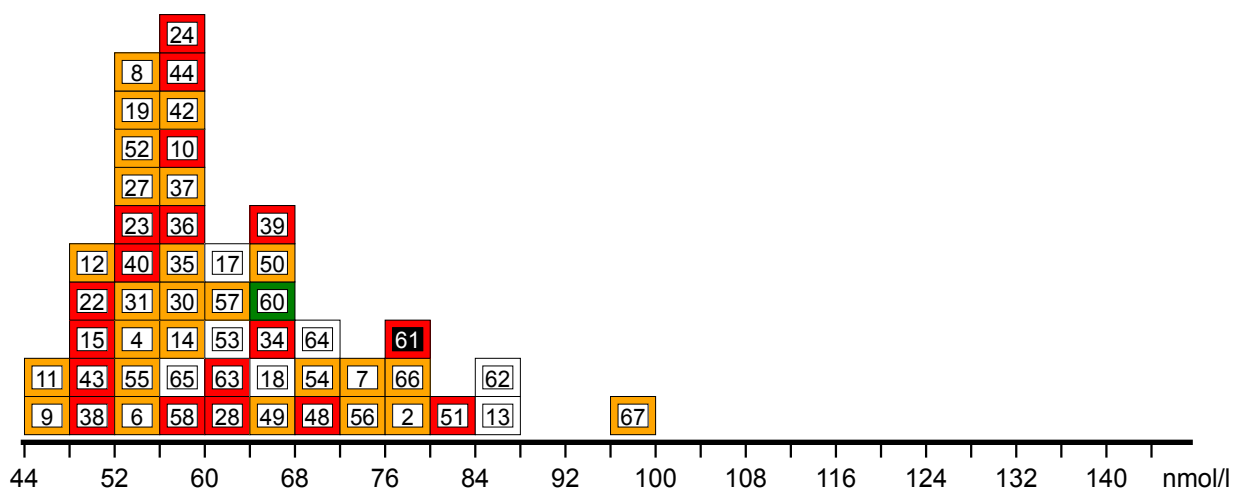
M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications								
								0	10	20	30	■	■	■	■	
All Kits		51	12.9	14.4	16.9	23.0	38.0						43	1	0	0
3	350	2	25.1		27.5		29.9						1	0	0	0
4	245	21	12.9	15.0	17.4	20.6	38.0						19	1	0	0
4	246	5	13.3		16.3		25.5						5	0	0	0
4	247	16	13.3	13.9	15.0	17.0	19.8						15	0	0	0
5	111	2	28.6		30.5		32.4						1	0	0	0

Other Kits: 2 9(1), 2 99(1), 4 91(1), 4 99(1), 6 99(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

Findings NBS2/19 -May 2019-
Neonatal - Screening, 17-OHP, Sample B
Participant No 9900667

Legend:	N = number of results	rn = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value	rn rn = normal CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	rn rn = CH/AGS/CF evident other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		rn = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 51	■ normal 1	1			
XM= 62,2 nmol/l	■ CH/AGS/CF possible 25		22	1	2
SD= 11,0 nmol/l	■ CH/AGS/CF evident 18		5	11	1
CV= 17,7 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications						
								0	50	100	■	■	■	■
All Kits	51	44.1	53.2	59.0	74.4	98.0		—+—	1	25	18	0		
3	350	2	64.6	74.2		83.8			0	0	1	0		
4	245	21	53.1	54.4	61.1	72.7	98.0	—+—	0	15	5	0		
4	246	5	44.1		55.9		77.7		0	3	2	0		
4	247	16	47.4	51.4	55.5	59.0	59.0	+—	0	6	9	0		
5	111	2	65.7		75.6		85.5		1	0	0	0		

Other Kits: 2 9(1),2 99(1),4 91(1),4 99(1),6 99(1),

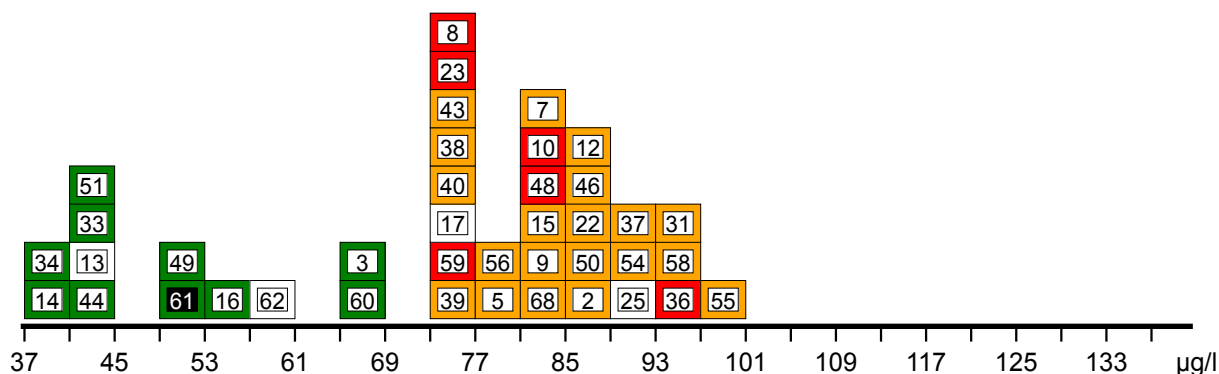
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

M Mu

Findings NBS2/19 -May 2019-
Neonatal - Screening, IRT, Sample A
Participant No 9900667



Legend:	N = number of results	r n = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value	r n r n = normal CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	r n r n = CH/AGS/CF evident other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		r n = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 40	■ normal 10	10			
XM= 74,3 µg/l	■ CH/AGS/CF possible 20		2		17
SD= 17,5 µg/l	■ CH/AGS/CF evident 6				6
CV= 23,5 %	other				

Kit Evaluation for Sample A

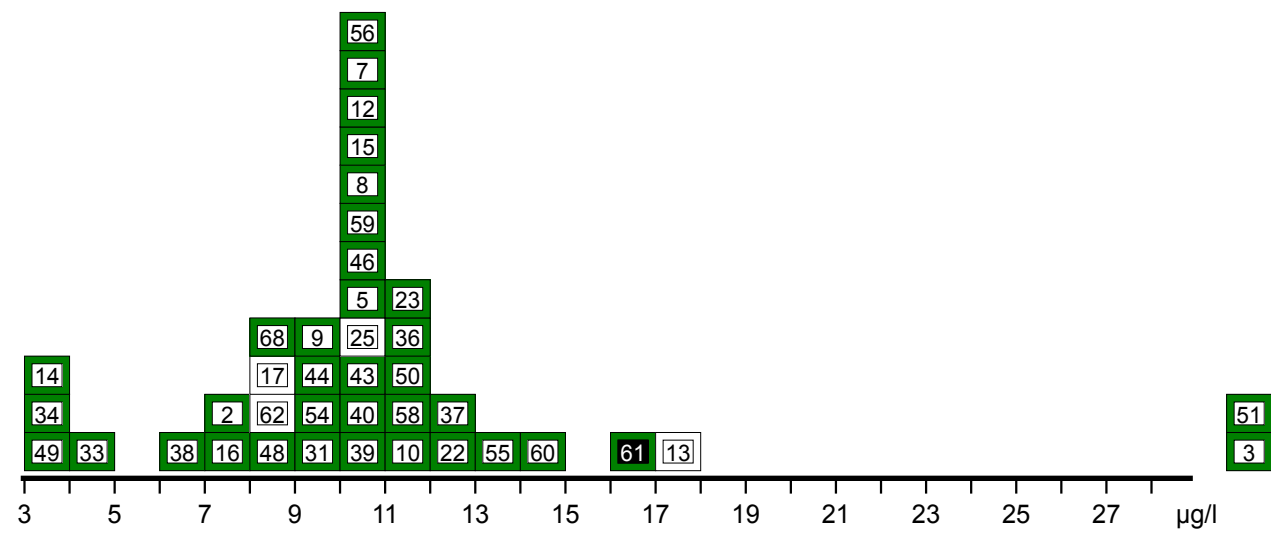
M	Kit	N	Min	16.P	50.P	84.P	Max	0	50	100	Kit Classifications			
											■	■	■	■
All Kits	40	37.3	48.3	77.6	90.0	98.0		—+—			10	20	6	0
2	52	2	51.1	60.0	68.8			•			2	0	0	0
4	245	15	39.0	63.8	82.3	90.0	96.4	—+—			2	10	2	0
4	246	3	53.8	75.0	86.3						1	2	0	0
4	247	15	37.3	41.7	82.5	94.1	98.0	—+—			3	8	4	0
5	111	2	59.6	62.6	65.7						1	0	0	0

Other Kits: 2 9(1),3 350(1),4 91(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -34.15 % -14.76 %

Findings NBS2/19 -May 2019-
Neonatal - Screening, IRT, Sample B
Participant No 9900667

Legend:	N = number of results	r n = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	r n r n = normal CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	r n r n = CH/AGS/CF evident other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		r n = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 40	■ normal 36	35			
XM= 10,3 µg/l	■ CH/AGS/CF possible				
SD= 4,5 µg/l	■ CH/AGS/CF evident				
CV= 43,5 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
All Kits	40	3.27	7.56	10.1	12.5	44.8			36 0 0 0
2	52	2	16.4	23.9		31.4			2 0 0 0
4	245	15	3.27	6.21	10.0	10.8	11.0		14 0 0 0
4	246	3	6.70		7.50	7.60			3 0 0 0
4	247	15	3.90	7.48	10.6	12.0	13.0		15 0 0 0
5	111	2	8.53		11.6	14.7			1 0 0 0

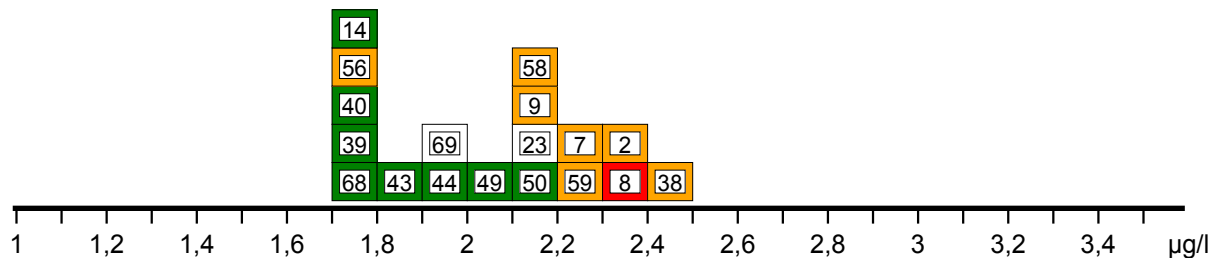
Other Kits: 2 9(1),3 350(1),4 91(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:	M	Mu
	61 %	-31.38 %

Findings NBS2/19 -May 2019-
 Neonatal - Screening, PAP, Sample A
 Participant No 9900667



Legend:	N = number of results	r n = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value		CH = congenital hypothyroidism
	SD = standard deviation	r n r n = normal CH/AGS/CF possible	AGS = adrenogen. syndrome
	CV = coefficient of variation	r n r n = CH/AGS/CF evident other	CF = cystic fibrosis
	M = method number		r n = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 18	■ normal 8	8			
XM= 2,0 µg/l	■ CH/AGS/CF possible 7		2		5
SD= 0,2 µg/l	■ CH/AGS/CF evident 1				1
CV= 11,7 %	other				

Kit Evaluation for Sample A

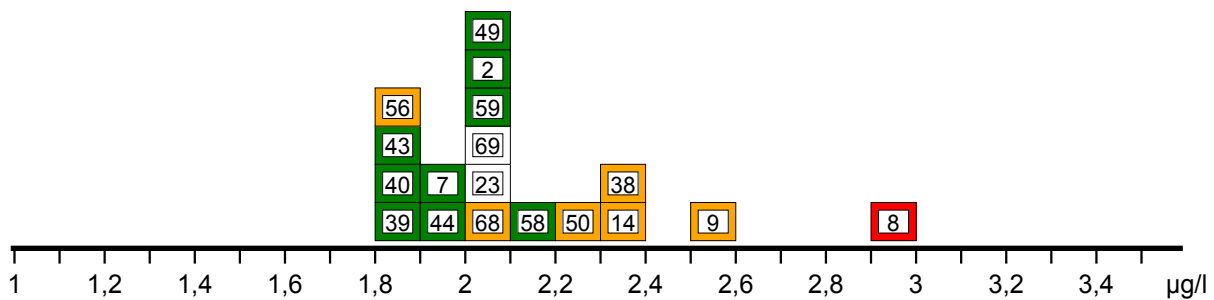
M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications								
								0,7	1,4	2,1	2,8	3,5	■	■	■	■
All Kits	18	1.70	1.70	2.05	2.30	2.40		—+—					8	7	1	0
2	255 3	1.70		1.73		2.10							2	1	0	0
4	255 14	1.70	1.73	2.05	2.32	2.40		—+—					6	5	1	0

Other Kits: 4 245(1),

Findings NBS2/19 -May 2019-
 Neonatal - Screening, PAP, Sample B
 Participant No 9900667



Legend:	N = number of results	r n = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value		CH = congenital hypothyroidism
	SD = standard deviation	r n r n = normal CH/AGS/CF possible	AGS = adrenogen. syndrome
	CV = coefficient of variation	r n r n = CH/AGS/CF evident other	CF = cystic fibrosis
	M = method number		r n = marks your result box



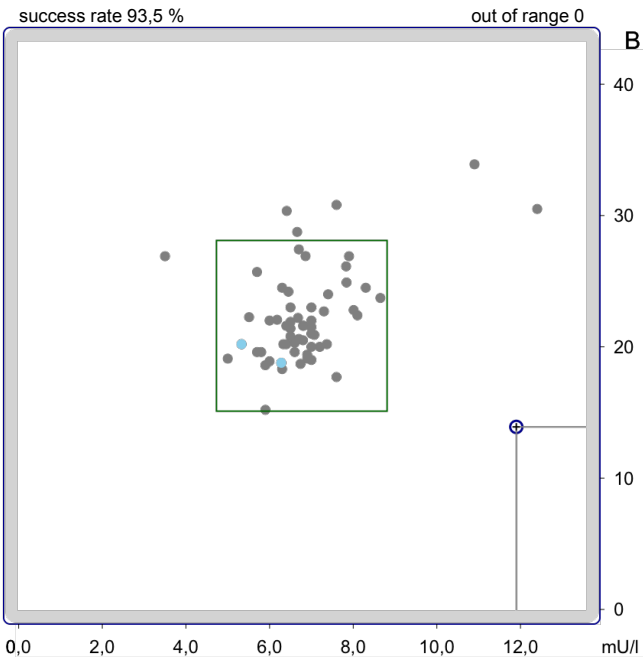
Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 18	■ normal 9	8			1
XM= 2,0 µg/l	■ CH/AGS/CF possible 6		3		3
SD= 0,2 µg/l	■ CH/AGS/CF evident 1				1
CV= 13,4 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications									
								0,7	1,4	2,1	2,8	3,5	■	■	■	■	
All Kits	18	18	1.80	1.80	2.00	2.30	2.90							9	6	1	0
2	255	3	1.80		1.85		2.20							1	2	0	0
4	255	14	1.80	1.84	2.02	2.42	2.90							7	4	1	0

Other Kits: 4 245(1),

Analyte **TSH**
Method all methods



No of participants	62	
sample/unit	A	B
mean	6.94	22.3
standard deviation	1.37	3.71
coefficient of variation	19.7	16.7

Sample A [mU/l]

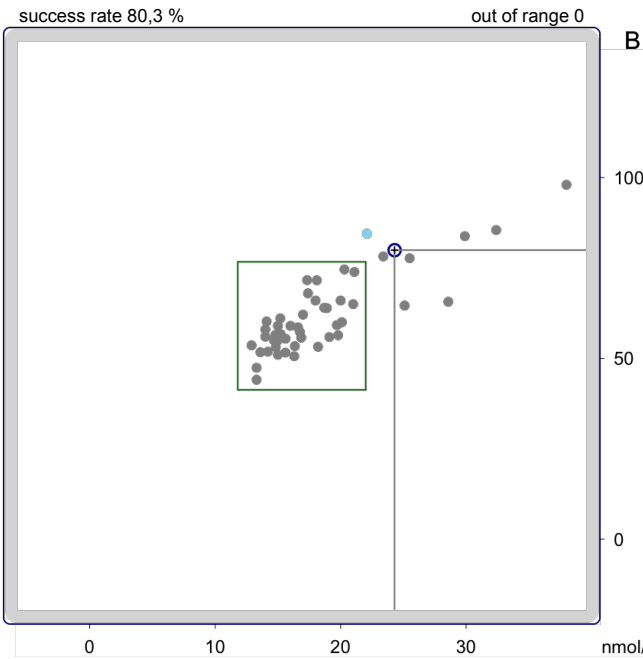
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		62	3.50	6.00	6.77	7.81	12.4
3	350	3	6.40		6.45		7.60
4	245	18	5.70	5.92	6.91	7.82	8.10
4	246	6	5.00		6.42		7.00
4	247	19	6.00	6.20	6.80	7.72	8.65
5	77	8	3.50	4.38	6.54	7.27	7.60

Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		62	13.9	19.1	21.6	26.1	33.9
3	350	3	17.7		20.2		24.2
4	245	18	18.6	19.6	21.3	23.0	24.9
4	246	6	15.2		20.1		21.9
4	247	19	18.3	19.0	21.6	24.3	26.9
5	77	8	22.3	23.8	27.2	30.6	30.8

Other kits (number):
1-77(1), 2-09(2), > 2-99(1)<, 4-91(1), 4-99(1), 5-111(2),

Analyte **17-OH-progesterone**
Method all methods



No of participants	51	
sample/unit	A	B
mean	18.5	62.3
standard deviation	5.19	11.1
coefficient of variation	28.1	17.8

Sample A [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		51	12.9	14.4	16.9	23.0	38.0
4	245	21	12.9	15.0	17.4	20.6	38.0
4	246	5	13.3		16.3		25.5
4	247	16	13.3	13.9	15.0	17.0	19.8

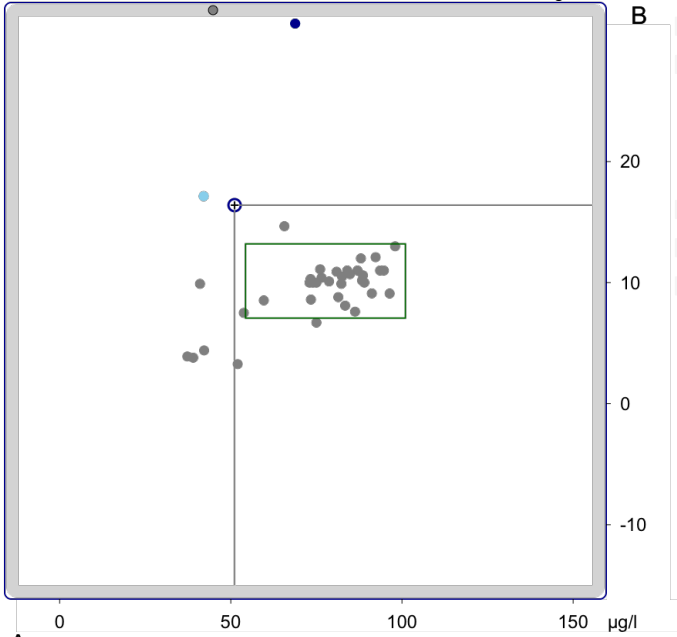
Sample B [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		51	44.1	53.2	59.0	74.4	98.0
4	245	21	53.1	54.4	61.1	72.7	98.0
4	246	5	44.1		55.9		77.7
4	247	16	47.4	51.4	55.5	59.0	59.0

Other kits (number):
2-09(1), > 2-99(1)<, 3-350(2), 4-91(1), 4-99(1), 5-111(2), 6-99(1),

Analyte **IRT**
Method all methods

success rate 70,0 % out of range 1



Sample A [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		40	37.3	48.3	77.6	90.0	98.0
2	52	2	51.1		60.0		68.8
4	245	15	39.0	63.8	82.3	90.0	96.4
4	246	3	53.8		75.0		86.3
4	247	15	37.3	41.7	82.5	94.1	98.0
5	111	2	59.6		62.6		65.7

Sample B [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		40	3.27	7.56	10.1	12.5	44.8
2	52	2	16.4		23.9		31.4
4	245	15	3.27	6.21	10.0	10.8	11.0
4	246	3	6.70		7.50		7.60
4	247	15	3.90	7.48	10.6	12.0	13.0
5	111	2	8.53		11.6		14.7

The deviation of your results from the median of the corresponding sub-collective (kit) is: A-14.76 % B-31.38 %

Other kits (number);
2-09(1), 3-350(1), 4-91(1),

No of participants	40	
sample/unit	A	B
mean	74.4	10.4
standard deviation	17.5	4.52
coefficient of variation	23.6	43.6