CERTIFICATE

Survey of 31 March 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:

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

Participant:
51071
The Japanese Association for Complement Research
Wakayama Medical University
811-1 Kimiidera, Wakayama
641-8509 Wakayama

DAkkS Deutsche Akkreditierungsstelle D-EP-15027-02-00

Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V. INSTAND Qualitätskontrolle und Ringversuch DÜSSELDORF

Düsseldorf, 24 April 2023

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

Prof. Dr. Zoltan Prohaszka
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 31 March 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 proteine
C3-Complement
C4-Complement
Classical pathway
Complement factor H
Complement factor I
Lectin pathway

(R) analysis is subject to the RiliBÄK

Participant:
51071
The Japanese Association for Complement Research
Wakayama Medical University
811-1 Kimiidera, Wakayama
641-8509 Wakayama

DAkkS Deutsche Akkreditierungsstelle D-EP-15027-02-00

Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V. INSTAND Qualitätskontrolle und Ringversuch DÜSSELDORF

Düsseldorf, 24 April 2023

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

Prof. Dr. Zoltan Prohaszka
(Adviser)

INSTAND

Listing and evaluation of the results

51071: The Japanese Association for Complement Research
Wakayama Medical University

Survey of 31 March 2023

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@med.semmelweis-univ.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	%	1.60		ET		<30.0		-1,43	+
	22		86.9	82.5	SV	33.0	132	5.3%	0,386	+
C1 inhibitor: activity	21	%	70.5	63.9	SV	32.0	95.9	10.3%	0,992	+
	22		116	110	SV	55.0	165	5.2%	0,784	+
C1q proteine (1)	21	g/l	0.058	0.035	SV	0.018	0.053	66.3%	0,58	
(1)	22		0.075	0.058	SV	0.029	0.087	29.8%	0,231	+
C3-Complement	21	g/l	1.40	1.27	SV	0.965	1.57	10.2%	1,33	+
	22		1.34	1.22	SV	0.927	1.51	9.6%	1,09	+
C4-Complement	21	g/l	0.266	0.269	SV	0.188	0.350	-1.1%	-0,188	+
	22		0.252	0.259	SV	0.181	0.337	-2.7%	-0,438	+
Classical pathway	21	%	25.7	29.4	SV	17.6	41.2	-12.6%	-0,487	+
	22		90.8	75.8	SV	45.5	106	19.8%	0,658	+
Complement factor H	21	mg/l	364	381	SV	191	572	-4.5%	-0,087	+
	22		436	350	SV	175	525	24.5%	0,592	+
Complement factor I	21	mg/l	48.4	45.5	SV	22.8	68.3	6.4%	0,102	+
	22		28.2	21.0	SV	10.5	31.5	34.3%	0,794	+
Lectin pathway	21	%	3.00		ET		<10.0		-0,807	+
	22		27.0	32.2	SV	12.9	51.5	-16.1%	-0,456	+

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Reference range
Alternative pathway	21	%	1.60	1.00	190	ZY		30-113
	22		86.9	1.00				
C1 inhibitor: activity	21	%	70.5	1.00	257	BW		79.1-139.5
	22		116	1.00				
C1q proteine	21	mg/l	58.2	0.001	190	ZY		not determined
	22		75.3	0.001				
C3-Complement	21	mg/l	1399	0.001	116	ZY		604-1432
	22		1337	0.001				
C4-Complement	21	mg/l	266	0.001	116	ZY		91-359
	22		252	0.001				
Classical pathway	21	%	25.7	1.00	190	ZY		31.7-50.5
	22		90.8	1.00				
Complement factor H	21	mg/l	364	1.00	190	ZY		285.9-710.7
	22		436	1.00				
Complement factor I	21	mg/l	48.4	1.00	190	ZY		28.8-55.6
	22		28.2	1.00				
Lectin pathway	21	%	3.00	1.00	190	ZY		0-125
	22		27.0	1.00				

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

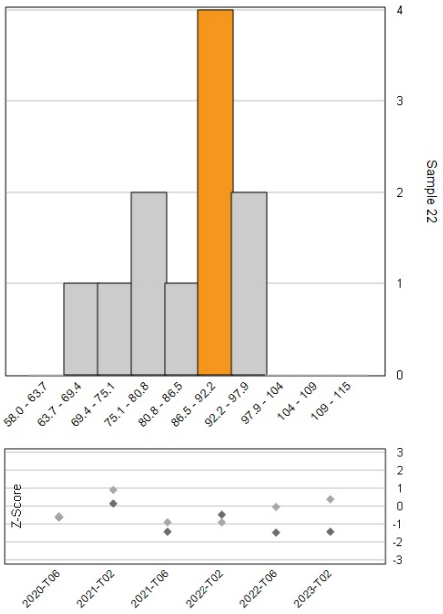
246 Complement Analysis 02 - Functions and proteins

Alternative pathway (%, N = 60)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
BINDING SITE, THE	21	54.8	21.9 - 87.7	54.8	10.9	9	88.9	88.9
	22	89.3	35.7 - 143	89.3	22.5	9	100	
EURO DIAGNOSTICA / QUIDEL	21		- <30.0	8.63	106	32	87.5	71.9
	22	80.3	32.1 - 128	80.3	42.2	32	78.1	
immunological / Functionaltest (ELISA)	21		- <30.0	9.97	58.6	12	100	91.7
	22	82.5	33.0 - 132	82.5	13.8	12	91.7	
M.333-335, 9999, R.BS, ZX-ZY (1)	21	22.3	8.92 - 35.7	22.3	74.9	7		
	22	61.8	24.7 - 98.9	61.8	72.7	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: 76,7%

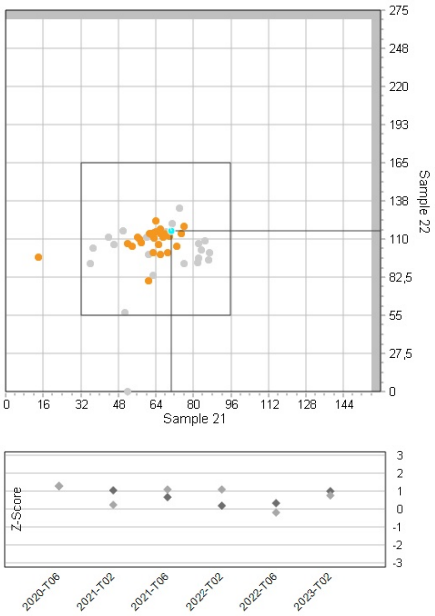


C1 inhibitor: activity (%, N = 61)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant unit (U / ml) (1)	21		Sample not evaluated			3		
	22		Sample not evaluated			3		
QUIDEL	21	84.2	42.1 - 126	84.2	9.61	16	100	100
	22	107	53.5 - 161	107	18.7	16	100	
SIEMENS	21	63.9	32.0 - 95.9	63.9	10.4	27	96.3	96.3
	22	110	55.0 - 165	110	6.61	27	100	
TECHNOCLONE	21	55.1	27.6 - 82.7	55.1	28.1	12	100	100
	22	117	58.5 - 176	117	16.6	12	100	
other methods (1)	21	49.3	24.7 - 73.9	49.3	28.8	3		
	22	82.6	41.3 - 124	82.6	30.9	3		

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

Rate of success: 98,3%

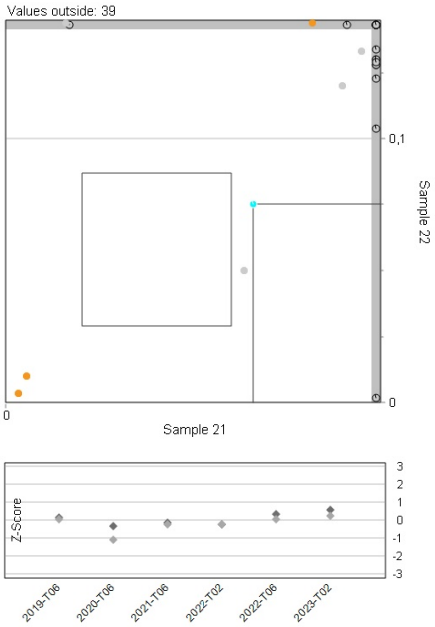


C1q proteine (g/l, N = 48)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
Immunodiffusion (Binding Site)	21	0.085	0.043 - 0.128	0.085	51.8	14	71.4	71.4
	22	0.138	0.069 - 0.207	0.138	13.0	14	100	
Immunodiffusion (1)	21	0.139	0.070 - 0.209	0.139	77.7	5		
	22	0.238	0.119 - 0.357	0.238	100	5		
Nephelometry	21	0.151	0.076 - 0.226	0.151	27.8	19	89.5	78.9
	22	0.257	0.129 - 0.386	0.257	21.0	19	84.2	
Turbidimetry (1)	21	0.134	0.067 - 0.201	0.134	25.4	6		
	22	0.250	0.125 - 0.375	0.250	23.2	6		
other methods (1)	21	0.035	0.018 - 0.053	0.035	114	4		
	22	0.058	0.029 - 0.087	0.058	129	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: 70,8%

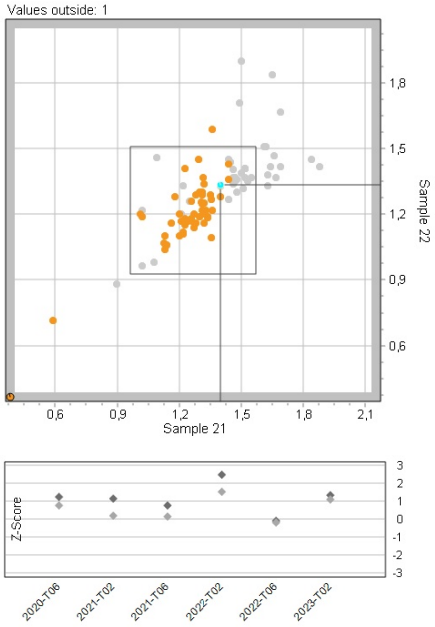


C3-Complement (g/l, N = 94)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
M.87, R.BE (1)	21	1.08	0.821 - 1.34	1.08	11.9	7		
	22	1.15	0.874 - 1.43	1.15	21.0	7		
Nephelometry - other providers	21	1.54	1.17 - 1.91	1.54	7.01	35	97.1	91.4
	22	1.40	1.06 - 1.74	1.40	6.00	35	94.3	
Turbidimetry (and other)	21	1.27	0.965 - 1.57	1.27	7.64	52	96.2	94.2
	22	1.22	0.927 - 1.51	1.22	8.77	52	94.2	

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

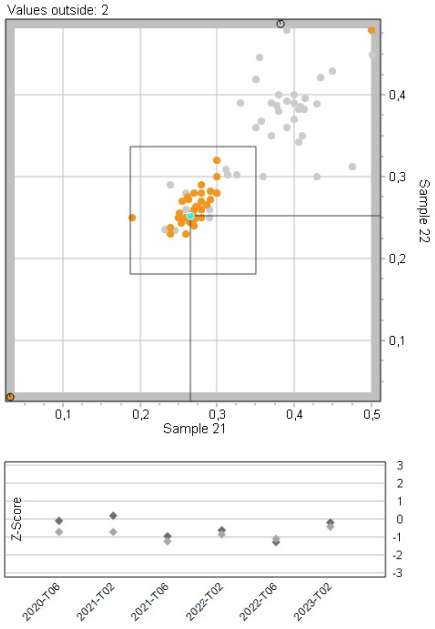
Rate of success: 92,6%



C4-Complement (g/l, N = 93)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
Nephelometry - BECKMAN COULTER	21	0.259	0.181 - 0.337	0.259	9.27	8	100	100
	22	0.256	0.179 - 0.333	0.256	8.59	8	100	
Nephelometry - other providers	21	0.383	0.268 - 0.498	0.383	12.0	35	91.4	88.6
	22	0.373	0.261 - 0.485	0.373	15.0	35	91.4	
Turbidimetry (and other)	21	0.269	0.188 - 0.350	0.269	5.95	50	96.0	96.0
	22	0.259	0.181 - 0.337	0.259	6.18	50	96.0	

Rate of success: 93,5%

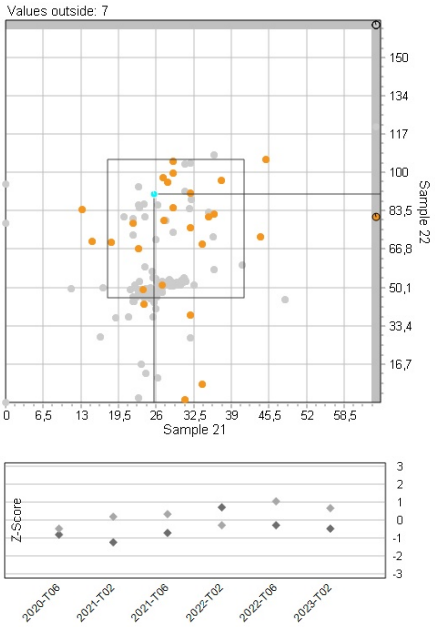


Classical pathway (%, N = 134)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
M.333, R.BS, artificial."U/ml" (1)	21	351	211 - 491	351	35.3	6		
	22	631	379 - 883	631	45.3	6		
BINDING SITE, THE	21	27.7	16.6 - 38.8	27.7	10.3	50	98.0	90.0
	22	50.5	30.3 - 70.7	50.5	8.75	50	92.0	
EURO DIAGNOSTICA / QUIDEL	21	25.1	15.1 - 35.1	25.1	33.6	27	77.8	66.7
	22	78.8	47.3 - 110	78.8	29.8	27	81.5	
WAKO	21	22.7	13.6 - 31.8	22.7	10.3	24	87.5	62.5
	22	40.3	24.2 - 56.4	40.3	41.9	24	66.7	
other providers	21	29.4	17.6 - 41.2	29.4	25.8	27	81.5	66.7
	22	75.8	45.5 - 106	75.8	30.1	27	85.2	

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

Rate of success: 73,9%

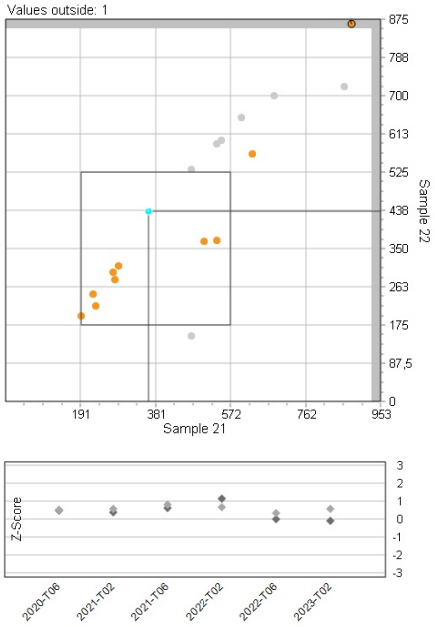


Complement factor H (mg/l, N = 20)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant unit (percent) (1)	21		Sample not evaluated			2		
	22		Sample not evaluated			2		
BindingSite (1)	21	583	292 - 875	583	21.6	7		
	22	603	302 - 905	603	18.6	7		
other providers	21	381	191 - 572	381	52.0	11	81.8	81.8
	22	350	175 - 525	350	41.4	11	81.8	

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

Rate of success: 83,3%

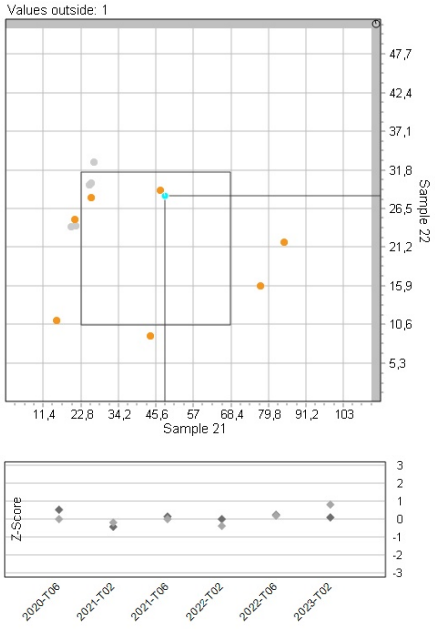


Complement factor I (mg/l, N = 17)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant unit (percent) (1)	21		Sample not evaluated			3		
	22		Sample not evaluated			3		
BindingSite (1)	21	25.6	12.8 - 38.4	25.6	22.1	6		
	22	30.3	15.2 - 45.5	30.3	23.9	6		
other providers	21	45.5	22.8 - 68.3	45.5	62.6	8	50.0	37.5
	22	21.0	10.5 - 31.5	21.0	43.2	8	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: 57,1%



Lectin pathway (%, N = 37)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant unit (ng / ml) (1)	21		Sample not evaluated			2		
	22		Sample not evaluated			2		
deviant unit (U / ml) (1)	21		Sample not evaluated			1		
	22		Sample not evaluated			1		
EURO DIAGNOSTICA	21		- <10.0	3.31	62.8	26	96.2	73.1
	22	23.8	9.52 - 38.1	23.8	47.5	26	76.9	
other providers	21		- <10.0	12.2	93.4	8	62.5	62.5
	22	32.2	12.9 - 51.5	32.2	35.4	8	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: 70,6%