

Survey: SD1/18
month: January 2018
Participant-No: 9900220
date of issue: 27.01.18



Referenzinstitut für Bioanalytik

CG Cytogenomics
Diagnostic Laboratory
Byzantioy 149
14233 N. IONIA, ATHENS
GREECE



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, 23. February 2018

Certificate

We confirm that you have participated in the survey for pregnancy diagnostic in serum.

You have met the requirements of the survey for the following analytes:

AFP	(4)	hCG	(4)	PAPP-A	(3)
beta-hCG free	(3)	anti-Müllerian hormone	(4)		

This certificate is valid until the end of July 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.

Survey: SD1/18
 month: January 2018
 Participant-No: 9900220



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)

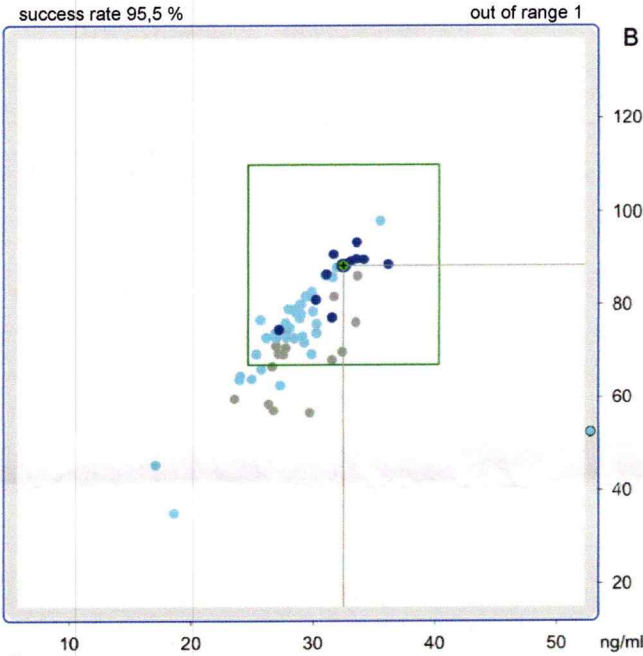
Certificate of participation

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
---------	--	----------------	--

	C	M	R	D/Dmax	T	LL	UL							
AFP [ng/ml]	+	4	A	32.5	0	32.5	24.6	40.4						
			B	88.4	-0.01	88.7	67.3	110						
hCG [mU/ml]	+	4	A	25184	0.44	22200	15500	28900						
			B	49739	0.15	47500	33200	61800						
PAPP-A [mU/l]	+	3	A	119	0	119	83.3	155						
			B	282	0.09	274	191	357						
beta-hCG free [ng/ml]	+	3	A	334	0.08	326	228	424						
			B	649	0.11	627	438	816						
anti-Müllerian hormone [pmol/l]	+	4	A	13.6	-0.88	18.6	12.9	24.3						
			B	21.2	-0.36	23.8	16.6	31.1						

Analyte **AFP**
Method all methods

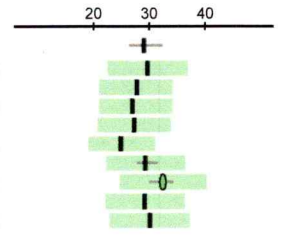


A

No of participants	67		
sample/unit	A	ng/ml	B
mean	29.0		75.4
standard deviation	3.40		11.0
coefficient of variation	11.8		14.6

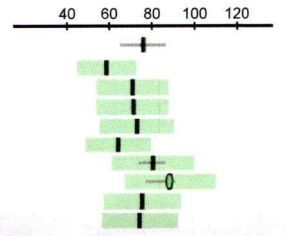
Sample A [ng/ml]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		67	17.1	26.4	29.0	32.4	123
2	42	5	26.4		29.8		32.4
3	48	3	26.7		27.8		33.7
3	91	3	23.6		27.0		28.0
4	4	7	25.4		27.3		29.1
4	13	5	17.1		25.0		25.8
4	30	18	18.6	27.8	29.4	31.6	35.5
4	40	11	27.2	30.0	32.5	34.4	36.2
4	44	6	27.8		29.2		30.3
4	77	4	27.0		30.2		123



Sample B [ng/ml]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		67	35.2	64.8	75.9	86.3	98.2
2	42	5	56.7		58.6		70.1
3	48	3	66.9		70.9		86.2
3	91	3	59.8		71.3		74.8
4	4	7	62.8		73.0		75.1
4	13	5	45.6		64.2		76.7
4	30	18	35.2	73.8	80.5	86.3	98.2
4	40	11	74.7	77.0	88.7	91.2	93.6
4	44	6	69.6		75.6		81.7
4	77	4	52.5		74.5		78.5

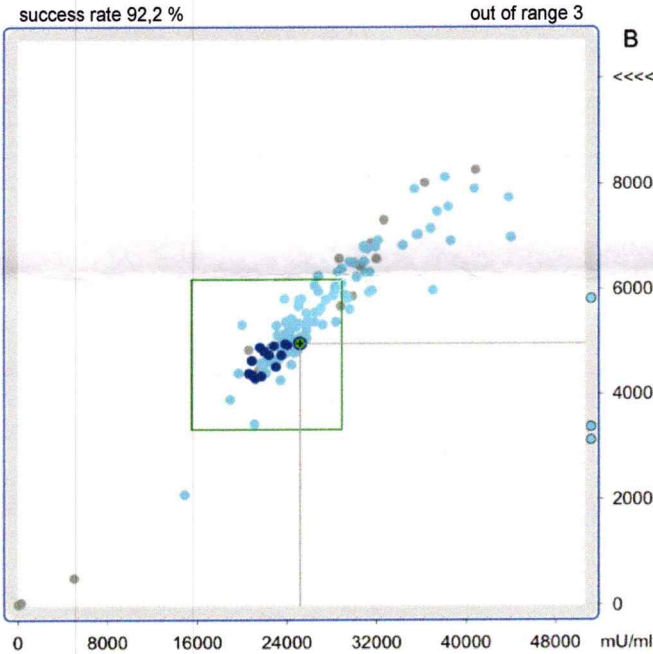


The deviation of your results from the median of the corresponding sub-collective (kit) is:

A	0 %
B	-0.3 %

Other kits (number):
1-111(2), 3-245(1), 4-335(1), 9-54(1),

Analyte **hCG**
Method all methods

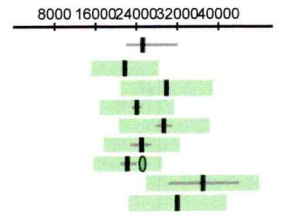


A

No of participants	129		
sample/unit	A	mU/ml	B
mean	26387		54616
standard deviation	6627		13242
coefficient of variation	25.1		24.2

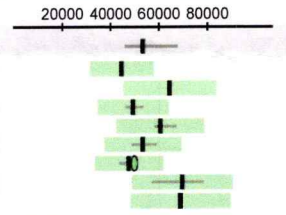
Sample A [mU/ml]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		129	31.7	21955	25267	32027	1313732
2	42	4	21500		21700		22500
3	21	5	276		29859		36318
4	4	16	21687	23149	24080	24989	28373
4	13	13	19700	27619	29380	30985	31193
4	30	44	14877	22761	25012	26816	31310
4	40	14	20624	20899	22194	23983	25184
4	44	20	21098	30241	36925	43955	1313732
8	328	3	31535		31997		32665



Sample B [mU/ml]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		129	60.9	45564	53310	67717	82800
2	42	4	44200		44450		46800
3	21	5	406		64265		80219
4	4	16	42671	45829	49227	53434	54433
4	13	13	44000	58068	60400	67110	68171
4	30	44	20895	48705	53232	59109	65208
4	40	14	43010	43488	47456	49515	49739
4	44	20	33673	56932	69510	78384	81361
8	328	3	65790		68756		72998

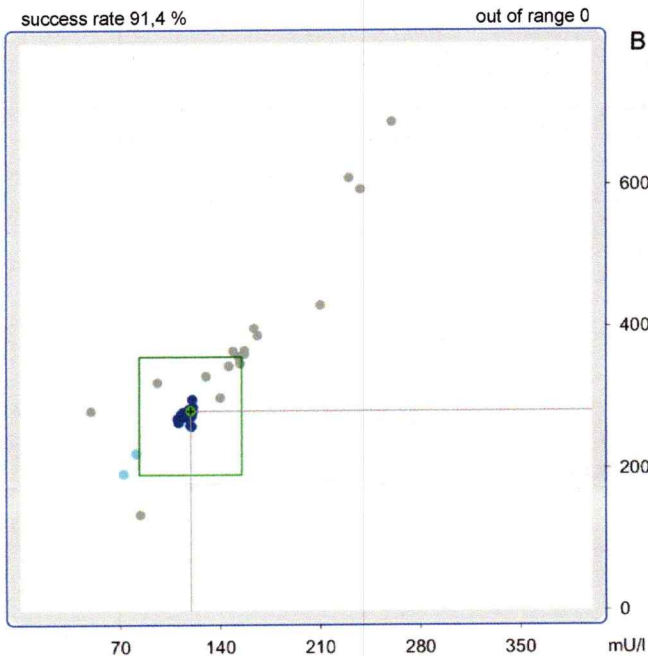


The deviation of your results from the median of the corresponding sub-collective (kit) is:

A	13 %
B	4.8 %

Other kits (number):
1-111(2), 3-48(1), 3-245(1), 4-08(2), 4-77(2), 4-335(1), 9-54(1),

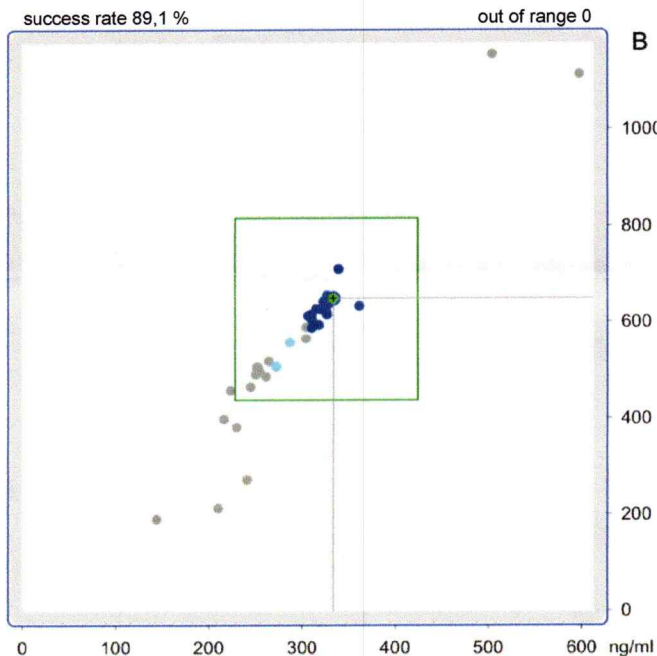
Analyte **PAPP-A**
Method all methods



A

No of participants	35	
sample/unit	A	B
mean	134	327
standard deviation	44.9	111
coefficient of variation	33.4	34.1

Analyte **beta-hCG free**
Method all methods



A

No of participants	37	
sample/unit	A	B
mean	299	570
standard deviation	77.3	183
coefficient of variation	25.8	32.1

Sample A [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	35	49.6	107	120	164	260	
1	111	2	96.0	113	130		
3	48	16	110	112	120	121	
3	91	2	72.4	76.8	81.1		
4	30	10	84.0	127	154	166	
4	44	3	230	238	260		

Sample B [mU/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	35	134	264	282	389	690	
1	111	2	321	326	330		
3	48	16	260	264	274	283	297
3	91	2	192	207	221		
4	30	10	134	260	359	389	397
4	44	3	594	610	690		

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

A	0.3 %
B	2.6 %

Other kits (number):
4-13(1), 4-335(1),

Sample A [ng/ml]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	37	144	241	306	331	597	
1	111	2	210	226	241		
3	48	17	306	310	326	334	361
3	91	2	272	279	287		
4	30	11	144	217	251	261	264
4	44	3	304	304	597		

Sample B [ng/ml]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	37	190	458	588	648	1156	
1	111	2	213	242	271		
3	48	17	586	602	627	651	709
3	91	2	507	532	556		
4	30	11	190	366	490	507	518
4	44	3	564	588	1114		

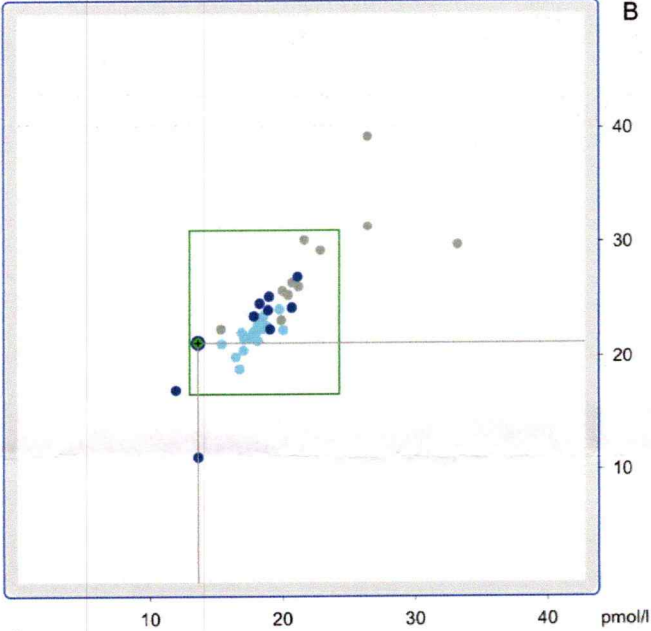
The deviation of your results from the median of the corresponding sub-collective (kit) is:

A	2.3 %
B	3.4 %

Other kits (number):
2-42(1), 4-335(1),

Analyte **anti-Müllerian hormone**
 Method **all methods**

success rate 90,9 % out of range 0

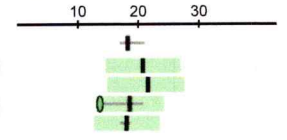


A

No of participants	44	
sample/unit	A	B
mean	19.0	23.5
standard deviation	3.50	4.19
coefficient of variation	18.5	17.8

Sample A [pmol/l]

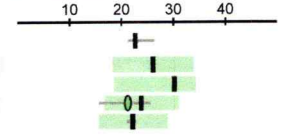
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		44	12.0	16.8	18.3	21.1	33.2
2	13	7	15.4		20.7		26.4
2	111	3	19.9		21.6		26.4
4	13	10	12.0	13.2	18.6	20.8	21.1
4	30	23	15.4	16.9	18.1	18.7	20.1



B

Sample B [pmol/l]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		44	11.1	21.3	22.7	26.4	39.3
2	13	7	22.4		26.1		39.3
2	111	3	23.2		30.2		31.4
4	13	10	11.1	15.6	23.8	25.6	26.9
4	30	23	18.9	21.1	22.2	22.8	24.1



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

A -26.8 %
 B -10.84 %

Other kits (number):
 2-99(1).