

# CERTIFICATE

Survey of 29 March 2024

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

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

Validity 12 months:

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

(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, 15 April 2024



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



Prof. Dr. Zoltan Prohaszka  
(Adviser)

# CERTIFICATE OF PARTICIPATION

Survey of 29 March 2024

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

Customer:  
10051071  
The Japanese Association for Complement  
Research  
Wakayama Medical University  
811-1 Kimiidera, Wakayama  
641-8509 Wakayama

Düsseldorf, 15 April 2024



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



Prof. Dr. Zoltan Prohaszka  
(Adviser)

## Listing and evaluation of the results

10051071: The Japanese Association for Complement Research  
Wakayama Medical University

Survey of 29 March 2024

Adviser:

**Prof. Dr. Zoltan Prohaszka**

Semmelweis University

Department of Internal Medicine and Hematology

Szentkirályi st. 46

1088 Budapest

Tel.: +361 3251379

Fax: +361 2129351

Mail: prohaszka.zoltan@semmelweis.hu

246

### Complement Analysis 02 - Functions and proteins

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
Alternative pathway	21	%	6.50	83.4	ET	33.4	<30.0		-1,29	+	
	22		82.4		SV				133		
C1 inhibitor: activity	21	%	66.6	53.1	SV	26.6	79.7	25.4%	1,29	+	
	22		105		SV				149		
C1q protein	(1) 21	g/l	0.034	0.061	SV	0.031	0.092	-44.8%	-0,463	+	
	(1) 22		0.045		SV				0.052		
C3-Complement	21	g/l	1.24	1.24	SV	0.942	1.54	-0.3%	-0,061	+	
	22		1.28		SV				0.958		
C4-Complement	21	g/l	0.198	0.202	SV	0.141	0.263	-2.0%	-0,25	+	
	22		0.192		ET				0.139		
Classical pathway	21	%	22.4	25.1	SV	15.1	35.1	-10.8%	-0,252	+	
	22		89.4		SV				39.6		
Complement factor H	21	mg/l	376	359	SV	180	539	4.8%	0,094	+	
	22		424		SV				181		
Complement factor I	21	mg/l	63.5	54.5	SV	27.3	81.8	16.5%	0,35	+	
	22		28.3		SV				11.7		
Lectin pathway	21	%	4.20	35.8	ET	14.3	<10.0		-0,527	+	
	22		27.7		SV				14.3		

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Reference range
Alternative pathway	21	%	6.50	1.00	190	ZY		30-113
	22		82.4	1.00				
C1 inhibitor: activity	21	%	66.6	1.00	257	BW		79.1-139.5
	22		105	1.00				
C1q protein	21	mg/l	33.7	0.001	190	ZY		not determined
	22		45.3	0.001				
C3-Complement	21	mg/l	1236	0.001	116	ZY		604-1432
	22		1277	0.001				
C4-Complement	21	mg/l	198	0.001	116	ZY		91-359
	22		192	0.001				
Classical pathway	21	%	22.4	1.00	190	ZY		31.7-50.5
	22		89.4	1.00				
Complement factor H	21	mg/l	376	1.00	190	ZY		285.9-710.7
	22		424	1.00				
Complement factor I	21	mg/l	63.5	1.00	190	ZY		28.8-55.6
	22		28.3	1.00				
Lectin pathway	21	%	4.20	1.00	190	ZY		0-125
	22		27.7	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 29 March 2024

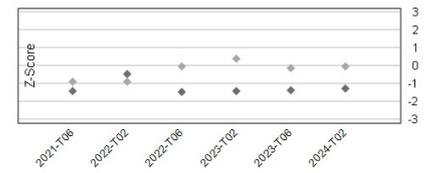
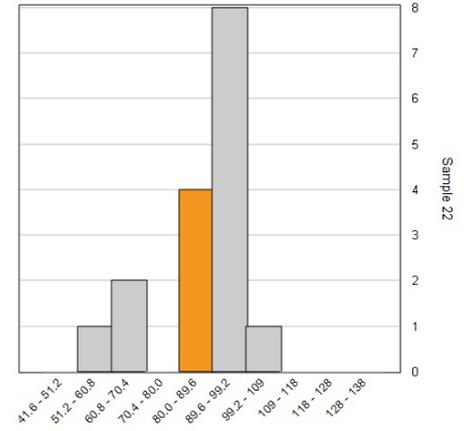
246

### Complement Analysis 02 - Functions and proteins

Alternative pathway (% , N = 63)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
BINDING SITE, THE	(1) 21	35.9	14.4 - 57.4	35.9	71.0	2				
	22	79.8	31.9 - 128	79.8	24.6	2				
EURO DIAGNOSTICA	21		- <30.0	14.4	89.6	38	84.2	78.9		
	22	87.0	34.8 - 139	87.0	20.7	38	94.7			
immunological / Functionaltest (ELISA)	21		- <30.0	14.4	42.6	18	94.4	88.9		
	22	83.4	33.4 - 133	83.4	23.0	18	94.4			
M.333-335, 9999, R.B5, ZX-ZY	(1) 21	37.2	14.9 - 59.5	37.2	72.0	5				
	22	56.6	22.6 - 90.6	56.6	62.5	5				

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

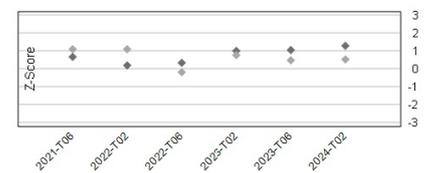
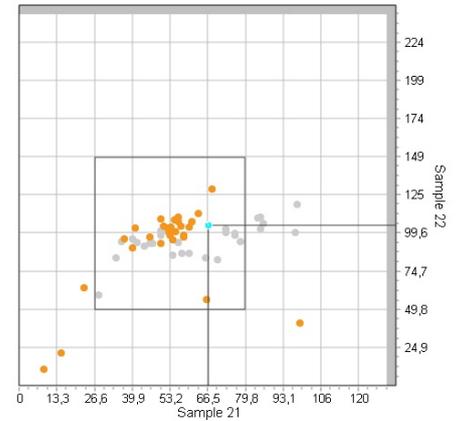
Rate of success: 79,4%



C1 inhibitor: activity (% , N = 66)										
Collective	Sample	Target value	Target range	Participants collective			Rate (%)			
				AVG	CV	Num.	Sam.	total		
deviant unit (U / ml)	(1) 21		Sample not evaluated			1				
	22		Sample not evaluated			1				
QUIDEL	21	80.9	40.5 - 121	80.9	18.4	18	100	100		
	22	104	52.0 - 156	104	13.2	18	100			
SIEMENS	21	53.1	26.6 - 79.7	53.1	19.8	30	86.7	86.7		
	22	99.5	49.8 - 149	99.5	9.78	30	90.0			
TECHNOCLONE	21	48.0	24.0 - 72.0	48.0	21.0	13	100	100		
	22	93.1	46.6 - 140	93.1	8.51	13	100			
other methods	(1) 21	39.0	19.5 - 58.5	39.0	35.6	4				
	22	96.5	48.3 - 145	96.5	35.8	4				

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

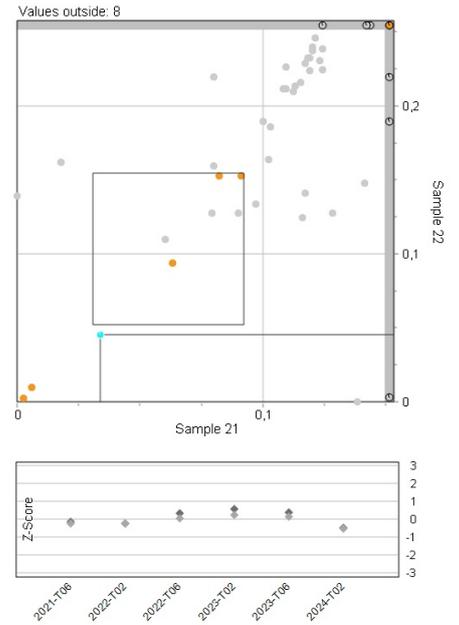
Rate of success: 93,8%



C1q protein (g/l, N = 49)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (percent)	(1) 21		Sample not evaluated				2		
	22		Sample not evaluated				2		
Immunodiffusion (Binding Site)	21	0.085	0.043 - 0.128	0.085	77.6	11	45.5	45.5	
	22	0.143	0.072 - 0.214	0.143	11.9	11	90.9		
Immunodiffusion	(1) 21	0.103	0.052 - 0.155	0.103	0.000	1			
	22	0.186	0.093 - 0.279	0.186	0.000	1			
Nephelometry	21	0.116	0.058 - 0.174	0.116	11.2	19	89.5	89.5	
	22	0.218	0.109 - 0.327	0.218	10.6	19	100		
Turbidimetry	21	0.122	0.061 - 0.183	0.122	24.6	9	100	100	
	22	0.239	0.120 - 0.359	0.239	29.3	9	100		
other methods	(1) 21	0.061	0.031 - 0.092	0.061	96.7	7			
	22	0.103	0.052 - 0.155	0.103	103	7			

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

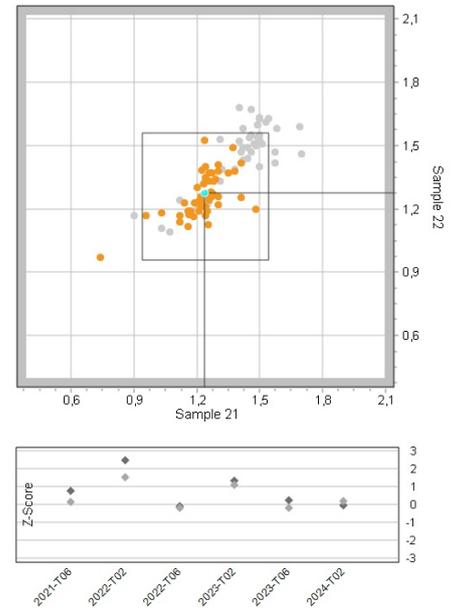
Rate of success: 74,5%



C3-Complement (g/l, N = 94)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
M.87, R.BE	(1) 21	1.11	0.844 - 1.38	1.11	14.4	6			
	22	1.20	0.912 - 1.49	1.20	9.50	6			
Nephelometry - other providers	21	1.47	1.12 - 1.82	1.47	5.03	34	100	100	
	22	1.52	1.16 - 1.88	1.52	6.38	34	100		
Turbidimetry (and other)	21	1.24	0.942 - 1.54	1.24	5.32	54	98.1	98.1	
	22	1.26	0.958 - 1.56	1.26	7.62	54	100		

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

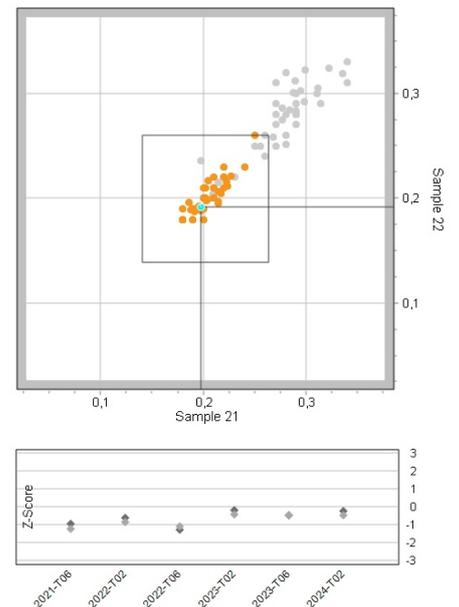
Rate of success: 97,9%



C4-Complement (g/l, N = 93)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
M.87, R.BE	(1) 21	0.209	0.146 - 0.272	0.209	4.78	7			
	22	0.213	0.149 - 0.277	0.213	5.16	7			
Nephelometry - other providers	21	0.286	0.200 - 0.372	0.286	7.34	35	100	100	
	22	0.286	0.200 - 0.372	0.286	9.44	35	100		
Turbidimetry (and other)	21	0.202	0.141 - 0.263	0.202	7.92	51	100	100	
	22	0.199	0.139 - 0.260	0.199	7.54	51	100		

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

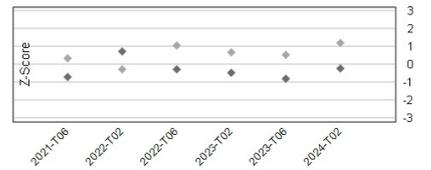
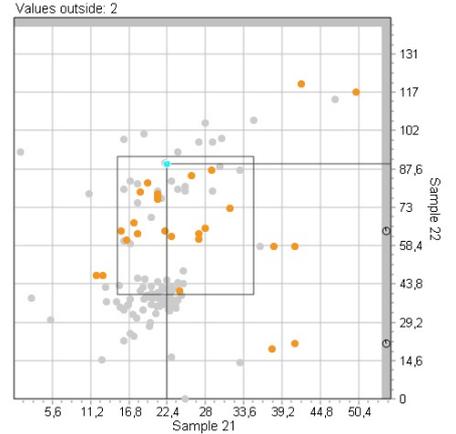
Rate of success: 100%



**Classical pathway (% , N = 140)**

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
BINDING SITE, THE	21	21.8	13.1 - 30.5	21.8	10.2	55	96.4	90.9
	22	38.4	23.0 - 53.8	38.4	12.5	55	94.5	
EURO DIAGNOSTICA / QUIDEL	21		- <40.0	23.0	35.9	34	94.1	85.3
	22	80.7	48.4 - 113	80.7	23.9	34	85.3	
WAKO	21	17.6	10.6 - 24.6	17.6	24.6	23	82.6	78.3
	22	36.6	22.0 - 51.2	36.6	17.4	23	82.6	
other providers	21	25.1	15.1 - 35.1	25.1	42.6	28	67.9	67.9
	22	66.0	39.6 - 92.4	66.0	29.7	28	82.1	

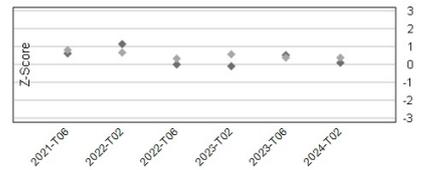
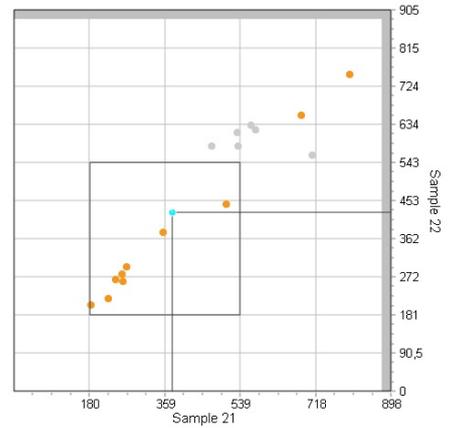
Rate of success: 82,9%


**Complement factor H (mg/l, N = 18)**

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (percent)	(1) 21		Sample not evaluated			1		
	22		Sample not evaluated			1		
BindingSite	(1) 21	558	279 - 837	558	13.4	6		
	22	598	299 - 897	598	5.25	6		
other providers	21	359	180 - 539	359	51.5	11	81.8	81.8
	22	362	181 - 543	362	44.8	11	81.8	

Rate of success: 88,2%

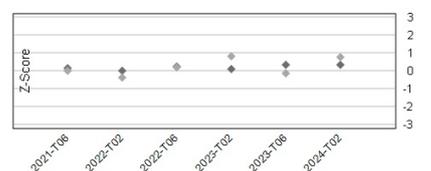
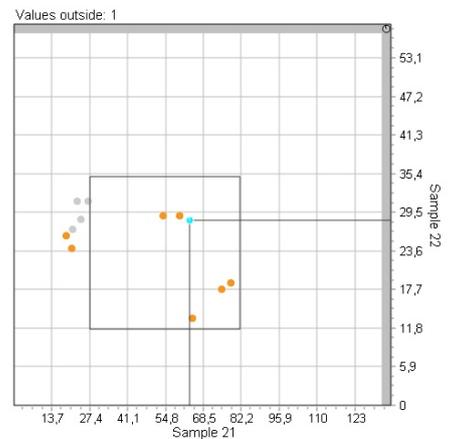
(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective &lt; 8 values.


**Complement factor I (mg/l, N = 15)**

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (percent)	(1) 21		Sample not evaluated			2		
	22		Sample not evaluated			2		
BindingSite	(1) 21	26.6	13.3 - 39.9	26.6	28.5	5		
	22	32.1	16.1 - 48.2	32.1	21.7	5		
other providers	21	54.5	27.3 - 81.8	54.5	47.2	8	75.0	75.0
	22	23.3	11.7 - 35.0	23.3	28.9	8	100	

Rate of success: 76,9%

(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 = 43)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (ng / ml)	(1) 21		Sample not evaluated			2			
						2			
deviant unit (U / ml)	(1) 21		Sample not evaluated			1			
						1			
EURO DIAGNOSTICA / QUIDEL	21		- <10.0	6.05	95.7	30	76.7	66.7	
	22	31.5	12.6 - 50.4	31.5	58.1	30	70.0		
other providers	21		- <10.0	7.44	82.7	10	70.0	40.0	
	22	35.8	14.3 - 57.3	35.8	89.9	10	50.0		

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

Rate of success: 60%

