CERTIFICATE

Survey of 01 April 2022

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
C1q proteine
C3-Complement
C4-Complement
Classical pathway
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, 20 April 2022

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

Prof. Dr. Zoltan Prohaszka
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 01 April 2022

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

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Düsseldorf, 20 April 2022

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 01 April 2022

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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	%	83.8	89.4	SV	35.8	143	-6.3%	-0,496	+	
	22		13.5	22.2	SV	8.88	35.5	-39.2%	-0,896	+	
C1 inhibitor: activity	21	%	111	110	SV	55.0	165	1.3%	0,177	+	
	22		76.5	70.7	SV	35.4	106	8.2%	1,09	+	
C1q proteine (1)	21	g/l	0.111	0.154	SV	0.077	0.231	-27.7%	-0,23	+	
(1)	22		0.073	0.111	SV	0.056	0.167	-34.3%	-0,243	+	
C3-Complement	21	g/l	1.42	1.22	SV	0.927	1.51	16.7%	2,46	+	
	22		1.39	1.28	SV	0.973	1.59	8.9%	1,52	+	
C4-Complement	21	g/l	0.245	0.257	SV	0.180	0.334	-4.7%	-0,6	+	
	22		0.256	0.271	SV	0.190	0.352	-5.5%	-0,882	+	
Classical pathway	21	%	92.2	80.4	SV	48.2	113	14.7%	0,694	+	
	22		30.0	33.1	SV	19.9	46.3	-9.4%	-0,274	+	
Complement factor H	21	mg/l	588	390	SV	195	585	50.7%	1,14	-	
	22		502	391	SV	196	587	28.4%	0,664	+	
Complement factor I (1)	21	mg/l	24.7	24.6	SV	12.3	36.9	0.4%	0,012	+	
(1)	22		45.9	57.2	SV	28.6	85.8	-19.8%	-0,404	+	
Lectin pathway	21	%	39.4	39.3	SV	15.7	62.9	0.3%	0,011	+	
	22		6.60	7.01	SV	2.80	11.2	-5.8%	-0,118	+	

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Reference range
Alternative pathway	21	%	83.8	1.00	190	ZY		30-113
	22		13.5	1.00				
C1 inhibitor: activity	21	%	111	1.00	257	BW		not determined
	22		76.5	1.00				
C1q proteine	21	mg/l	111	0.001	190	ZY		not determined
	22		72.9	0.001				
C3-Complement	21	mg/l	1424	0.001	116	ZY		604-1432
	22		1394	0.001				
C4-Complement	21	mg/l	245	0.001	116	ZY		91-359
	22		256	0.001				
Classical pathway	21	%	92.2	1.00	190	ZY		31.7-50.5
	22		30.0	1.00				
Complement factor H	21	mg/l	588	1.00	190	ZY		285.9-710.7
	22		502	1.00				
Complement factor I	21	mg/l	24.7	1.00	190	ZY		28.8-55.6
	22		45.9	1.00				
Lectin pathway	21	%	39.4	1.00	190	ZY		0-125
	22		6.60	1.00				

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

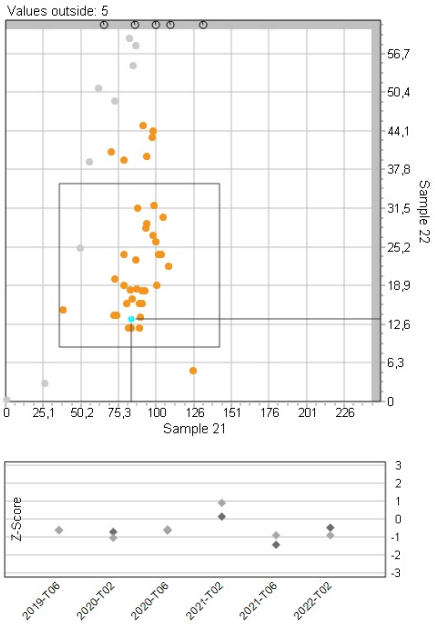
246 Complement Analysis 02 - Functions and proteins

Alternative pathway (%, N = 57)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant (1) unit (U / ml)	21		Sample not evaluated			2		
	22		Sample not evaluated			2		
hemolytical test (Gel and other)	21	85.9	34.4 - 137	85.9	41.1	16	87.5	68.8
	22	53.2	21.3 - 85.1	53.2	54.7	16	68.8	
immunological / functional test (ELISA)	21	89.4	35.8 - 143	89.4	12.6	39	100	82.1
	22	22.2	8.88 - 35.5	22.2	43.7	39	82.1	

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

Rate of success: 78,2%

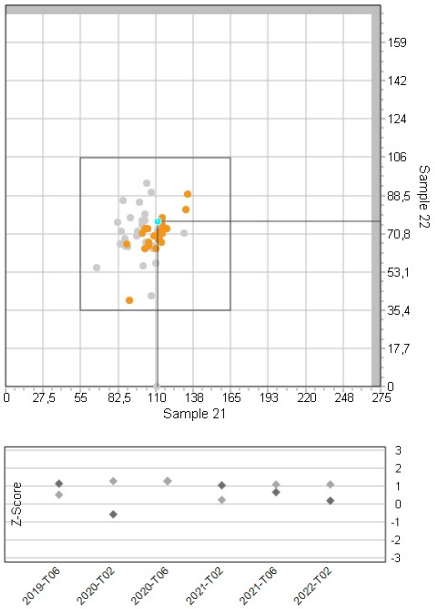


C1 inhibitor: activity (%, N = 62)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant (1) unit (U / ml)	21		Sample not evaluated			2		
	22		Sample not evaluated			2		
QUIDEL	21	95.7	47.9 - 144	95.7	15.0	18	100	94.4
	22	74.1	37.1 - 111	74.1	16.7	18	94.4	
SIEMENS	21	110	55.0 - 165	110	7.19	24	100	100
	22	70.7	35.4 - 106	70.7	7.50	24	100	
TECHNOCLONE	21	120	60.0 - 180	120	20.5	13	100	100
	22	68.1	34.1 - 102	68.1	10.3	13	100	
other methods (1)	21	106	53.0 - 159	106	6.70	5		
	22	69.3	34.7 - 104	69.3	31.0	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: 96,7%

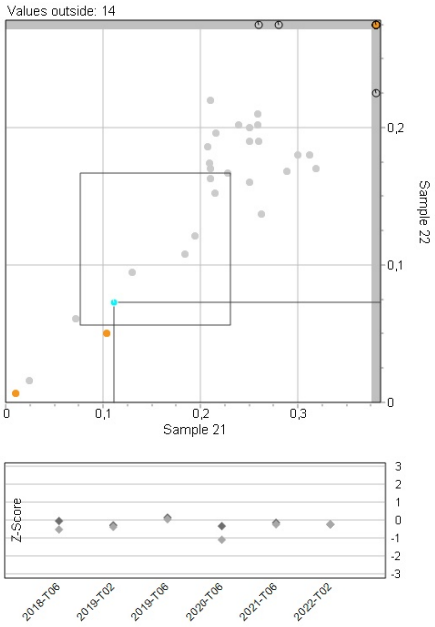


C1q proteine (g/l, N = 46)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant unit (percent) (1)	21		Sample not evaluated			1		
	22		Sample not evaluated			1		
Immunodiffusion (Binding Site)	21	168	84.0 - 252	168	11.2	13	100	30.8
	22	43.9	22.0 - 65.9	43.9	106	13	30.8	
Immunodiffusion (1)	21	0.170	0.085 - 0.255	0.170	57.6	7		
	22	0.121	0.061 - 0.182	0.121	52.9	7		
Nephelometry / Turbidimetry	21	0.251	0.126 - 0.377	0.251	19.5	21	95.2	90.5
	22	0.188	0.094 - 0.282	0.188	18.1	21	95.2	
other methods (1)	21	0.154	0.077 - 0.231	0.154	121	4		
	22	0.111	0.056 - 0.167	0.111	141	4		

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

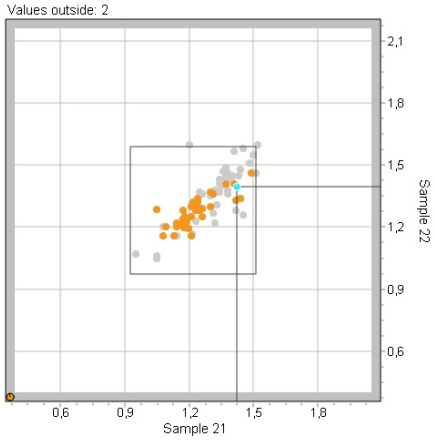
Rate of success: 64,4%

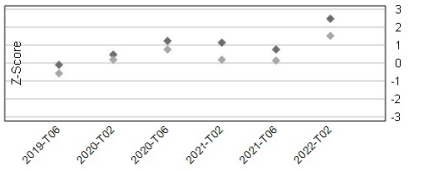


C3-Complement (g/l, N = 87)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
Nephelometry - BECKMAN COULTER	21	1.17	0.889 - 1.45	1.17	14.1	9	100	88.9
	22	1.23	0.935 - 1.53	1.23	15.9	9	88.9	
Nephelometry - SIEMENS	21	1.36	1.03 - 1.69	1.36	6.54	35	100	100
	22	1.40	1.06 - 1.74	1.40	8.36	35	100	
Turbidimetry (and other)	21	1.22	0.927 - 1.51	1.22	6.80	43	95.3	95.3
	22	1.28	0.973 - 1.59	1.28	5.86	43	95.3	

Rate of success: 96,6%

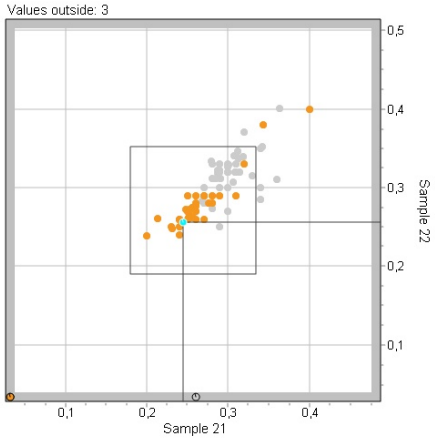


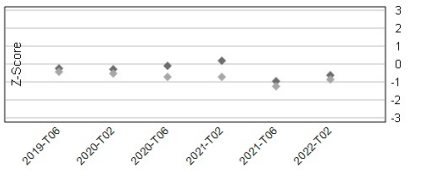


C4-Complement (g/l, N = 87)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
Nephelometry - BECKMAN COULTER	21	0.283	0.198 - 0.368	0.283	13.4	10	100	100
	22	0.280	0.196 - 0.364	0.280	9.29	10	100	
Nephelometry - SIEMENS	21	0.302	0.211 - 0.393	0.302	7.28	36	100	97.2
	22	0.324	0.227 - 0.421	0.324	6.17	36	97.2	
Turbidimetry (and other)	21	0.257	0.180 - 0.334	0.257	7.78	41	90.2	90.2
	22	0.271	0.190 - 0.352	0.271	6.27	41	90.2	

Rate of success: 94,3%



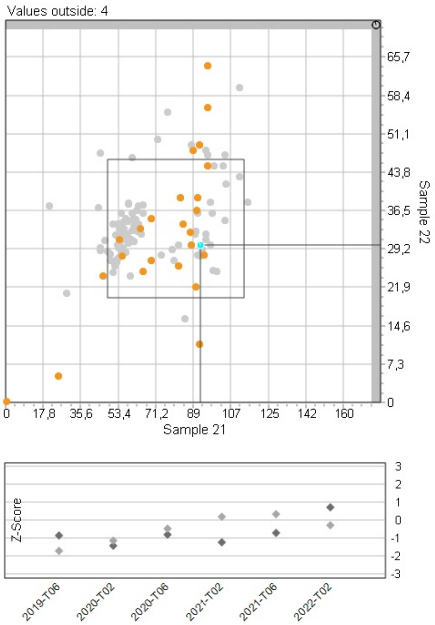


Classical pathway (%, N = 124)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
M.333, R.BS, artificial."U/ml" (1)	21	632	379 - 885	632	18.5	5		
	22	344	206 - 482	344	44.8	5		
BINDING SITE, THE	21	58.3	35.0 - 81.6	58.3	9.66	43	97.7	90.7
	22	33.3	20.0 - 46.6	33.3	10.5	43	93.0	
EURO DIAGNOSTICA / QUIDEL	21	94.7	56.8 - 133	94.7	10.5	29	100	93.1
	22	35.5	21.3 - 49.7	35.5	26.0	29	93.1	
WAKO	21	52.3	31.4 - 73.2	52.3	12.8	22	90.9	86.4
	22	30.0	18.0 - 42.0	30.0	18.0	22	95.5	
other providers	21	80.4	48.2 - 113	80.4	21.1	25	88.0	68.0
	22	33.1	19.9 - 46.3	33.1	34.1	25	72.0	

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

Rate of success: 85,5%

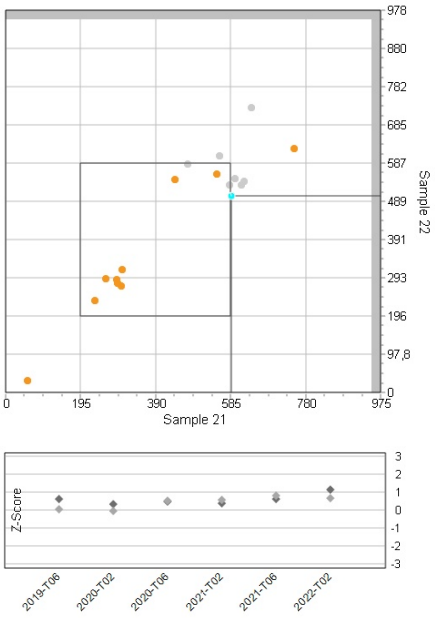


Complement factor H (mg/l, N = 20)

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	590	295 - 885	590	7.98	7		
	22	569	285 - 854	569	8.45	7		
other providers	21	390	195 - 585	390	44.6	11	72.7	72.7
	22	391	196 - 587	391	42.7	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%

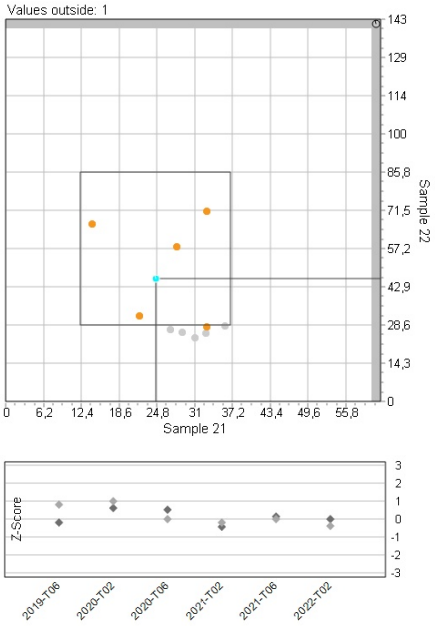


Complement factor I (mg/l, N = 15)

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	33.1	16.6 - 49.7	33.1	19.3	6		
	22	27.1	13.6 - 40.7	27.1	11.1	6		
other providers (1)	21	24.6	12.3 - 36.9	24.6	33.6	7		
	22	57.2	28.6 - 85.8	57.2	49.0	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: 84,6%



Lectin pathway (%, N = 36)

Collective	Sam-ple	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
deviant (1) unit (ng / ml)	21	1678	671 - 2685	1678	21.3	4		
	22	1423	569 - 2277	1423	50.2	4		
deviant (1) unit (U / ml)	21		Sample not evaluated			1		
	22		Sample not evaluated			1		
Immunological / functional test (ELISA)	21	39.3	15.7 - 62.9	39.3	23.5	31	90.3	77.4
	22	7.01	2.80 - 11.2	7.01	49.4	31	80.6	

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

Rate of success: 77,1%