Survey: **NBS3/18**
month: **July 2018**
Participant-No: **9900667**
date of issue: **28.07.18**

Referenzinstitut für Bioanalytik

DAkkS Deutsche Akkreditierungsstelle D-EP-15117-01-00

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

Bonn, 15. August 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: **NBS3/18**
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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 annax 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 3.85	-1.91	9.03	6.32	11.8
			B 13.5	-1.42	23.7	16.5	30.9
17-OH-progesterone [nmol/l]	±	2	A 20.4	0.70	16.8	11.7	21.9
			B 142	1.26	103	72.1	134
IRT [µg/l]	±	2	A 47.5	-1.14	72.3	50.6	94.0
			B 7.60	-1.80	16.8	11.7	21.9

Findings NBS3/18 -July 2018-
Neonatal - Screening, TSH, Sample A
Participant No 9900667

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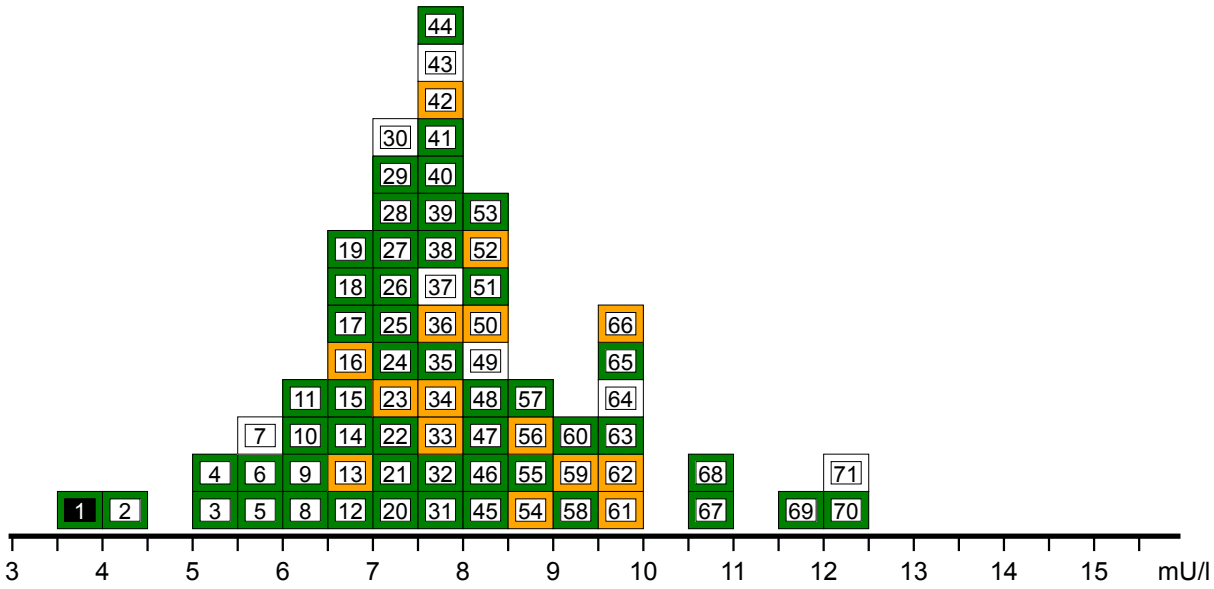
Legend:

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			CF	= cystic fibrosis
M	= method number	r n r n	= CH/AGS/CF evident | other	r n	= marks your result box



Descriptive Statistics

N = 70
XM = 7,7 mU/l
SD = 1,5 mU/l
CV = 19,5 %

Statistics of classifications

		none	new card	plasma sample	other
normal	49	47	1		
CH/AGS/CF possible	15		14		
CH/AGS/CF evident					
other	1		1		

Statistics of Implications, related to Classifications

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All	Kits	70	3.85	6.44	**7.65**	9.35	12.1	49	15	0	1
2	9	2	8.20		**9.03**		9.86	0	1	0	0
2	99	2	3.85		**7.93**		12.0	2	0	0	0
3	99	2	7.94		**8.33**		8.71	1	0	0	0
4	91	2	5.90		**6.81**		7.71	1	0	0	0
4	245	22	6.75	7.17	**7.85**	8.75	11.6	18	5	0	0
4	246	9	6.50	6.68	**7.80**	9.28	9.70	7	2	0	0
4	247	18	6.00	6.50	**7.38**	9.48	9.80	11	7	0	0
5	77	8	4.40	4.81	**6.03**	8.18	8.49	7	0	0	0
5	111	2	9.79		**10.2**		10.6	1	0	0	0

Other Kits: 1 77(1),3 247(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:	M	Mu
	-49.67 %	-51.42 %

Findings NBS3/18 -July 2018-
Neonatal - Screening, TSH, Sample B
Participant No 9900667

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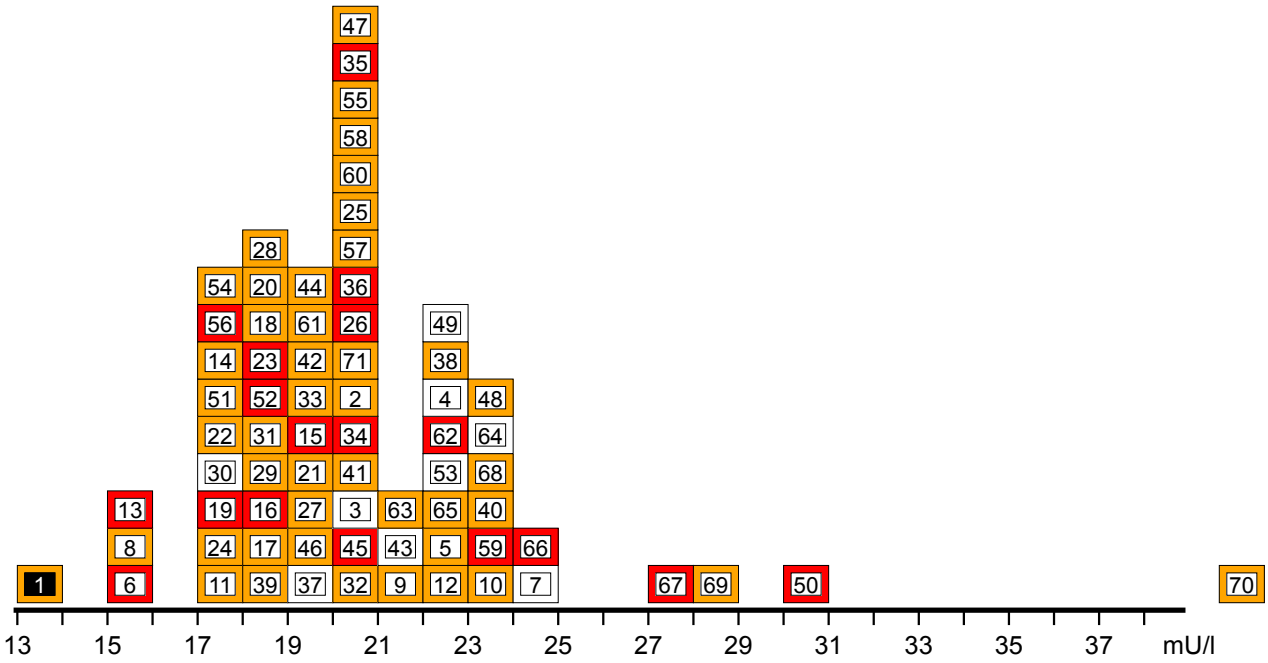
Legend:

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 = 70
XM = 20,3 mU/l
SD = 2,9 mU/l
CV = 14,6 %

Statistics of classifications

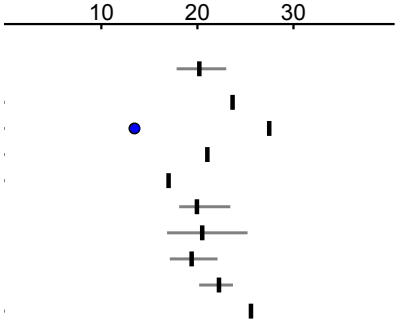
normal	
CH/AGS/CF possible	44
CH/AGS/CF evident	18
other	3

Statistics of Implications, related to Classifications

	none	new card	plasma sample	other
normal				
CH/AGS/CF possible	44	35	9	
CH/AGS/CF evident	18		17	
other	3	3		

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All	Kits	70	13.5	17.8	**20.2**	23.0	41.5	0	44	18	3
2	9	2	22.7		**23.7**		24.6	0	0	1	0
2	99	2	13.5		**27.5**		41.5	0	2	0	0
3	99	2	20.6		**21.0**		21.5	0	1	0	0
4	91	2	15.0		**17.0**		19.0	0	0	1	0
4	245	22	17.2	18.1	**20.0**	23.4	28.9	0	16	7	0
4	246	9	15.1	16.8	**20.5**	25.2	30.5	0	6	3	0
4	247	18	15.0	17.1	**19.4**	22.1	23.0	0	13	5	0
5	77	8	20.0	20.2	**22.2**	23.7	24.3	0	5	0	2
5	111	2	23.8		**25.6**		27.4	0	0	1	0



Other Kits: 1 77(1),3 247(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:	M	Mu
	-33.42 %	-51.05 %

Findings NBS3/18 -July 2018-
Neonatal - Screening, 17-OHP, Sample A
Participant No 9900667

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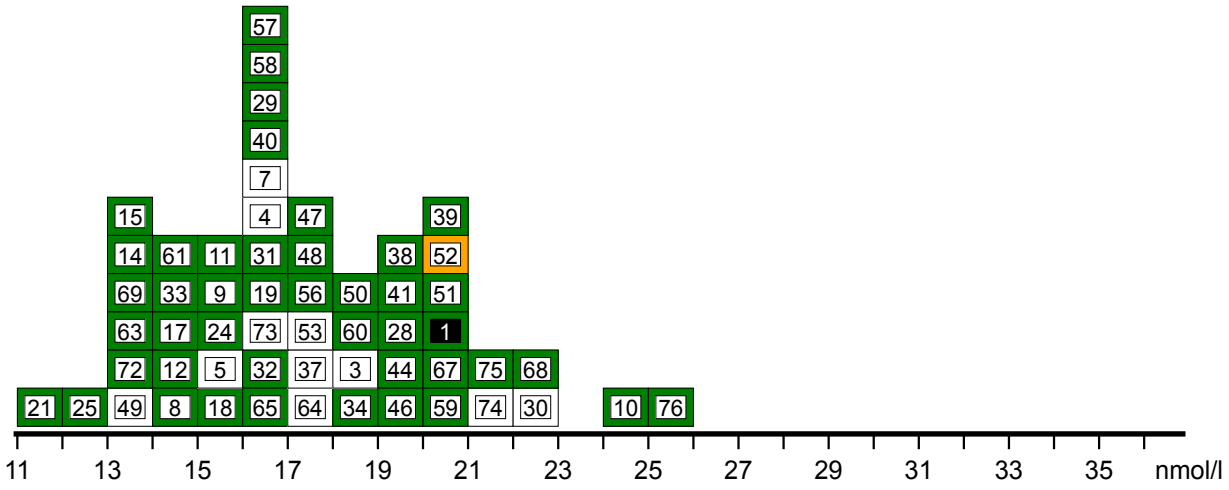
Legend:

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 = 55
XM = 17,2 nmol/l
SD = 2,9 nmol/l
CV = 17,1 %

Statistics of classifications

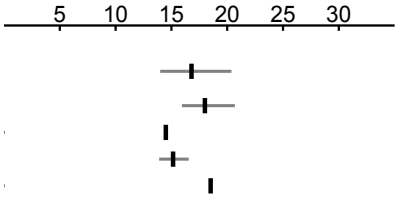
normal	44
CH/AGS/CF possible	1
CH/AGS/CF evident	
other	

Statistics of Implications, related to Classifications

	none	new card	plasma sample	other
normal	42	1		
CH/AGS/CF possible		1		

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All	Kits	55	11.2	14.0	**16.8**	20.4	25.0	44	1	0	0
4	245	23	13.9	15.9	**18.0**	20.7	25.0	18	1	0	0
4	246	7	11.2		**14.5**		20.9	7	0	0	0
4	247	16	12.3	13.9	**15.2**	16.5	20.0	15	0	0	0
5	111	2	17.0		**18.5**		20.0	1	0	0	0



Other Kits: 2 9(1),2 99(1),3 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

Findings NBS3/18 -July 2018-
Neonatal - Screening, 17-OHP, Sample B
Participant No 9900667

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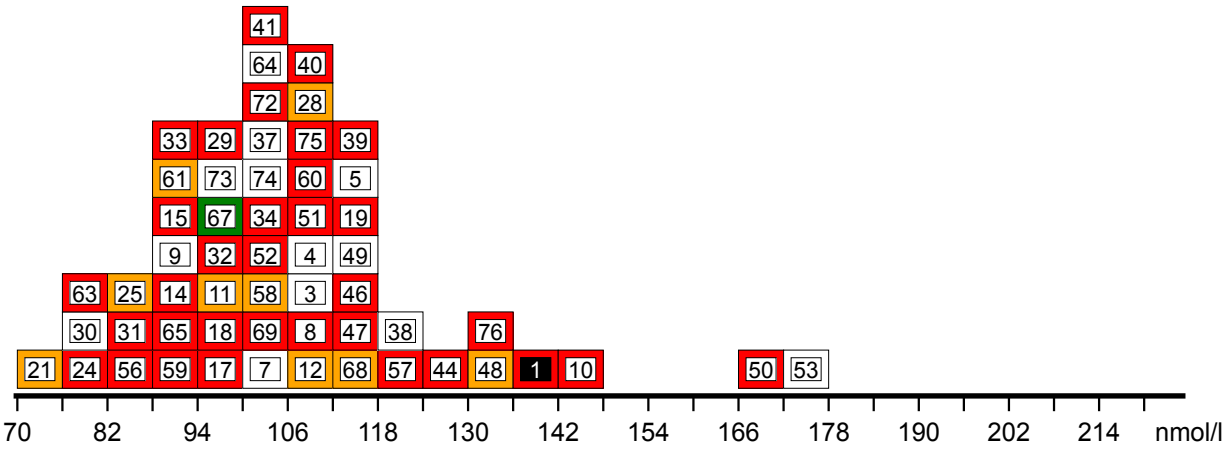
Legend:

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				CF =	cystic fibrosis
M	=	method number	r n r n	=	CH/AGS/CF evident | other	r n =	marks your result box



Descriptive Statistics

N = 55
XM = 106,0 nmol/l
SD = 19,7 nmol/l
CV = 18,6 %

Statistics of classifications

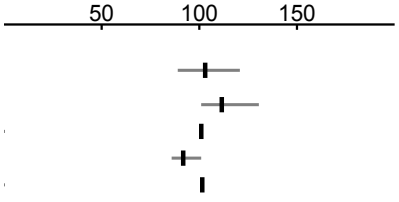
normal	1
CH/AGS/CF possible	9
CH/AGS/CF evident	33
other	1

Statistics of Implications, related to Classifications

	none	new card	plasma sample	other
normal	1			
CH/AGS/CF possible		5	4	
CH/AGS/CF evident		6	22	4
other		1		

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All	Kits	55	70.3	89.0	**103**	121	176	1	9	33	1
4	245	23	90.6	101	**112**	130	176	0	3	14	1
4	246	7	70.3		**101**		167	0	2	5	0
4	247	16	76.3	85.8	**91.8**	101	106	0	4	11	0
5	111	2	98.1		**102**		105	1	0	0	0



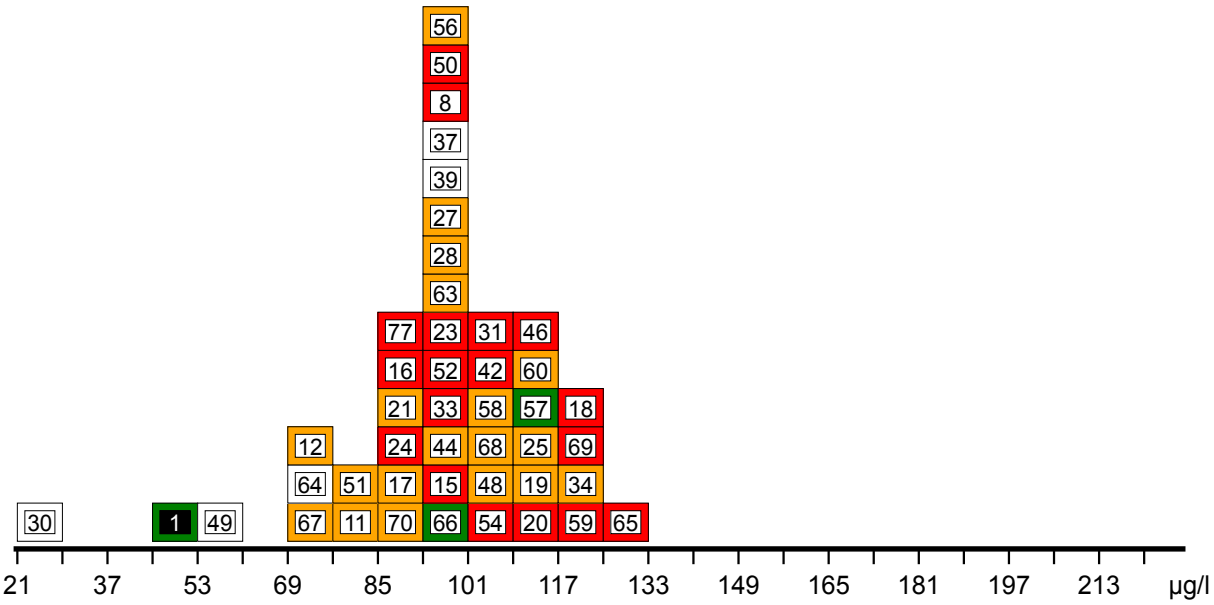
Other Kits: 2 9(1),2 99(1),3 99(1),3 247(1),4 91(1),4 99(1),6 99(1),

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

Findings NBS3/18 -July 2018-
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				CH =	congenital hypothyroidism
SD	=	standard deviation	r n r n	=	normal | CH/AGS/CF possible	AGS =	adrenogen. syndrome
CV	=	coefficient of variation				CF =	cystic fibrosis
M	=	method number	r n r n	=	CH/AGS/CF evident | other	r n =	marks your result box



Descriptive Statistics

N = 44
XM = 96,3 µg/l
SD = 19,9 µg/l
CV = 20,6 %

Statistics of classifications

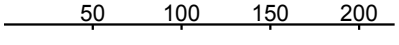
normal	3
CH/AGS/CF possible	19
CH/AGS/CF evident	18
other	1

Statistics of Implications, related to Classifications

	none	new card	plasma sample	other
normal	2	1		
CH/AGS/CF possible		6	1	12
CH/AGS/CF evident			1	16
other				1

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All	Kits	44	21.7	78.6	**98.8**	112	127	3	19	18	1
2	52	3	47.5		**85.0**		94.1	2	1	0	0
4	245	16	90.7	92.0	**99.9**	117	124	0	11	6	0
4	246	5	89.5		**100**		110	0	2	2	1
4	247	14	76.9	82.5	**99.9**	122	127	0	4	10	0
5	111	2	72.5		**72.6**		72.7	0	1	0	0



Other Kits: 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
	-51.95 %	-44.18 %

Findings NBS3/18 -July 2018-
Neonatal - Screening, IRT, Sample B
Participant No 9900667

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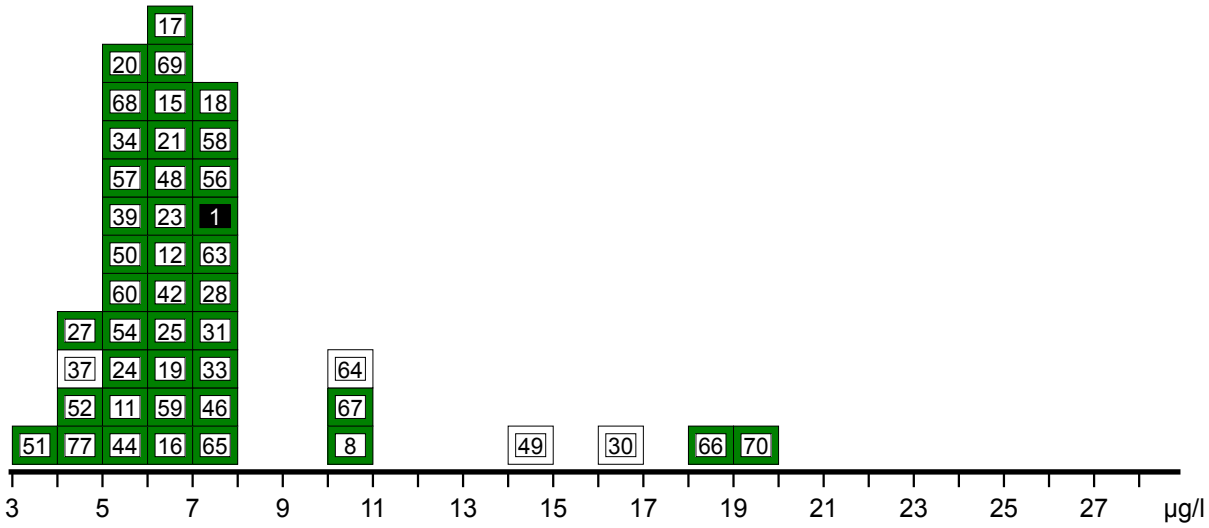
Legend:

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				CF =	cystic fibrosis
M	=	method number	r n r n	=	CH/AGS/CF evident | other	r n =	marks your result box



Descriptive Statistics

N = 44
XM = 7,4 µg/l
SD = 3,5 µg/l
CV = 47,6 %

Statistics of classifications

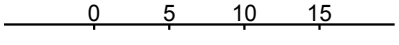
normal	41
CH/AGS/CF possible	
CH/AGS/CF evident	
other	

Statistics of Implications, related to Classifications

none	new card	plasma sample	other
40			

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All	Kits	44	4.50	5.00	**6.35**	9.58	19.5	41	0	0	0
2	52	3	7.60		**18.6**		19.5	3	0	0	0
4	245	16	4.50	4.79	**5.90**	7.08	7.40	17	0	0	0
4	246	5	5.10		**5.80**		7.70	5	0	0	0
4	247	14	5.00	5.40	**6.40**	7.78	10.0	14	0	0	0
5	111	2	10.2		**10.3**		10.4	1	0	0	0



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

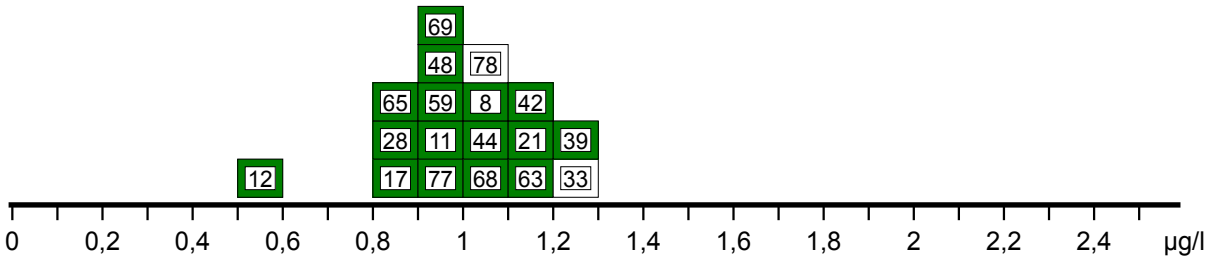
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:	M	Mu
	19 %	-59.14 %

Findings NBS3/18 -July 2018-
Neonatal - Screening, PAP, Sample A
Participant No 9900667

RfB Referenzinstitut für Bioanalytik

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				CF =	cystic fibrosis
M	=	method number	r n r n	=	CH/AGS/CF evident | other	r n =	marks your result box



Descriptive Statistics

N = 18
XM = 0,9 µg/l
SD = 0,1 µg/l
CV = 16,2 %

Statistics of classifications

normal	16
CH/AGS/CF possible	
CH/AGS/CF evident	
other	

Statistics of Implications, related to Classifications

none	new card	plasma sample	other
16			

Kit Evaluation for Sample A

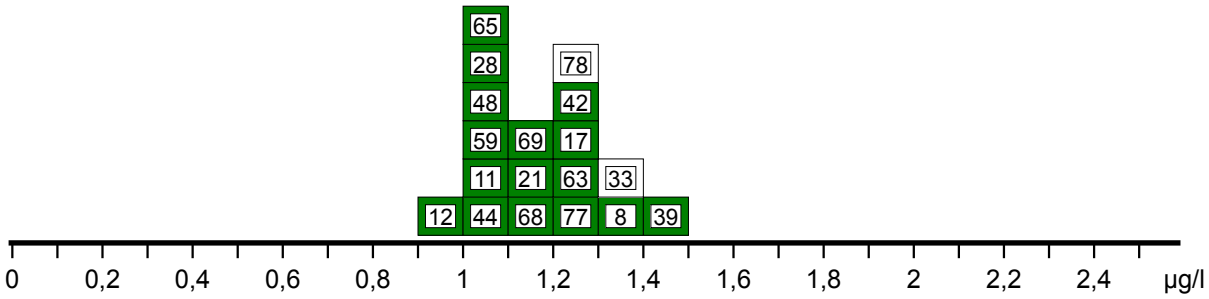
M	Kit	N	Min	16.P	50.P	84.P	Max	0,5 — 1 — 1,5	Kit Classifications			
All	Kits	18	0.560	0.834	**0.985**	1.10	1.22		16	0	0	0
2	255	3	0.833		**0.970**		1.00		3	0	0	0
4	255	15	0.560	0.828	**1.00**	1.14	1.22		13	0	0	0

Other Kits:

Findings NBS3/18 -July 2018-
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				CF =	cystic fibrosis
M	=	method number	r n r n	=	CH/AGS/CF evident | other	r n =	marks your result box



Descriptive Statistics

N = 18
XM = 1,1 µg/l
SD = 0,1 µg/l
CV = 11,4 %

Statistics of classifications

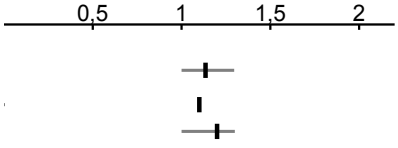
normal	16
CH/AGS/CF possible	
CH/AGS/CF evident	
other	

Statistics of Implications, related to Classifications

none	new card	plasma sample	other
16			

Kit Evaluation for Sample B

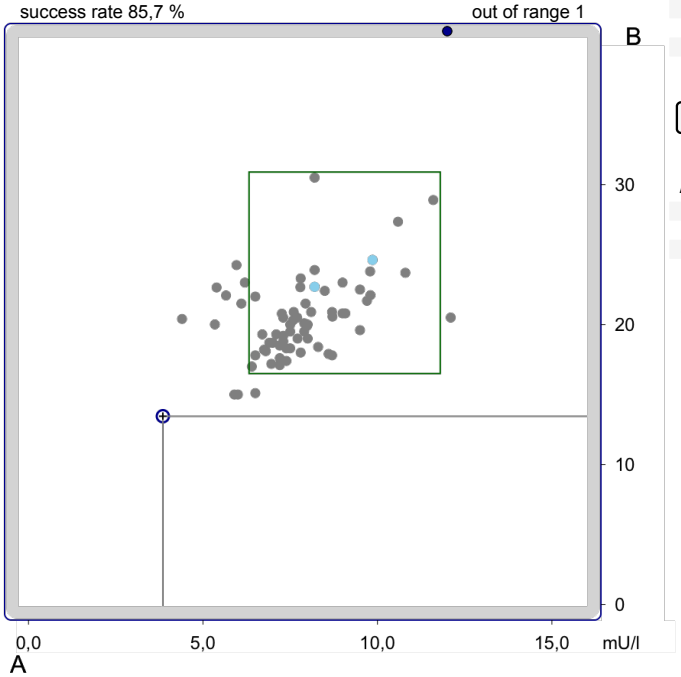
M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications
All	Kits	18	0.920	1.00	**1.14**	1.30	1.41	16 0 0 0
2	255	3	1.04		**1.10**		1.17	3 0 0 0
4	255	15	0.920	1.00	**1.20**	1.30	1.41	13 0 0 0



Other Kits:

Analyte **TSH**
Method all methods

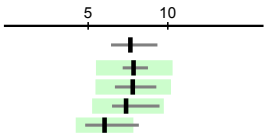
success rate 85,7 % out of range 1



No of participants		70	
sample/unit	A	mU/l	B
mean	7.73		20.4
standard deviation	1.51		2.98
coefficient of variation	19.5		14.7

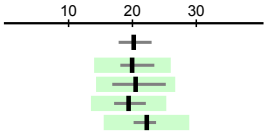
Sample A [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		70	3.85	6.44	7.65	9.35	12.1
4	245	22	6.75	7.17	7.85	8.75	11.6
4	246	9	6.50	6.68	7.80	9.28	9.70
4	247	18	6.00	6.50	7.38	9.48	9.80
5	77	8	4.40	4.81	6.03	8.18	8.49



Sample B [mU/l]

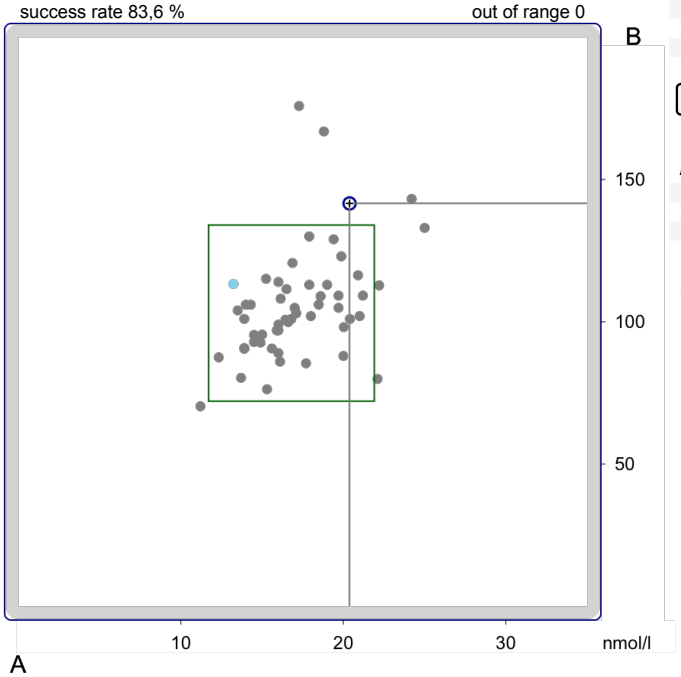
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		70	13.5	17.8	20.2	23.0	41.5
4	245	22	17.2	18.1	20.0	23.4	28.9
4	246	9	15.1	16.8	20.5	25.2	30.5
4	247	18	15.0	17.1	19.4	22.1	23.0
5	77	8	20.0	20.2	22.2	23.7	24.3



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

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

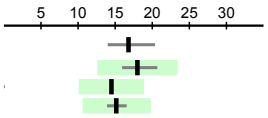
success rate 83,6 % out of range 0



No of participants		55	
sample/unit	A	nmol/l	B
mean	17.2		106
standard deviation	2.96		19.8
coefficient of variation	17.2		18.6

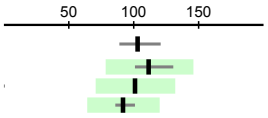
Sample A [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		55	11.2	14.0	16.8	20.4	25.0
4	245	23	13.9	15.9	18.0	20.7	25.0
4	246	7	11.2		14.5		20.9
4	247	16	12.3	13.9	15.2	16.5	20.0



Sample B [nmol/l]

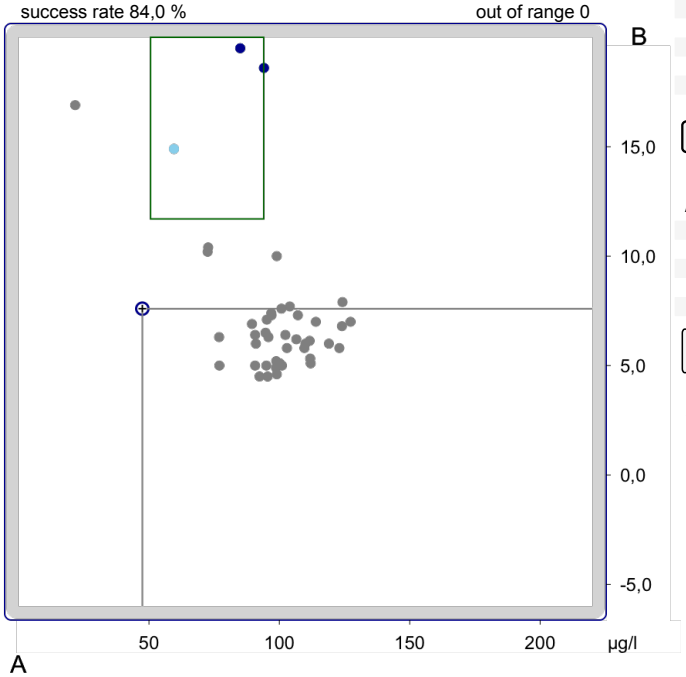
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		55	70.3	89.0	103	121	176
4	245	23	90.6	101	112	130	176
4	246	7	70.3		101		167
4	247	16	76.3	85.8	91.8	101	106



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

Analyte **IRT**
Method all methods

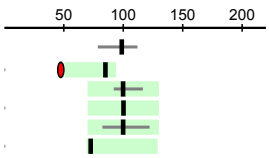
success rate 84,0 % out of range 0



No of participants		44	
sample/unit	A	µg/l	B
mean	96.3		7.43
standard deviation	19.9		3.54
coefficient of variation	20.7		47.6

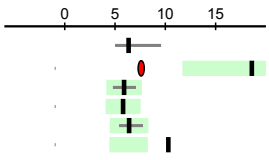
Sample A [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		44	21.7	78.6	98.8	112	127
2	52	3	47.5		85.0		94.1
4	245	16	90.7	92.0	99.9	117	124
4	246	5	89.5		100		110
4	247	14	76.9	82.5	99.9	122	127
5	111	2	72.5		72.6		72.7



Sample B [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		44	4.50	5.00	6.35	9.58	19.5
2	52	3	7.60		18.6		19.5
4	245	16	4.50	4.79	5.90	7.08	7.40
4	246	5	5.10		5.80		7.70
4	247	14	5.00	5.40	6.40	7.78	10.0
5	111	2	10.2		10.3		10.4



The deviation of your results from the median of the corresponding sub-collective (kit) is:
A-44.18 %
B-59.14 %

Other kits (number):
2-09(1), 3-99(1), 3-247(1), 4-91(1),