

Survey: **NBS4/19**
month: **October 2019**
Participant-No: **9900667**
date of issue: **12.10.19**



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, 31. October 2019

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) | IRT (2)

This certificate is valid until the end of April 2020.

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?ln=9900667&n_id=NBS_194&version=0&urlid=2CECE9A17D342ADA8803EB9ACDEE79

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Dr. A. Kessler

Bonn, 31. October 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: **NBS4/19**
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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.

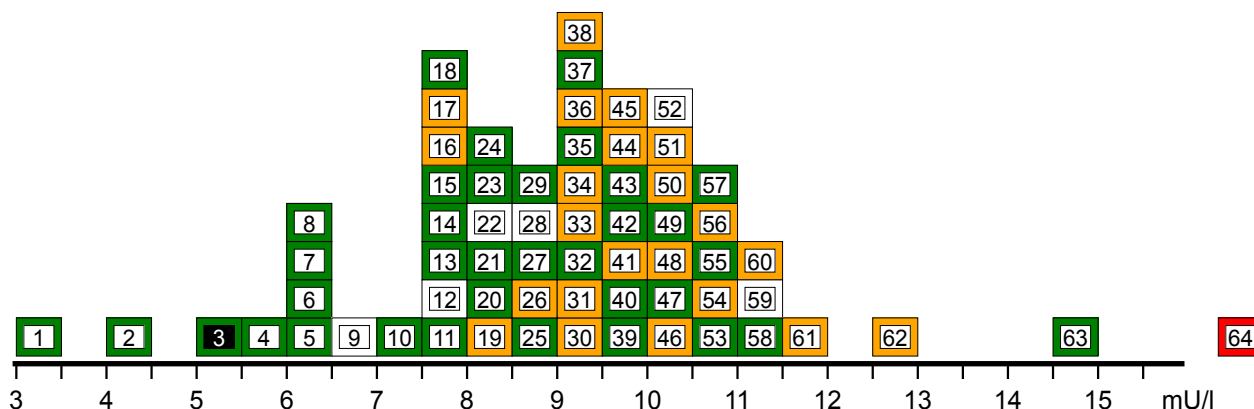
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL UL = 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	5.40	-1.33	9.01	6.30	11.8							
			B	12.8	-0.78	16.8	11.7	21.9							
17-OH-progesterone [nmol/l]	+	2	A	81.2	-0.48	95.0	66.5	124							
			B	33.7	0.47	29.5	20.6	38.4							
IRT [µg/l]	+	2	A	122	0.45	107	74.9	140							
			B	62.0	-0.98	87.9	61.5	115							

Findings NBS4/19 -October 2019-
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 = 64	■ normal 35	35			
XM = 8,8 mU/l	■ CH/AGS/CF possible 22		19	2	1
SD = 1,9 mU/l	■ CH/AGS/CF evident 1			1	
CV = 21,9 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	15	Kit Classifications			
												■	■	■	■
All Kits	64	3.40	7.40	9.01	10.6	19.3						35	22	1	0
2	99	2	5.40	6.48		7.55			●			1	0	0	0
3	350	3	7.71	11.0		14.9						1	1	0	0
4	245	18	7.86	8.58	9.25	10.7	19.3					12	5	1	0
4	246	7	7.85		10.5		11.6					3	4	0	0
4	247	18	7.50	8.00	9.55	10.0	11.3					6	11	0	0
5	77	8	4.00	4.68	6.26	7.66	7.70					8	0	0	0
5	111	2	10.4		11.7		12.9					0	1	0	0

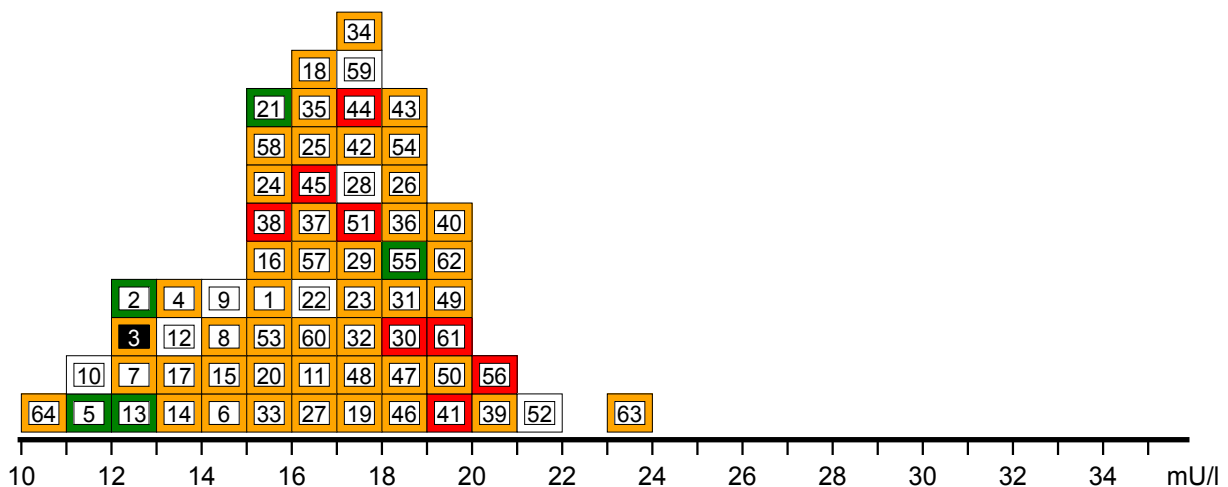
Other Kits: 1 9(1), 1 77(1), 2 9(1), 3 99(1), 4 91(1), 4 99(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -40.03 % -16.6 %

Findings NBS4/19 -October 2019-
Neonatal - Screening, TSH, 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 = 64	■ normal 5	4	1		
XM= 16,6 mU/l	■ CH/AGS/CF possible 44		35	7	2
SD= 2,4 mU/l	■ CH/AGS/CF evident 8			8	
CV= 14,7 %	other 1		1		

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	15	20	25	30	Kit Classifications			
															■	■	■	■
All Kits	64	10.7	13.7	16.8	18.9	23.7									5	44	8	1
2	99	2	12.8	13.3		13.7									0	1	0	0
3	350	3	15.1	17.8		23.7									0	2	0	0
4	245	18	10.7	15.4	17.1	18.6	19.6								1	16	1	0
4	246	7	13.6		16.0		20.5								0	5	2	0
4	247	18	15.0	15.7	17.5	19.1	20.2								1	11	5	0
5	77	8	11.1	11.8	13.7	14.6	14.7								2	6	0	0
5	111	2	19.8		20.7		21.7								0	1	0	0

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

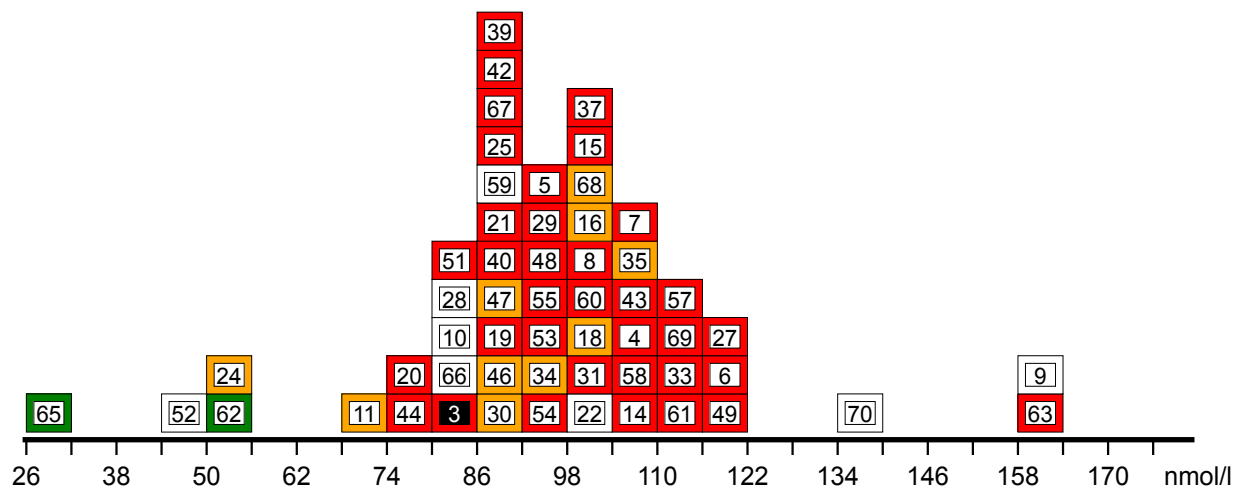
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

M	Mu
-23.7 %	-3.2 %

Findings NBS4/19 -October 2019-
Neonatal - Screening, 17-OHP, 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 = 55	■ normal 2	2			
XM= 95,8 nmol/l	■ CH/AGS/CF possible 10		9	1	
SD= 22,7 nmol/l	■ CH/AGS/CF evident 35	1	4	19	11
CV= 23,7 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	50	100	150	Kit Classifications			
All Kits	55	26.8	81.2	95.0	114	162					■	■	■	0
3	350	3	88.2	102	161						0	1	1	0
4	245	21	81.6	102	114	118					0	4	16	0
4	246	7	51.2	93.8	121						0	1	6	0
4	247	16	72.2	87.0	96.1	99.5					0	4	10	0
5	111	2	49.1	49.7	50.2						1	0	0	0

Other Kits: 2 9(1),2 99(1),4 91(1),4 99(1),4 350(1),6 99(1),

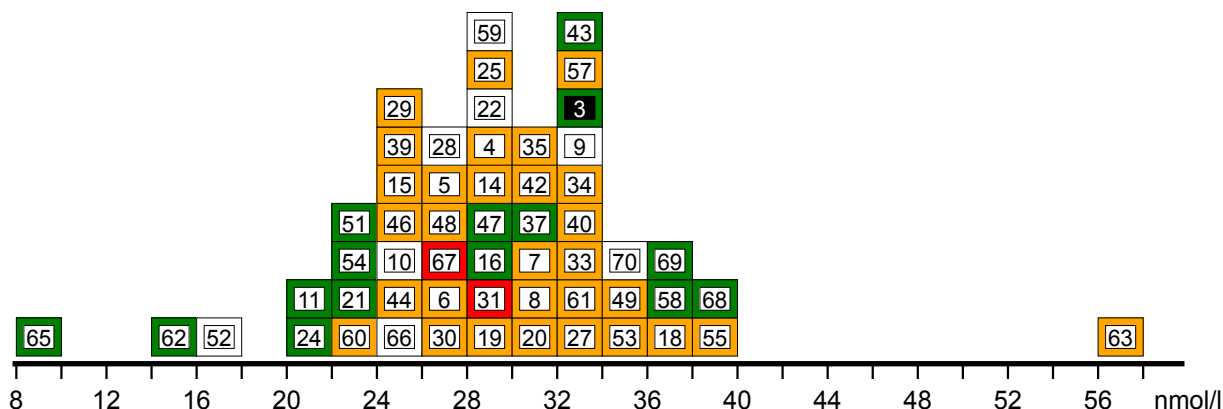
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

M	Mu
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Findings NBS4/19 -October 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 = 55	■ normal 15	15			
XM= 29,1 nmol/l	■ CH/AGS/CF possible 30	1	27	1	1
SD = 6,8 nmol/l	■ CH/AGS/CF evident 2			2	
CV = 23,6 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Percentile Range (10-50)					Kit Classifications				
								10	20	30	40	50	■	■	■	■	
All Kits	55	8.42	23.4	29.5	34.4	57.0								15	30	2	0
3	350	3	28.3	29.9	57.0									1	1	0	0
4	245	21	24.9	31.4	38.0									3	17	0	0
4	246	7	21.3	32.3	36.4									3	3	1	0
4	247	16	21.9	25.8	29.3	33.0								4	9	1	0
5	111	2	14.4	15.5	16.6									1	0	0	0

Other Kits: 2 9(1),2 99(1),4 91(1),4 99(1),4 350(1),6 99(1),

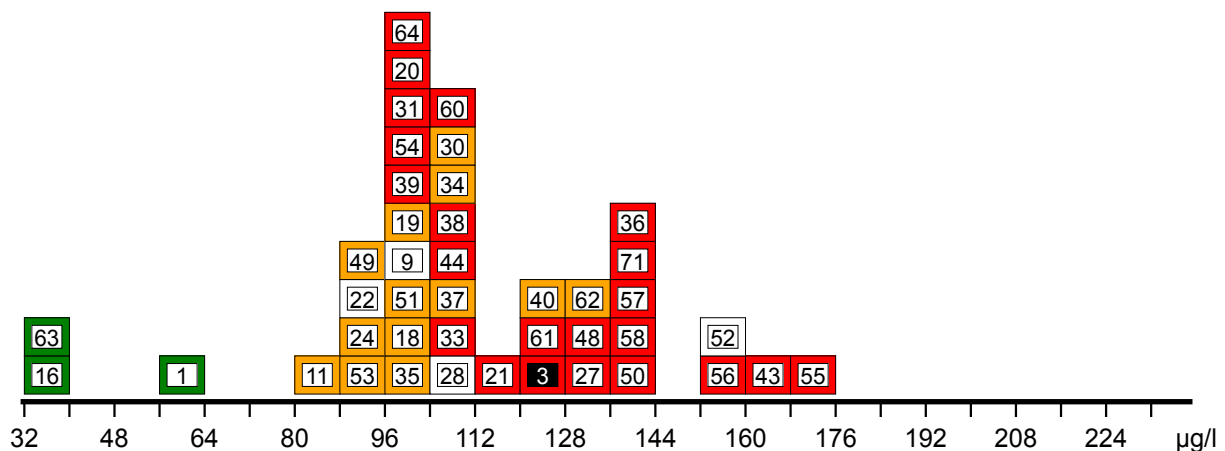
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

M	Mu
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Findings NBS4/19 -October 2019-
Neonatal - Screening, IRT, 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 = 42	normal 3	3			
XM = 111,3 µg/l	CH/AGS/CF possible 13		6		7
SD = 28,7 µg/l	CH/AGS/CF evident 22			1	20
CV = 25,8 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
	All Kits	42	32.1	92.4	107	142	171	3	13	22	0
	2	9	2	62.8	80.8		98.8	1	0	0	0
	3	350	2	32.1	34.1		36.0	2	0	0	0
	4	245	14	91.8	108	156	171	0	6	8	0
	4	246	6	91.2	126		155	0	2	4	0
	4	247	14	87.6	106	121	129	0	4	9	0
	5	111	2	131	144		156	0	1	0	0

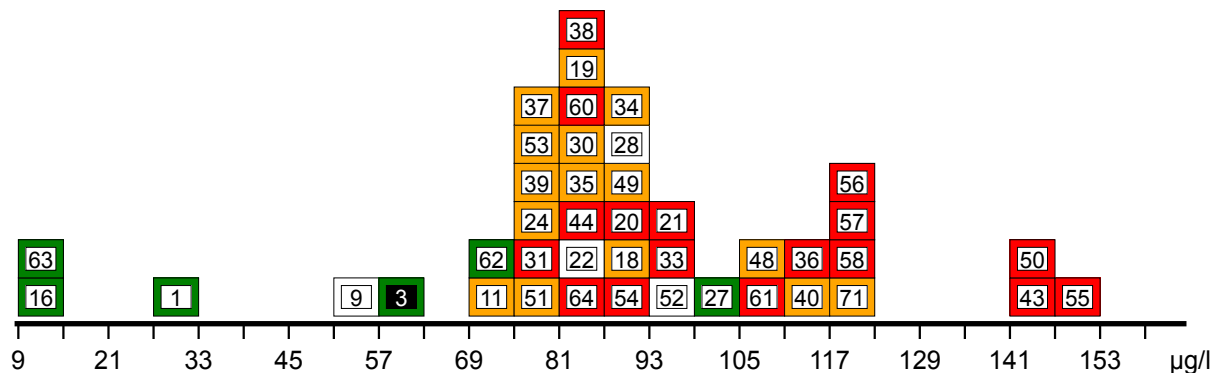
Other Kits: 2 52(1),4 91(1),

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

Findings NBS4/19 -October 2019-
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			
	normal	CH/AGS/CF possible	none	new card	plasma sample	other
N = 42	6	15	6	5	1	10
XM = 89,0 µg/l						
SD = 28,9 µg/l						
CV = 32,4 %						

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
	All Kits	42	9.67	73.2	87.9	117	150	6	15	17	0
2	9	2	32.4		43.5		54.6	1	0	0	0
3	350	2	9.67		10.7		11.8	2	0	0	0
4	245	14	76.6	81.0	94.0	142	150	0	7	7	0
4	246	6	75.3		103		122	1	2	3	0
4	247	14	72.6	77.0	85.9	104	113	0	6	7	0
5	111	2	73.3		84.1		95.0	1	0	0	0

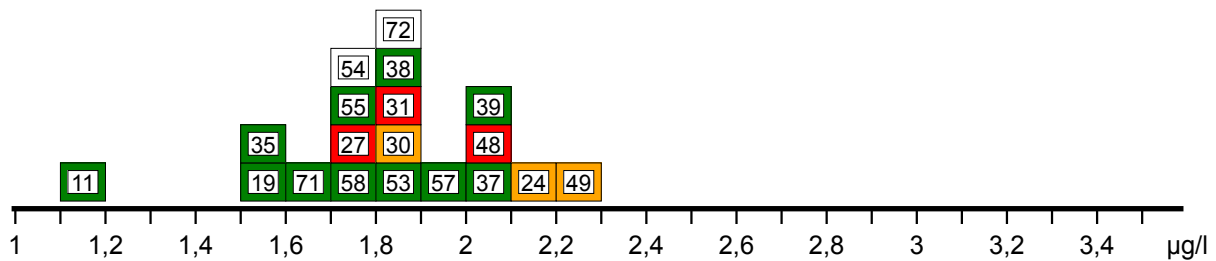
Other Kits: 2 52(1),4 91(1),

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

Findings NBS4/19 -October 2019-
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	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 = 19	■ normal 11	11			
XM = 1,7 µg/l	■ CH/AGS/CF possible 3		1		2
SD = 0,2 µg/l	■ CH/AGS/CF evident 3				3
CV = 13,5 %	other				

Kit Evaluation for Sample A

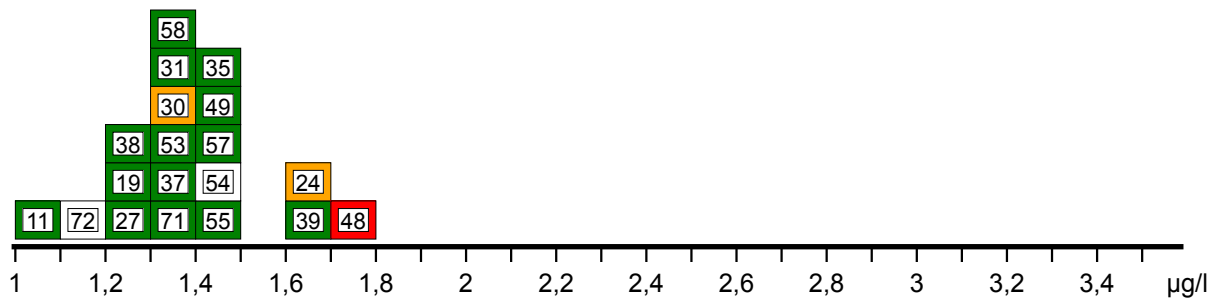
M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications				
								■	■	■	■	
	All Kits	19	1.19	1.57	1.80	2.04	2.25		11	3	3	0
	2	255	3	1.56	1.70		2.00		3	0	0	0
	4	255	16	1.19	1.80	2.06	2.25		8	3	3	0

Other Kits:

Findings NBS4/19 -October 2019-
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	



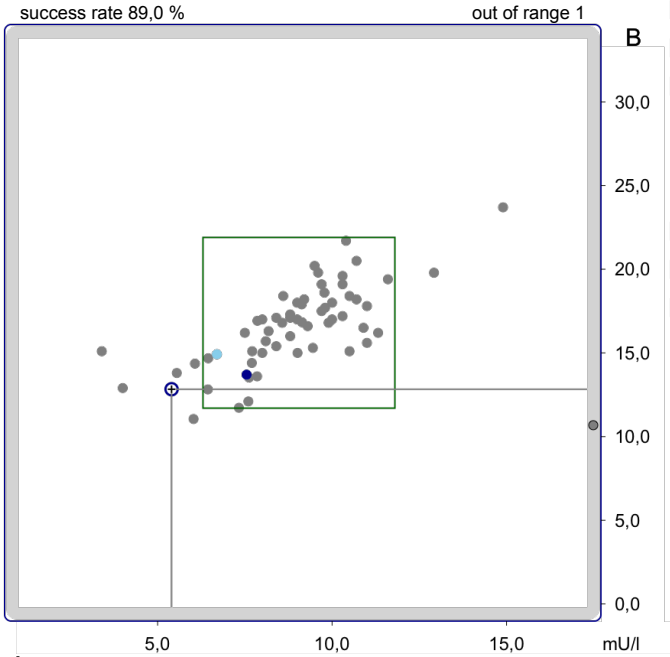
Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 19	■ normal 14	14			
XM = 1,3 µg/l	■ CH/AGS/CF possible 2		1		1
SD = 0,1 µg/l	■ CH/AGS/CF evident 1				1
CV = 11,8 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications							
								0,5	1	1,5	2	■	■	■	■
All Kits	19	1.07	1.20	1.30	1.57	1.70						14	2	1	0
2	255	3	1.30	1.40	1.45	1.45						3	0	0	0
4	255	16	1.07	1.19	1.30	1.60	1.70					11	2	1	0

Other Kits:

Analyte **TSH**
Method all methods



No of participants	64	
sample/unit	A	B
mean	8.87	16.6
standard deviation	1.95	2.45
coefficient of variation	22.0	14.7

Sample A [mU/l]

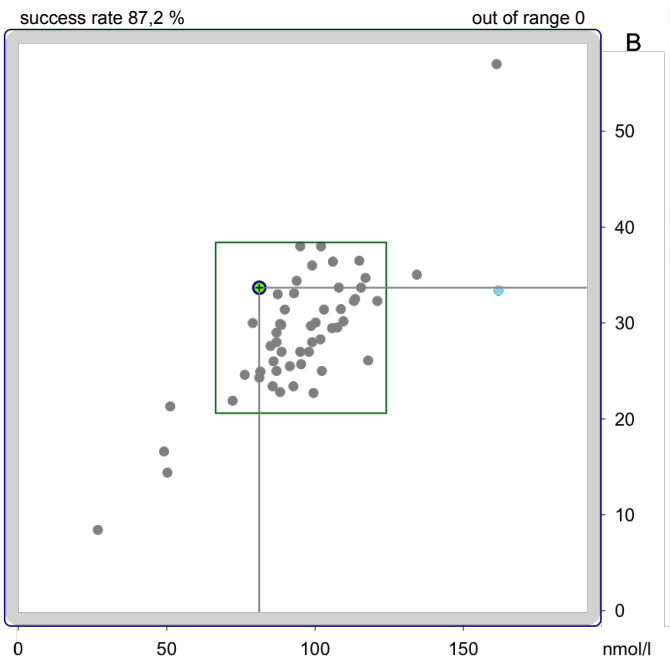
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		64	3.40	7.40	9.01	10.6	19.3
3	350	3	7.71		11.0		14.9
4	245	18	7.86	8.58	9.25	10.7	19.3
4	246	7	7.85		10.5		11.6
4	247	18	7.50	8.00	9.55	10.0	11.3
5	77	8	4.00	4.68	6.26	7.66	7.70

Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		64	10.7	13.7	16.8	18.9	23.7
3	350	3	15.1		17.8		23.7
4	245	18	10.7	15.4	17.1	18.6	19.6
4	246	7	13.6		16.0		20.5
4	247	18	15.0	15.7	17.5	19.1	20.2
5	77	8	11.1	11.8	13.7	14.6	14.7

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

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



No of participants	55	
sample/unit	A	B
mean	95.9	29.1
standard deviation	22.7	6.89
coefficient of variation	23.7	23.7

Sample A [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		55	26.8	81.2	95.0	114	162
3	350	3	88.2		102		161
4	245	21	81.6	91.4	102	114	118
4	246	7	51.2		93.8		121
4	247	16	72.2	78.2	87.0	96.1	99.5

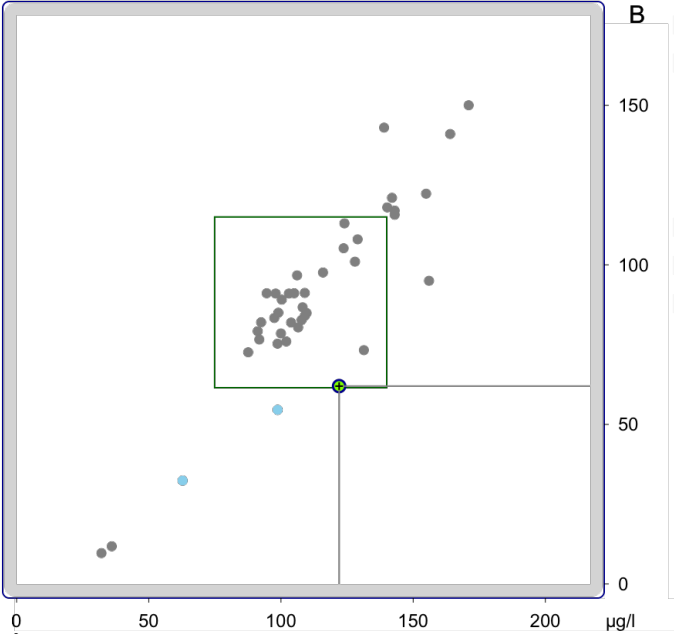
Sample B [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		55	8.42	23.4	29.5	34.4	57.0
3	350	3	28.3		29.9		57.0
4	245	21	24.9	25.9	31.4	35.3	38.0
4	246	7	21.3		32.3		36.4
4	247	16	21.9	22.8	25.8	29.3	33.0

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

Analyte **IRT**
 Method all methods

success rate 71,4 % out of range 0



No of participants	42	
sample/unit	A	B
mean	111	89.1
standard deviation	28.8	28.9
coefficient of variation	25.8	32.4

Sample A [µg/l]							
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	42	32.1	92.4	107	142	171	
2	9	2	62.8		80.8		98.8
3	350	2	32.1		34.1		36.0
4	245	14	91.8	95.8	108	156	171
4	246	6	91.2		126		155
4	247	14	87.6	99.4	106	121	129
5	111	2	131		144		156

Sample B [µg/l]							
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	42	9.67	73.2	87.9	117	150	
2	9	2	32.4		43.5		54.6
3	350	2	9.67		10.7		11.8
4	245	14	76.6	81.0	94.0	142	150
4	246	6	75.3		103		122
4	247	14	72.6	77.0	85.9	104	113
5	111	2	73.3		84.1		95.0

Other kits (number):
 > 2-52(1)<, 4-91(1),