



Evaluation data

Clinical evaluation of Boditech COVID-19 Ab test

		RT-PCR		Total
		Positive	Negative	
Boditech COVID-19 Ab	Positive	46	0	46
	Indetermined	2	4	6
	negative	0	131	131
Total		48	135	183

Percent positive agreement (%) = 95.8 %

Percent negative agreement (%) = 97.0 %

Overall percent agreement (%) = 96.7%



Evaluation data

PCR confirmed vs suspected (not confirmed) group (Site B)

No.	Sample Type	Clinical info.	PCR	IgM	IgM Result	IgG	IgG Result	Overall result
1	SERUM	COVID-19 Confirmed (PCR) case	POS	4.13	POS	18.12	POS	POS
2	SERUM		POS	3.52	POS	19.95	POS	POS
3	SERUM		POS	2.67	POS	20.00	POS	POS
4	SERUM		POS	1.80	POS	18.70	POS	POS
5	SERUM		POS	4.70	POS	18.20	POS	POS
6	SERUM		POS	3.92	POS	20.68	POS	POS
7	SERUM		POS	3.37	POS	20.68	POS	POS
8	SERUM		POS	2.06	POS	20.13	POS	POS
9	SERUM		POS	3.15	POS	18.87	POS	POS
10	SERUM		POS	2.49	POS	20.29	POS	POS
11	SERUM		POS	0.39	NEG	0.00	NEG	NEG
12	SERUM		POS	1.56	POS	20.77	POS	POS
13	SERUM		POS	1.32	POS	1.32	POS	POS
101	SERUM	Covid-19 suspected but PCR negative (with symptoms)	NEG	0.00	NEG	0.00	NEG	NEG
102	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
103	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
104	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
105	SERUM		NEG	0.06	NEG	0.00	NEG	NEG
106	SERUM		NEG	0.96	IND	0.00	NEG	IND
107	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
108	SERUM		NEG	0.27	NEG	18.50	POS	POS
109	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
110	SERUM		NEG	0.58	NEG	0.00	NEG	NEG
111	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
112	SERUM		NEG	0.00	NEG	0.00	NEG	NEG
113	SERUM		NEG	0.29	NEG	0.00	NEG	NEG
114	SERUM		NEG	0.25	NEG	0.00	NEG	NEG
115	SERUM	NEG	0.00	NEG	0.00	NEG	NEG	

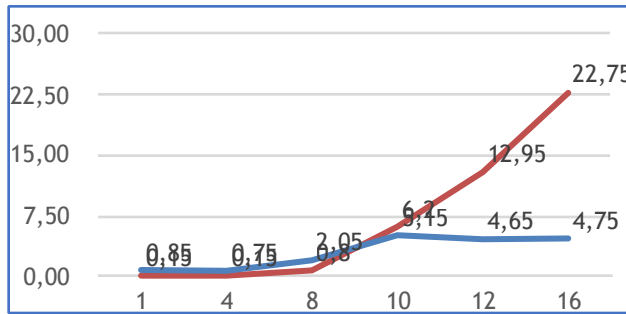
- PCR confirmed group, patients are 3-10 days after onset of symptoms
- Covid-19 suspected but PCR negative group, patients are 7 day with suspected symptoms
- Case No. 108 had typical sever COVID-19 symptoms and tentatively classified as COVID-19 positive



Evaluation data

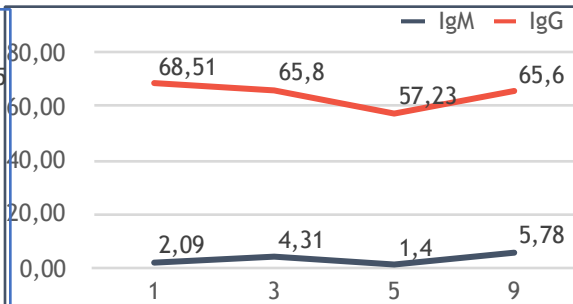
Serology of COVID-19 cases (Site C)

COI



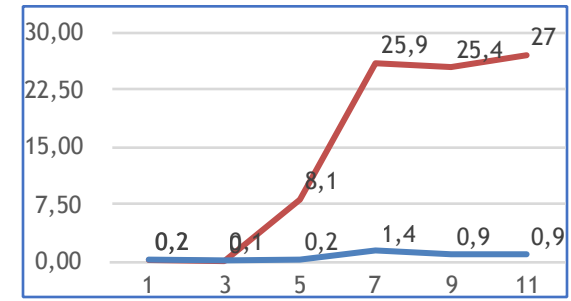
Days after hospitalization

COI

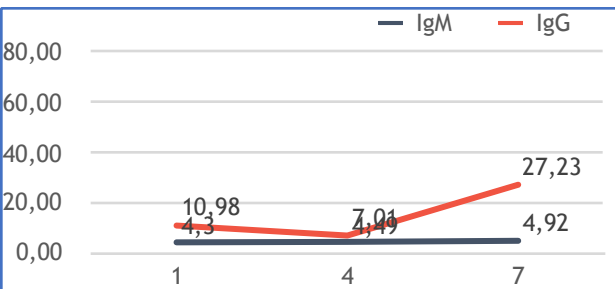


Days after hospitalization

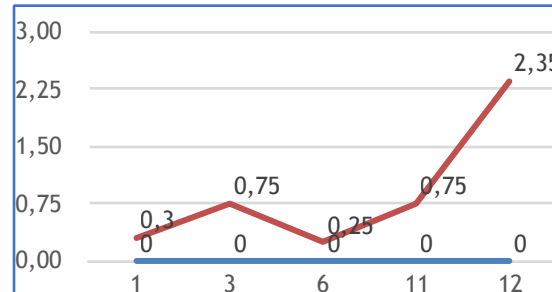
COI



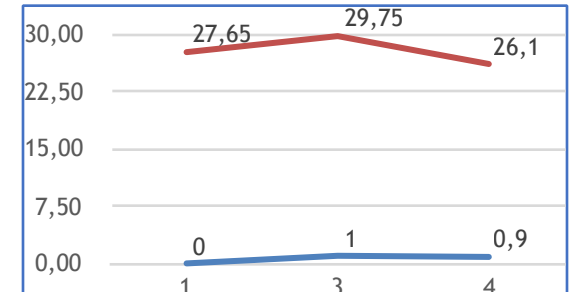
Days after hospitalization



Days after hospitalization



Days after hospitalization



Days after hospitalization



Evaluation data

Common coronavirus cold patient sample test

No.	Sample TYPE	PCR Result*	Boditech COVID-19				
			IgM	IgM Result	IgG	IgG Result	Overall result
1	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
2	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
3	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
4	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
5	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
6	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
7	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
8	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
9	SERUM	CORONA	0.19	NEG	0.00	NEG	NEG
10	SERUM	CORONA	0.14	NEG	0.00	NEG	NEG
11	SERUM	CORONA	0.26	NEG	0.00	NEG	NEG
12	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
13	SERUM	CORONA	0.00	NEG	0.00	NEG	NEG
14	SERUM	COVID-19	0.22	NEG	20.85	POS	Positive
15	SERUM	COVID-19	0.00	NEG	19.95	POS	Positive

* Strain of infected coronavirus is unknown.

→ ***No cross reactivity with common cold coronavirus !***



Conclusion

- Superior Performance
 - Percent positive agreement (%) = 95.8 %
 - Percent negative agreement (%) = 97.0 %
 - Overall percent agreement (%) = 96.7%
- Qualitative result with COI value (relative amount of IgM/IgG)
 - Monitoring of patient with serial test
 - Equal or better than ELISA (not rapid type)
- IgG level in cured patient
 - Test for acquired immunity to COVID-19
 - Plasma therapy purpose

Thank you
for your attention