

Survey: **NBS1/18**
month: **February 2018**
Participant-No: **9900667**
date of issue: **17.02.18**



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, 6. March 2018

Certificate

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

You have met the requirements of the survey for the following analytes:

17-OH-progesterone (2)

This certificate is valid until the end of August 2018.

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.

http://www.rfb.bio/cgi/certificate?nr=9900667&rv_id=NBS_181&version=0&uid=04f623f4b8994ec9a1e636c14e1a70b7

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Bonn, 6. March 2018

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: **NBS1/18**
 month: **February 2018**
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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.

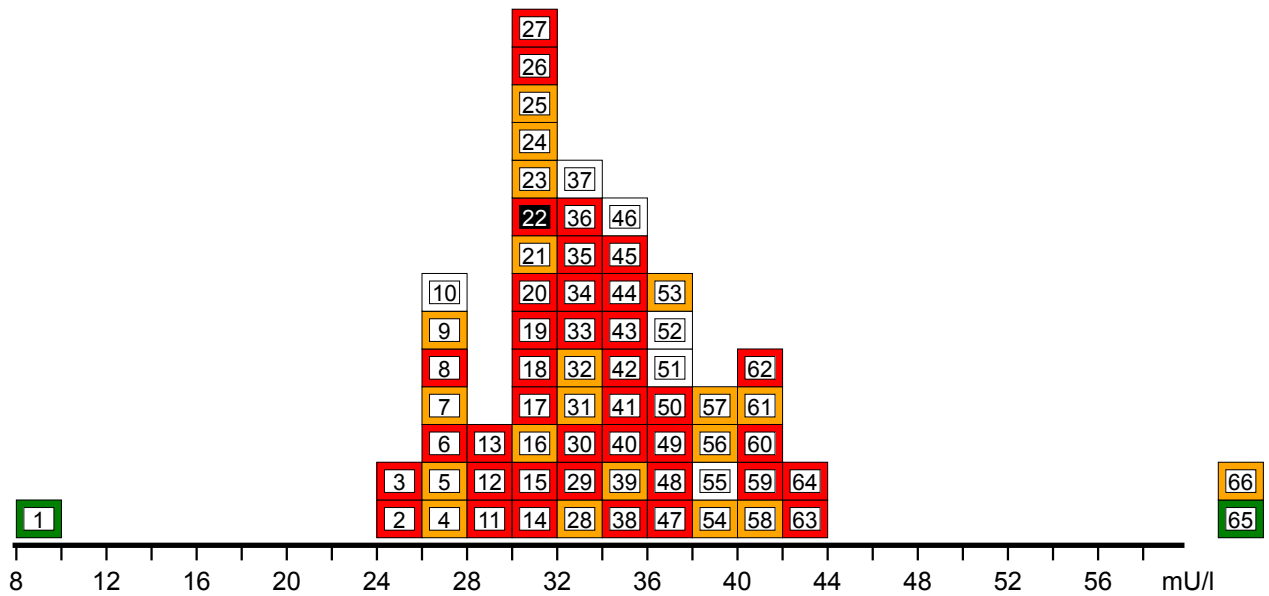
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL UL = 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
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	C	M	R	D/Dmax	T	LL	UL							
TSH [mU/l]	±	2	A	31.4	-1.25	50.2	35.1	65.3						
			B	3.60	-2.04	9.30	6.51	12.1						
17-OH-progesterone [nmol/l]	+	2	A	66.9	0.23	62.5	43.7	81.3						
			B	24.8	0.83	19.8	13.8	25.8						
IRT [µg/l]	±	2	A	16.5	-1.16	25.4	17.7	33.1						
			B	48.6	-1.00	69.4	48.5	90.3						

Findings NBS1/18 -February 2018-
Neonatal - Screening, TSH, Sample A
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 = 66	■ normal 2	1		1	
XM= 33,4 mU/l	■ CH/AGS/CF possible 20		11	7	
SD = 4,4 mU/l	■ CH/AGS/CF evident 38		2	35	1
CV = 13,4 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	10	20	30	40	50	Kit Classifications			
													■	■	■	■
All Kits	66	8.93	27.9	33.3	39.2	69.9							2	20	38	0
2	99	2	31.4	50.2		69.0							1	0	1	0
3	350	2	33.9	38.3		42.7							0	0	1	0
4	99	2	27.6	31.2		34.8							0	1	1	0
4	245	20	25.1	27.3	30.5	34.1	39.6						0	4	16	0
4	246	8	25.2	25.8	32.2	37.0	37.7						0	5	3	0
4	247	16	8.93	30.0	33.4	35.2	39.0						1	5	10	0
5	77	8	30.2	32.9	40.3	41.6	41.9						0	4	4	0
5	111	2	35.7		39.2		42.7						0	0	1	0

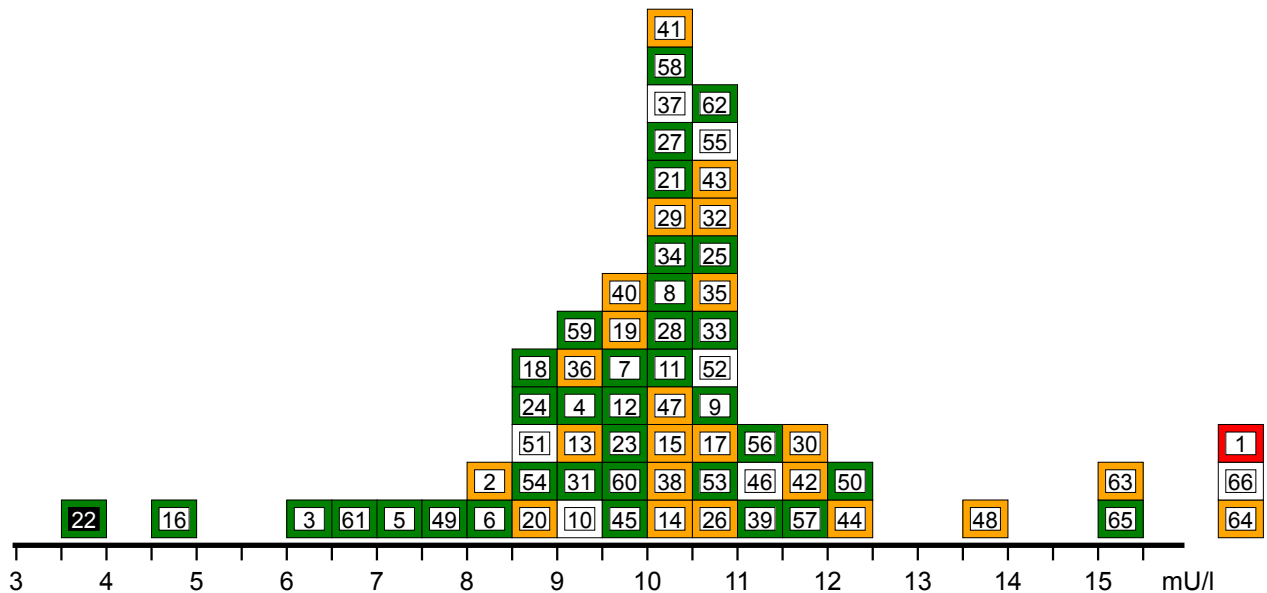
Other Kits: 1 77(1),2 2(1),2 9(1),3 99(1),3 247(1),4 91(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: M Mu -5.5 % -37.45 %

Findings NBS1/18 -February 2018-
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 = 66	■ normal 35	32	1		
XM= 9,9 mU/l	■ CH/AGS/CF possible 23		22	1	
SD = 1,9 mU/l	■ CH/AGS/CF evident 1			1	
CV = 19,5 %	other 1		1		

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	15	Kit Classifications			
												■	■	■	■
All Kits	66	3.60	8.72	10.2	11.7	29.7						35	23	1	1
2	99	2	3.60		9.30	15.0		●				2	0	0	0
3	350	2	10.3		13.2	16.1						0	1	0	0
4	99	2	9.80		10.3	10.8						1	1	0	0
4	245	20	8.00	8.91	10.1	10.6	12.1					12	8	0	0
4	246	8	6.10	6.54	10.3	11.4	11.8					5	3	0	0
4	247	16	8.60	9.02	10.1	11.9	29.7					7	8	1	0
5	77	8	4.60	5.53	9.05	10.6	10.9					8	0	0	0
5	111	2	11.1		13.3	15.4						0	1	0	0

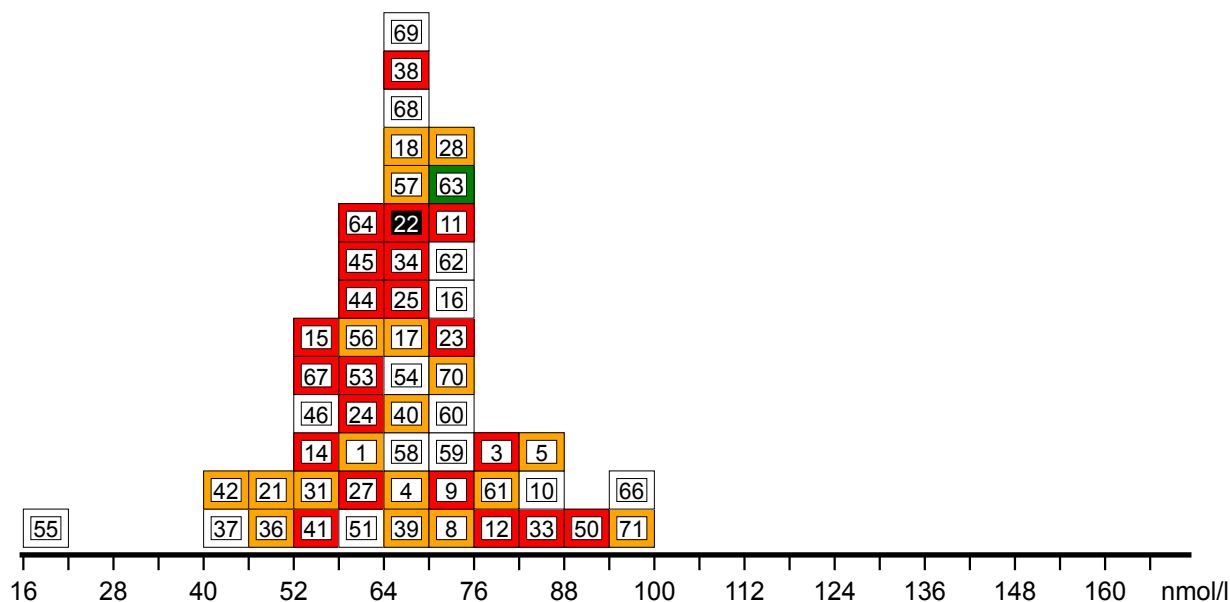
Other Kits: 1 77(1),2 2(1),2 9(1),3 99(1),3 247(1),4 91(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -64.53 % -61.29 %

Findings NBS1/18 -February 2018-
Neonatal - Screening, 17-OHP, Sample A
Participant No 9900667



Legend:	N = number of results	rn = result box/result code no.	\pm = 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 = 54	■ normal 1	1			
XM= 67,1 nmol/l	■ CH/AGS/CF possible 18		12	2	3
SD= 11,2 nmol/l	■ CH/AGS/CF evident 21		4	16	
CV= 16,7 %	■ other 1		1		

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
	All Kits	54	16.8	56.4	66.5	76.1	96.2	\pm	1 18 21 1
	3	350	2	43.0	53.2	63.4	63.4		0 0 1 0
	4	245	22	64.8	70.6	85.1	96.2	\pm	0 9 6 1
	4	246	6	56.7	69.8	87.5	87.5		0 1 5 0
	4	247	16	44.5	58.4	65.4	69.5	\pm	0 7 8 0
	5	111	2	56.5	65.3	74.1	74.1		1 0 0 0

Other Kits: 2 9(1),2 99(1),3 247(1),4 91(1),4 99(1),6 99(1),

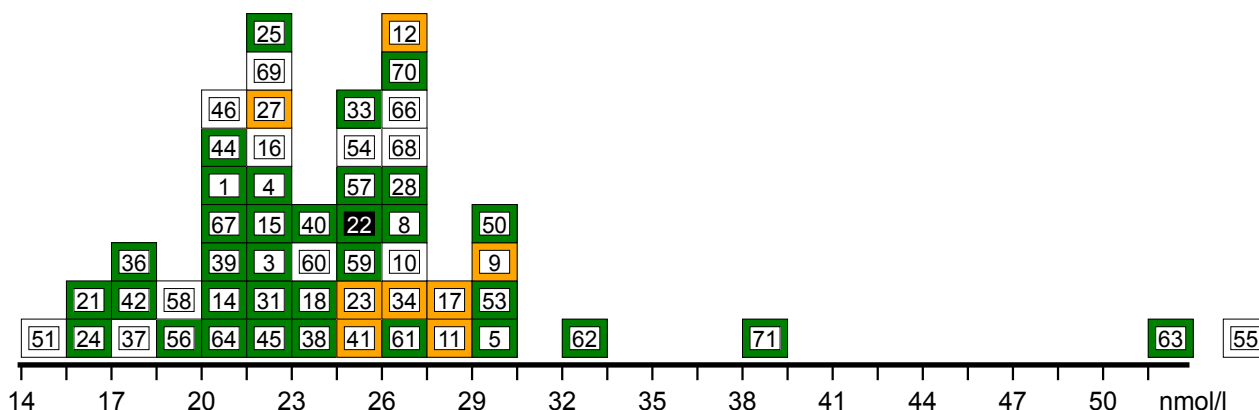
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

M	Mu
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Findings NBS1/18 -February 2018-
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 = 54	■ normal 33	30	1		
XM = 24,3 nmol/l	■ CH/AGS/CF possible 8		8		
SD = 5,8 nmol/l	■ CH/AGS/CF evident				
CV = 24,1 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
	All Kits	54	14.8	19.9	23.7	28.9	89.7		■ 34 ■ 8 ■ 0 0
	3	350	2	17.3	18.7	20.0			■ 1 ■ 0 ■ 0 0
	4	245	22	19.7	23.0	29.4	38.0		■ 12 ■ 5 ■ 0 0
	4	246	6	20.7	23.6	29.1			■ 5 ■ 1 ■ 0 0
	4	247	16	16.0	17.9	22.5	24.5		■ 13 ■ 2 ■ 0 0
	5	111	2	21.4	37.2	53.0			■ 1 ■ 0 ■ 0 0

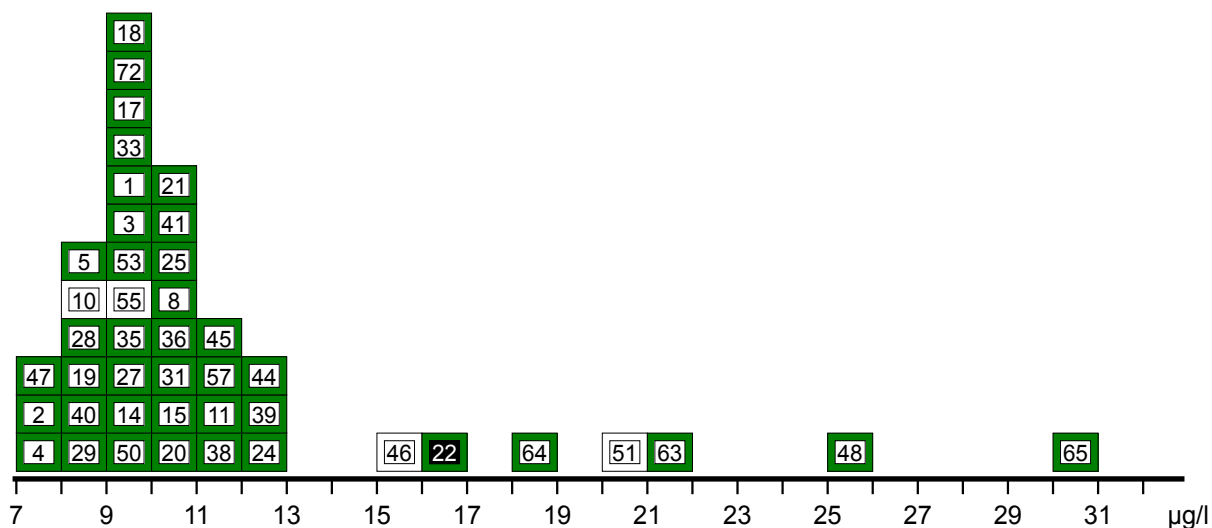
Other Kits: 2 9(1),2 99(1),3 247(1),4 91(1),4 99(1),6 99(1),

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

Findings NBS1/18 -February 2018-
Neonatal - Screening, IRT, Sample A
Participant No 9900667



Legend:	N = number of results	rn = result box/result code no.	\pm = 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
N = 43	■ normal 39 ■ CH/AGS/CF possible ■ CH/AGS/CF evident other	none 38 new card plasma sample other
XM = 11,5 µg/l		
SD = 4,8 µg/l		
CV = 41,9 %		

Kit Evaluation for Sample A														
M	Kit	N	Min	16.P	50.P	84.P	Max	5 10 15 20 25 30			Kit Classifications			
All Kits		43	7.45	8.50	10.0	15.2	30.0	+-----			39	0	0	0
2	52	3	16.5		25.4		30.0			3	0	0	0
4	245	15	7.45	7.82	9.00	10.4	11.1	+			15	0	0	0
4	246	5	7.80		9.30		10.5			5	0	0	0
4	247	14	9.00	9.18	10.6	12.0	12.0	+-----			14	0	0	0
5	111	2	15.3		18.5		21.7			1	0	0	0

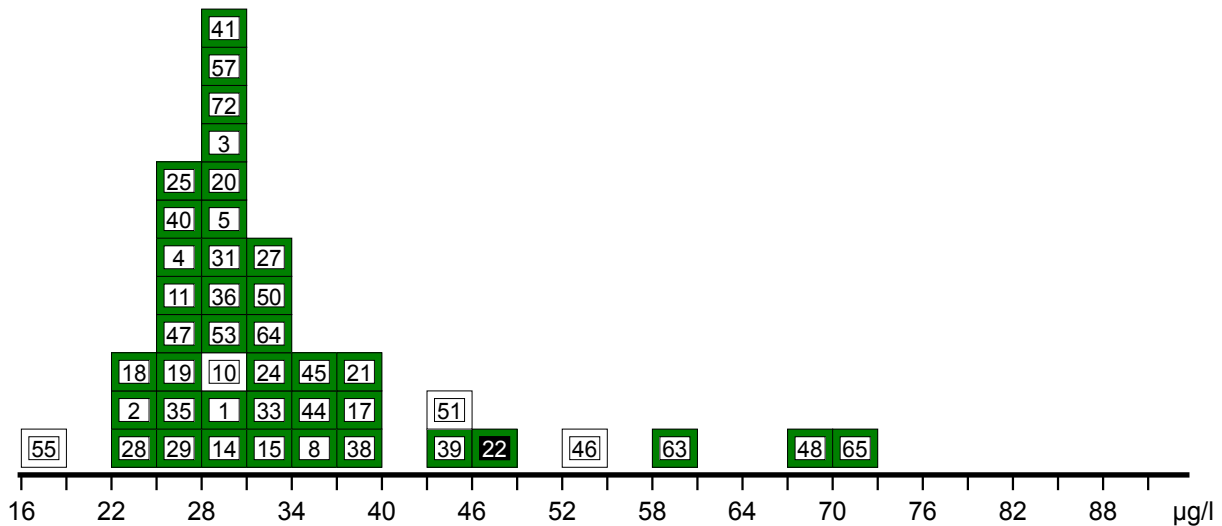
Other Kits: 2 9(1),3 247(1),3 350(1),4 91(1),

The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:	65 %	-35.04 %

Findings NBS1/18 -February 2018-
Neonatal - Screening, IRT, 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		
N = 43	■ normal 39	none 37	new card 1	plasma sample 0
XM = 33,8 µg/l	■ CH/AGS/CF possible			other 0
SD = 11,5 µg/l	■ CH/AGS/CF evident			
CV = 34,0 %	other			

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
	All Kits	43	16.2	26.2	30.3	42.8	72.0		■ 39 ■ 0 ■ 0 0
2	52	3	48.6		69.4		72.0		■ 3 ■ 0 ■ 0 0
4	245	15	24.0	24.4	27.1	32.4	37.6		■ 15 ■ 0 ■ 0 0
4	246	5	26.7		29.8		34.0		■ 5 ■ 0 ■ 0 0
4	247	14	28.0	28.3	31.5	37.5	43.0		■ 14 ■ 0 ■ 0 0
5	111	2	54.0		57.2		60.4		■ 1 ■ 0 ■ 0 0

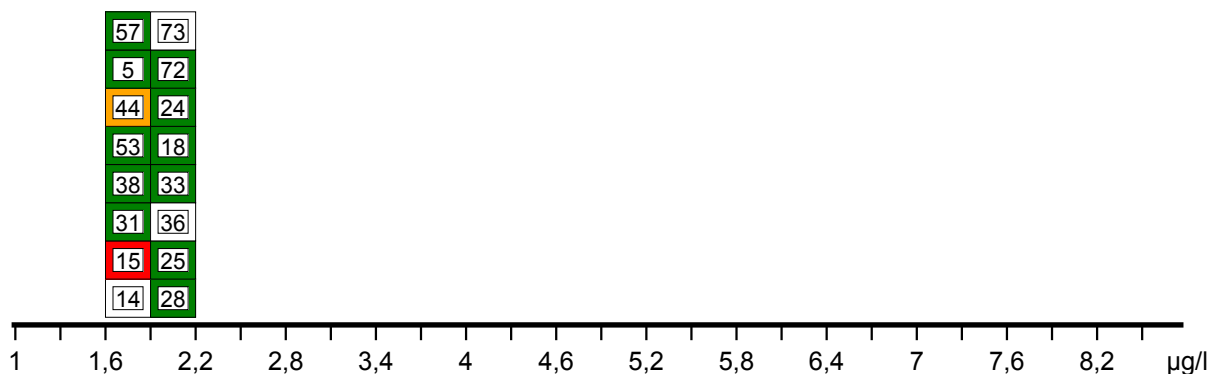
Other Kits: 2 9(1),3 247(1),3 350(1),4 91(1),

The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:	60 %	-29.97 %

Findings NBS1/18 -February 2018-
Neonatal - Screening, PAP, Sample A
Participant No 9900667



Legend:	N = number of results	rn = result box/result code no.	—+ = 16. bis 84. percentile with median
	XM = mean value		CH = congenital hypothyroidism
	SD = standard deviation	rn rn = normal CH/AGS/CF possible	AGS = adrenogen. syndrome
	CV = coefficient of variation	rn rn = CH/AGS/CF evident other	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 = 16	■ normal 11	11		
XM = 1,8 µg/l	■ CH/AGS/CF possible 1			1
SD = 0,1 µg/l	■ CH/AGS/CF evident 1			1
CV = 7,7 %	other			

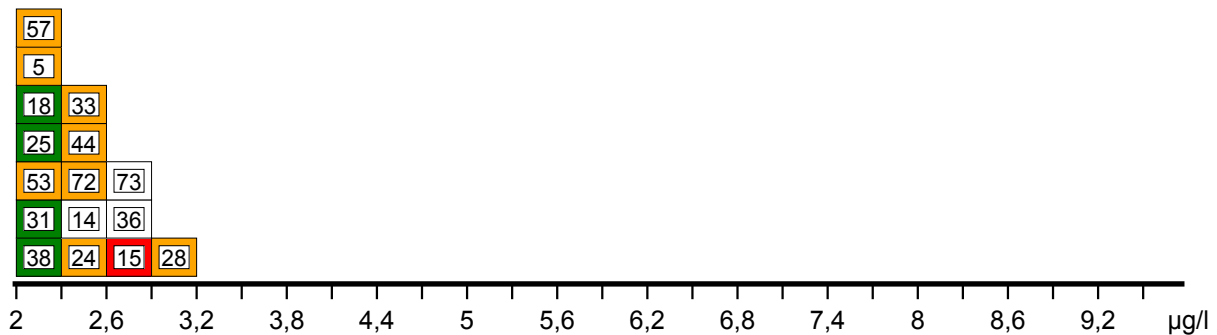
Kit Evaluation for Sample A																		
M	Kit	N	Min	16.P	50.P	84.P	Max	0,7	1,4	2,1	2,8	3,5	Kit Classifications					
All Kits	16	1.60	1.61	1.89	2.00	2.00								■	■	■		
2	255	3	1.87	1.90	1.96	1.96												
4	255	12	1.60	1.63	1.86	2.00	2.00											

Other Kits: 4 247(1),

Findings NBS1/18 -February 2018-
Neonatal - Screening, PAP, 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	

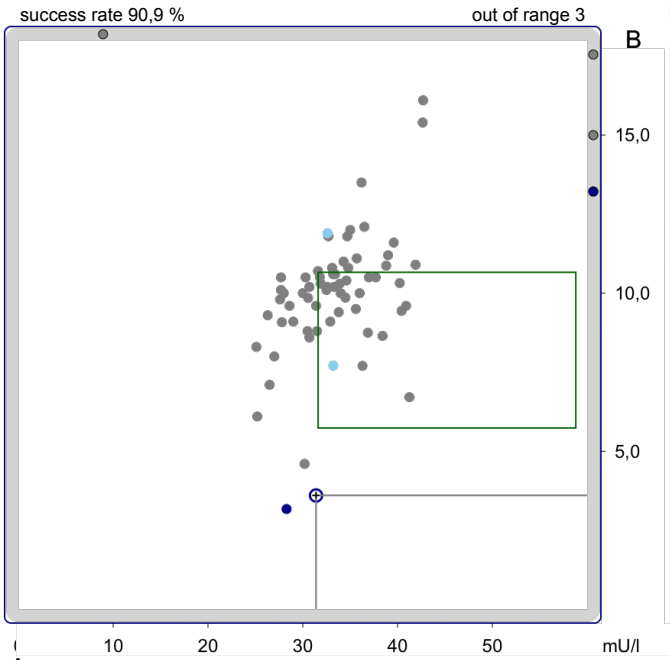


Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 16	■ normal 4	4			
XM = 2,3 µg/l	■ CH/AGS/CF possible 8		1		7
SD = 0,3 µg/l	■ CH/AGS/CF evident 1				1
CV = 12,8 %	other				

Kit Evaluation for Sample B															
M	Kit	N	Min	16.P	50.P	84.P	Max	Percentiles		Kit Classifications					
								0,7	1,4	2,1	2,8	■	■	■	■
All Kits	16	2.00	2.10	2.40	2.73	3.10						4	8	1	0
2	255	3	2.14	2.24		3.10						1	2	0	0
4	255	12	2.00	2.09	2.40	2.68	2.80					3	6	0	0

Other Kits: 4 247(1),

Analyte **TSH**
Method all methods



A

No of participants	66		
sample/unit	A	mU/l	B
mean	33.4		9.94
standard deviation	4.49		1.95
coefficient of variation	13.4		19.6

Sample A [mU/l]

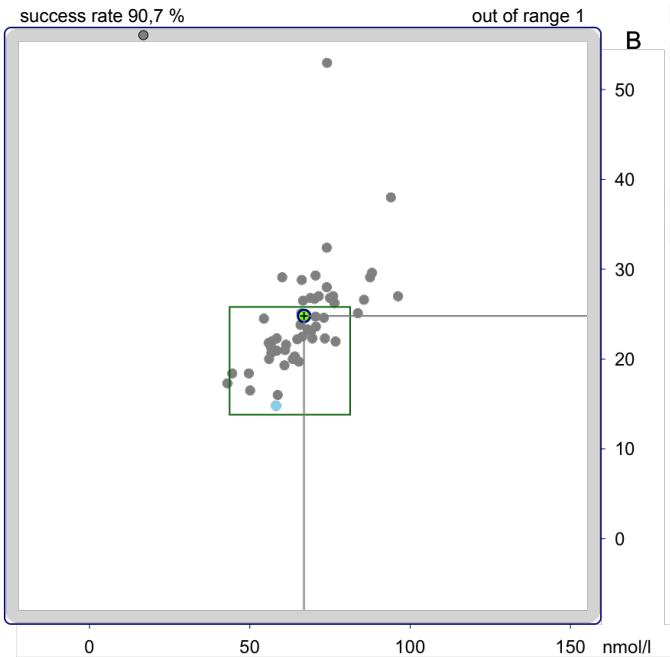
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		66	8.93	27.9	33.3	39.2	69.9
4	245	20	25.1	27.3	30.5	34.1	39.6
4	246	8	25.2	25.8	32.2	37.0	37.7
4	247	16	8.93	30.0	33.4	35.2	39.0
5	77	8	30.2	32.9	40.3	41.6	41.9

Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		66	3.60	8.72	10.2	11.7	29.7
4	245	20	8.00	8.91	10.1	10.6	12.1
4	246	8	6.10	6.54	10.3	11.4	11.8
4	247	16	8.60	9.02	10.1	11.9	29.7
5	77	8	4.60	5.53	9.05	10.6	10.9

Other kits (number):
1-77(1), 2-02(1), 2-09(1), > 2-99(2)<, 3-99(1), 3-247(1), 3-350(2), 4-91(1), 4-99(2), 5-111(2),

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



A

No of participants	54		
sample/unit	A	nmol/l	B
mean	67.2		24.3
standard deviation	11.2		5.87
coefficient of variation	16.7		24.1

Sample A [nmol/l]

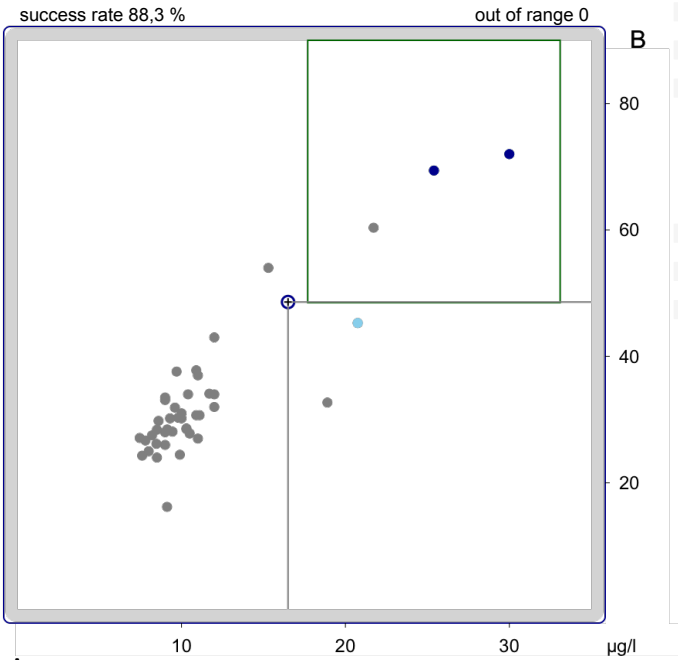
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		54	16.8	56.4	66.5	76.1	96.2
4	245	22	64.8	66.0	70.6	85.1	96.2
4	246	6	56.7		69.8		87.5
4	247	16	44.5	50.0	58.4	65.4	69.5

Sample B [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		54	14.8	19.9	23.7	28.9	89.7
4	245	22	19.7	23.0	26.4	29.4	38.0
4	246	6	20.7		23.6		29.1
4	247	16	16.0	17.9	21.0	22.5	24.5

Other kits (number):
2-09(1), > 2-99(1)<, 3-247(1), 3-350(2), 4-91(1), 4-99(1), 5-111(2), 6-99(1),

Analyte **IRT**
 Method all methods



A

No of participants	43	
sample/unit	A	B
mean	11.6	33.8
standard deviation	4.86	11.5
coefficient of variation	42.0	34.1

Sample A [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		43	7.45	8.50	10.0	15.2	30.0
2	52	3	16.5		25.4		30.0
4	245	15	7.45	7.82	9.00	10.4	11.1
4	246	5	7.80		9.30		10.5
4	247	14	9.00	9.18	10.6	12.0	12.0
5	111	2	15.3		18.5		21.7

Sample B [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		43	16.2	26.2	30.3	42.8	72.0
2	52	3	48.6		69.4		72.0
4	245	15	24.0	24.4	27.1	32.4	37.6
4	246	5	26.7		29.8		34.0
4	247	14	28.0	28.3	31.5	37.5	43.0
5	111	2	54.0		57.2		60.4

The deviation of your results from the median of the corresponding sub-collective (kit) is:
 A-35.04 %
 B-29.97 %

Other kits (number):
 2-09(1), 3-247(1), 3-350(1), 4-91(1),