

# CERTIFICATE

Survey of 10 November 2023

You have fulfilled the requirements of the External Quality Assessment with the following analysis

## Complement Analysis 02 - Functions and proteins (246):

Validity 12 months:

C1 inhibitor: activity

C1q protein

C3-Complement

C4-Complement

Classical pathway

Complement factor H

Complement factor I

(R) analysis is subject to the RiliBÄK

Customer:

10051071

The Japanese Association for Complement  
Research

Wakayama Medical University

811-1 Kimiidera, Wakayama

641-8509 Wakayama

Düsseldorf, 06 December 2023



Prof. Dr. med. Michael Spannagl  
(Head of Reference Institution)



Prof. Dr. Zoltan Prohaszka  
(Adviser)

# CERTIFICATE OF PARTICIPATION

Survey of 10 November 2023

You have participated in the External Quality Assessment with the following analysis

## Complement Analysis 02 - Functions and proteins (246):

Alternative pathway  
C1 inhibitor: activity  
C1q protein  
C3-Complement  
C4-Complement  
Classical pathway  
Complement factor H  
Complement factor I  
Lectin pathway

(R) analysis is subject to the RiliBÄK

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Prof. Dr. Zoltan Prohaszka  
(Adviser)

## Listing and evaluation of the results

10051071: The Japanese Association for Complement Research  
Wakayama Medical University

Survey of 10 November 2023

**Adviser:**

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### Complement Analysis 02 - Functions and proteins

Analyte	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
Alternative pathway	61	%	4.70	19.2	SV	7.68	30.7	-75.5%	-1,39	-	
	62		91.3	92.5	SV	37.0	148	-1.3%	-0,14	+	
C1 inhibitor: activity	61	%	61.2	56.4	SV	28.2	84.6	8.5%	1,03	+	
	62		105	102	SV	51.0	153	2.6%	0,463	+	
C1q protein	(1) 61	g/l	0.042	0.030	SV	0.015	0.045	38.7%	0,387	+	
	(1) 62		0.057	0.049	SV	0.025	0.074	16.9%	0,16	+	
C3-Complement	61	g/l	1.22	1.20	SV	0.912	1.49	1.5%	0,231	+	
	62		1.17	1.18	SV	0.897	1.46	-1.1%	-0,186	+	
C4-Complement	61	g/l	0.200	0.206	SV	0.144	0.268	-2.9%	-0,462	+	
	62		0.194	0.201	SV	0.141	0.261	-3.5%	-0,467	+	
Classical pathway	61	%	21.8	30.6	SV	18.4	42.8	-28.8%	-0,807	+	
	62		89.2	79.6	SV	47.8	111	12.1%	0,539	+	
Complement factor H	61	mg/l	379	290	SV	145	435	30.8%	0,538	+	
	62		417	333	SV	167	500	25.1%	0,404	+	
Complement factor I	61	mg/l	80.0	64.9	SV	32.5	97.4	23.3%	0,34	+	
	62		38.3	43.1	SV	21.6	64.7	-11.1%	-0,131	+	
Lectin pathway	61	%	5.60	17.0	SV	6.80	27.2	-67.1%	-0,648	-	
	62		37.2	45.7	SV	18.3	73.1	-18.6%	-0,467	+	

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Reference range
Alternative pathway	61	%	4.70	1.00	190	ZY		30-113
	62		91.3	1.00				
C1 inhibitor: activity	61	%	61.2	1.00	257	BW		79.1-139.5
	62		105	1.00				
C1q protein	61	mg/l	41.6	0.001	190	ZY		not determined
	62		57.3	0.001				
C3-Complement	61	mg/l	1218	0.001	116	ZY		604-1432
	62		1167	0.001				
C4-Complement	61	mg/l	200	0.001	116	ZY		91-359
	62		194	0.001				
Classical pathway	61	%	21.8	1.00	190	ZY		31.7-50.5
	62		89.2	1.00				
Complement factor H	61	mg/l	379	1.00	190	ZY		285.9-710.7
	62		417	1.00				
Complement factor I	61	mg/l	80.0	1.00	190	ZY		28.8-55.6
	62		38.3	1.00				
Lectin pathway	61	%	5.60	1.00	190	ZY		0-125
	62		37.2	1.00				

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Additional information on the evaluation is available for download in the RV-Online system in the column "Report".

## Individual summary of results

10051071: The Japanese Association for Complement Research  
Wakayama Medical University

Survey of 10 November 2023

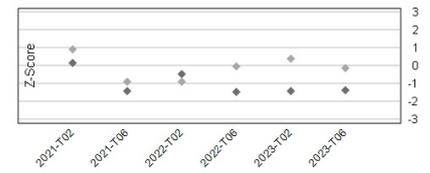
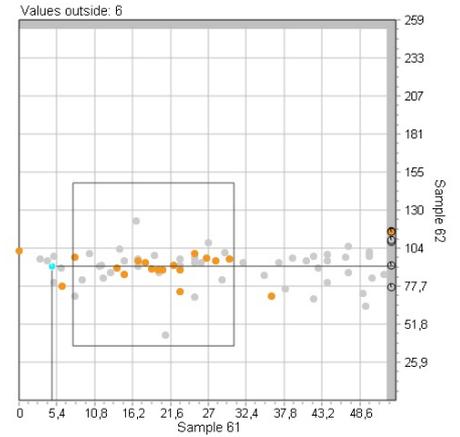
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### Complement Analysis 02 - Functions and proteins

Alternative pathway (% , N = 78)										
Collective	Sample	Target value	Target range			Participants collective			Rate (%)	
						AVG	CV	Num.	Sam.	total
BINDING SITE, THE	61	53.6	21.4	-	85.8	53.6	22.6	12	100	100
	62	91.4	36.6	-	146	91.4	18.3	12	100	
EURO DIAGNOSTICA / QUIDEL	61	22.2	8.88	-	35.5	22.2	68.0	38	60.5	60.5
	62	93.4	37.4	-	149	93.4	8.05	38	100	
Immunological / Functionaltest (ELISA)	61	19.2	7.68	-	30.7	19.2	54.2	21	76.2	76.2
	62	92.5	37.0	-	148	92.5	9.26	21	100	
M.333-335, 9999, R.BS, ZX-ZY (1)	61	40.8	16.3	-	65.3	40.8	23.6	7		
	62	83.0	33.2	-	133	83.0	18.0	7		

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

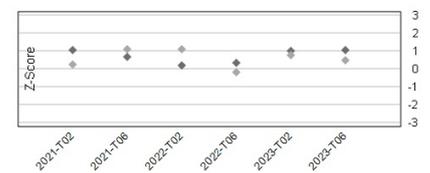
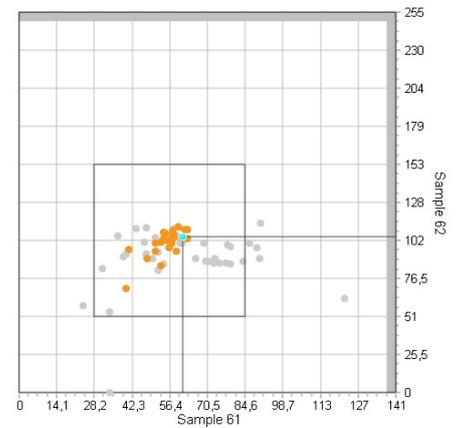
Rate of success: 74,4%



C1 inhibitor: activity (% , N = 68)										
Collective	Sample	Target value	Target range			Participants collective			Rate (%)	
						AVG	CV	Num.	Sam.	total
QUIDEL	61	74.4	37.2	-	112	74.4	15.2	19	94.7	94.7
	62	92.3	46.2	-	138	92.3	8.16	19	100	
SIEMENS	61	56.4	28.2	-	84.6	56.4	8.26	28	100	100
	62	102	51.0	-	153	102	5.72	28	100	
TECHNOCLONE	61	53.1	26.6	-	79.7	53.1	18.2	14	85.7	85.7
	62	97.2	48.6	-	146	97.2	11.9	14	100	
other methods (1)	61	55.0	27.5	-	82.5	55.0	57.3	7		
	62	83.6	41.8	-	125	83.6	46.2	7		

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

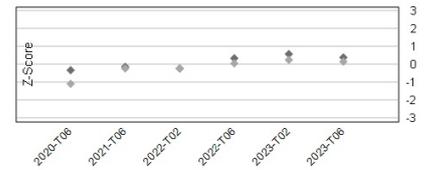
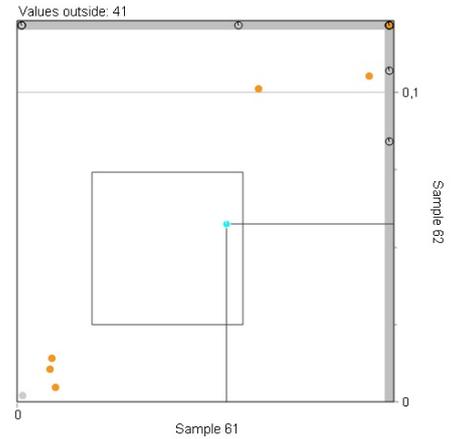
Rate of success: 89,7%



C1q protein (g/l, N = 51)										
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Immunodiffusion (Binding Site)	61	0.077	0.039 - 0.115	0.077	92.2	13	23.1	23.1		
	62	0.140	0.070 - 0.210	0.140	15.0	13	92.3			
Immunodiffusion (1)	61	0.093	0.047 - 0.140	0.093	0.000	2				
	62	0.162	0.081 - 0.243	0.162	0.000	2				
Nephelometry	61	0.126	0.063 - 0.189	0.126	16.7	21	81.0	76.2		
	62	0.216	0.108 - 0.324	0.216	18.5	21	90.5			
Turbidimetry	61	0.129	0.065 - 0.194	0.129	17.1	8	100	100		
	62	0.245	0.123 - 0.368	0.245	17.6	8	100			
other methods (1)	61	0.030	0.015 - 0.045	0.030	100	7				
	62	0.049	0.025 - 0.074	0.049	106	7				

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

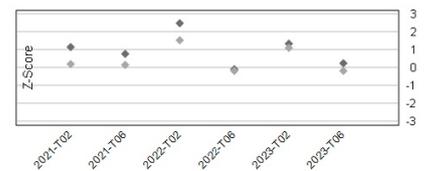
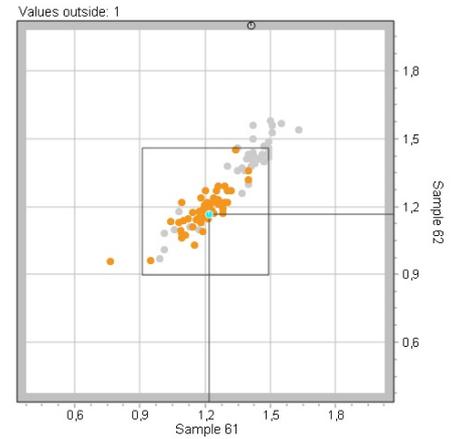
Rate of success: 56,9%



C3-Complement (g/l, N = 101)										
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
M.87, R.BE (1)	61	1.07	0.813 - 1.33	1.07	7.76	7				
	62	1.10	0.836 - 1.36	1.10	10.6	7				
Nephelometry - other providers	61	1.43	1.09 - 1.77	1.43	4.90	36	100	97.2		
	62	1.43	1.09 - 1.77	1.43	6.71	36	97.2			
Turbidimetry (and other)	61	1.20	0.912 - 1.49	1.20	6.50	58	98.3	98.3		
	62	1.18	0.897 - 1.46	1.18	5.93	58	100			

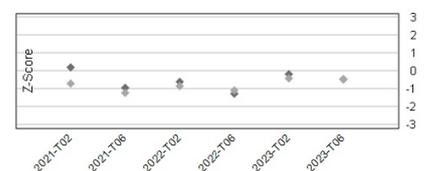
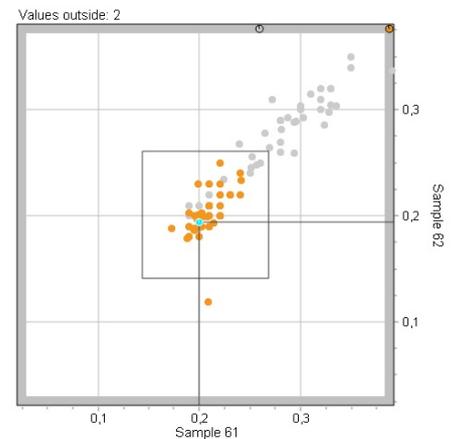
(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 97%



C4-Complement (g/l, N = 99)										
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
Nephelometry - BECKMAN COULTER	61	0.215	0.151 - 0.280	0.215	10.7	8	100	100		
	62	0.225	0.158 - 0.293	0.225	17.3	8	100			
Nephelometry - other providers	61	0.292	0.204 - 0.380	0.292	13.7	36	91.7	88.9		
	62	0.288	0.202 - 0.374	0.288	12.8	36	94.4			
Turbidimetry (and other)	61	0.206	0.144 - 0.268	0.206	6.31	55	98.2	96.4		
	62	0.201	0.141 - 0.261	0.201	7.46	55	96.4			

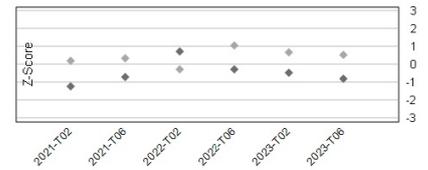
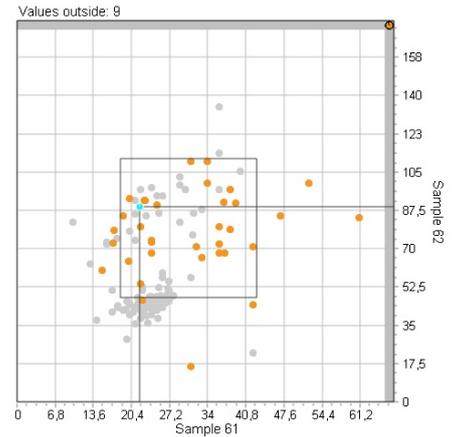
Rate of success: 93,9%



**Classical pathway (% , N = 153)**

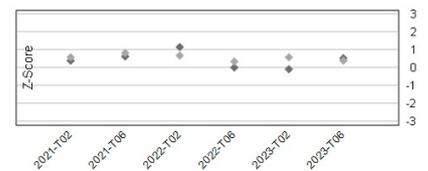
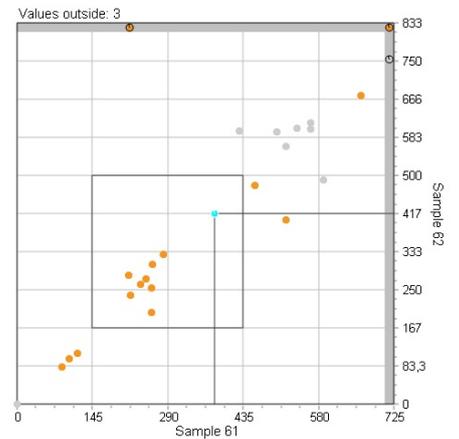
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
BINDING SITE, THE (hemolytical test)	61	289	173 - 405	289	31.2	10	100	100
	62	615	369 - 861	615	15.7	10	100	100
BINDING SITE, THE	61	24.7	14.8 - 34.6	24.7	8.83	58	98.3	96.6
	62	45.7	27.4 - 64.0	45.7	9.98	58	98.3	96.4
EURO DIAGNOSTICA / QUIDEL	61	25.0	15.0 - 35.0	25.0	32.6	28	78.6	78.6
	62	87.5	52.5 - 122	87.5	16.3	28	96.4	96.4
WAKO	61	20.0	12.0 - 28.0	20.0	13.6	21	95.2	95.2
	62	43.5	26.1 - 60.9	43.5	8.55	21	95.2	95.2
other providers	61	30.6	18.4 - 42.8	30.6	35.6	36	80.6	72.2
	62	79.6	47.8 - 111	79.6	22.4	36	88.9	88.9

Rate of success: 87,6%


**Complement factor H (mg/l, N = 26)**

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
BindingSite	61	529	265 - 794	529	19.3	9	88.9	88.9
	62	580	290 - 870	580	13.8	9	88.9	88.9
other providers	61	290	145 - 435	290	57.2	17	58.8	52.9
	62	333	167 - 500	333	62.2	17	64.7	64.7

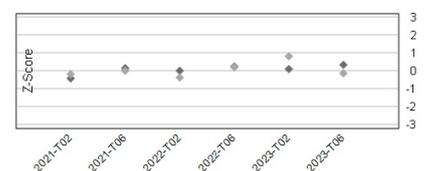
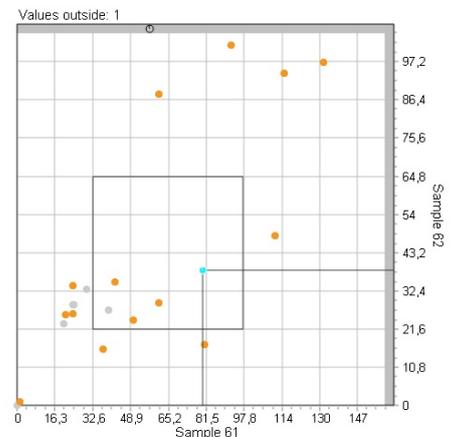
Rate of success: 65,4%


**Complement factor I (mg/l, N = 23)**

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
BindingSite (1)	61	27.8	13.9 - 41.7	27.8	71.6	7		
	62	28.0	14.0 - 42.0	28.0	61.8	7		
other providers	61	64.9	32.5 - 97.4	64.9	68.4	16	56.3	25.0
	62	43.1	21.6 - 64.7	43.1	85.2	16	50.0	50.0

Rate of success: 39,1%

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective &lt; 8 values.





Lectin pathway (% , N = 45)									
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (ng / ml)	(1) 61		Sample not evaluated			2			
		62	Sample not evaluated			2			
deviant unit (U / ml)	(1) 61		Sample not evaluated			1			
		62	Sample not evaluated			1			
EURO DIAGNOSTICA / QUIDEL	61	8.77	3.51 - 14.0	8.77	81.4	27	55.6	55.6	
		62	48.9	19.6 - 78.2	48.9	49.1	27	85.2	
other providers	61	17.0	6.80 - 27.2	17.0	104	15	26.7	26.7	
		62	45.7	18.3 - 73.1	45.7	39.8	15	80.0	

(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 45,2%

