

CERTIFICATE

Survey of 03 April 2020

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

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

Düsseldorf, 24 April 2020



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



Prof. Zoltan Prohaszka
(Adviser)

CERTIFICATE OF PARTICIPATION

Survey of 03 April 2020

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

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

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

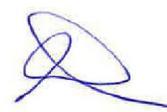
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Prof. Zoltan Prohaszka
(Adviser)

Listing and evaluation of the results

51071: The Japanese Association for Complement Research

Survey of 03 April 2020

Adviser:

Prof. Zoltan Prohaszka

Semmelweis University

IIIrd Department of Medicine, Research Laboratory

Kutvölgyi st. 4.

1125 Budapest

Tel.: +361 3251379

Fax: +361 2129351

Mail: prohaszka.zoltan@med.semmelweis-univ.hu

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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	21	%	77.3	89.5	SV	35.8	143	-13.6%	-0,693	+	
	22		3.40		ET						
C1 inhibitor: activity	21	%	102	108	SV	54.0	162	-5.7%	-0,579	+	
	22		69.1		55.7						
C1 inhibitor: proteine	21	g/l	0.169	0.268	SV	0.188	0.348	-36.9%	-6,6	-	
	22		0.094		0.197						
C1q proteine	(1)	g/l	0.085								Sample not evaluated
	(1)		0.050								
C3-Complement	21	g/l	1.24	1.20	SV	0.912	1.49	3.2%	0,469	+	
	22		1.23		1.22						
C4-Complement	21	g/l	0.251	0.259	SV	0.181	0.337	-3.1%	-0,296	+	
	22		0.250		0.264						
Classical pathway	21	%	34.8	72.6	SV	43.6	102	-52.1%	-1,44	-	
	22		18.4		31.0						
Complement factor H	(1)	mg/l	439	371	SV	186	557	18.3%	0,333	+	
	(1)		347		356						
Complement factor I	(1)	mg/l	31.1	26.1	SV	13.1	39.2	19.2%	0,631	+	
	(1)		84.2		58.4						
Lectin pathway	21	%	38.1	45.2	SV	18.1	72.3	-15.7%	-0,314	+	
	22		6.00								

Analyte	Sam- ple	Your unit	Stated value	Conversion factor	Method	Manu- facturer	Device	Reference range
Alternative pathway	21	%	77.3	1.00	190	ED		30-113
	22		3.40	1.00				
C1 inhibitor: activity	21	%	102	1.00	257	ZY		not determined
	22		69.1	1.00				
C1 inhibitor: proteine	21	mg/l	169	0.001	190	ZY		not determined
	22		93.8	0.001				
C1q proteine	21	mg/l	84.8	0.001	190	ZY		not determined
	22		49.8	0.001				
C3-Complement	21	mg/l	1238	0.001	116	ZY		604-1432
	22		1232	0.001				
C4-Complement	21	mg/l	251	0.001	116	ZY		91-359
	22		250	0.001				
Classical pathway	21	U/ml	34.8	1.00	335	ZY		31.7-50.5
	22		18.4	1.00				
Complement factor H	21	mg/l	439	1.00	190	ZY		285.9-710.7
	22		347	1.00				
Complement factor I	21	mg/l	31.1	1.00	190	ZY		28.8-55.6
	22		84.2	1.00				
Lectin pathway	21	%	38.1	1.00	190	ED		0-125
	22		6.00	1.00				

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

Individual summary of results

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Survey of 03 April 2020

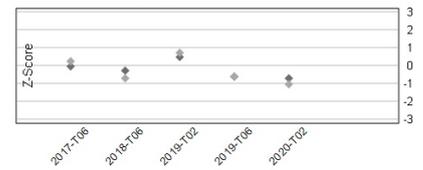
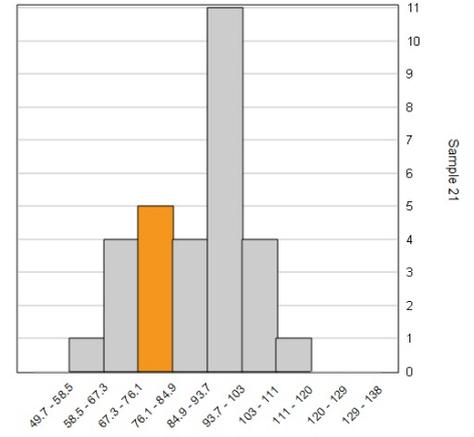
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Complement Analysis 02 (Functions and proteins)

Alternative pathway (% , N = 53)										
Collective	Sample	Target value	Target range		Participants collective			Rate (%)		
					AVG	CV	Num.	Sam.	total	
deviant unit (U / ml)	(1) 21	57.8	23.1	- 92.5	57.8	93.6	3			
	22	30.1	12.0	- 48.2	30.1	96.0	3			
hemolytical test (Gel and other)	21	102	40.8	- 163	102	17.5	16	100	81.3	
	22	59.3	23.7	- 94.9	59.3	38.1	16	81.3		
immunological / Functionaltest (ELISA)	21	89.5	35.8	- 143	89.5	19.7	34	91.2	76.5	
	22		- <25.0		14.0	70.6	34	85.3		

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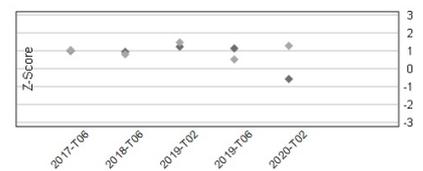
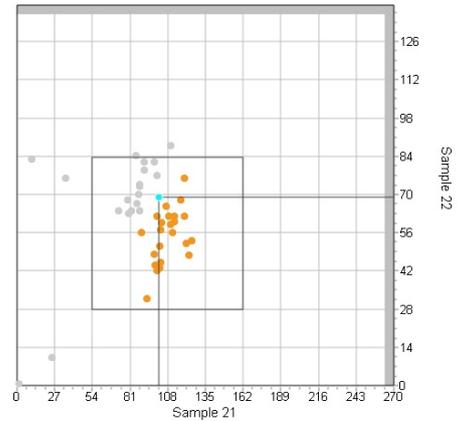
Rate of success: 75,5%



C1 inhibitor: activity (% , N = 44)										
Collective	Sample	Target value	Target range		Participants collective			Rate (%)		
					AVG	CV	Num.	Sam.	total	
chromogenic assays (U / ml)	(1) 21	24.7	12.4	- 37.1	24.7	0.000	1			
	22	10.2	5.10	- 15.3	10.2	0.000	1			
chromogenic assays	21	108	54.0	- 162	108	9.91	24	100	100	
	22	55.7	27.9	- 83.6	55.7	18.3	24	100		
other methods (U / ml)	(1) 21	1.25	0.625	- 1.88	1.25	0.000	1			
	22	0.760	0.380	- 1.14	0.760	0.000	1			
other methods	21	86.9	43.5	- 130	86.9	14.5	18	88.9	88.9	
	22	74.0	37.0	- 111	74.0	12.1	18	100		

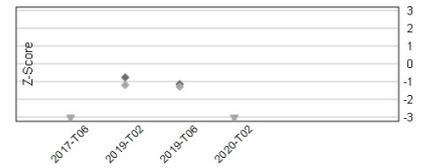
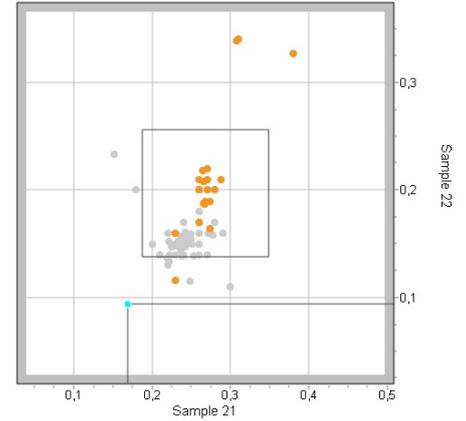
(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 95,5%



C1 inhibitor: proteine (g/l, N = 73)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Nephelometry	21	0.241	0.169 - 0.313	0.241	8.71	49	98.0	91.8	
	22	0.151	0.106 - 0.196	0.151	8.61	49	91.8		
Turbidimetry (and other)	21	0.268	0.188 - 0.348	0.268	5.60	24	91.7	79.2	
	22	0.197	0.138 - 0.256	0.197	15.2	24	79.2		

Rate of success: 87,7%



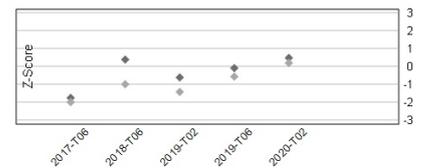
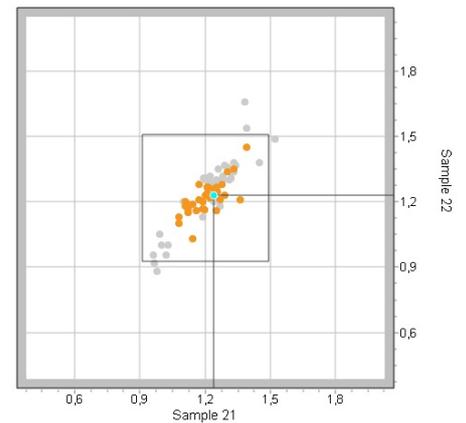
C1q proteine (g/l, N = 38)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Nephelometry	21	0.194	0.097 - 0.291	0.194	29.9	13	92.3	92.3	
	22	0.162	0.081 - 0.243	0.162	25.9	13	100		
immune diffusion	21	0.163	0.082 - 0.245	0.163	22.7	21	95.2	81.0	
	22	0.114	0.057 - 0.171	0.114	40.4	21	85.7		
deviant unit (percent)	(1) 21	34.0	17.0 - 51.0	34.0	0.000	1			
	22	71.0	35.5 - 107	71.0	0.000	1			
other methods	(1) 21		Sample not evaluated			3			
	22		Sample not evaluated			3			

Rate of success: 85,7%

Graphical representation not useful

C3-Complement (g/l, N = 68)									
Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)		
				AVG	CV	Num.	Sam.	total	
Nephelometry - BECKMAN COULTER	21	1.02	0.775 - 1.26	1.02	6.76	8	100	100	
	22	1.03	0.783 - 1.28	1.03	12.0	8	100		
Nephelometry	21	1.28	0.973 - 1.59	1.28	5.78	27	100	92.6	
	22	1.33	1.01 - 1.65	1.33	4.06	27	92.6		
Turbidimetry (and other)	21	1.20	0.912 - 1.49	1.20	6.75	33	100	100	
	22	1.22	0.927 - 1.51	1.22	5.08	33	100		

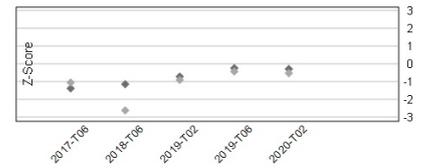
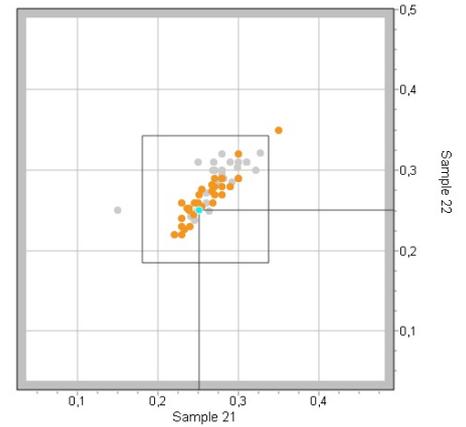
Rate of success: 97,1%



C4-Complement (g/l, N = 67)

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
Nephelometry	21	0.274	0.192 - 0.356	0.274	9.49	34	97.1	97.1
	22	0.286	0.200 - 0.372	0.286	10.5	34	100	
Turbidimetry (and other)	21	0.259	0.181 - 0.337	0.259	10.4	33	97.0	97.0
	22	0.264	0.185 - 0.343	0.264	9.85	33	97.0	

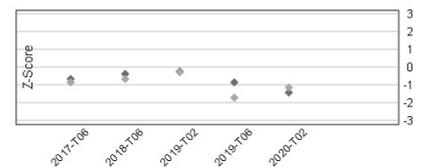
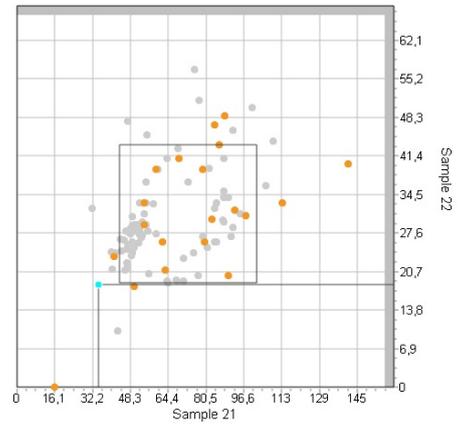
Rate of success: 97%


Classical pathway (% , N = 113)

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
M.333, R.BS (1)	21		Sample not evaluated			5		
	22		Sample not evaluated			5		
BINDING SITE, THE	21	52.9	31.7 - 74.1	52.9	12.6	30	90.0	90.0
	22	30.0	18.0 - 42.0	30.0	17.1	30	90.0	
EURO DIAGNOSTICA	21	81.5	48.9 - 114	81.5	15.6	29	96.6	86.2
	22	28.6	17.2 - 40.0	28.6	28.7	29	89.7	
WAKO	21	49.3	29.6 - 69.0	49.3	12.5	28	96.4	82.1
	22	26.9	16.1 - 37.7	26.9	22.8	28	82.1	
OTHER MANUFACTURERS	21	72.6	43.6 - 102	72.6	36.2	21	76.2	61.9
	22	31.0	18.6 - 43.4	31.0	36.1	21	76.2	

Rate of success: 81,5%

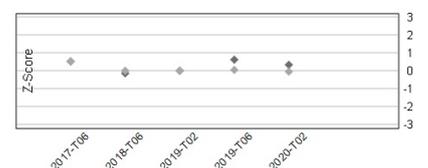
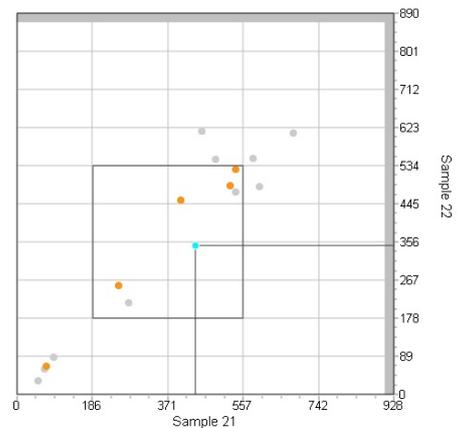
(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.


Complement factor H (mg/l, N = 16)

Collective	Sam-ple	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (percent) (1)	21	79.5	39.8 - 119	79.5	23.1	2		
	22	73.0	36.5 - 110	73.0	28.5	2		
BindingSite	21	476	238 - 714	476	39.3	8	87.5	75.0
	22	457	229 - 686	457	43.3	8	75.0	
other providers (1)	21	371	186 - 557	371	55.0	6		
	22	356	178 - 534	356	55.3	6		

Rate of success: 81,3%

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

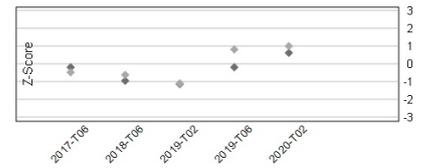
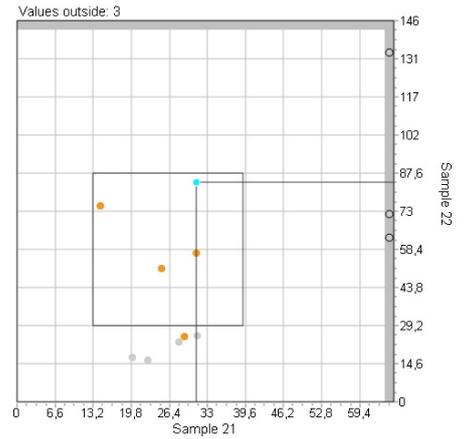


Complement factor I (mg/l, N = 12)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (percent)	(1) 21	96.0	48.0 - 144	96.0	30.1	2		
	22	103	51.5 - 155	103	48.3	2		
BindingSite	(1) 21	31.6	15.8 - 47.4	31.6	51.3	5		
	22	25.8	12.9 - 38.7	25.8	56.2	5		
other providers	(1) 21	26.1	13.1 - 39.2	26.1	30.4	5		
	22	58.4	29.2 - 87.6	58.4	44.7	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: 83,3%


Lectin pathway (% , N = 32)

Collective	Sample	Target value	Target range	Participants collective			Rate (%)	
				AVG	CV	Num.	Sam.	total
deviant unit (ng / ml)	(1) 21		Sample not evaluated			5		
	22		Sample not evaluated			5		
Immunological test (ELISA)	21	45.2	18.1 - 72.3	45.2	50.0	27	74.1	74.1
	22		- <20.0	6.90	49.4	27	92.6	

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

Rate of success: 74,1%

