

Survey: SD1/19  
month: January 2019  
Participant-No: 9900220  
date of issue: 26.01.19



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, 27. February 2019

## 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 2019.**

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: SD1/19  
 month: January 2019  
 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)

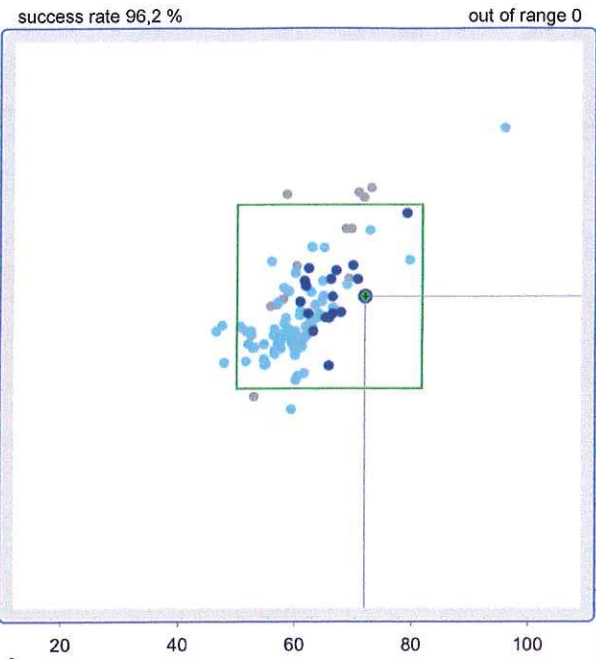
Certificate of participation

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	72.0	0.38	65.9	49.9	81.9						
			B	8.80	0	8.80	6.67	11.0						
hCG [mU/ml]	+	4	A	18977	0.08	18500	12900	24100						
			B	5248	-0.01	5260	3680	6840						
PAPP-A [mU/l]	+	3	A	197	-0.02	198	138	258						
			B	135	0.02	134	93.8	175						
beta-hCG free [ng/ml]	+	3	A	17.3	-0.21	18.5	12.9	24.1						
			B	49.2	-0.14	51.4	35.9	66.9						
anti-Müllerian hormone [pmol/l]	+	4	A	20.7	-0.49	24.3	16.9	31.6						
			B	20.6	-0.37	23.2	16.2	30.3						

Analyte **AFP**  
Method all methods



**A**

No of participants	<b>107</b>	
sample/unit	A	B
mean	61.1	8.45
standard deviation	7.03	1.08
coefficient of variation	11.5	12.7

**Sample A [ng/ml]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		107	46.5	54.9	60.4	66.5	95.9
2	42	5	56.8		68.7		69.6
3	48	8	52.5	53.9	59.5	72.5	73.0
4	4	17	52.5	53.0	57.4	60.3	62.7
4	13	8	46.5	46.9	51.6	57.1	57.1
4	30	36	52.3	58.3	61.1	64.7	95.9
4	40	18	60.8	61.8	66.0	70.7	79.2
4	44	6	59.4		60.3		61.6
4	77	5	55.9		62.9		66.5

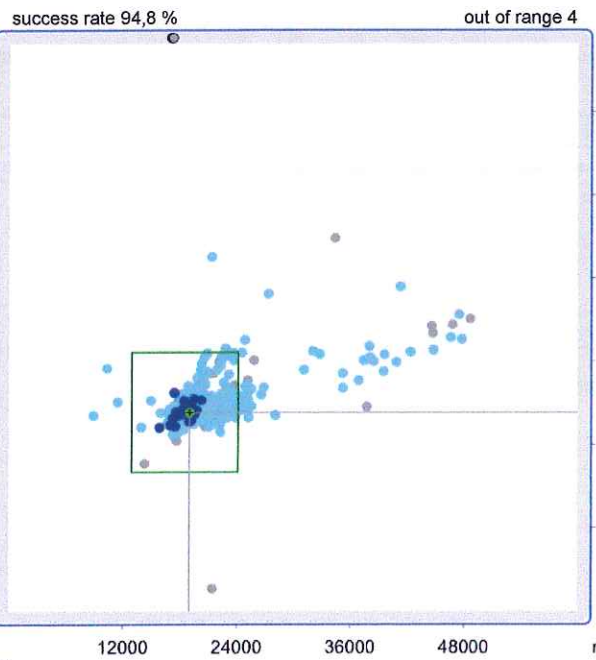
**Sample B [ng/ml]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		107	6.19	7.60	8.13	9.38	12.7
2	42	5	8.60		9.22		10.4
3	48	8	8.00	8.25	9.21	11.3	11.3
4	4	17	7.24	7.58	7.90	8.26	9.00
4	13	8	7.28	7.29	7.86	8.42	8.65
4	30	36	7.22	7.60	8.03	8.93	12.7
4	40	18	7.20	8.30	8.80	9.45	10.7
4	44	6	6.19		7.00		7.80
4	77	5	8.54		9.60		9.94

The deviation of your results from the median of the corresponding sub-collective (kit) is:  
A 9.1 %  
B 0.0 %

Other kits (number):  
1-111(2), 3-91(1), 4-335(1),

Analyte **hCG**  
Method all methods



**A**

No of participants	<b>294</b>	
sample/unit	A	B
mean	22674	5626
standard deviation	6229	783
coefficient of variation	27.5	13.9

**Sample A [mU/ml]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		294	8873	18410	21240	24817	48660
2	42	4	17000		17100		17200
3	21	10	17368	17551	20945	24226	25811
3	48	4	44570		45743		48660
3	61	5	17765		19239		20330
4	4	46	8873	18639	19741	21188	23152
4	8	4	19863		20064		23289
4	13	23	10310	19744	20898	23818	27335
4	30	125	13910	19177	22600	24462	41285
4	40	27	15833	17299	18481	19372	20251
4	44	20	11446	32304	38050	45935	47744
4	77	3	14926		17250		17780
8	328	16	19414	20545	22073	24098	25337

**Sample B [mU/ml]**

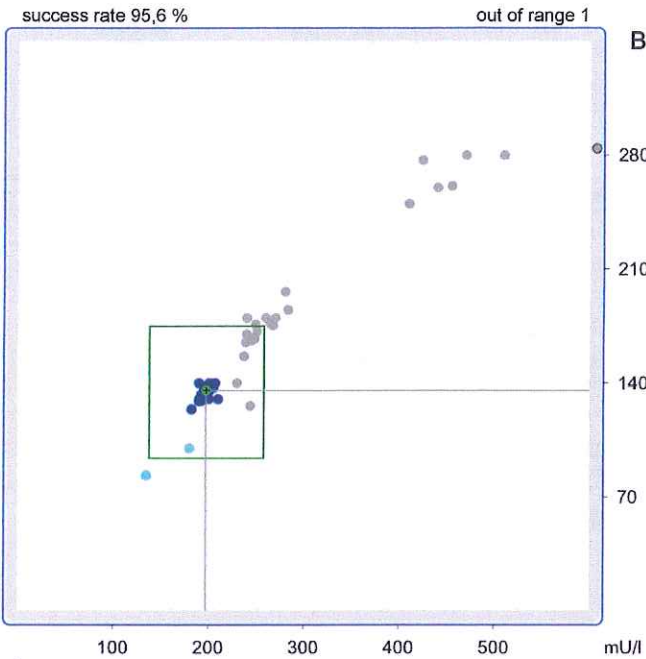
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		294	585	5101	5445	6335	52100
2	42	4	51700		52000		52100
3	21	10	585	3559	5570	6370	6632
3	48	4	7350		7562		7727
3	61	5	5049		5200		5525
4	4	46	4795	5042	5231	5502	6256
4	8	4	5746		6076		6724
4	13	23	5678	6120	6496	6986	9367
4	30	125	4700	5168	5430	5745	8578
4	40	27	4850	4970	5255	5537	5774
4	44	20	5530	6169	6681	7123	7839
4	77	3	4670		5072		5563
8	328	16	4875	4984	5398	5893	6108

The deviation of your results from the median of the corresponding sub-collective (kit) is:  
A 2.6 %  
B -0.1 %

Other kits (number):  
1-111(2), 2-61(1), 4-331(1), 4-228(1), 4-335(1), 11-99(1),



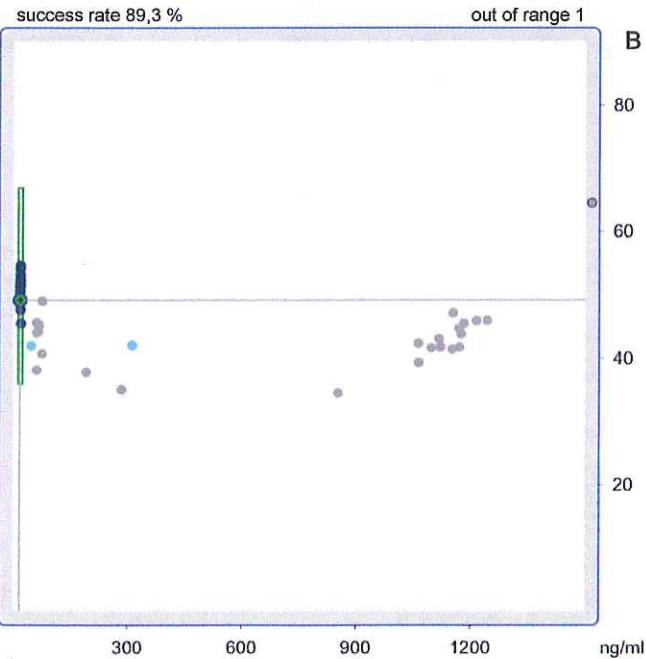
Analyte **PAPP-A**  
Method all methods



A

No of participants	46		
sample/unit	A	mU/l	B
mean	250		163
standard deviation	86.5		47.6
coefficient of variation	34.6		29.2

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



A

No of participants	47		
sample/unit	A	ng/ml	B
mean	380		46.4
standard deviation	506		5.29
coefficient of variation	133		11.4

**Sample A [mU/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	46	135	191	234	344	671	
1	111	2	230		237	244	
3	48	20	182	190	198	204	210
4	30	14	237	239	250	276	283
4	44	6	410		448	510	

**Sample B [mU/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	46	83.3	130	140	222	284	
1	111	2	126		133	140	
3	48	20	124	129	134	139	140
4	30	14	156	165	174	183	196
4	44	6	250		269	280	

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

A -0.4 %  
B 1.2 %

Other kits (number):  
3-44(1), 3-91(1), 4-13(1), 4-335(1).

**Sample A [ng/ml]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	47	17.3	18.2	62.0	1159	2650	
1	111	2	191		237	283	
3	48	21	17.3	17.7	18.5	19.1	20.1
4	30	14	852	1063	1154	1202	1244
4	44	6	61.3		64.4	76.3	

**Sample B [ng/ml]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle	47	34.5	41.5	46.0	52.1	64.5	
1	111	2	35.0		36.4	37.8	
3	48	21	45.4	48.8	51.4	53.6	54.6
4	30	14	34.5	40.1	42.7	45.9	47.1
4	44	6	38.1		44.7	49.0	

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

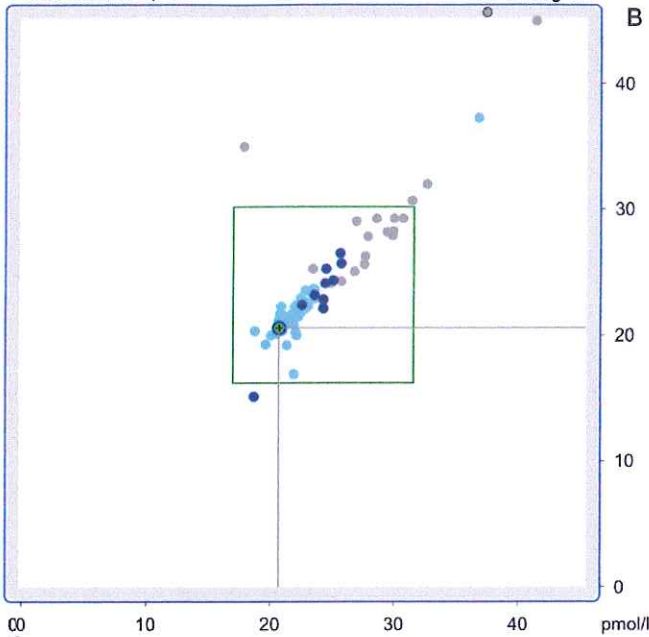
A -6.3 %  
B -4.4 %

Other kits (number):  
2-42(1), 3-44(1), 3-91(1), 4-335(1).

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

success rate 93,2 %

out of range 1



A

No of participants	<b>74</b>	
sample/unit	A	B
mean	24.0	23.9
standard deviation	4.06	4.51
coefficient of variation	16.9	18.9

**Sample A [pmol/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		74	17.9	20.9	22.6	27.9	41.4
2	5	2	29.4		31.0		32.6
2	13	11	17.9	24.4	28.6	32.2	41.4
2	111	5	23.4		26.8		30.7
4	13	11	18.7	20.6	24.3	25.6	25.7
4	30	42	18.8	20.8	22.1	23.1	36.8

**Sample B [pmol/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		74	15.1	20.7	22.5	28.2	47.5
2	5	2	28.2		30.1		32.0
2	13	11	24.1	25.5	29.1	35.8	45.0
2	111	5	24.3		25.3		29.3
4	13	11	15.1	20.1	23.2	25.8	26.5
4	30	42	16.9	20.2	21.7	23.0	37.3

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

A -14.72 %  
 B -11.35 %

Other kits (number):  
 1-99(1), 2-41(1), 4-335(1),