

Survey: **NBS1/20**
month: **February 2020**
Participant-No: **9900667**
date of issue: **15.02.20**

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, 4. March 2020

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)

This certificate is according to the current version of the RiliBÄK valid until the end of August 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.

Survey: **NBS1/20**
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Referenzinstitut für Bioanalytik

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Dr. A. Kessler

Bonn, 4. March 2020

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: **NBS1/20**
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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.

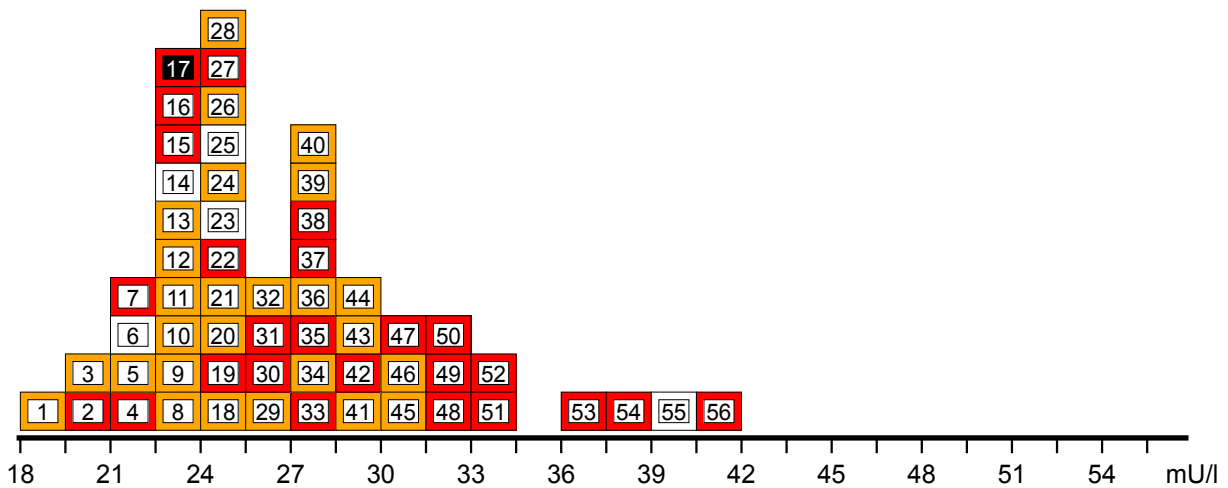
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T)	Certification: + = fulfilled (quotient D/Dmax <= 1.0) - = not fulfilled (quotient D/Dmax > 1.0) ± = certification cancelled because of technical and/or analytical reasons
	Dmax= maximum allowable amount of difference in measurement, 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	

	C	M	R	D/Dmax	T	LL	UL								
TSH [mU/l]	+	2	A	23.7	0.02	23.5	16.4	30.6							
			B	9.20	0.32	8.38	5.86	10.9							
17-OH-progesterone [nmol/l]	±	2	A	85.4	0.74	69.7	48.7	90.7							
			B	34.9	1.74	22.9	16.0	29.8							
IRT [µg/l]	±	2	A	44.0											
			B	18.7	-1.27	30.3	21.2	39.4							

Findings NBS1/20 -February 2020-
Neonatal - Screening, TSH, 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	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 = 56	■ normal				
XM= 26,8 mU/l	■ CH/AGS/CF possible 26	1	18	7	
SD= 4,8 mU/l	■ CH/AGS/CF evident 25		1	22	1
CV= 18,1 %	other 1		1		

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max		10	20	30	40	Kit Classifications				
														■	■	■	
All Kits	56	18.2	22.9	25.5	31.5	41.1								0	26	25	1
2	9	3	20.2		23.2		38.7							0	0	2	0
3	350	2	22.9		31.3		39.7							0	1	0	0
4	99	2	23.1		25.6		28.1							0	1	1	0
4	245	17	20.9	22.5	25.1	29.1	41.1							0	10	6	0
4	246	7	18.2		23.0		30.6							0	5	2	0
4	247	15	21.9	24.0	27.0	30.7	33.1							0	7	8	0
5	77	8	24.6	25.4	31.4	35.5	37.0							0	2	5	1

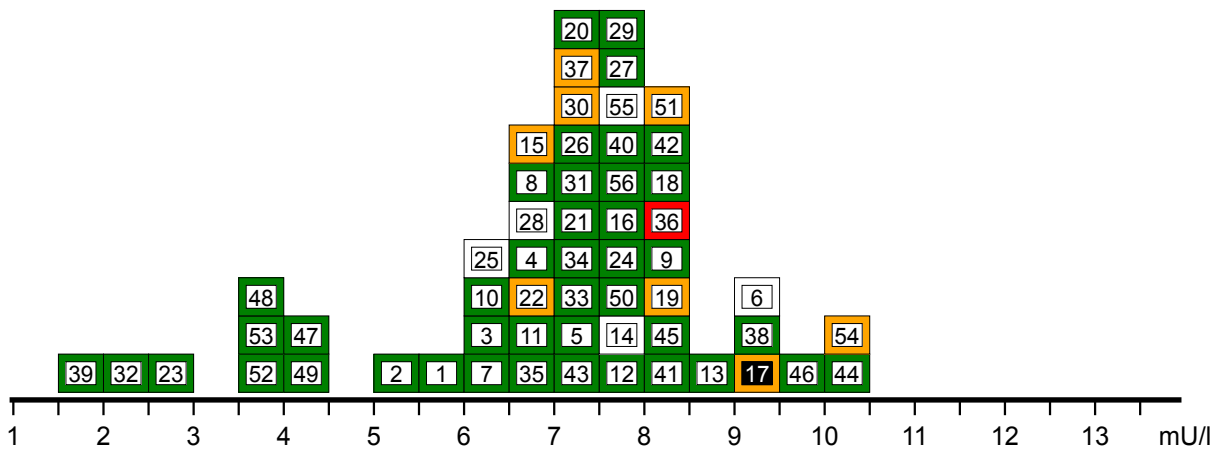
Other Kits: 2 99(1),3 99(1),

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

Findings NBS1/20 -February 2020-
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			
	normal	CH/AGS/CF possible	none	new card	plasma sample	other
N = 56	42	8	42			
XM= 6,9 mU/l				7		
SD= 1,8 mU/l		1		1		
CV= 26,6 %		other				1

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	5		10	Kit Classifications			
											■	■	■	■
All Kits	56	1.80	5.20	7.07	8.29	10.5					42	8	1	1
2	9	3	5.14	7.56		10.5					1	1	0	0
3	350	2	7.80	7.90		8.00					1	0	0	0
4	99	2	8.50	8.91		9.32					2	0	0	0
4	245	17	6.20	6.43	7.11	8.01	8.30				13	2	1	0
4	246	7	5.60		6.80		9.50				6	1	0	0
4	247	15	6.80	6.96	7.60	8.24	10.0				11	3	0	1
5	77	8	1.80	1.99	3.56	4.14	4.19				8	0	0	0

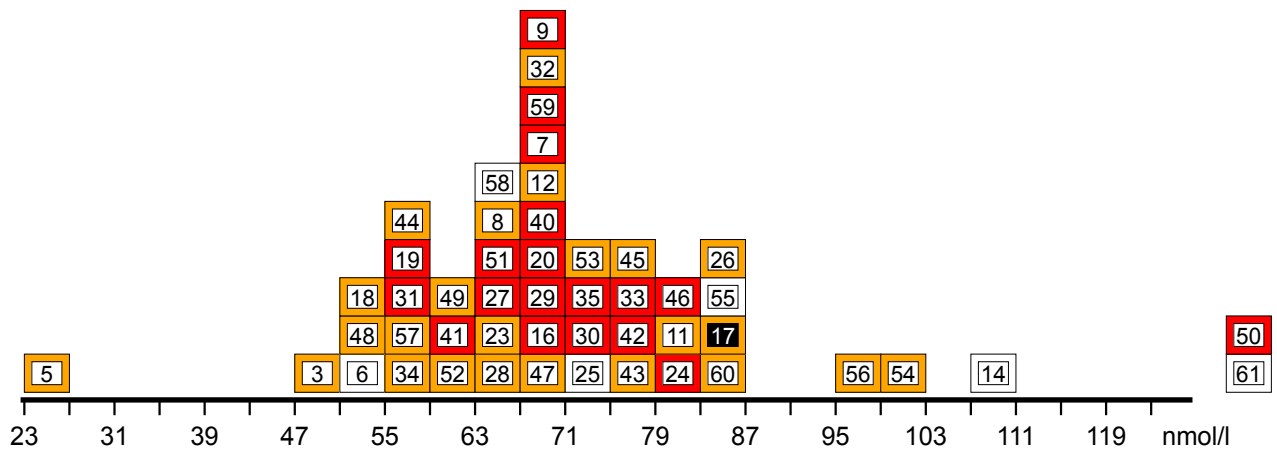
Other Kits: 2 99(1),3 99(1),

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 NBS1/20 -February 2020-
Neonatal - Screening, 17-OHP, 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	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 = 49	■ normal				
XM= 71,7 nmol/l	■ CH/AGS/CF possible 24	1	18	1	3
SD= 15,5 nmol/l	■ CH/AGS/CF evident 19		3	12	4
CV= 21,7 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	50	100	Kit Classifications			
										■	■	■	■
All Kits	49	23.0	56.0	69.7	85.4	152				0	24	19	0
2	9	2	103	107		111				0	1	0	0
3	350	2	70.3	77.9		85.4				0	0	1	0
4	245	20	51.8	62.6	69.9	78.7	97.7			0	12	7	0
4	246	6	23.0		68.8		81.6			0	3	3	0
4	247	14	54.4	56.0	63.7	75.6	152			0	5	8	0
6	99	3	56.0		83.1		131			0	2	0	0

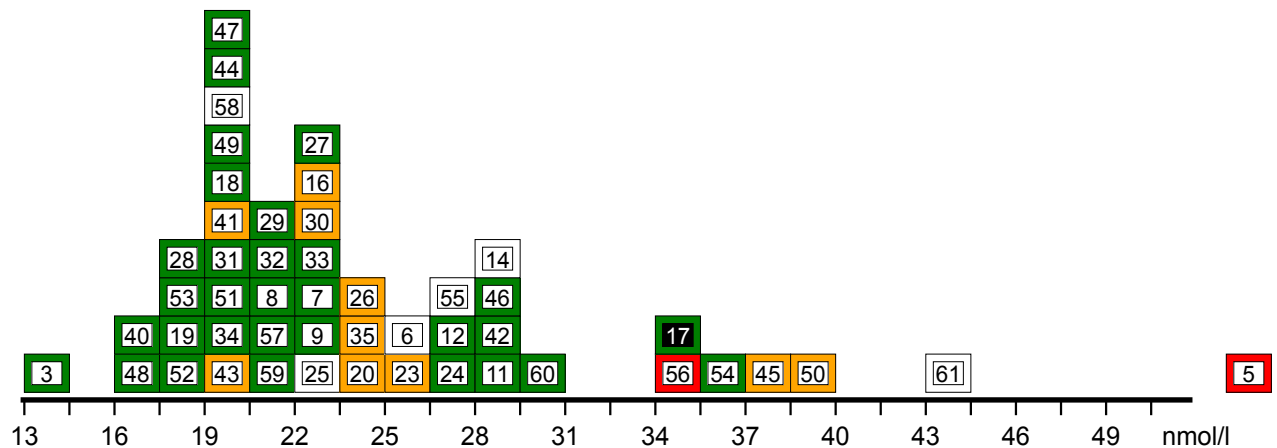
Other Kits: 2 99(1),3 99(1),

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

Findings NBS1/20 -February 2020-
Neonatal - Screening, 17-OHP, 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 = 49	■ normal 31	30			
XM= 23,8 nmol/l	■ CH/AGS/CF possible 10		9		1
SD= 6,2 nmol/l	■ CH/AGS/CF evident 2		1	1	
CV= 26,0 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications							
								10	20	30	40	■	■	■	■
All Kits	49	13.4	19.0	22.9	30.8	92.8		—+—				31	10	2	0
2	9	2	28.8		32.9	36.9		—+—				1	0	0	0
3	350	2	22.5		25.2	27.9		—+—				1	0	0	0
4	245	20	16.2	18.8	23.1	27.9	37.9	—+—				12	6	1	0
4	246	6	13.4		25.7	92.8		—+—				4	1	1	0
4	247	14	17.4	18.1	19.2	23.2	39.0	—+—				10	3	0	0
6	99	3	21.0		30.8	43.9		—+—				2	0	0	0

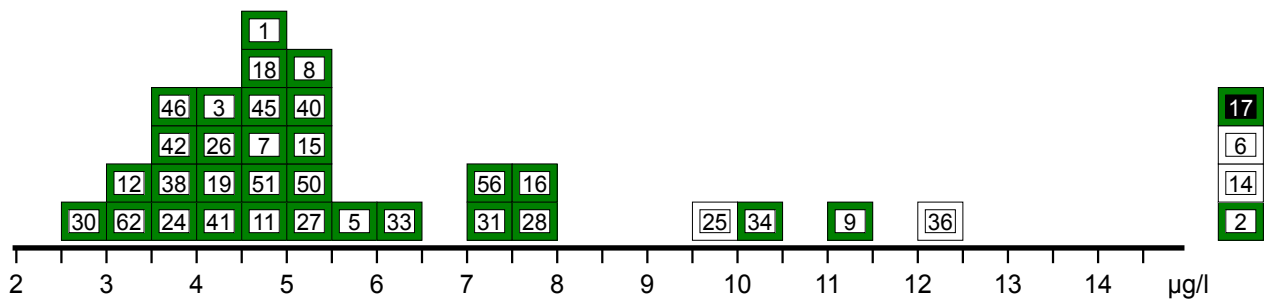
Other Kits: 2 99(1),3 99(1),

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

Findings NBS1/20 -February 2020-
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	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			
	normal	CH/AGS/CF possible	none	new card	plasma sample	other
N = 36	32		32			
XM= 5,6 µg/l						
SD= 2,3 µg/l						
CV= 42,1 %						

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max		0	5	10	Kit Classifications			
												■	■	■	
All Kits	36	2.67	3.80	5.00	11.1	44.0						32	0	0	0
2	9	2	16.9		17.2	17.5						1	0	0	0
4	245	14	2.67	3.28	4.49	8.86	12.4					12	0	0	0
4	246	6	3.79		4.70	7.80						6	0	0	0
4	247	11	4.00	4.00	5.00	7.82	10.0					11	0	0	0

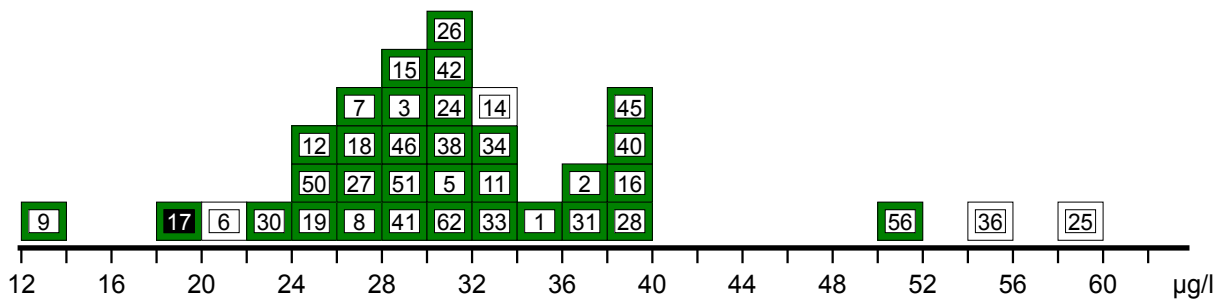
Other Kits: 2 52(1),3 99(1),3 350(1),

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

Findings NBS1/20 -February 2020-
Neonatal - Screening, IRT, 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

N = 36
XM= 32,5 µg/l
SD= 9,0 µg/l
CV= 27,9 %

Statistics of classifications

■ normal 32
■ CH/AGS/CF possible
■ CH/AGS/CF evident
other

Statistics of Implications, related to Classifications

none 32 new card plasma sample other

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	10	20	30	40	50	Kit Classifications			
													■	■	■	
All Kits	36	12.4	25.2	30.3	39.1	59.3							32	0	0	0
2	9	2	33.9	35.2		36.5							1	0	0	0
4	245	14	23.8	26.2	30.5	52.7	59.3						12	0	0	0
4	246	6	28.8		31.6		39.1						6	0	0	0
4	247	11	25.0	25.2	28.4	38.7	39.5						11	0	0	0

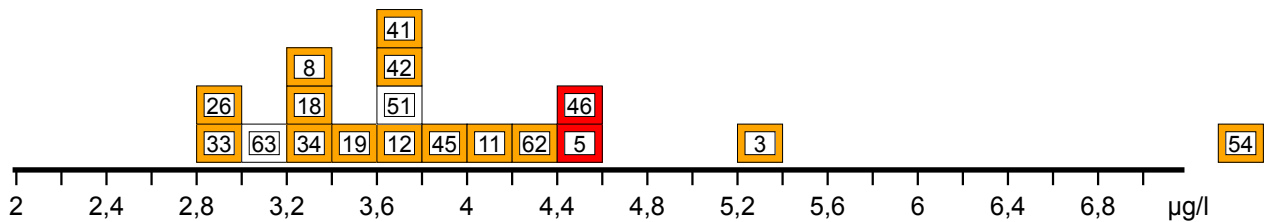
Other Kits: 2 52(1),3 99(1),3 350(1),

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

Findings NBS1/20 -February 2020-
Neonatal - Screening, PAP, Sample A
Participant No 9900667



Legend:	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 = 18	normal				
XM= 3,7 µg/l	CH/AGS/CF possible	14	3		9
SD= 0,6 µg/l	CH/AGS/CF evident	2			2
CV= 16,5 %	other				

Kit Evaluation for Sample A

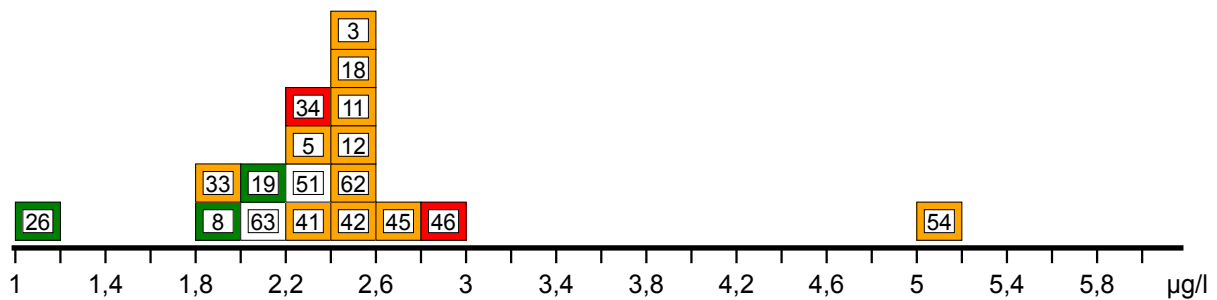
M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications			
All Kits	18	2.90	3.14	3.65	4.50	7.78		0	14	2	0
2	255	3	3.33	3.60		3.80		0	3	0	0
4	255	14	2.90	3.02	3.65	4.46	5.20	0	10	2	0

Other Kits: 2 9(1),

Findings NBS1/20 -February 2020-
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	= 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



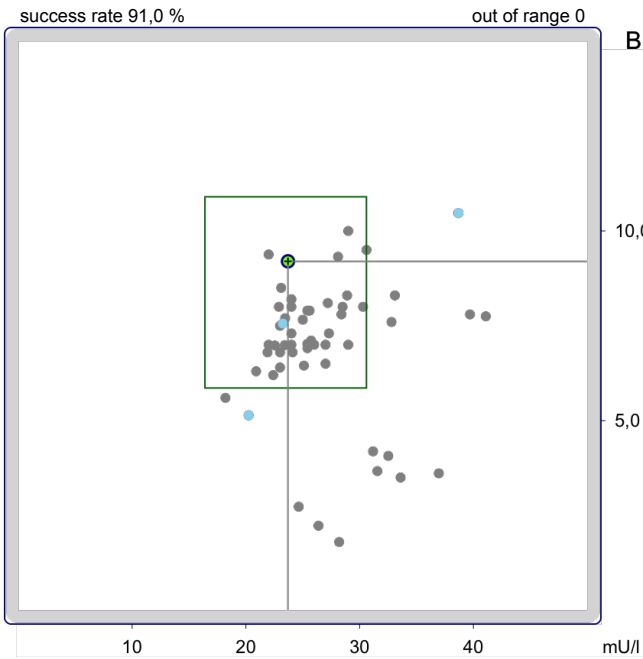
Descriptive Statistics	Statistics of classifications		Statistics of Implications, related to Classifications			
	normal	CH/AGS/CF possible	none	new card	plasma sample	other
N = 18	3	11	3	2		8
XM= 2,2 µg/l						
SD= 0,3 µg/l						
CV= 16,7 %						

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max					Kit Classifications				
								1	2	3	4	normal	possible	evident	other	
All Kits	18	1.17	1.91	2.35	2.60	5.18							3	11	2	0
2	255	3	1.85	2.40		2.60							1	2	0	0
4	255	14	1.17	1.96	2.30	2.48	2.90						2	8	2	0

Other Kits: 2 9(1),

Analyte **TSH**
Method all methods



No of participants	56		
sample/unit	A	mU/l	B
mean	26.8		6.94
standard deviation	4.86		1.85
coefficient of variation	18.1		26.6

Sample A [mU/l]

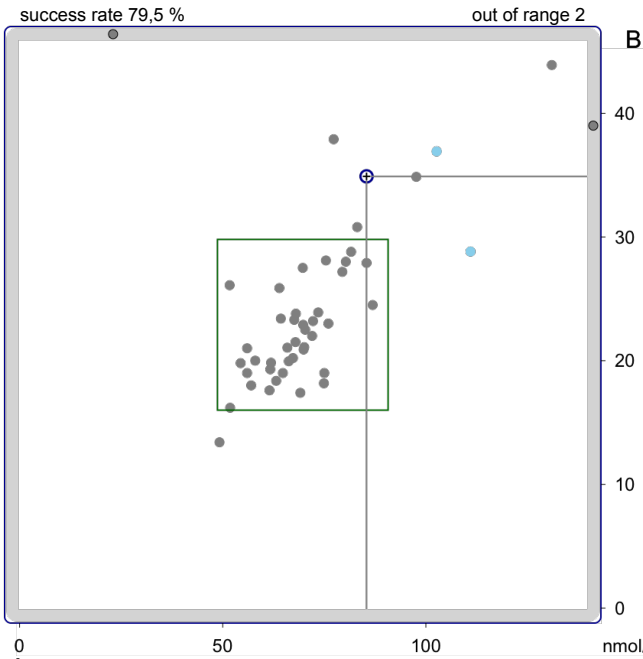
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	56	18.2	22.9	25.5	31.5	41.1	
2	9	3	20.2	23.2		38.7	
3	350	2	22.9		31.3	39.7	
4	99	2	23.1		25.6	28.1	
4	245	17	20.9	22.5	25.1	29.1	41.1
4	246	7	18.2		23.0		30.6
4	247	15	21.9	24.0	27.0	30.7	33.1
5	77	8	24.6	25.4	31.4	35.5	37.0

Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	56	1.80	5.20	7.07	8.29	10.5	
2	9	3	5.14		7.56	10.5	
3	350	2	7.80		7.90	8.00	
4	99	2	8.50		8.91	9.32	
4	245	17	6.20	6.43	7.11	8.01	8.30
4	246	7	5.60		6.80		9.50
4	247	15	6.80	6.96	7.60	8.24	10.0
5	77	8	1.80	1.99	3.56	4.14	4.19

Other kits (number):
> 2-99(1)<, 3-99(1),

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



No of participants	49		
sample/unit	A	nmol/l	B
mean	71.8		23.8
standard deviation	15.6		6.22
coefficient of variation	21.7		26.1

Sample A [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	49	23.0	56.0	69.7	85.4	152	
2	9	2	103		107	111	
3	350	2	70.3		77.9	85.4	
4	245	20	51.8	62.6	69.9	78.7	97.7
4	246	6	23.0		68.8		81.6
4	247	14	54.4	56.0	63.7	75.6	152
6	99	3	56.0		83.1		131

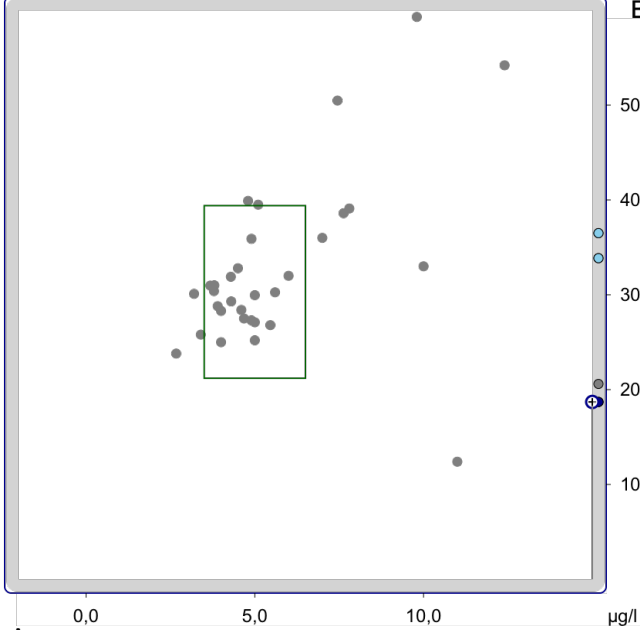
Sample B [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	49	13.4	19.0	22.9	30.8	92.8	
2	9	2	28.8		32.9	36.9	
3	350	2	22.5		25.2	27.9	
4	245	20	16.2	18.8	23.1	27.9	37.9
4	246	6	13.4		25.7		92.8
4	247	14	17.4	18.1	19.2	23.2	39.0
6	99	3	21.0		30.8		43.9

Other kits (number):
> 2-99(1)<, 3-99(1),

Analyte **IRT**
Method all methods

success rate 58,3 % out of range 4



A

No of participants	36		
sample/unit	A	µg/l	B
mean	5.61		32.5
standard deviation	2.37		9.08
coefficient of variation	42.2		27.9

Sample A [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	36	2.67	3.80	5.00	11.1	44.0	
2	9	2	16.9		17.2		17.5
4	245	14	2.67	3.28	4.49	8.86	12.4
4	246	6	3.79		4.70		7.80
4	247	11	4.00	4.00	5.00	7.82	10.0

Sample B [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	36	12.4	25.2	30.3	39.1	59.3	
2	9	2	33.9		35.2		36.5
4	245	14	23.8	26.2	30.5	52.7	59.3
4	246	6	28.8		31.6		39.1
4	247	11	25.0	25.2	28.4	38.7	39.5

Other kits (number):
> 2-52(1), < 3-99(1), 3-350(1),