293836

Methods

ELISAs:

    Architect IgG

    LIAISON IgG

    Wantai Ig and IgM

    EDI IgG ELISA

Rapid test:

    Orient Gene IgG/IgM

Serum panel (N=36)

COVID-19 patients: n=12
    Convalescent sera (>/=7d)
        hospitalized patients (severe)
        ambulant patients (milder)
    Acute symptomatic (<7 d)   Unavailable

Negative controls: n=24
    CoV NL63, HKU1 and RSV positive
    Rheumafactor, EBV and CMV IgM positive
    Sera from 2018

Results: COVID-19 patients

COVID-19 panel	Panel	Days after onset symptoms	Serum timing vs PCR	Architect SARS-CoV-2 IgG Index	IgG	Diasorin LIAISON IgG AU/ml	IgG	Wantai SARS-CoV-2 AbT, IgM Ig (Total)	IgM	EDI Novel Coronavirus COVID-19 IgG, IgM IgG	IgM	Orient Gene sneltest COVID-19 IgG, IgM IgG	IgM
1	SARS-CoV-2 PCR+, hospitalized	23	2d after pos pcr, 1st IC day	7,15	pos		35,1 pos	18,53 / pos	7,06 / pos	4,09 / pos	7,30 / pos	pos	pos
2	SARS-CoV-2 PCR+, hospitalized	21	0d after pos pcr, 1st IC day	5,01	pos		14,4 grens	18,53 / pos	2,40 / pos	3,66 / pos	4,96 / pos	pos	Borderline
3	SARS-CoV-2 PCR+, hospitalized	8	-	1,68	pos	<3,8	neg	8,69 / pos	3,19 / pos	2,96 / pos	2,69 / pos	neg	Borderline
4	SARS-CoV-2 PCR+, hospitalized	16	1d after pos pcr	-	-		19,7 pos	18,53 / pos	11,62 / pos	0,41 / neg	0,55 / neg	pos	Pos
5	SARS-CoV-2 PCR+, hospitalized	7	4d after pos pcr	4,83	pos		17,6 pos	18,53 / pos	11,62 / pos	2,67 / pos	1,84/ pos	pos	Pos
6	SARS-CoV-2 PCR+, hospitalized	14	9d after pos pcr	4,19	pos		26 pos	0,84 / neg	11,62 / pos	3,63 / pos	1,70 / pos	pos	Pos
7	SARS-CoV-2 PCR+, hospitalized	9	2d after pos pcr	0,08	neg	<3,80	neg	3,43 /pos	0,30 / neg	0,19 / neg	0,48 / neg	Borderline	Neg
8	SARS-CoV-2 PCR+, hospitalized	9	1d after pos pcr	0,13	neg	<3,80	neg	7,62 / pos	0,79 / neg	0,97 / grens	0,58 / neg	borderline	Neg
9	SARS-CoV-2 PCR+, hospitalized	10	2d after pos pcr	0,52	neg	<3,80	neg	14,84 / pos	1,85 / pos	1,07 / grens	0,52 / neg	Pos	Borderline
10	SARS-CoV-2 PCR+, ambulant	12	0d after pos pcr	-	-	-	-	Pos	Pos	-	-	Neg	Neg
11	SARS-CoV-2 PCR+, ambulant	7	0d after pos pcr	-	-	-	-	Pos	Pos	-	-	Pos	Pos
12	SARS-CoV-2 PCR+, ambulant	14	0d after pos pcr (onset 14d)	5,17	pos	-	-	pos	pos	-	-	pos	Pos

Results: negative panel

#	Panel	Architect SARS-CoV-2 IgG		Diasorin LIAISON IgG		Wantai SARS-CoV-2 AbT, IgM		EDI Novel Coronavirus COVID-19 IgG, IgM		Orient Gene sneltest COVID-19 IgG, IgM	
		Index	IgG	AU/ml	IgG	Ig (Total)	IgM	IgG	IgM	IgG	IgM
13	NL63 PCR+	0,01	neg	9,92	neg	0,05 /neg	0,02 / neg	0,22 / neg	0,36 / neg	neg	borderline
14	NL63, RV PCR+	0,01	neg	9,58	neg	0,08 / neg	0,02 / neg	0,212 / neg	0,37 / neg	neg	neg
15	HKU1 PCR+	0,01	neg	<3,80	neg	0,03 / neg	0,03 / neg	0,21 / neg	0,33 / neg	neg	neg
16	HKU1 PCR+	0,06	neg	8,15	neg	0,03 / neg	0,02 / neg	0,43 / neg	0,36 / neg	neg	neg
17	RSV PCR+	0,04	neg	7,55	neg	0,03 / neg	0,02 / neg	0,72 / neg	0,38 / neg	neg	neg
18	HKU1 PCR+	0,03	neg	4,4	neg	0,03 / neg	0,02 / neg	0,20 / neg	0,58 / neg	neg	neg
19	Rheumafactor+	-	-	-	-	0,03 / neg	0,02 / neg	0,24 / neg	0,43 / neg	neg	neg
20	Rheumafactor+	-	-	-	-	0,03 / neg	0,02 / neg	0,68 / neg	1,09 / borderline	neg	neg
21	Rheumafactor+	-	-	-	-	0,03 / neg	0,02 / neg	0,48 / neg	0,35 / neg	neg	neg
22	Rheumafactor+	-	-	-	-	0,03 / neg	0,02 / neg	0,28 / neg	0,37 / neg	-	-
23	Rheumafactor+	-	-	-	-	0,03 / neg	0,02 / neg	1,04 / grens	0,45 / neg	-	-
24	EBV IgM+	0,08	neg	6,32	neg	0,03 / neg	0,02 / neg	0,57 / neg	0,40 / neg	neg	neg
25	EBV IgM+	0,03	neg	4,66	neg	0,03 / neg	0,02 / neg	0,46 / neg	0,43 / neg	neg	neg
26	EBV IgM+	0,05	neg	<3,80	neg	0,03 / neg	0,02 / neg	0,57 / neg	0,34 / neg	neg	neg
27	EBV IgM+	0,04	neg	4,18	neg	0,03 / neg	0,02 / neg	0,52 / neg	0,40 / neg	neg	neg
28	EBV IgM+	0,12	neg	4,97	neg	0,03 / neg	0,02 / neg	0,63 / neg	0,38 / neg	neg	neg
29	NC serum uit 2018	0,03	neg	6,35	neg	0,03 / neg	0,02 / neg	0,64 / neg	0,34 / neg	neg	neg
30	NC serum uit 2018	0,06	neg	4,16	neg	0,03 / neg	0,02 / neg	0,52 / neg	0,45 / neg	neg	neg
31	NC serum uit 2018	0,06	neg	24,2	pos	0,03 / neg	0,02 / neg	0,67 / neg	0,45 / neg	neg	neg
32	NC serum uit 2018	0,06	neg	5,1	neg	0,03 / neg	0,02 / neg	0,92 / borderline	0,34 / neg	-	-
33	NC serum uit 2018	0,04	neg	610	neg	0,03 / neg	0,02 / neg	0,69 / neg	0,37 / neg	-	-
34	NC serum uit 2018	0,03	neg	<3,80	neg	0,03 / neg	0,02 / neg	0,36 / neg	0,41 / neg	-	-
35	NC serum uit 2018	0,03	neg	<3,80	neg	0,03 / neg	0,02 / neg	0,66 / neg	0,36 / neg	-	-
36	NC serum uit 2018	0,03	neg	4,82	neg	0,03 / neg	0,02 / neg	0,43 / neg	0,39 / neg	-	-

Sensitivity, specificity

N=36		Architect IgG	LIAISON IgG	Wantai Ig	Wantai IgM	EDI IgG	EDI IgM	Orient Gene IgG	Orient Gene IgM
Overall sensitivity N=12		6/9 (67%)	4/9 + 1 borderline (44%-56%)	11/12 (92%)	10/12 (83%)	5/9+2borderline (56-78%)	5/9 (56%)	8/12+2borderline (67-83%)	6/12+3borderline (50-75%)
Sensitivity hospitalized patients N=9	Overall (onset 7-23d)	5/8 (63%)	4/9 + 1 borderline (44%-56%)	8/9 (89%)	7/9 (78%)	5/9+2borderline (56-78%)	5/9 (56%)	6/9+2borderline (67-89%)	4/9+3borderline (44-78%)
	>14d	3/3 (100%)	¾ +1 borderline (75-100%)	¾ (75%)	4/4 (100%)	¾ (75%)	¾ (75%)	4/4 100%	¾+1 borderline (75-100%)
Sensitivity ambulant patients N=3	>=7d	1/1 (100%)	-	3/3 (100%)	3/3 (100%)	-	-	2/3 (67%)	2/3 (67%)
Specificity N=24		19/19 (100%)	18/19 (95%)	24/24 (100%)	24/24 (100%)	22/24 (92%)	23/24 (96%)	17/17 (100%)	16/17 (94%)

Conclusions and discussion

These data will be combined with the (Architect IgG) data from other laboratories (UMCG, ATAL-medial) to increase the numbers of sera tested. In particular additional data on the performance in the subcategories of patients in the earlier stages of the disease are needed.

When looking at the overall performance of the assays tested with in the current LUMC panel (this panel will be extended over time), the Wantai and Architect SARS-CoV-2 assays seem to have a combination of both higher sensitivity and specificity when compared to the other assays included