

Survey: **NBS2/18**
month: **May 2018**
Participant-No: **9900667**
date of issue: **05.05.18**



Referenzinstitut für Bioanalytik



Survey directors

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Head of RfB

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Bonn, 23. May 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: **NBS2/18**
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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.

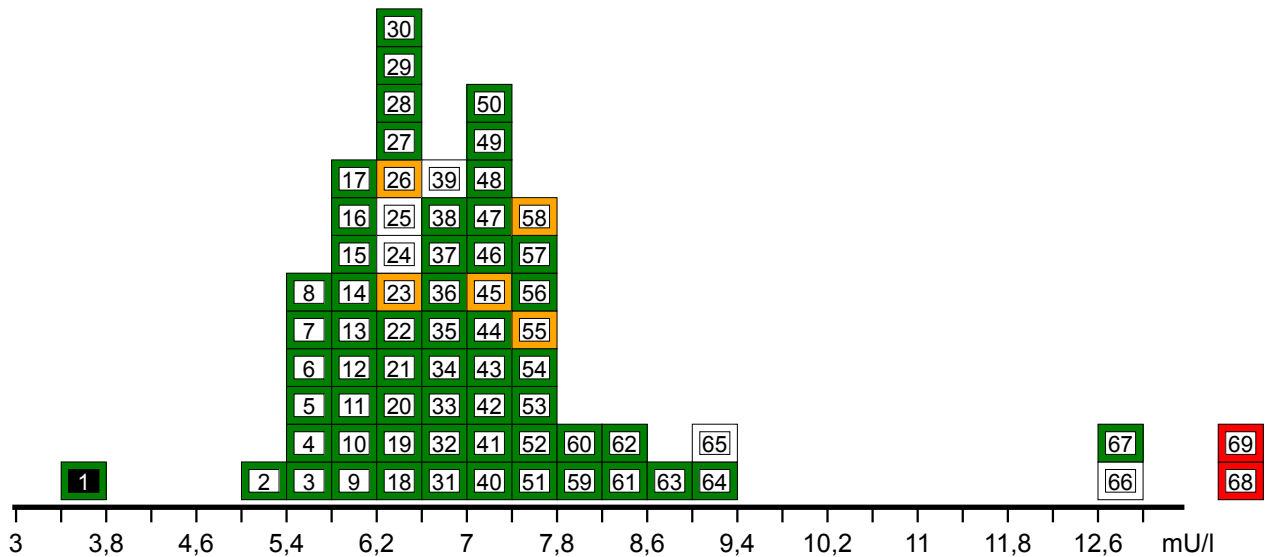
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL UL = 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	3.40	-1.02	5.85	3.45	8.25							
			B	36.2	-0.40	41.2	28.8	53.6							
17-OH-progesterone [nmol/l]	±	2	A	30.8	-1.26	49.5	34.6	64.4							
			B	15.2	-0.52	18.0	12.6	23.4							
IRT [µg/l]	±	2	A	79.2	-0.68	99.7	69.7	130							
			B	15.3	-1.17	23.6	16.5	30.7							

Findings NBS2/18 -May 2018-
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		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 = 69	■ normal 57	54	1		
XM= 6,9 mU/l	■ CH/AGS/CF possible 5		5		
SD= 1,4 mU/l	■ CH/AGS/CF evident 2			2	
CV= 20,2 %	other				

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max					Kit Classifications						
								2	4	6	8	10	12	■	■	■	■	
All Kits	69	3.40	6.00	6.83	7.86	154									57	5	2	0
3	99	3	6.44		7.41		154								1	0	1	0
3	350	2	6.90		9.85		12.8								1	0	0	0
4	91	2	6.40		6.73		7.05								1	0	0	0
4	245	22	5.50	5.84	6.50	7.23	47.7								20	1	1	0
4	246	7	5.40		6.32		8.65								6	1	0	0
4	247	19	5.10	5.82	7.00	7.50	8.00								17	2	0	0
5	77	8	6.00	6.10	7.01	11.2	12.8								7	0	0	0
5	111	2	8.29		8.79		9.29								1	0	0	0

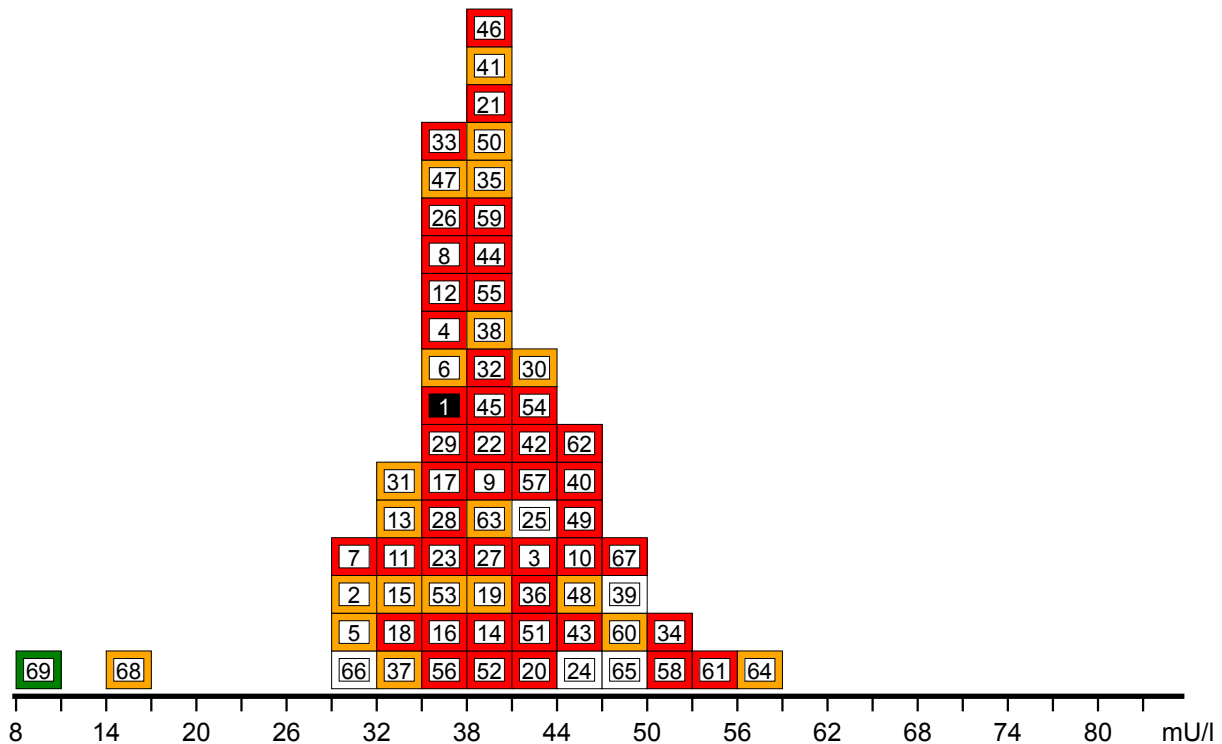
Other Kits: 1 77(1),2 2(1),2 99(1),4 99(1),

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

Findings NBS2/18 -May 2018-
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		CH = congenital hypothyroidism
	SD = standard deviation	r n r n = normal CH/AGS/CF possible	AGS = adrenogen. syndrome
	CV = coefficient of variation	r n r n = CH/AGS/CF evident other	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 = 69	■ normal 1	1			
XM= 40,0 mU/l	■ CH/AGS/CF possible 20		11	8	
SD= 5,6 mU/l	■ CH/AGS/CF evident 43		2	37	2
CV= 14,0 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		20	40	60	Kit Classifications			
												■	■	■	
All Kits	69	8.20	34.4	39.3	45.4	56.4						1	20	43	0
3	99	3	8.20		35.2	42.8						1	1	0	0
3	350	2	49.0		49.4	49.8						0	0	1	0
4	91	2	39.9		42.0	44.0						0	0	1	0
4	245	22	15.7	32.2	37.5	40.3	50.6					0	6	16	0
4	246	7	32.0		35.3	42.3						0	4	3	0
4	247	19	31.2	35.3	39.3	44.1	49.0					0	6	13	0
5	77	8	30.6	33.9	41.8	51.5	56.4					0	2	5	0
5	111	2	47.7		51.3	55.0						0	0	1	0

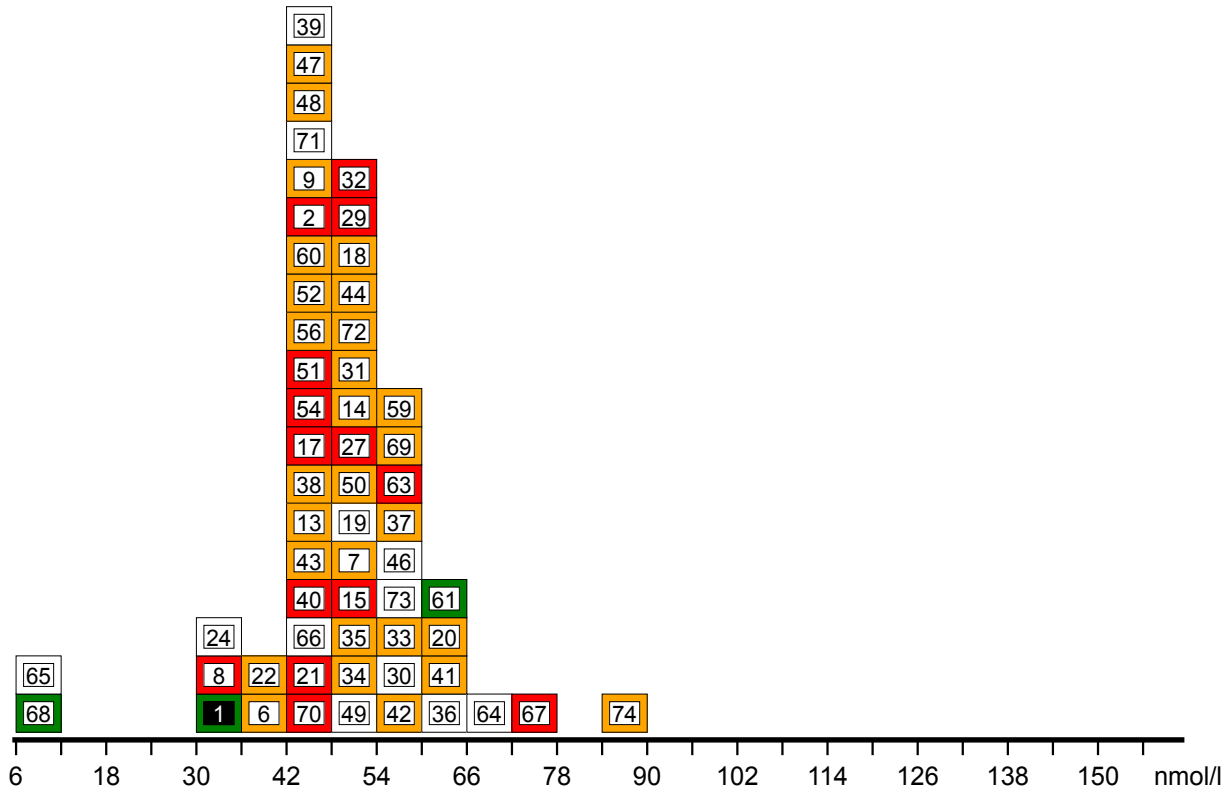
Other Kits: 1 77(1),2 2(1),2 99(1),4 99(1),

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

Findings NBS2/18 -May 2018-
Neonatal - Screening, 17-OHP, Sample A
Participant No 9900667



Legend:	N = number of results	rn = result box/result code no.	\pm = 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 = 57	normal 3	3			
XM = 49,2 nmol/l	CH/AGS/CF possible 28		24	3	1
SD = 12,3 nmol/l	CH/AGS/CF evident 14		4	9	
CV = 25,1 %	other 1		1		

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max	0	50	100	Kit Classifications
All Kits	57	6.84	43.2	49.5	58.4	87.0			\pm		3 28 14 1
3	350	2	47.9	61.9		75.8					0 0 1 0
4	91	2	35.4	43.3		51.2					0 1 0 0
4	245	23	6.84	44.5	51.0	61.0	87.0		\pm		1 13 2 1
4	246	6	42.5		50.4		58.2				0 2 4 0
4	247	18	33.4	40.1	45.6	51.1	54.0		\pm		0 10 7 0
5	111	2	8.02		36.4		64.8				1 0 0 0

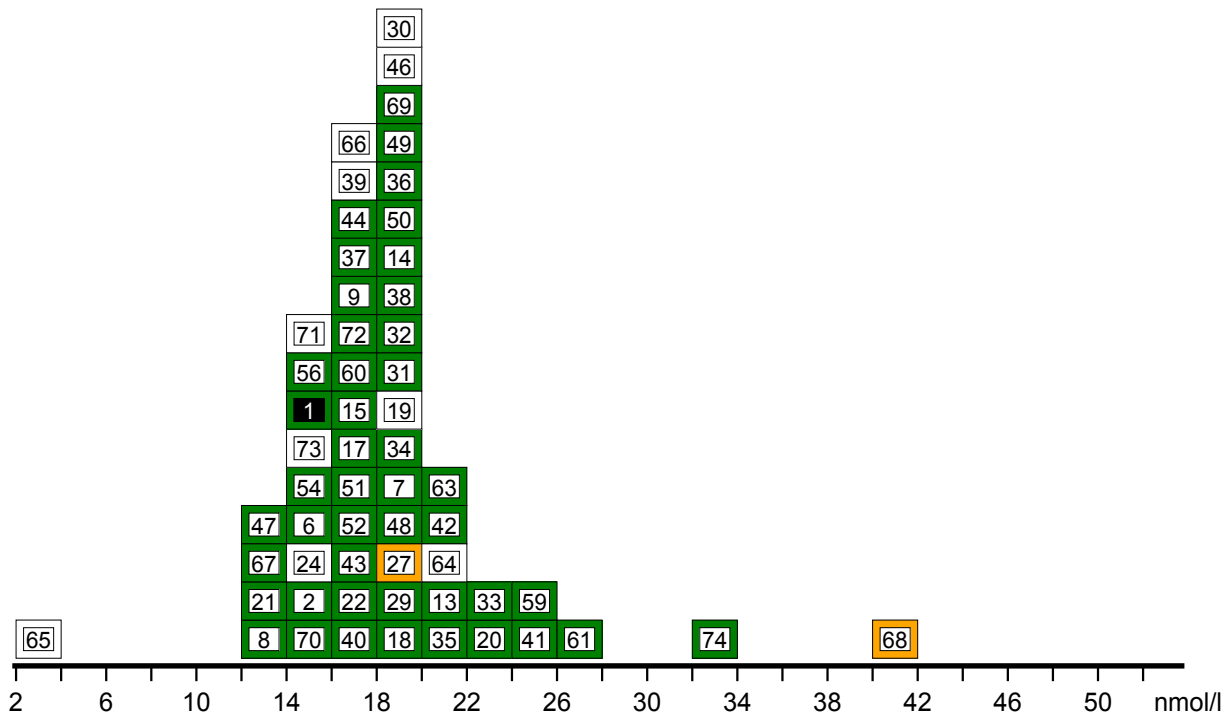
Other Kits: 2 99(1), 3 99(1), 4 99(1), 6 99(1),

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

Findings NBS2/18 -May 2018-
Neonatal - Screening, 17-OHP, Sample B
Participant No 9900667



Legend:	N = number of results	rn = result box/result code no.	\pm = 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 = 57	■ normal 44	42	1		
XM= 18,3 nmol/l	■ CH/AGS/CF possible 2		2		
SD= 5,1 nmol/l	■ CH/AGS/CF evident				
CV= 28,0 %	other				

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		0	10	20	30	40	50	Kit Classifications			
															■	■	■	
All Kits	57	2.74	14.6	18.0	21.0	41.2					\pm				45	2	0	0
3	350	2	13.6	15.7		17.8									1	0	0	0
4	91	2	14.1	15.7		17.3									1	0	0	0
4	245	23	17.2	18.0	19.5	25.0	41.2				\pm				16	2	0	0
4	246	6	14.0	17.1		21.3									6	0	0	0
4	247	18	12.5	13.6	16.0	18.7	21.0				\pm				17	0	0	0
5	111	2	2.74	15.1		27.4									1	0	0	0

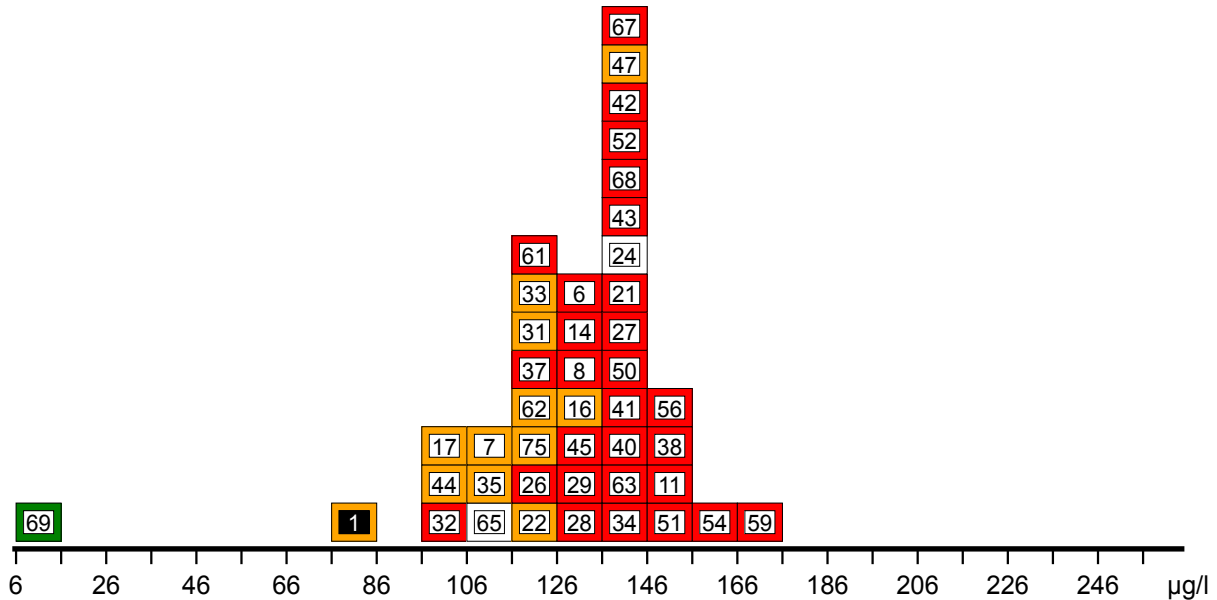
Other Kits: 2 99(1),3 99(1),4 99(1),6 99(1),

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

Findings NBS2/18 -May 2018-
Neonatal - Screening, IRT, Sample A
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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 = 43	<ul style="list-style-type: none"> ■ normal 1 ■ CH/AGS/CF possible 12 ■ CH/AGS/CF evident 28 other 	1	7	3	5
XM = 131,7 µg/l					
SD = 15,5 µg/l					
CV = 11,8 %					

Kit Evaluation for Sample A

M	Kit	N	Min	16.P	50.P	84.P	Max		Kit Classifications
All Kits	43	6.92	114	132	144	167		+	■ 1 ■ 12 ■ 28 0
2	52	2	79.2	99.7		120	•		0 2 0 0
4	91	2	99.4	119		139			0 1 0 0
4	245	16	114	117	131	144	167	+	0 5 11 0
4	246	4	100	130		147			0 1 3 0
4	247	15	96.4	116	139	150	157	+	0 3 12 0
5	111	2	109	117		125			0 0 1 0

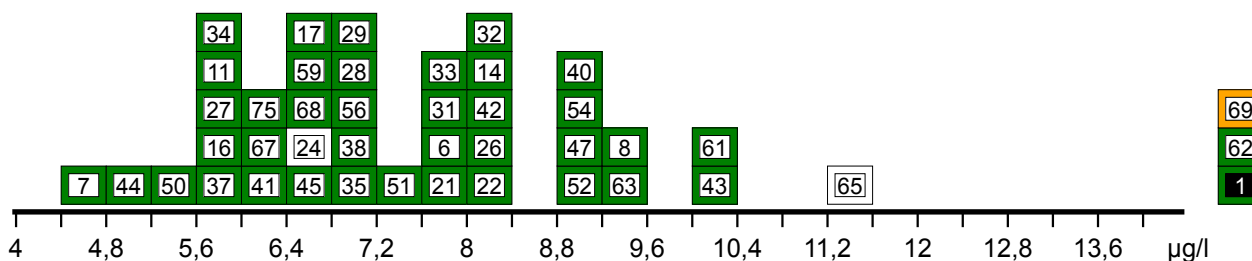
Other Kits: 3 99(1),3 350(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:	M	Mu
	-40 %	-20.56 %

Findings NBS2/18 -May 2018-
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

N = 43
XM= 7,3 µg/l
SD= 1,5 µg/l
CV= 20,6 %

Statistics of classifications

■ normal 40
■ CH/AGS/CF possible 1
■ CH/AGS/CF evident
other

Statistics of Implications, related to Classifications

none 38 new card plasma sample 1 other 1

Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	Kit Classifications
All Kits	43	4.50	5.90	7.30	9.50	37.3					40 1 0 0
2	52	2	15.3	23.6		31.9					2 0 0 0
4	91	2	4.95	5.68		6.40					1 0 0 0
4	245	16	4.50	5.84	6.50	7.93	9.50				16 0 0 0
4	246	4	5.50		5.75		6.50				4 0 0 0
4	247	15	7.00	7.47	8.00	9.22	10.0				15 0 0 0
5	111	2	10.3		10.7		11.2				1 0 0 0

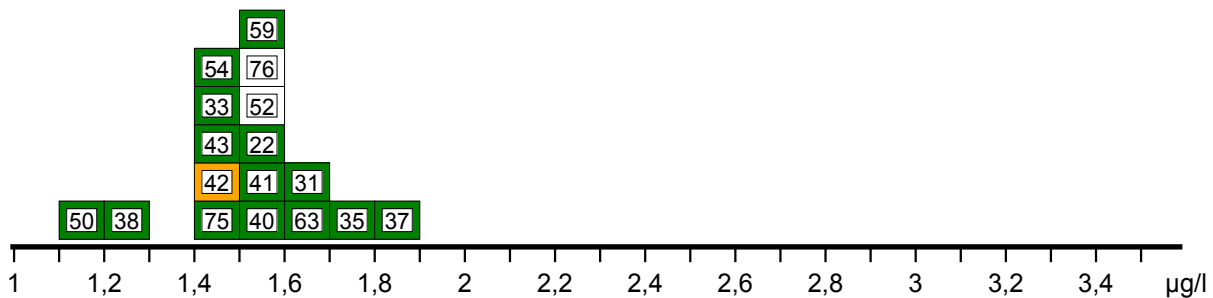
Other Kits: 3 99(1),3 350(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: M 110 % Mu -35.17 %

Findings NBS2/18 -May 2018-
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 = 17	■ normal 14	14			
XM= 1,4 µg/l	■ CH/AGS/CF possible 1				1
SD= 0,1 µg/l	■ CH/AGS/CF evident				
CV= 11,6 %	other				

Kit Evaluation for Sample A

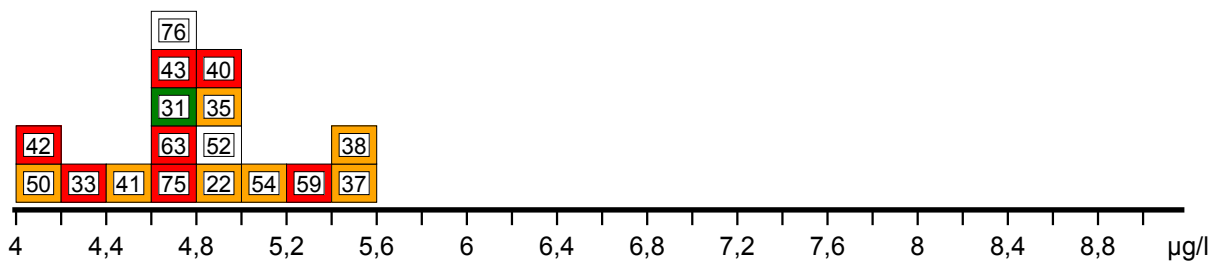
M	Kit	N	Min	16.P	50.P	84.P	Max	0,5	1	1,5	2	2,5	Kit Classifications			
													■	■	■	■
All Kits	17	1.10	1.38	1.50	1.68	1.83				—+—			14	1	0	0
2	255	3	1.21	1.40		1.50							3	0	0	0
4	255	14	1.10	1.50	1.70	1.83				—+—			11	1	0	0

Other Kits:

Findings NBS2/18 -May 2018-
 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 = 17	■ normal 1	1			
XM= 4,7 µg/l	■ CH/AGS/CF possible 7		1		6
SD= 0,4 µg/l	■ CH/AGS/CF evident 7				7
CV = 8,6 %	■ other				

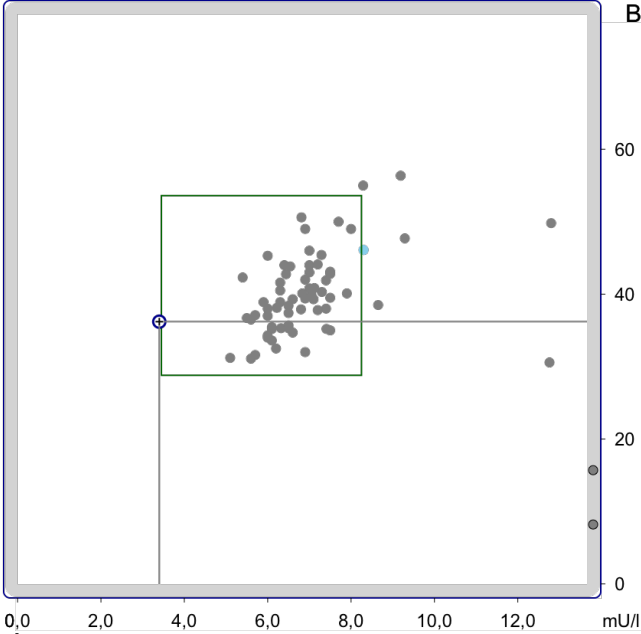
Kit Evaluation for Sample B

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications				
								—+—	■	■	■	■
All Kits	17	4.00	4.26	4.74	5.24	5.43		—+—	1	7	7	0
2	255	3	4.30	4.50		5.43			0	2	1	0
4	255	14	4.00	4.24	4.77	5.17	5.40	—+—	1	5	6	0

Other Kits:

Analyte **TSH**
Method all methods

success rate 88,4 % out of range 2



No of participants	69	
sample/unit	A	B
mean	6.92	40.1
standard deviation	1.40	5.62
coefficient of variation	20.2	14.0

Sample A [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		69	3.40	6.00	6.83	7.86	154
3	99	3	6.44		7.41		154
4	245	22	5.50	5.84	6.50	7.23	47.7
4	246	7	5.40		6.32		8.65
4	247	19	5.10	5.82	7.00	7.50	8.00
5	77	8	6.00	6.10	7.01	11.2	12.8

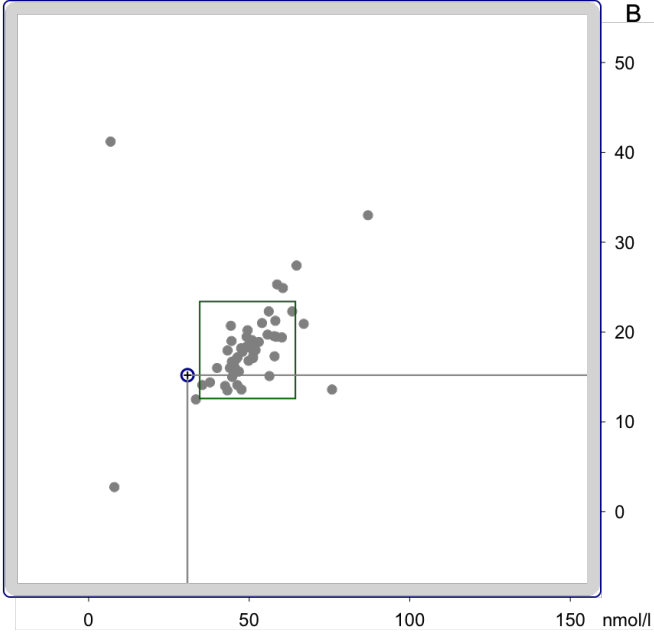
Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		69	8.20	34.4	39.3	45.4	56.4
3	99	3	8.20		35.2		42.8
4	245	22	15.7	32.2	37.5	40.3	50.6
4	246	7	32.0		35.3		42.3
4	247	19	31.2	35.3	39.3	44.1	49.0
5	77	8	30.6	33.9	41.8	51.5	56.4

Other kits (number):
1-77(1), 2-02(1), > 2-99(1)<, 3-350(2), 4-91(2), 4-99(1), 5-111(2),

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

success rate 87,7 % out of range 0



No of participants	57	
sample/unit	A	B
mean	49.2	18.3
standard deviation	12.4	5.15
coefficient of variation	25.2	28.1

Sample A [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		57	6.84	43.2	49.5	58.4	87.0
4	245	23	6.84	44.5	51.0	61.0	87.0
4	246	6	42.5		50.4		58.2
4	247	18	33.4	40.1	45.6	51.1	54.0

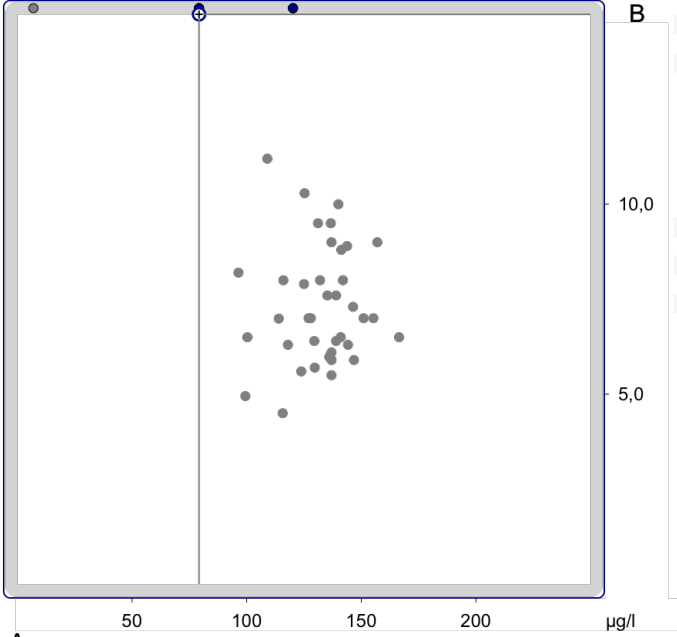
Sample B [nmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		57	2.74	14.6	18.0	21.0	41.2
4	245	23	17.2	18.0	19.5	25.0	41.2
4	246	6	14.0		17.1		21.3
4	247	18	12.5	13.6	16.0	18.7	21.0

Other kits (number):
> 2-99(1)<, 3-99(1), 3-350(2), 4-91(2), 4-99(1), 5-111(2), 6-99(1),

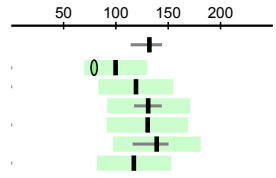
Analyte **IRT**
Method all methods

success rate 83,7 % out of range 3



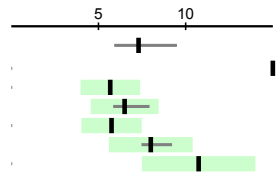
Sample A [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		43	6.92	114	132	144	167
2	52	2	79.2		99.7		120
4	91	2	99.4		119		139
4	245	16	114	117	131	144	167
4	246	4	100		130		147
4	247	15	96.4	116	139	150	157
5	111	2	109		117		125



Sample B [µg/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		43	4.50	5.90	7.30	9.50	37.3
2	52	2	15.3		23.6		31.9
4	91	2	4.95		5.68		6.40
4	245	16	4.50	5.84	6.50	7.93	9.50
4	246	4	5.50		5.75		6.50
4	247	15	7.00	7.47	8.00	9.22	10.0
5	111	2	10.3		10.7		11.2



The deviation of your results from the median of the corresponding sub-collective (kit) is:

A-20.56 %
B-35.17 %

Other kits (number):
3-99(1), 3-350(1),

A

No of participants	43		
sample/unit	A	µg/l	B
mean	132		7.37
standard deviation	15.6		1.52
coefficient of variation	11.8		20.7