

Survey: **NBS4/17**
month: **October 2017**
Participant-No: **9900667**
date of issue: **14.10.17**



Referenzinstitut für Bioanalytik

Tijen Tanyalcin MD,PH
Tanyalcin Tip laboratuvari
Kizilkanat Sag lik Sitesi 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. November 2017

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:

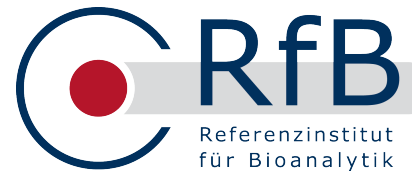
17-OH-progesterone (2) | IRT (2)

This certificate is valid until the end of April 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.

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Dr. A. Kessler

Bonn, 6. November 2017

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: **NBS4/17**
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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.

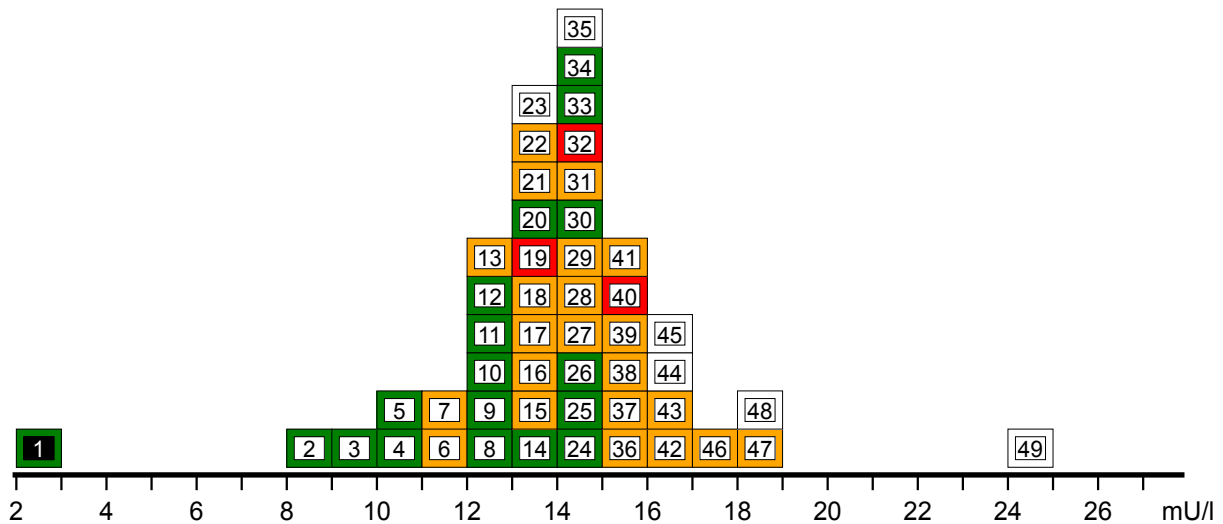
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL UL = 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	2.50	-2.74	14.0	9.80	18.2							
			B	1.50	-2.85	10.4	7.28	13.6							
17-OH-progesterone [nmol/l]	+	2	A	42.3	-0.09	43.5	30.4	56.6							
			B	23.4	0.46	20.5	14.3	26.7							
IRT [µg/l]	+	2	A	25.4	-0.40	28.9	20.2	37.6							
			B	19.7	0.77	16.0	11.2	20.8							

Findings NBS4/17 -October 2017-
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 = 49	■ normal 18	16			
XM = 13,9 mU/l	■ CH/AGS/CF possible 22		22		
SD = 3,0 mU/l	■ CH/AGS/CF evident 3		1	2	
CV = 22,1 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
	All Kits	49	2.50	12.0	14.1	16.0	24.8		18 22 3 0
	2	99	2	2.50	13.7		24.8		1 0 0 0
	3	99	3	14.8	14.9		18.9		1 0 0 0
	4	245	17	11.0	13.8	14.6	15.5		7 8 2 0
	4	246	8	9.00	10.1	12.9	17.4		4 4 0 0
	4	247	11	10.1	12.3	14.5	18.6		4 6 1 0
	5	111	2	13.1	14.9		16.7		0 1 0 0

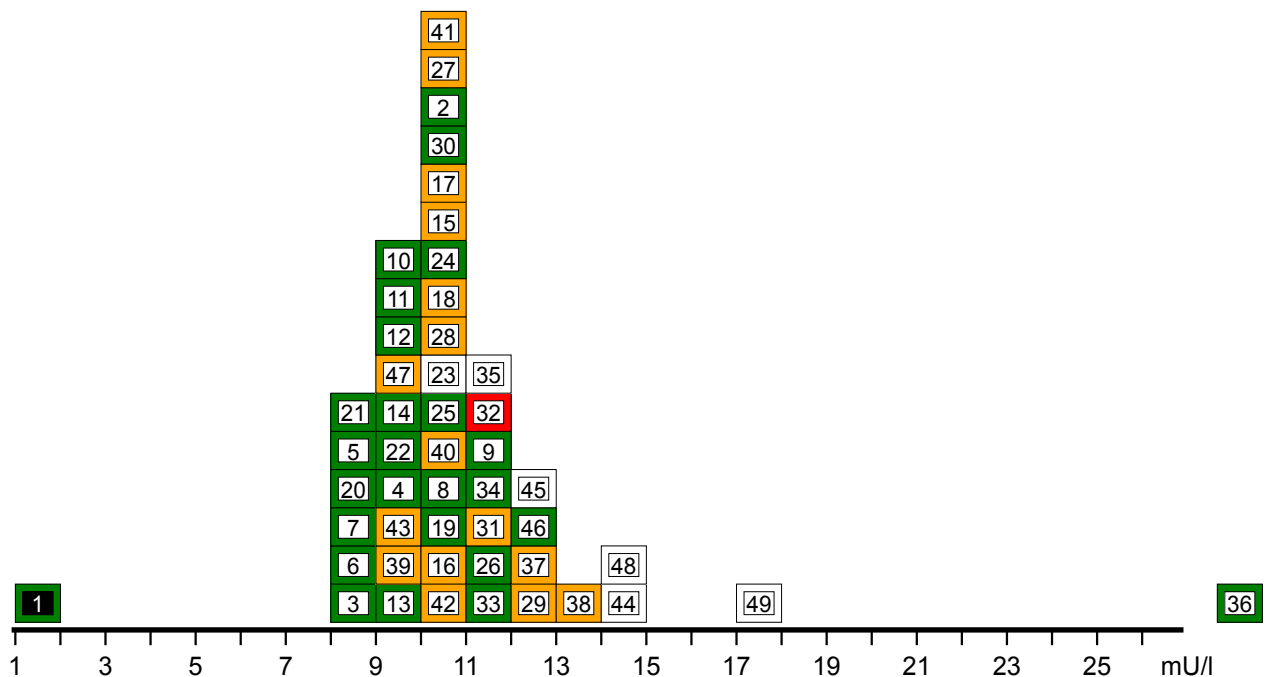
Other Kits: 2 2(1),2 9(1),4 91(1),4 99(1),5 48(1),5 77(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -82.27 % -81.68 %

Findings NBS4/17 -October 2017-
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 = 49	■ normal 26	24			
XM= 10,4 mU/l	■ CH/AGS/CF possible 16		16		
SD= 2,2 mU/l	■ CH/AGS/CF evident 1			1	
CV= 21,1 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	15	Kit Classifications			
												■	■	■	■
All Kits		49	1.50	9.10	10.4	12.0	30.6					26	16	1	0
2	99	2	1.50		9.60		17.7	●				1	0	0	0
3	99	3	11.3		11.8		14.7					1	0	0	0
4	245	17	8.69	9.45	10.2	11.0	12.0					10	7	0	0
4	246	8	8.00	8.04	9.60	12.0	12.5					6	2	0	0
4	247	11	8.74	9.16	10.0	12.9	30.6					6	4	1	0
5	111	2	10.5		11.7		12.9					0	1	0	0

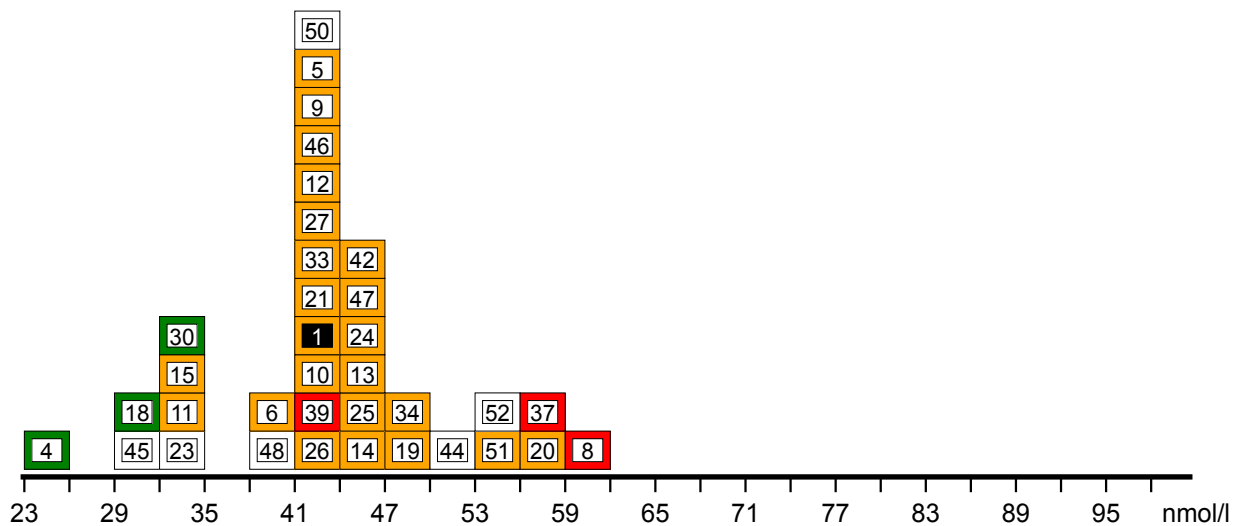
Other Kits: 2 2(1),2 9(1),4 91(1),4 99(1),5 48(1),5 77(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -85.58 % -84.38 %

Findings NBS4/17 -October 2017-
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 = 35	■ normal 3	1			
XM= 44,1 nmol/l	■ CH/AGS/CF possible 23		21	1	
SD= 7,2 nmol/l	■ CH/AGS/CF evident 3			2	
CV= 16,4 %	■ other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
	All Kits	35	23.9	33.9	43.5	51.8	60.0	3	23	3	0
	3	99	2	40.2	44.7	49.2	49.2	0	1	0	0
	4	245	11	43.1	44.8	58.2	60.0	0	9	2	0
	4	246	5	40.7	43.5	57.5	57.5	0	5	0	0
	4	247	10	23.9	41.7	45.9	46.0	2	6	1	0
	5	111	2	31.9	31.9	32.0	32.0	1	0	0	0

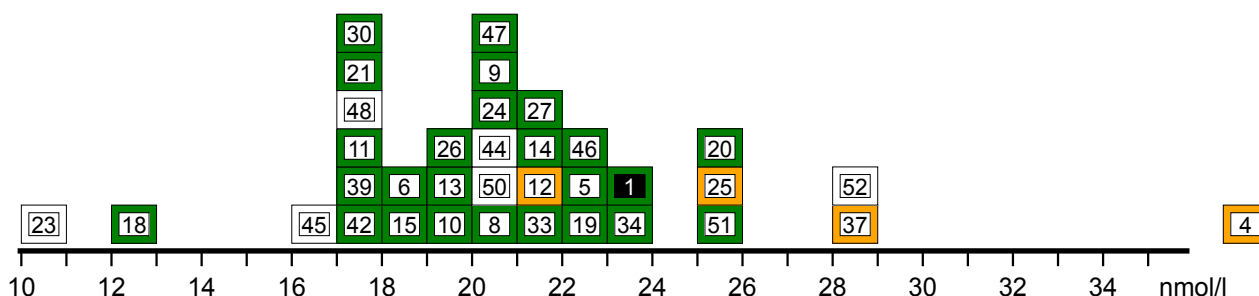
Other Kits: 2 9(1),2 99(1),4 91(1),4 99(1),6 99(1),

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

Findings NBS4/17 -October 2017-
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 = 35	■ normal 25	23			
XM = 20,3 nmol/l	■ CH/AGS/CF possible 4		3		
SD = 3,7 nmol/l	■ CH/AGS/CF evident				
CV = 18,4 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		10	20	30	Kit Classifications
	All Kits	35	10.9	17.4	20.5	25.0	90.5					25 4 0 0
	3	99	2	17.5	20.3		23.0					1 0 0 0
	4	245	11	19.4	21.5	25.3	28.0					8 3 0 0
	4	246	5	18.2	20.5		25.8					5 0 0 0
	4	247	10	17.0	18.0	37.4	90.5					8 1 0 0
	5	111	2	12.2	14.2		16.3					1 0 0 0

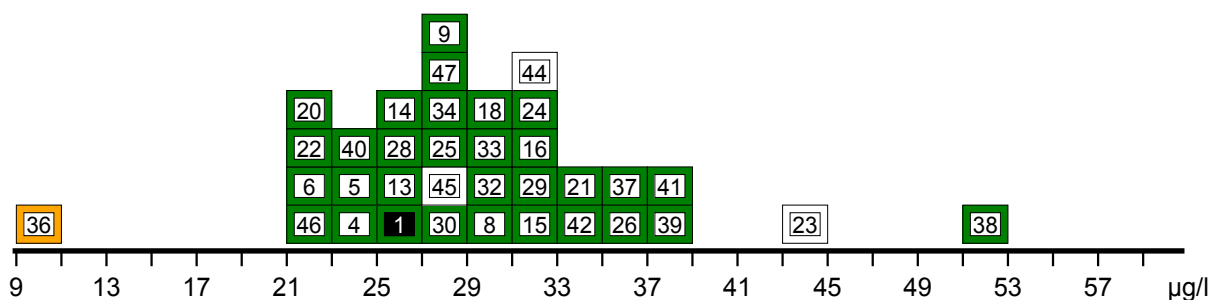
Other Kits: 2 9(1),2 99(1),4 91(1),4 99(1),6 99(1),

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 NBS4/17 -October 2017-
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			
		new card	plasma sample	other	none
N = 35	normal 31	29			
XM = 28,6 µg/l	CH/AGS/CF possible 1		1		
SD = 6,1 µg/l	CH/AGS/CF evident				
CV = 21,3 %	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	35	9.90	23.0	28.8	35.6	52.0								31	1	0	0
2	52	2	25.4	38.7		52.0								2	0	0	0
4	245	14	21.6	27.3	32.1	36.0								14	0	0	0
4	246	4	21.6	25.7		37.3								4	0	0	0
4	247	10	9.90	30.2	35.9	37.0								9	1	0	0
5	111	2	27.5	29.1		30.6								1	0	0	0

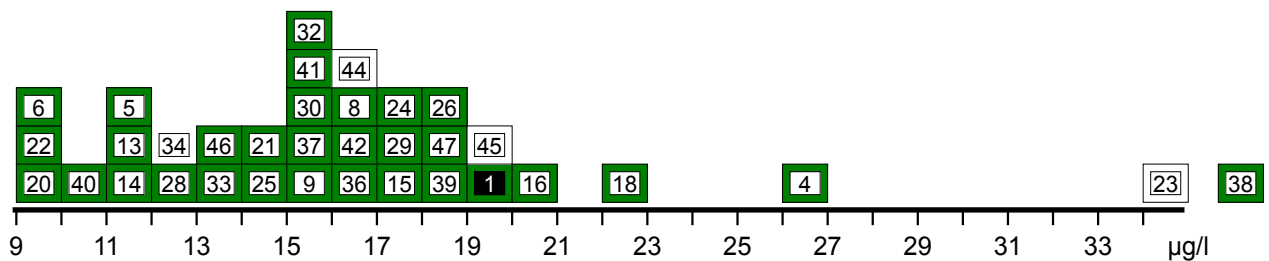
Other Kits: 2 9(1),3 99(1),4 91(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -11.81 % -34.37 %

Findings NBS4/17 -October 2017-
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			CH	= congenital hypothyroidism
	SD = standard deviation	rn	rn	AGS	= adrenogen. syndrome
	CV = coefficient of variation	rn	rn	CF	= cystic fibrosis
M = method number				rn	= marks your result box
					= CH/AGS/CF evident other



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications
N = 35	<ul style="list-style-type: none"> ■ normal 31 ■ CH/AGS/CF possible ■ CH/AGS/CF evident other 	<ul style="list-style-type: none"> none 29 new card plasma sample other
XM = 16,0 µg/l		
SD = 4,9 µg/l		
CV = 31,1 %		

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
	All Kits	35	9.30	11.6	15.9	19.9	49.0		31 0 0 0
2	52	2	19.7		34.4		49.0		2 0 0 0
4	245	14	9.30	10.8	13.1	17.2	20.0		14 0 0 0
4	246	4	9.30		12.3		15.9		4 0 0 0
4	247	10	14.8	14.9	16.5	20.3	26.7		10 0 0 0
5	111	2	19.9		21.3		22.7		1 0 0 0

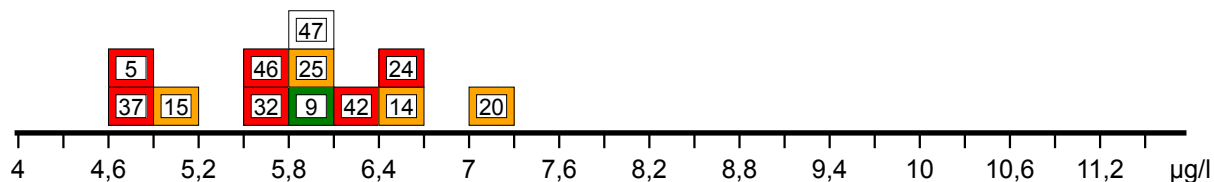
Other Kits: 2 9(1),3 99(1),4 91(1),

The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:	23 %	-42.65 %

Findings NBS4/17 -October 2017-
 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 = 12	■ normal 1	1			
XM= 5,8 µg/l	■ CH/AGS/CF possible 4				4
SD= 0,7 µg/l	■ CH/AGS/CF evident 6				6
CV= 12,8 %	other				

Kit Evaluation for Sample A

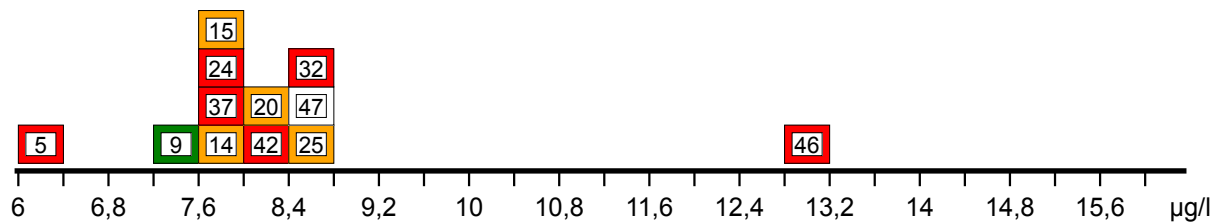
M	Kit	N	Min	16.P	50.P	84.P	Max						Kit Classifications			
								■	■	■	■					
All Kits	12	4.60	4.88	5.80	6.65	7.10						1	4	6	0	
2	255	3	4.87	5.80	6.50	6.50						0	2	1	0	
4	255	9	4.60	4.84	5.80	6.84	7.10					1	2	5	0	

Other Kits:

Findings NBS4/17 -October 2017-
Neonatal - Screening, PAP, Sample B
Participant No 9900667



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



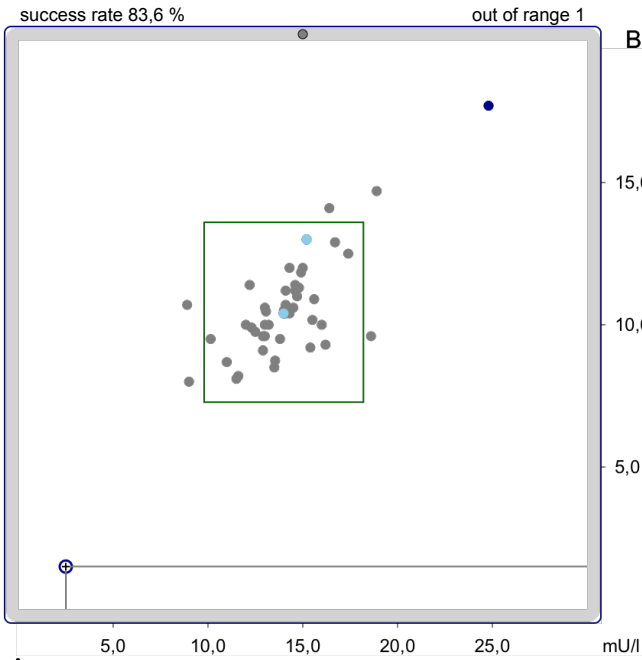
Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 12	normal 1	1			
XM= 8,2 µg/l	CH/AGS/CF possible 4				4
SD= 1,5 µg/l	CH/AGS/CF evident 6				6
CV= 18,6 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
All Kits	12	6.24	7.52	7.95	8.58	12.8			1 4 6 0
2	255	3	6.24	7.80		8.40			0 2 1 0
4	255	9	7.50	7.68	8.00	10.3	12.8		1 2 5 0

Other Kits:

Analyte **TSH**
Method all methods



A

No of participants	49		
sample/unit	A	mU/l	B
mean	13.9		10.4
standard deviation	3.08		2.21
coefficient of variation	22.2		21.1

Sample A [mU/l]

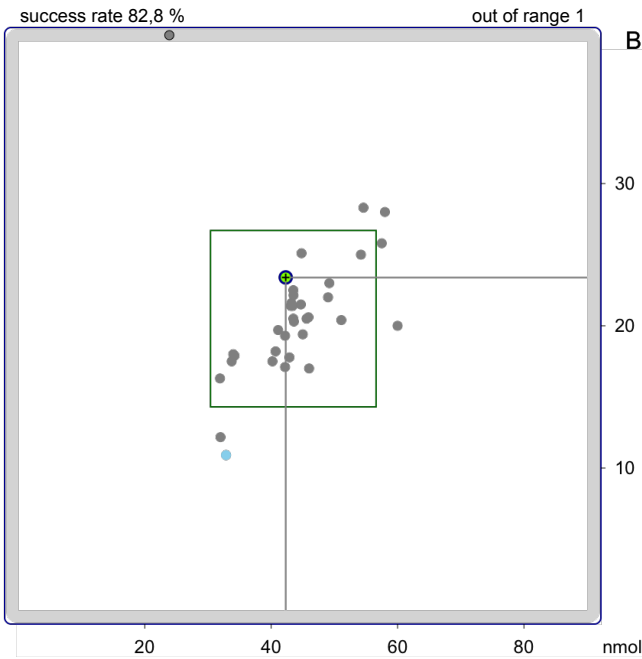
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	49	2.50	12.0	14.1	16.0	24.8	
3	99	3	14.8		14.9	18.9	
4	245	17	11.0	12.8	13.8	14.6	15.5
4	246	8	9.00	10.1	12.9	16.9	17.4
4	247	11	10.1	12.3	14.5	16.2	18.6

Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	49	1.50	9.10	10.4	12.0	30.6	
3	99	3	11.3		11.8	14.7	
4	245	17	8.69	9.45	10.2	11.0	12.0
4	246	8	8.00	8.04	9.60	12.0	12.5
4	247	11	8.74	9.16	10.0	12.9	30.6

Other kits (number):
2-02(1), 2-09(1), > 2-99(2)<, 4-91(1), 4-99(1), 5-48(1), 5-77(1), 5-111(2).

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



A

No of participants	35		
sample/unit	A	nmol/l	B
mean	44.1		20.4
standard deviation	7.24		3.75
coefficient of variation	16.4		18.4

Sample A [nmol/l]

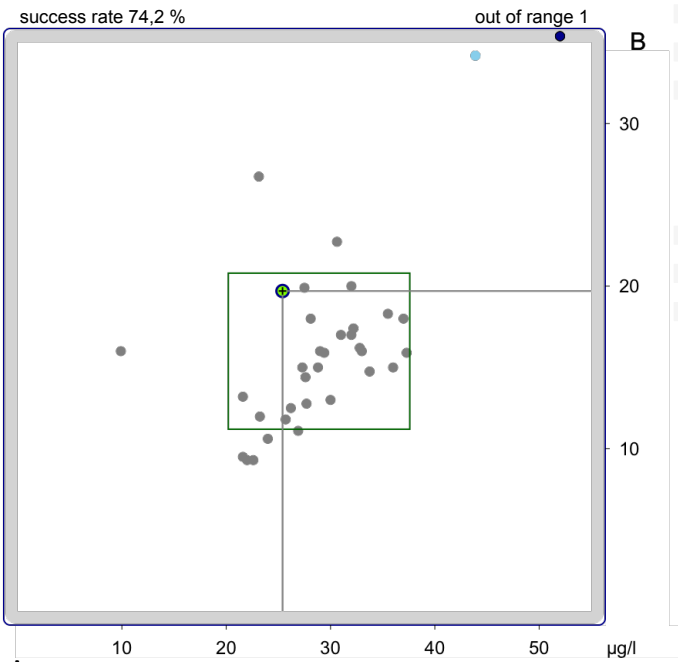
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	35	23.9	33.9	43.5	51.8	60.0	
4	245	11	43.1	43.2	44.8	58.2	60.0
4	246	5	40.7		43.5	57.5	
4	247	10	23.9	31.4	41.7	45.9	46.0

Sample B [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	35	10.9	17.4	20.5	25.0	90.5	
4	245	11	19.4	20.0	21.5	25.3	28.0
4	246	5	18.2		20.5	25.8	
4	247	10	17.0	17.1	18.0	37.4	90.5

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

Analyte **IRT**
 Method all methods



A

No of participants	35	
sample/unit	A	B
mean	28.7	16.0
standard deviation	6.12	4.98
coefficient of variation	21.3	31.1

Sample A [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		35	9.90	23.0	28.8	35.6	52.0
2	52	2	25.4		38.7		52.0
4	245	14	21.6	22.5	27.3	32.1	36.0
4	246	4	21.6		25.7		37.3
4	247	10	9.90	20.0	30.2	35.9	37.0
5	111	2	27.5		29.1		30.6

Sample B [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		35	9.30	11.6	15.9	19.9	49.0
2	52	2	19.7		34.4		49.0
4	245	14	9.30	10.8	13.1	17.2	20.0
4	246	4	9.30		12.3		15.9
4	247	10	14.8	14.9	16.5	20.3	26.7
5	111	2	19.9		21.3		22.7

The deviation of your results from the median of the corresponding sub-collective (kit) is:
 A-34.37 %
 B-42.65 %

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