

CERTIFICATE

Survey of 08 November 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:

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

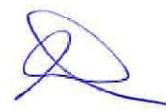
811-1 Kimiidera, Wakayama

641-8509 Wakayama

Düsseldorf, 13 December 2024



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



Prof. Dr. Zoltan Prohaszka
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 08 November 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

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(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 08 November 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	Sam- ple	Unit	Your value	Target value	TV- Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
Alternative pathway	61	%	6.70	29.5	SV	11.8	47.2	-77.3%	-1,65	-	
	62		59.8	85.2	SV	34.1	136	-29.8%	-1,48	+	
C1 inhibitor: activity	61	%	58.8	54.2	SV	27.1	81.3	8.5%	0,701	+	
	62		98.6	97.1	SV	48.6	146	1.5%	0,209	+	
C1q protein	(1) 61	g/l	0.065	0.063	SV	0.032	0.095	2.5%	0,017	+	
	(1) 62		0.095	0.099	SV	0.050	0.149	-3.7%	-0,026	+	
C3-Complement	61	g/l	1.43	1.28	SV	0.973	1.59	11.3%	1,75	+	
	62		1.40	1.26	SV	0.958	1.56	11.0%	1,28	+	
C4-Complement	61	g/l	0.234	0.227	SV	0.159	0.295	3.1%	0,389	+	
	62		0.213	0.218	SV	0.153	0.283	-2.3%	-0,357	+	
Classical pathway	61	%	22.0	29.2	SV	17.5	40.9	-24.7%	-0,831	+	
	62		79.7	76.5	SV	45.9	107	4.2%	0,203	+	
Complement factor H	61	mg/l	429	338	SV	169	507	27.0%	0,648	+	
	62		455	323	SV	162	485	40.9%	1,29	+	
Complement factor I	61	mg/l	50.1	36.5	SV	18.3	54.8	37.3%	0,589	+	
	62		28.5	25.1	SV	12.6	37.7	13.5%	0,359	+	
Lectin pathway	61	%	3.40	12.2	ET	0.000	22.8	-72.1%	-0,624	+	
	62		22.6	41.7	ET	6.20	78.8	-45.8%	-0,479	+	

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Reference range
Alternative pathway	61	%	6.70	1.00	190	ZY		30-113
	62		59.8	1.00				
C1 inhibitor: activity	61	%	58.8	1.00	257	BW		79.1-139.5
	62		98.6	1.00				
C1q protein	61	mg/l	64.6	0.001	190	ZY		not determined
	62		95.3	0.001				
C3-Complement	61	mg/l	1425	0.001	116	ZY		604-1432
	62		1398	0.001				
C4-Complement	61	mg/l	234	0.001	116	ZY		91-359
	62		213	0.001				
Classical pathway	61	%	22.0	1.00	190	ZY		31.7-50.5
	62		79.7	1.00				
Complement factor H	61	mg/l	429	1.00	190	ZY		285.9-710.7
	62		455	1.00				
Complement factor I	61	mg/l	50.1	1.00	190	ZY		28.8-55.6
	62		28.5	1.00				
Lectin pathway	61	%	3.40	1.00	190	ZY		0-125
	62		22.6	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 08 November 2024

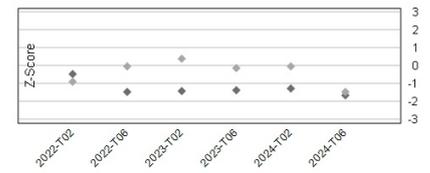
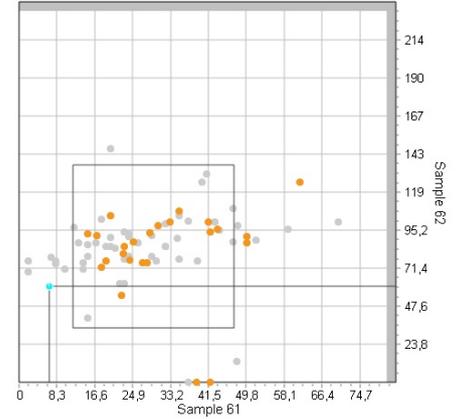
246

Complement Analysis 02 - Functions and proteins

Alternative pathway (% , N = 80)									
Collective	Sample	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (U / ml) (1)	61		Sample not evaluated						
	62		Sample not evaluated						
EURO DIAGNOSTICA	61	24.5	9.80 - 39.2	24.5	58.0	43	69.8	65.1	
	62	85.0	34.0 - 136	85.0	15.4	43	93.0		
immunological / Functionaltest (ELISA)	61	29.5	11.8 - 47.2	29.5	46.8	26	84.6	76.9	
	62	85.2	34.1 - 136	85.2	20.2	26	92.3		
hemolytical test (Gel and other)	61	39.5	15.8 - 63.2	39.5	43.8	9	88.9	88.9	
	62	90.0	36.0 - 144	90.0	19.0	9	100		

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

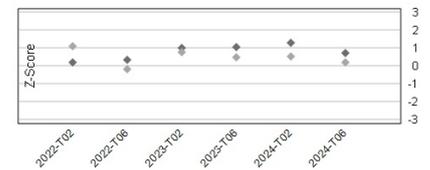
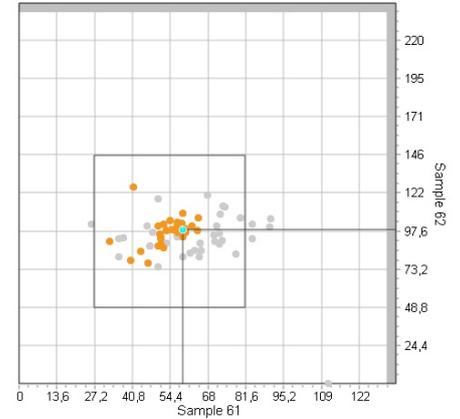
Rate of success: 71,8%



C1 inhibitor: activity (% , N = 74)									
Collective	Sample	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (U / ml) (1)	61		Sample not evaluated						
	62		Sample not evaluated						
QUIDEL	61	70.1	35.1 - 105	70.1	19.4	21	100	100	
	62	93.6	46.8 - 140	93.6	12.6	21	100		
SIEMENS	61	54.2	27.1 - 81.3	54.2	12.1	31	100	100	
	62	97.1	48.6 - 146	97.1	7.40	31	100		
TECHNOCLONE	61	50.8	25.4 - 76.2	50.8	35.4	13	92.3	92.3	
	62	103	51.5 - 155	103	17.0	13	100		
other methods (1)	61	57.2	28.6 - 85.8	57.2	46.7	5			
	62	95.8	47.9 - 144	95.8	11.0	5			

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

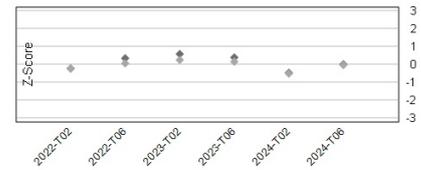
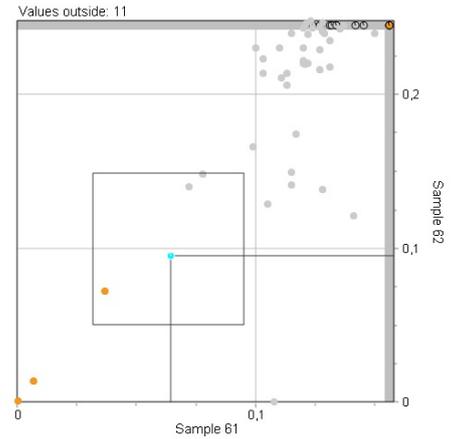
Rate of success: 95,7%



C1q protein (g/l, N = 56)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (percent) (1)	61		Sample not evaluated			1			
	62		Sample not evaluated			1			
Immunodiffusion (Binding Site)	61	0.109	0.055 - 0.164	0.109	24.8	10	80.0	70.0	
	62	0.149	0.075 - 0.223	0.149	30.9	10	90.0		
Nephelometry, Immunodiffusion	61	0.120	0.060 - 0.180	0.120	9.17	28	96.4	96.4	
	62	0.232	0.116 - 0.348	0.232	8.62	28	100		
Turbidimetry	61	0.135	0.068 - 0.203	0.135	9.63	12	100	100	
	62	0.247	0.124 - 0.371	0.247	13.0	12	100		
other methods (1)	61	0.063	0.032 - 0.095	0.063	151	5			
	62	0.099	0.050 - 0.149	0.099	145	5			

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

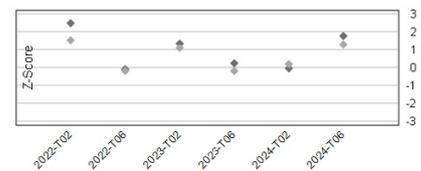
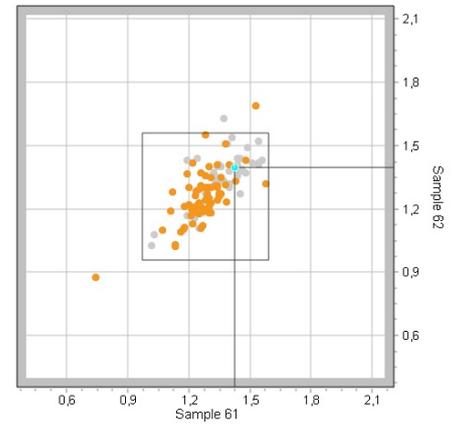
Rate of success: 87,3%



C3-Complement (g/l, N = 113)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
M.87, R.BE (1)	61	1.19	0.904 - 1.48	1.19	11.2	4			
	62	1.15	0.874 - 1.43	1.15	6.17	4			
Nephelometry - other providers	61	1.39	1.06 - 1.72	1.39	7.19	40	97.5	97.5	
	62	1.38	1.05 - 1.71	1.38	5.65	40	97.5		
Turbidimetry (and other)	61	1.28	0.973 - 1.59	1.28	6.48	69	98.6	97.1	
	62	1.26	0.958 - 1.56	1.26	8.57	69	97.1		

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

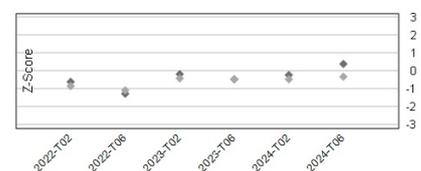
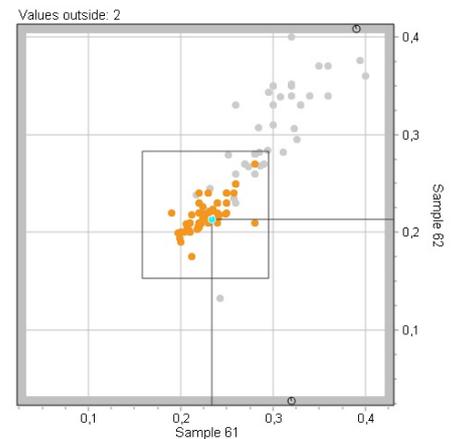
Rate of success: 97,3%



C4-Complement (g/l, N = 112)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
M.87, R.BE (1)	61	0.242	0.169 - 0.315	0.242	8.68	5			
	62	0.213	0.149 - 0.277	0.213	18.8	5			
Nephelometry - other providers	61	0.302	0.211 - 0.393	0.302	12.9	41	95.1	90.2	
	62	0.312	0.218 - 0.406	0.312	15.1	41	95.1		
Turbidimetry (and other)	61	0.227	0.159 - 0.295	0.227	7.93	66	100	100	
	62	0.218	0.153 - 0.283	0.218	6.42	66	100		

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

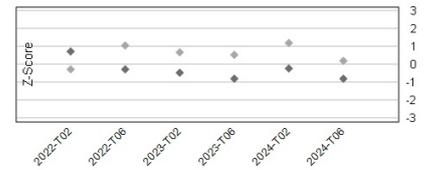
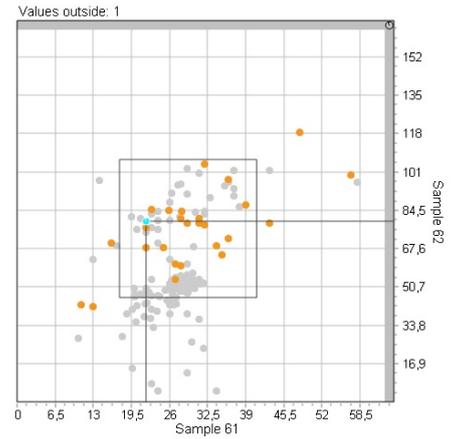
Rate of success: 95,5%



Classical pathway (% , N = 166)

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
BINDING SITE, THE	61	27.6	16.6 - 38.6	27.6	7.86	70	100	92.9
	62	49.9	29.9 - 69.9	49.9	10.5	70	92.9	
reference range 69-129%	61	28.0	16.8 - 39.2	28.0	25.3	24	91.7	70.8
	62	73.7	44.2 - 103	73.7	33.9	24	79.2	
EURO DIAGNOSTICA / QUIDEL	61	28.5	17.1 - 39.9	28.5	29.0	24	83.3	79.2
	62	85.8	51.5 - 120	85.8	18.6	24	91.7	
WAKO	61	21.4	12.8 - 30.0	21.4	8.64	21	95.2	90.5
	62	44.6	26.8 - 62.4	44.6	11.5	21	95.2	
other providers	61	29.2	17.5 - 40.9	29.2	29.7	27	77.8	77.8
	62	76.5	45.9 - 107	76.5	20.7	27	88.9	

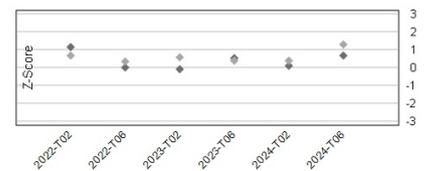
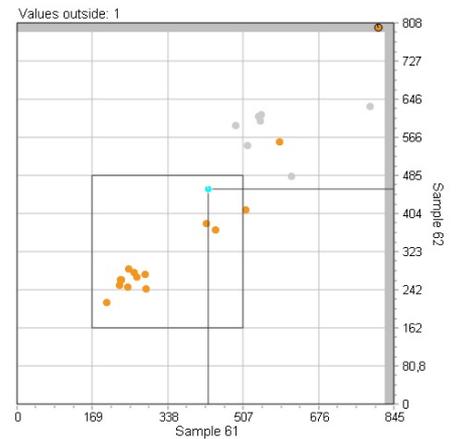
Rate of success: 84,9%


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

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (percent)	(1) 61		Sample not evaluated			3		
	62		Sample not evaluated			3		
BindingSite	(1) 61	559	280 - 839	559	11.8	7		
	62	588	294 - 882	588	7.57	7		
other providers	61	338	169 - 507	338	41.7	16	81.3	81.3
	62	323	162 - 485	323	31.6	16	87.5	

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

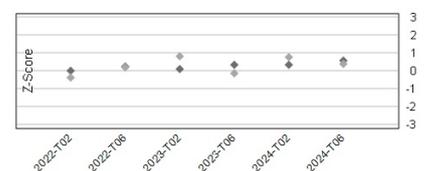
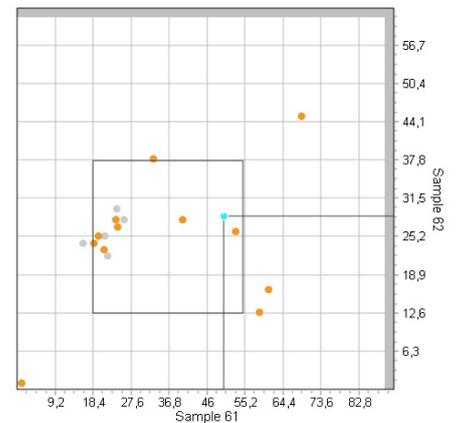
Rate of success: 87%


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

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (percent)	(1) 61		Sample not evaluated			5		
	62		Sample not evaluated			5		
BindingSite	(1) 61	21.9	11.0 - 32.8	21.9	19.5	5		
	62	25.8	12.9 - 38.7	25.8	13.7	5		
other providers	61	36.5	18.3 - 54.8	36.5	63.3	13	69.2	61.5
	62	25.1	12.6 - 37.7	25.1	37.7	13	76.9	

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

Rate of success: 72,2%





Lectin pathway (% , N = 51)									
Collective	Sam- ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
deviant unit (ng / ml)	(1) 61		Sample not evaluated			3			
	62		Sample not evaluated			3			
deviant unit (U / ml)	(1) 61		Sample not evaluated			2			
	62		Sample not evaluated			2			
EURO DIAGNOSTICA / QUIDEL	61	6.29	2.52 - 10.1	6.29	64.9	31	74.2	67.7	
	62	35.1	14.0 - 56.2	35.1	44.7	31	83.9		
other providers	61	12.2	0.000 - 22.8	12.2	116	15	80.0	60.0	
	62	41.7	6.20 - 78.8	41.7	95.7	15	60.0		

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

Rate of success: 65,2%

