

Survey: **NBS3/19**  
month: **July 2019**  
Participant-No: **9900667**  
date of issue: **27.07.19**



**Referenzinstitut für Bioanalytik**



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

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

Bonn, 22. August 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:

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

**This certificate is valid until the end of January 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\\_193&version=0&urlid=EC98315203949F3DB77A94533CB8C8ACD3](http://www.rfb.bio/cgi/certificate?ln=9900667&n_id=NBS_193&version=0&urlid=EC98315203949F3DB77A94533CB8C8ACD3)

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Bonn, 22. August 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.

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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.

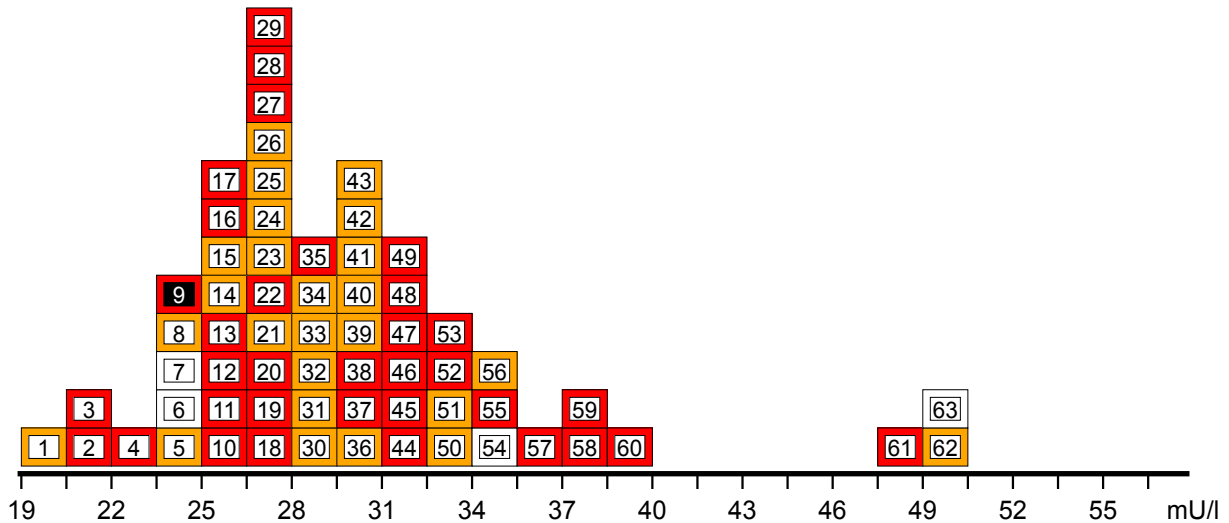
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL   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	24.9	-0.39	28.2	19.7	36.7						
			B	6.26	0.72	4.51	2.11	6.91						
17-OH-progesterone [nmol/l]	+	2	A	20.0	0.03	19.8	13.8	25.8						
			B	63.7	0.55	54.6	38.2	71.0						
IRT [µg/l]	±	2	A	24.6	2.73	13.4	9.38	17.5						
			B	99.9	0.68	82.6	57.8	108						

Findings NBS3/19 -July 2019-  
Neonatal - Screening, TSH, Sample A  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">rn</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="border: 1px solid green; padding: 2px;">rn</span> <span style="border: 1px solid orange; padding: 2px;">rn</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid red; padding: 2px;">rn</span> <span style="border: 1px solid black; padding: 2px;">rn</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">rn</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 63	<span style="color: green;">■</span> normal				
XM = 29,6 mU/l	<span style="color: orange;">■</span> CH/AGS/CF possible 25		18	7	
SD = 5,9 mU/l	<span style="color: red;">■</span> CH/AGS/CF evident 34			33	1
CV = 20,0 %	other				

**Kit Evaluation for Sample A**

M	Kit	N	Min	16.P	50.P	84.P	Max	10 20 30 40 50					Kit Classifications			
													<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	<span style="color: black;">■</span>
All Kits	63	19.9	25.2	<b>28.2</b>	33.9	50.3							0	25	34	0
2	99	2	24.9	<b>37.3</b>		49.7							0	1	1	0
3	350	3	27.2	<b>28.5</b>		34.2							0	2	0	0
4	245	19	23.9	25.6	<b>28.2</b>	31.2	34.9						0	9	9	0
4	246	6	26.0	<b>26.8</b>		32.0							0	3	3	0
4	247	17	21.0	24.9	<b>27.7</b>	31.6	33.0						0	5	12	0
5	77	8	30.8	31.0	<b>35.4</b>	38.2	38.8						0	1	7	0
5	111	2	48.4	<b>49.4</b>		50.3							0	0	1	0

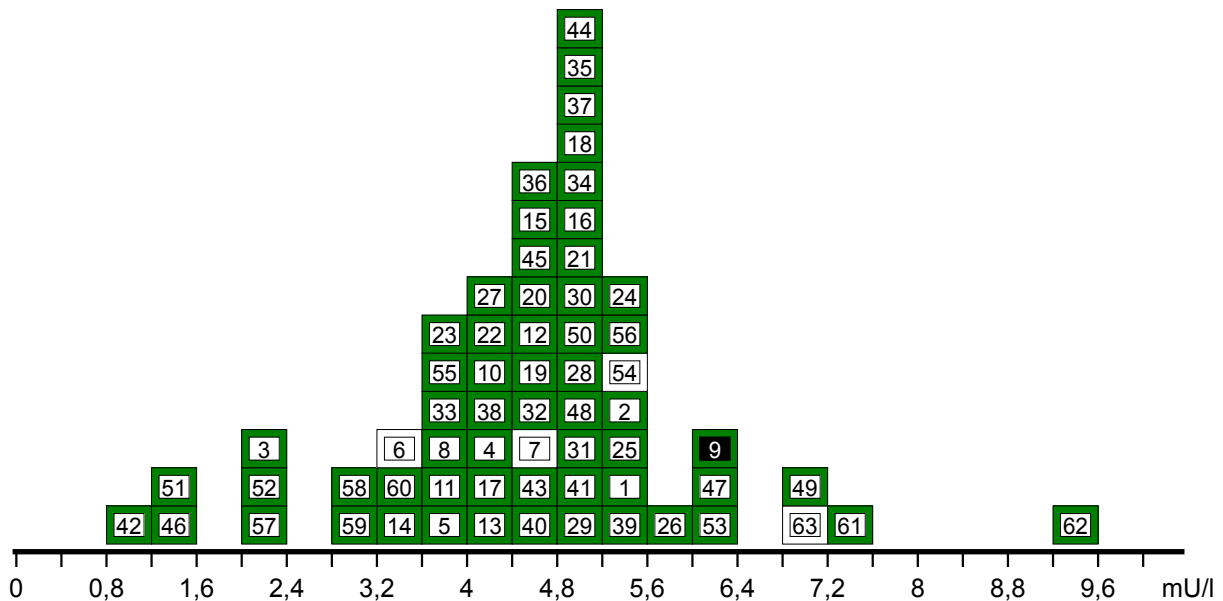
Other Kits: 1 9(1),1 77(1),2 9(1),3 99(1),4 99(1),4 216(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: M Mu -11.7 % -33.24 %

Findings NBS3/19 -July 2019-  
Neonatal - Screening, TSH, Sample B  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">rn</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="border: 1px solid green; padding: 2px;">rn</span> <span style="border: 1px solid orange; padding: 2px;">rn</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid red; padding: 2px;">rn</span> <span style="border: 1px solid black; padding: 2px;">rn</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
M = method number			<span style="border: 1px solid black; padding: 2px;">rn</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications
N = 63	<span style="color: green;">■</span> normal 59 <span style="color: orange;">■</span> CH/AGS/CF possible <span style="color: red;">■</span> CH/AGS/CF evident other	none 59 new card plasma sample other
XM = 4,5 mU/l		
SD = 1,4 mU/l		
CV = 31,4 %		

**Kit Evaluation for Sample B**

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
								0 5 10	<span style="color: green;">■</span> <span style="color: orange;">■</span> <span style="color: red;">■</span>
All Kits	63	0.900	3.55	<b>4.51</b>	5.45	9.55			59 0 0 0
2	99	2	6.26	<b>7.91</b>		9.55			2 0 0 0
3	350	3	3.73	<b>5.30</b>		5.90			2 0 0 0
4	245	19	3.57	3.71	<b>4.70</b>	5.00	5.50		18 0 0 0
4	246	6	3.20		<b>4.70</b>		7.00		6 0 0 0
4	247	17	3.90	4.00	<b>4.95</b>	5.38	6.10		17 0 0 0
5	77	8	0.900	1.11	<b>2.52</b>	3.73	3.88		8 0 0 0
5	111	2	6.90		<b>7.14</b>		7.38		1 0 0 0

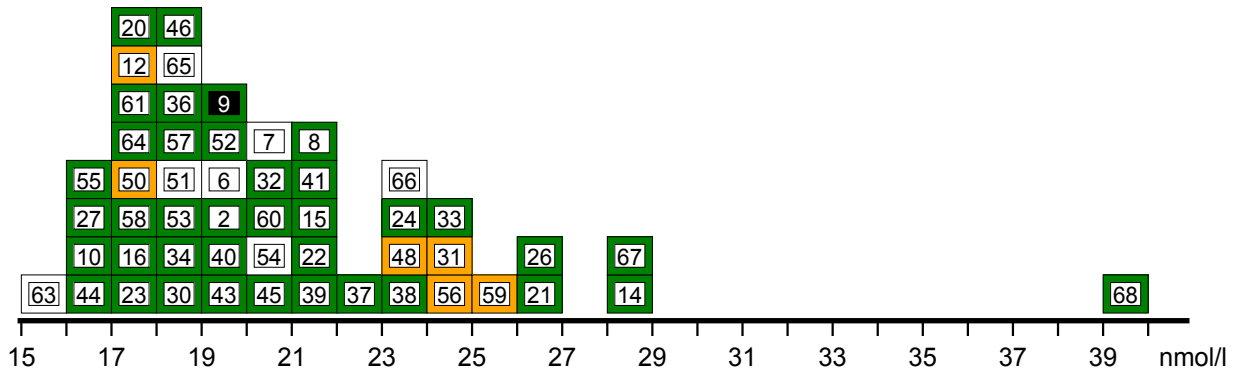
Other Kits: 1 9(1),1 77(1),2 9(1),3 99(1),4 99(1),4 216(1),

The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:	38 %	-20.81 %

Findings NBS3/19 -July 2019-  
Neonatal - Screening, 17-OHP, Sample A  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">rn</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="border: 1px solid green; padding: 2px;">rn</span> <span style="border: 1px solid orange; padding: 2px;">rn</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid red; padding: 2px;">rn</span> <span style="border: 1px solid black; padding: 2px;">rn</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">rn</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 51	<span style="color: green;">■</span> normal 38	38			
XM = 20,6 nmol/l	<span style="color: orange;">■</span> CH/AGS/CF possible 6		6		
SD = 4,2 nmol/l	<span style="color: red;">■</span> CH/AGS/CF evident				
CV = 20,3 %	other				

**Kit Evaluation for Sample A**

M	Kit	N	Min	16.P	50.P	84.P	Max		10	20	30	Kit Classifications			
												<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	<span style="color: black;">■</span>
All Kits	51	15.5	17.2	<b>19.8</b>	24.6	39.0						38	6	0	0
3	350	3	20.2	<b>24.8</b>	26.5	26.5						2	0	0	0
4	245	22	16.7	18.2	<b>20.8</b>	24.8	39.0					16	4	0	0
4	246	6	17.4		<b>20.1</b>	28.5						6	0	0	0
4	247	14	16.0	16.2	<b>17.7</b>	19.0	21.6					11	2	0	0
5	111	2	15.5		<b>16.5</b>	17.5						1	0	0	0

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

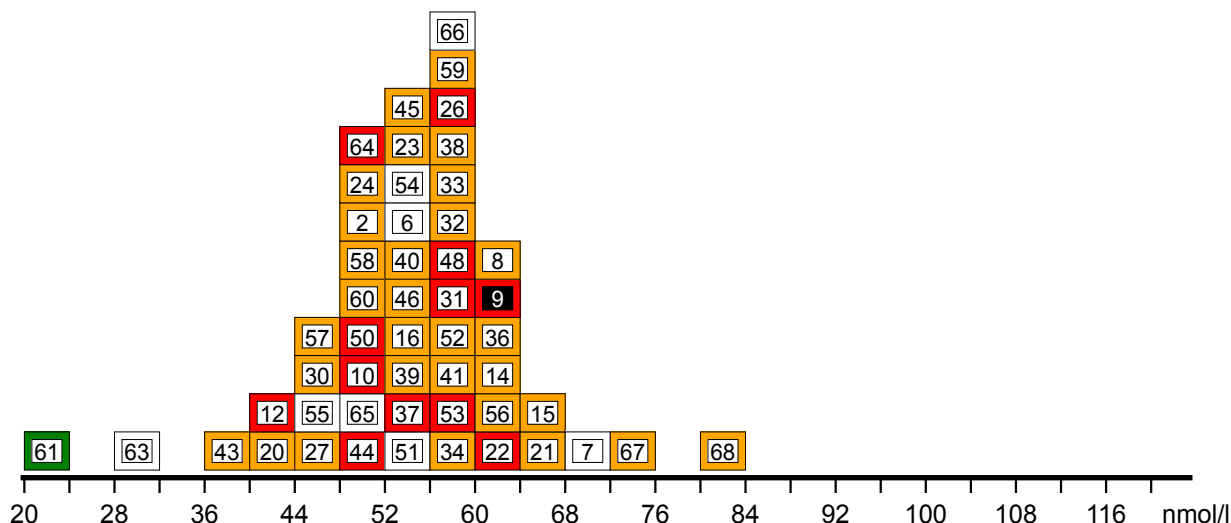
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

M	Mu
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Findings NBS3/19 -July 2019-  
Neonatal - Screening, 17-OHP, Sample B  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">rn</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="background-color: green; border: 1px solid black; padding: 2px;">rn</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">rn</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="background-color: red; border: 1px solid black; padding: 2px;">rn</span> <span style="border: 1px solid black; padding: 2px;">rn</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">rn</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 51	<span style="background-color: green;">■</span> normal 1	1			
XM= 54,0 nmol/l	<span style="background-color: orange;">■</span> CH/AGS/CF possible 30		28	2	
SD = 9,9 nmol/l	<span style="background-color: red;">■</span> CH/AGS/CF evident 12		2	10	
CV = 18,4 %	other 1		1		

**Kit Evaluation for Sample B**

M	Kit	N	Min	16.P	50.P	84.P	Max		20	40	60	80	100	Kit Classifications
All Kits	51	20.9	46.0	<b>54.6</b>	62.8	83.0								<span style="background-color: green;">■</span> 1 <span style="background-color: orange;">■</span> 30 <span style="background-color: red;">■</span> 12 <span style="background-color: black;">■</span> 1
3	350	3	54.6	<b>57.6</b>	58.2	83.0								0 1 1 0
4	245	22	45.3	<b>56.7</b>	64.0	83.0								0 15 4 1
4	246	6	37.4	<b>51.8</b>	61.2	83.0								0 5 1 0
4	247	14	42.3	<b>48.8</b>	56.0	56.1								0 8 5 0
5	111	2	20.9	<b>26.3</b>	31.7	83.0								1 0 0 0

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

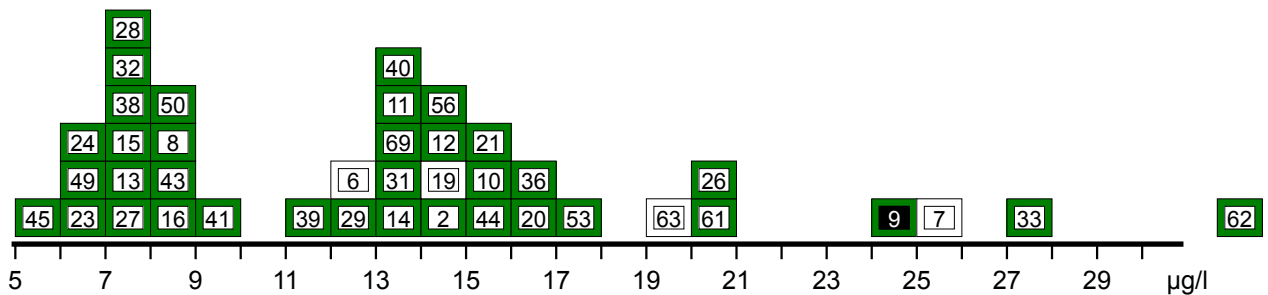
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

Findings NBS3/19 -July 2019-  
Neonatal - Screening, IRT, Sample A  
Participant No 9900667



**Legend:**

N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	<span style="display: inline-block; width: 10px; height: 10px; background-color: black; vertical-align: middle;"></span> = 16. bis 84. percentile with median
XM = mean value		CH = congenital hypothyroidism
SD = standard deviation	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	AGS = adrenogen. syndrome
CV = coefficient of variation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	CF = cystic fibrosis
M = method number		<span style="border: 1px solid black; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications
N = 40	<span style="background-color: green;">■</span> normal 36	none 35
XM = 13,0 µg/l	<span style="background-color: orange;">■</span> CH/AGS/CF possible	new card 1
SD = 5,6 µg/l	<span style="background-color: red;">■</span> CH/AGS/CF evident	plasma sample
CV = 43,1 %	other	other

**Kit Evaluation for Sample A**

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	15	20	25	Kit Classifications
														<span style="background-color: green;">■</span> <span style="background-color: orange;">■</span> <span style="background-color: red;">■</span>
All Kits	40	5.40	7.39	<b>13.4</b>	19.9	64.5								36 0 0 0
2	52	2	24.6		<b>44.5</b>	64.5								2 0 0 0
3	350	2	20.4		<b>24.2</b>	27.9								2 0 0 0
4	245	9	12.7	12.7	<b>13.5</b>	16.1	16.8							7 0 0 0
4	246	3	11.6		<b>13.2</b>	13.8								3 0 0 0
4	247	6	14.0		<b>15.3</b>	17.0								6 0 0 0
4	745	7	5.40		<b>7.50</b>	8.44								7 0 0 0
4	747	7	6.60		<b>7.90</b>	9.00								7 0 0 0
5	111	2	19.5		<b>20.0</b>	20.4								1 0 0 0

Other Kits: 2 9(1),4 746(1),

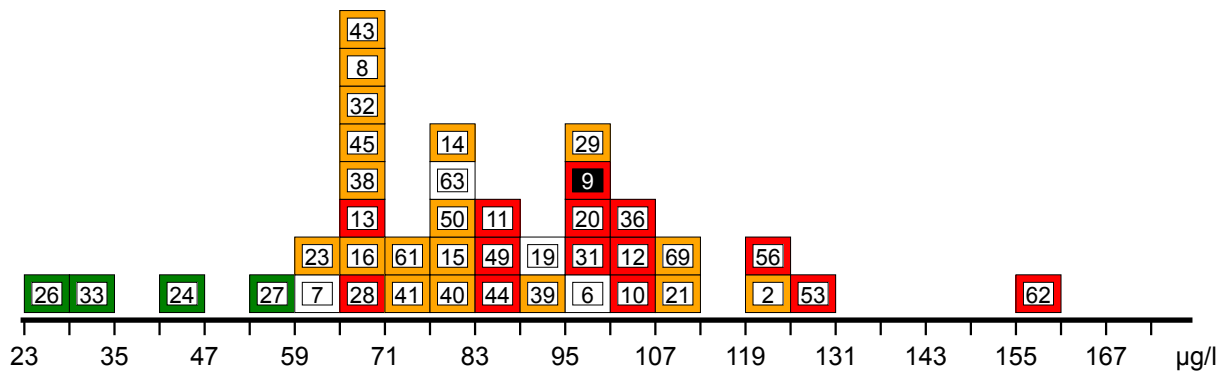
The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:	84 %	-44.83 %



Findings NBS3/19 -July 2019-  
Neonatal - Screening, IRT, Sample B  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="border: 1px solid green; padding: 2px;">r n</span> <span style="border: 1px solid orange; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid red; padding: 2px;">r n</span> <span style="border: 1px solid grey; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="border: 1px solid black; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 40	<span style="color: green;">■</span> normal 4	4			
XM = 82,7 µg/l	<span style="color: orange;">■</span> CH/AGS/CF possible 18		6		12
SD = 23,1 µg/l	<span style="color: red;">■</span> CH/AGS/CF evident 14	1	1	1	11
CV = 27,9 %	other				

**Kit Evaluation for Sample B**

M	Kit	N	Min	16.P	50.P	84.P	Max		50	100	150	Kit Classifications
All Kits	40	23.5	64.7	<b>82.6</b>	108	160						4 18 14 0
2	52	2	99.9		<b>130</b>	160						0 0 2 0
3	350	2	23.5		<b>28.5</b>	33.5						2 0 0 0
4	245	9	87.5	91.4	<b>101</b>	116	123					0 3 4 0
4	246	3	78.7		<b>82.8</b>	93.5						0 3 0 0
4	247	6	85.0		<b>103</b>	127						0 1 5 0
4	745	7	46.1		<b>68.0</b>	79.1						1 6 0 0
4	747	7	57.7		<b>66.0</b>	80.5						1 4 2 0
5	111	2	74.0		<b>78.2</b>	82.4						0 1 0 0

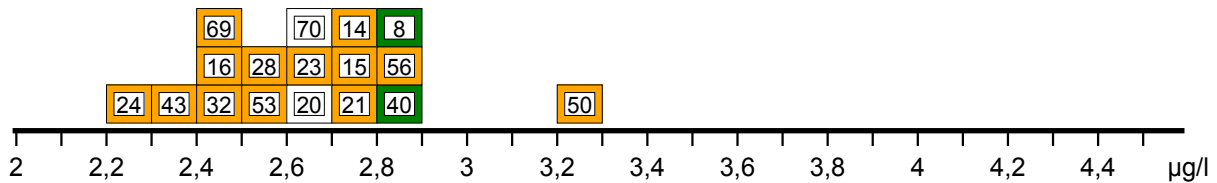
Other Kits: 2 9(1),4 746(1),

The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:	21 %	-23 %

Findings NBS3/19 -July 2019-  
 Neonatal - Screening, PAP, Sample A  
 Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">rn</span> = result box/result code no.	$\pm$ = 16. bis 84. percentile with median
	XM = mean value		CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid green; padding: 2px;">rn</span> <span style="border: 1px solid orange; padding: 2px;">rn</span> = normal   CH/AGS/CF possible	AGS = adrenogen. syndrome
	CV = coefficient of variation	<span style="border: 1px solid red; padding: 2px;">rn</span> <span style="border: 1px solid black; padding: 2px;">rn</span> = CH/AGS/CF evident   other	CF = cystic fibrosis
M = method number		<span style="border: 1px solid black; padding: 2px;">rn</span> = marks your result box	



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 17	<span style="color: green;">■</span> normal 2	2			
XM = 2,6 µg/l	<span style="color: orange;">■</span> CH/AGS/CF possible 13		2		11
SD = 0,2 µg/l	<span style="color: red;">■</span> CH/AGS/CF evident				
CV = 9,4 %	other				

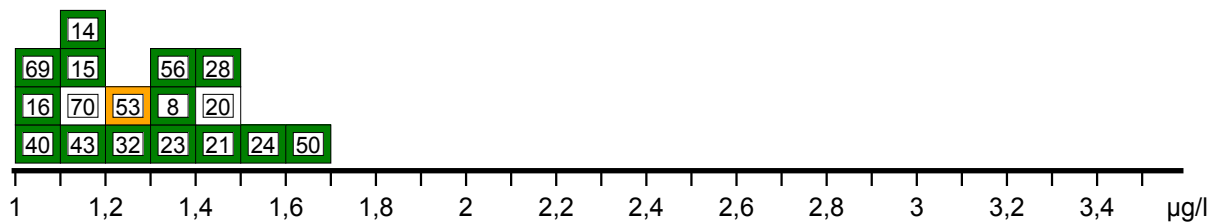
Kit Evaluation for Sample A											Kit Classifications				
M	Kit	N	Min	16.P	50.P	84.P	Max	1	2	3	4	<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	
All Kits	17	2.20	2.39	<b>2.66</b>	2.82	3.25						2	13	0	0
2	255	3	2.40	<b>2.82</b>	2.82	2.82						1	2	0	0
4	255	14	2.20	2.34	<b>2.63</b>	2.78	3.25					1	11	0	0

Other Kits:

Findings NBS3/19 -July 2019-  
 Neonatal - Screening, PAP, Sample B  
 Participant No 9900667



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



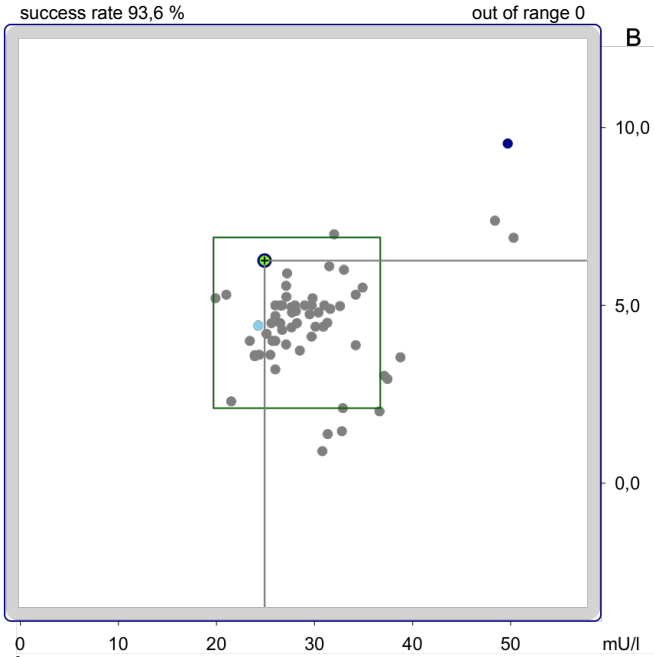
Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 17	normal 14	13			1
XM = 1,2 µg/l	CH/AGS/CF possible 1				1
SD = 0,1 µg/l	CH/AGS/CF evident				
CV = 14,3 %	other				

**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	17	1.00	1.05	<b>1.20</b>	1.42	1.60			14 1 0 0
2	255 3	1.20		<b>1.33</b>		1.35			3 0 0 0
4	255 14	1.00	1.02	<b>1.20</b>	1.49	1.60			11 1 0 0

Other Kits:

Analyte **TSH**  
Method all methods



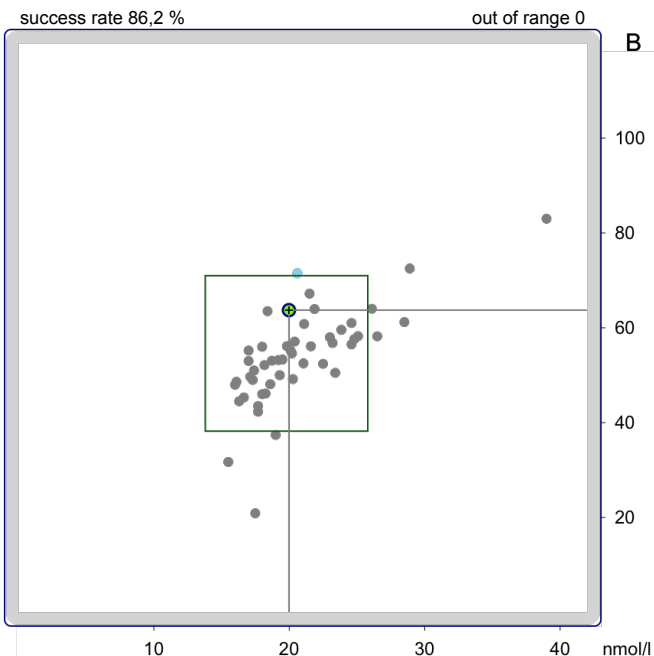
No of participants	<b>63</b>		
sample/unit	A	mU/l	B
mean	29.7		4.52
standard deviation	5.96		1.42
coefficient of variation	20.1		31.4

Sample A [mU/l]							
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		63	19.9	25.2	28.2	33.9	50.3
3	350	3	27.2		28.5		34.2
4	245	19	23.9	25.6	28.2	31.2	34.9
4	246	6	26.0		26.8		32.0
4	247	17	21.0	24.9	27.7	31.6	33.0
5	77	8	30.8	31.0	35.4	38.2	38.8

Sample B [mU/l]							
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		63	0.900	3.55	4.51	5.45	9.55
3	350	3	3.73		5.30		5.90
4	245	19	3.57	3.71	4.70	5.00	5.50
4	246	6	3.20		4.70		7.00
4	247	17	3.90	4.00	4.95	5.38	6.10
5	77	8	0.900	1.11	2.52	3.73	3.88

Other kits (number):  
1-09(1), 1-77(1), 2-09(1), > 2-99(2)<, 3-99(1), 4-99(1), 4-216(1), 5-111(2),

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



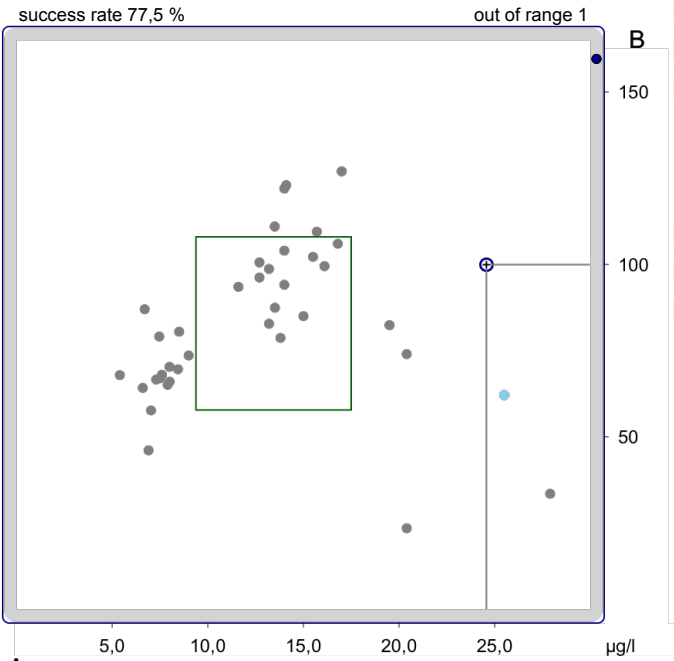
No of participants	<b>51</b>		
sample/unit	A	nmol/l	B
mean	20.7		54.0
standard deviation	4.20		9.96
coefficient of variation	20.3		18.4

Sample A [nmol/l]							
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		51	15.5	17.2	19.8	24.6	39.0
3	350	3	20.2		24.8		26.5
4	245	22	16.7	18.2	20.8	24.8	39.0
4	246	6	17.4		20.1		28.5
4	247	14	16.0	16.2	17.7	19.0	21.6

Sample B [nmol/l]							
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		51	20.9	46.0	54.6	62.8	83.0
3	350	3	54.6		57.6		58.2
4	245	22	45.3	49.5	56.7	64.0	83.0
4	246	6	37.4		51.8		61.2
4	247	14	42.3	43.9	48.8	56.0	56.1

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

Analyte **IRT**  
 Method all methods



**A**

No of participants	<b>40</b>	
sample/unit	A	B
mean	13.0	82.7
standard deviation	5.61	23.1
coefficient of variation	43.2	28.0

**Sample A [µg/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		40	5.40	7.39	13.4	19.9	64.5
4	245	9	12.7	12.7	13.5	16.1	16.8
4	246	3	11.6		13.2		13.8
4	247	6	14.0		15.3		17.0
	PE2	7	5.40		7.50		8.44
	PE3	7	6.60		7.90		9.00

**Sample B [µg/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		40	23.5	64.7	82.6	108	160
4	245	9	87.5	91.4	101	116	123
4	246	3	78.7		82.8		93.5
4	247	6	85.0		103		127
	PE2	7	46.1		68.0		79.1
	PE3	7	57.7		66.0		80.5

Other kits (number):  
 2-09(1), > 2-52(2)<, 3-350(2), 4-746(1), 5-111(2),