

Survey: SD2/24  
month: April 2024  
Participant-No: 9900220  
date of issue: 20.04.24



Referenzinstitut für Bioanalytik

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Survey directors

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Bonn, 15. May 2024

## 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 according to the current version of the RiliBÄK valid until the end of October 2024.**

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.

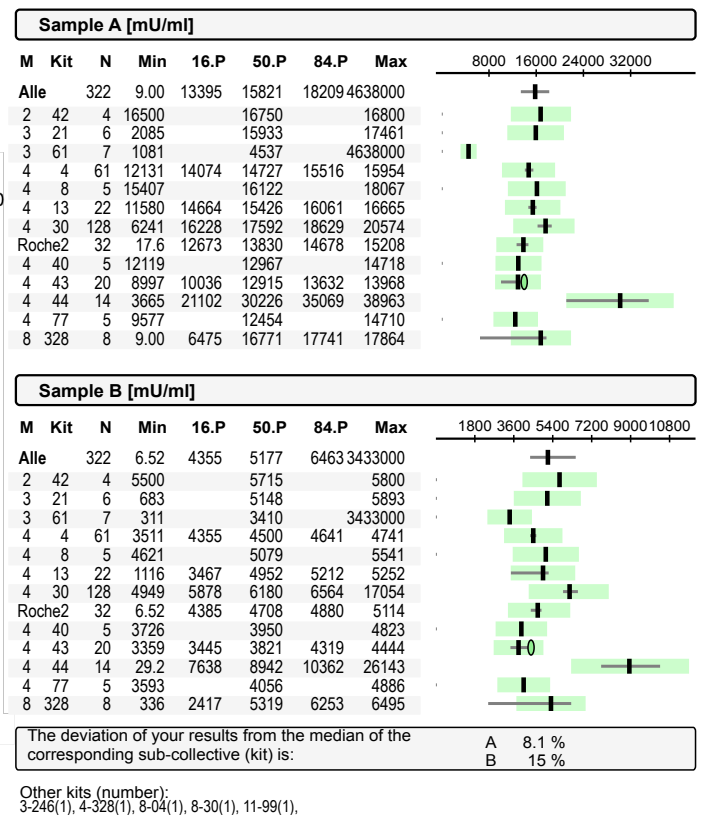
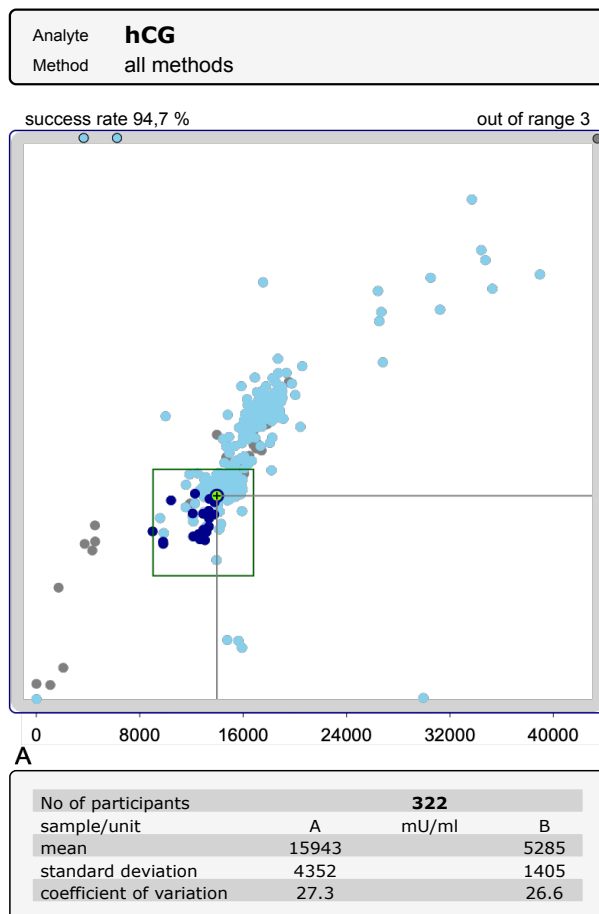
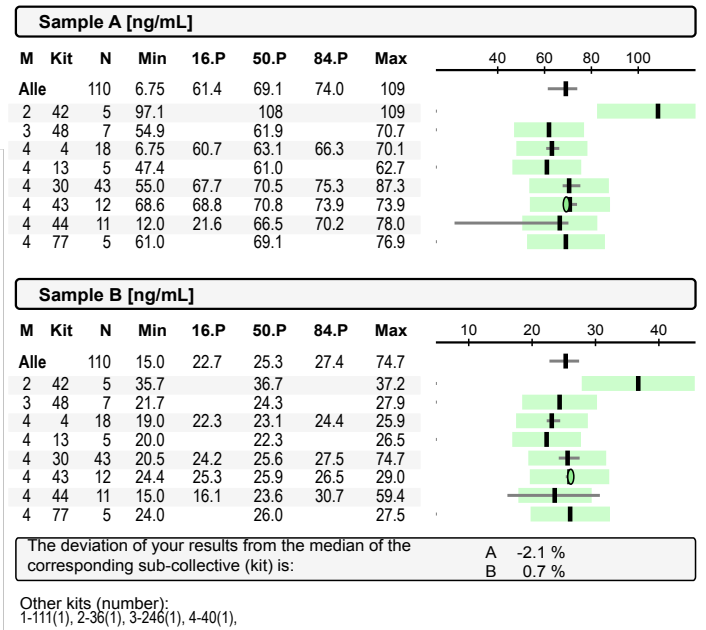
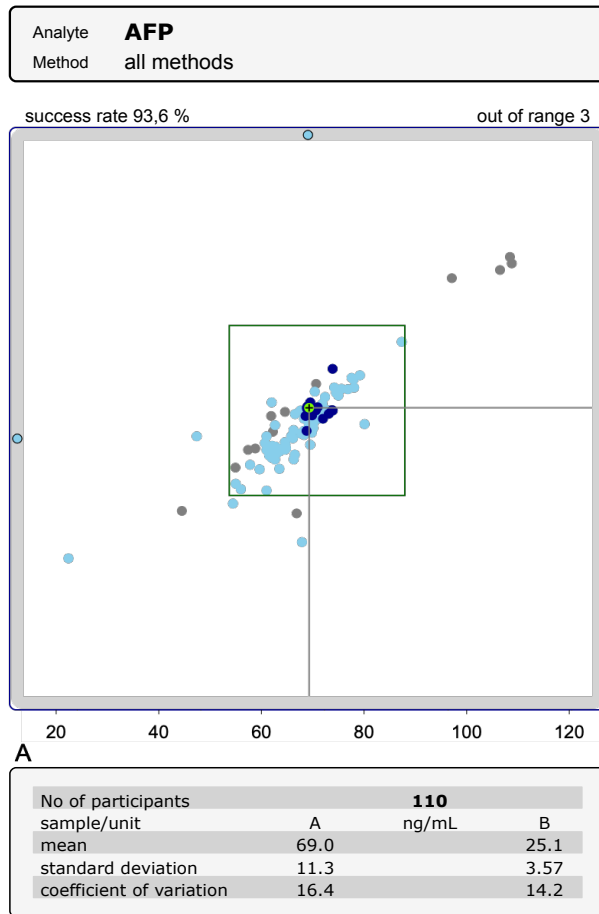
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**RfB**  
Referenzinstitut  
für Bioanalytik

	C	M	R	D/Dmax	T	LL	UL							
AFP	+	4	A	69.3	-0.09	70.8	53.7	88.0						
[ng/mL]			B	26.1	0.03	25.9	19.6	32.2						
hCG	+	4	A	13968	0.27	12900	9030	16800						
[mU/ml]			B	4398	0.50	3820	2670	4970						
PAPP-A	+	3	A	6.50	-0.18	7.90	0	20.0						
[mU/L]			B	8.70	0.02	8.40	0	20.0						
beta-hCG free	+	3	A	28.4	-0.13	29.6	20.7	38.5						
[ng/mL]			B	22.8	-0.08	23.4	16.3	30.5						
anti-Müllerian hormone	+	4	A	17.2	-0.13	17.9	12.4	23.3						
[pmol/L]			B	22.0	-0.03	22.2	15.4	29.0						

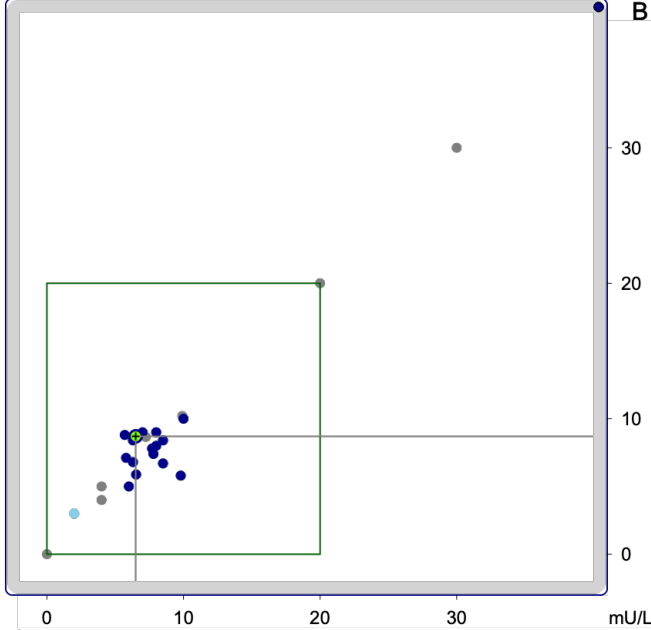




Analyte **PAPP-A**  
Method all methods






success rate 94,4 %

out of range 3








No of participants	54	
sample/unit	A	B
mean	11.4	11.6
standard deviation	8.52	8.42
coefficient of variation	74.7	72.7

#### Sample A [mU/L]

M	Kit	N	Min	16.P	50.P	84.P	Max	
Alle		54	0	6.30	8.00	30.0	6470	
3	48	20	5.70	6.11	7.90	10.0	75.0	
3	246	2	0		1.00		2.00	
4	30	22	4.00	8.00	8.00	13.2	6470	
4	44	8	30.0	30.0	30.0	30.0	30.0	

#### Sample B [mU/L]

M	Kit	N	Min	16.P	50.P	84.P	Max	
Alle		54	0	6.78	8.68	30.0	8030	
3	48	20	5.00	6.18	8.40	10.0	75.0	
3	246	2	0		1.50		3.00	
4	30	22	4.00	8.00	8.00	13.3	8030	
4	44	8	30.0	30.0	30.0	30.0	30.0	

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

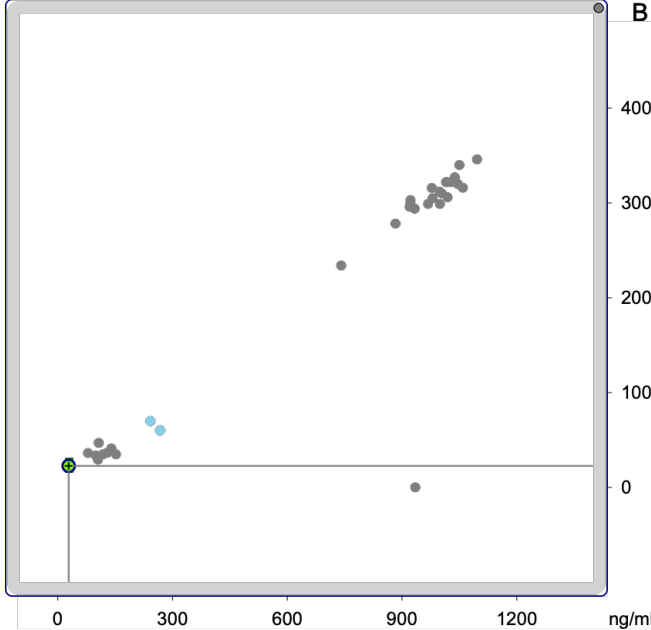
A -17.72 %  
B 3.5 %

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

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

success rate 87,5 %

out of range 2









No of participants	56	
sample/unit	A	B
mean	442	138
standard deviation	455	138
coefficient of variation	103	100

#### Sample A [ng/mL]

M	Kit	N	Min	16.P	50.P	84.P	Max	
Alle		56	27.7	29.3	141	1019	15189	
3	48	20	27.7	28.9	29.6	30.2	32.0	
3	246	2	242		255		267	
4	30	21	741	921	999	1048	1096	
4	44	9	78.9	91.3	129	145	152	
8	30	2	933		8061		15189	

#### Sample B [ng/mL]

M	Kit	N	Min	16.P	50.P	84.P	Max	
Alle		56	0.131	23.3	38.7	320	5097	
3	48	20	22.0	23.2	23.4	24.1	24.3	
3	246	2	60.2		65.1		70.0	
4	30	21	0.131	287	310	324	346	
4	44	9	29.2	31.9	36.3	39.7	41.2	
8	30	2	294		2696		5097	

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

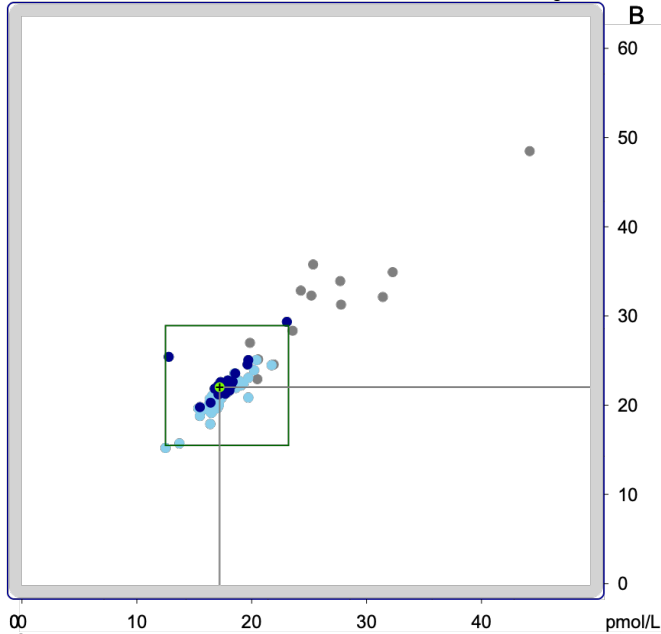
A -4.0 %  
B -2.7 %

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

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

success rate 97,2 %

out of range 0



No of participants	<b>108</b>		
sample/unit	A	pmol/L	B
mean	18.4		22.4
standard deviation	4.00		4.40
coefficient of variation	21.7		19.7

#### Sample A [pmol/L]

M	Kit	N	Min	16.P	50.P	84.P	Max	
Alle		108	12.5	16.4	17.2	19.8	44.2	
2	13	5	23.6		27.8		32.3	
2	36	2	17.5		19.0		20.5	
2	111	5	19.9		24.3		44.2	
4	13	21	12.8	16.6	17.9	19.1	23.1	
4	30	63	12.5	16.4	16.9	17.5	19.7	
4	40	4	18.6		19.5		20.2	
4	43	3	19.1		20.4		21.7	
4	335	2	13.7		15.1		16.6	

#### Sample B [pmol/L]

M	Kit	N	Min	16.P	50.P	84.P	Max	
Alle		108	15.2	19.7	21.1	24.5	48.5	
2	13	5	28.4		32.1		35.8	
2	36	2	21.8		22.4		22.9	
2	111	5	24.6		32.3		48.5	
4	13	21	19.8	21.3	22.2	24.8	29.4	
4	30	63	15.2	19.6	20.6	21.4	22.7	
4	40	4	22.0		22.8		23.9	
4	43	3	22.2		24.5		25.1	
4	335	2	15.7		17.5		19.4	

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

A -3.6 %  
B -0.9 %

Other kits (number):  
2-05(1), 2-35(1), 4-74(1),

