Supplementary data

Revised JCM

Evaluating ten commercially-available SARS-CoV-2 rapid serological tests using the STARD (Standards for Reporting of Diagnostic Accuracy Studies) method.

Supplemental figures: 4
Supplemental tables: 3

Supplemental Figures

Figure S1. Index (panel A) and results of negative, weak positive, medium/high positive, and undetermined tests.

A

Rating index	Reading intensity scale
0	Not reactive
1	Very weak, but definitely reactive
2	Medium to high reactivity
U	Undetermined

B

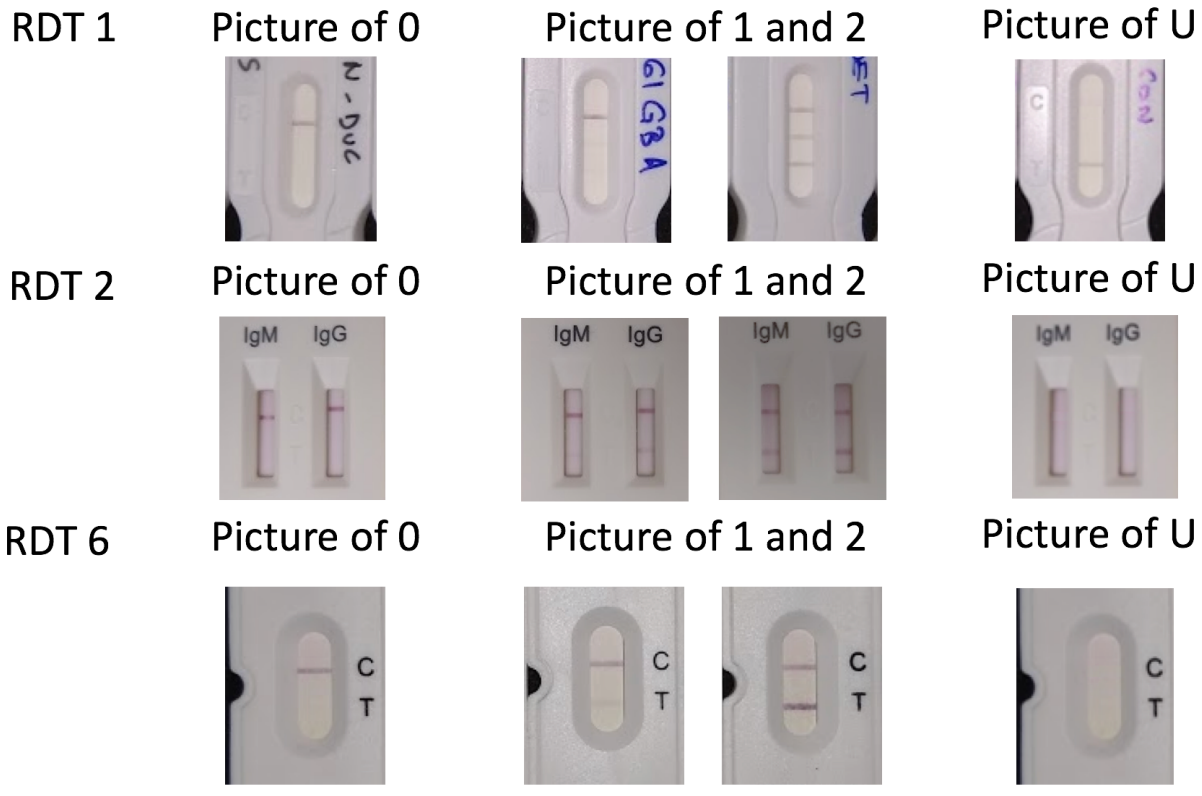


Figure S2. Assessment of cumulative positivity stratified by the number days after symptom appearance.

Day after onset of symptoms	1	2	3	4	5	6	...	N
Patient 1	n	n	n	n	**N**			
Patient 2	**N**							
Patient 3					**P**	p	p	p
Patient 4	n	n	**N**				**P**	p
Patient 5	**N**	n	n	**N**		**P**	p	p
Patient 6	**P**	p	p	p	p	p	p	p

Cumulative number of negative results	4	3	3	2	1	0	0	0
Cumulative number of positive results	1	1	1	1	2	3	4	4
Cumulative % of positivity	**20**	**25**	**25**	**33,33**	**66,67**	**100**	**100**	**100**

P Sample tested positive

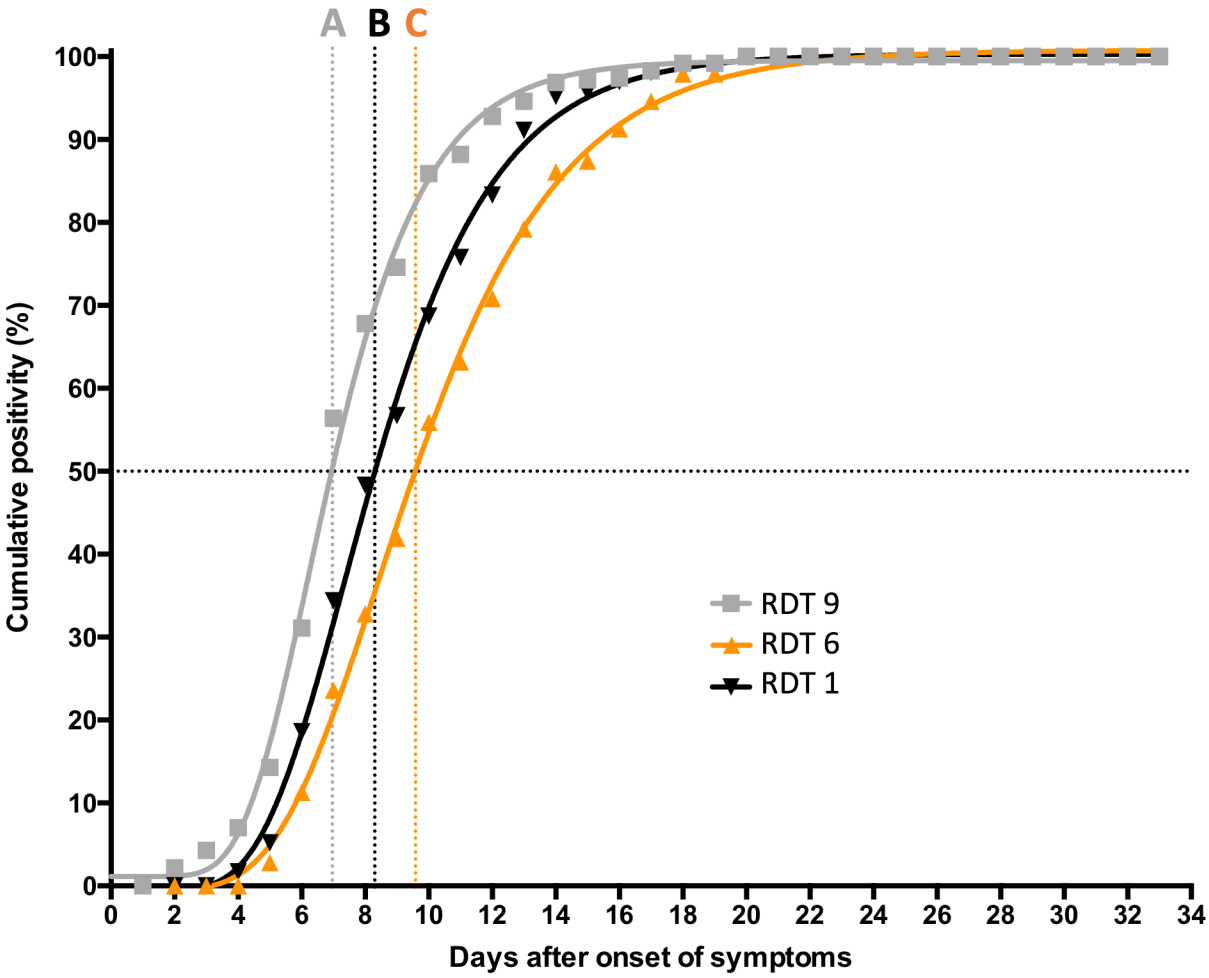
N Sample tested negative

p Sample interpreted as positive

n Sample interpreted as negative

Only one serum was available (and tested) for patients 1, 2, 3 and 6
Two sera were available (and tested) for patients 4
Three sera were available (and tested) for patients 5

Figure S3. Best fit asymmetric curve for RDT 1, RDT 6 and RDT 9 test cumulative positivity.

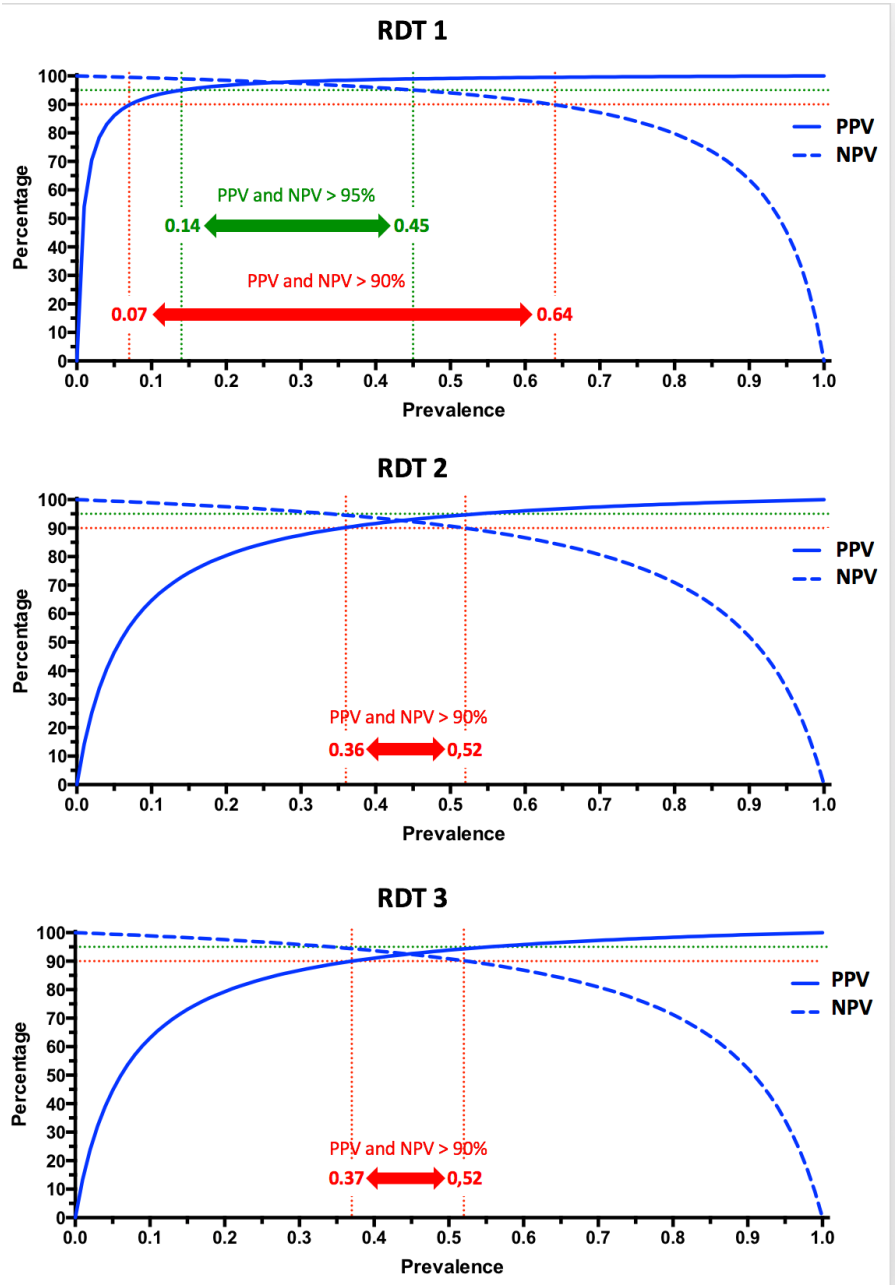


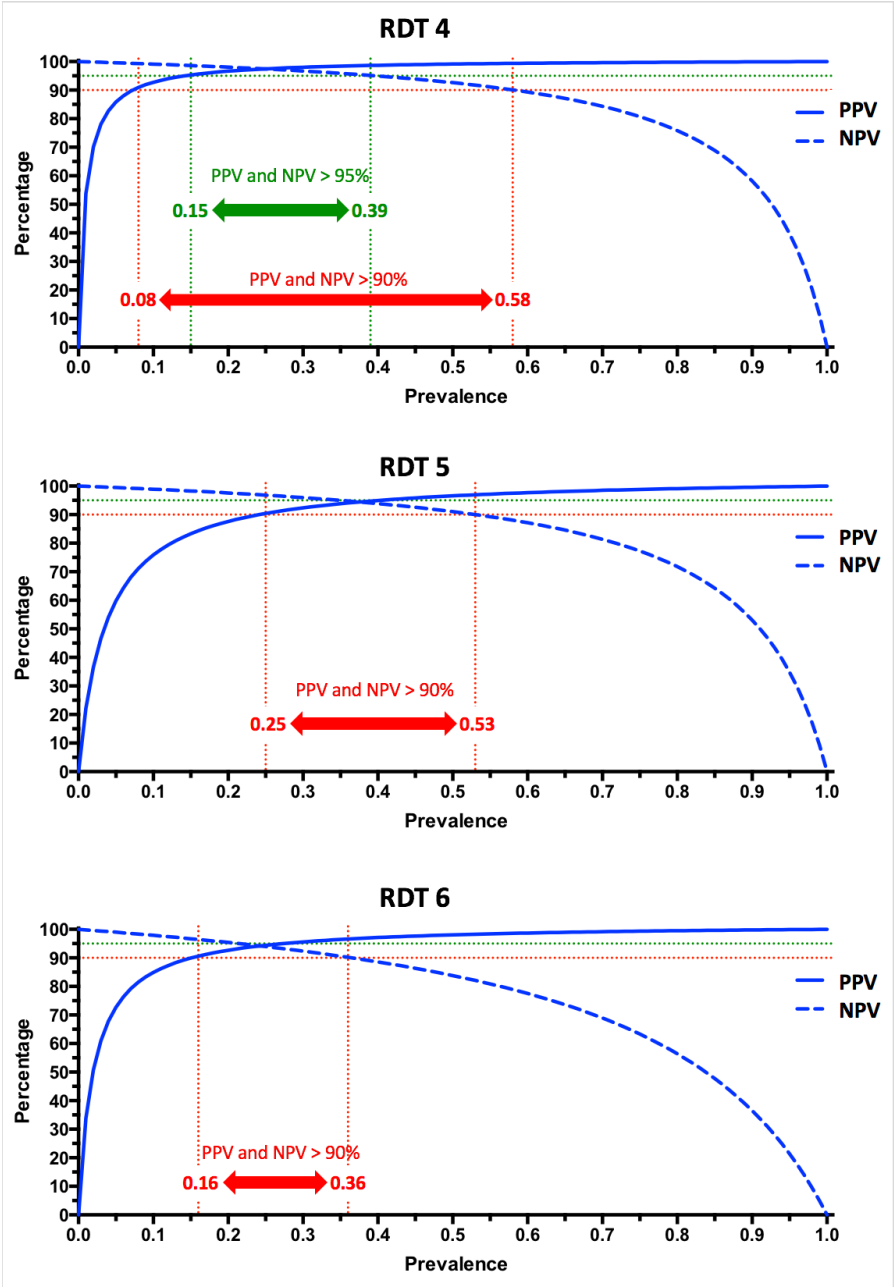
A = 6.962 (CI95%: 6.837 – 7.087)

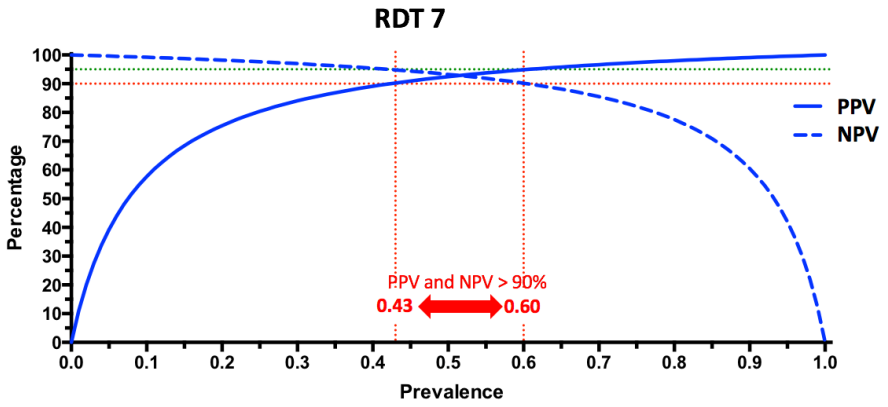
B = 8.297 (CI95%: 8.185 – 8.409)

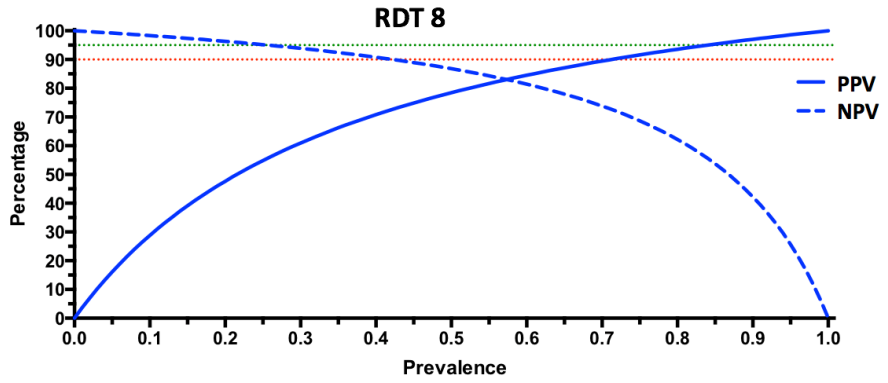
C = 9.579 (CI95%: 9.437 – 9.722)

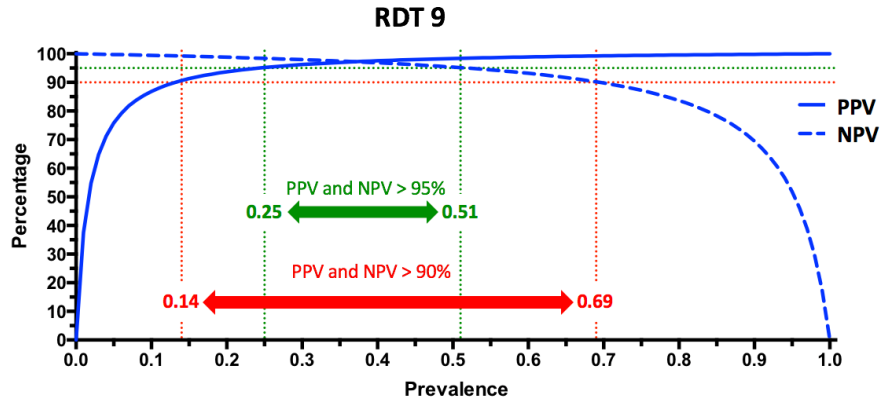
Figure S4. Influence of population prevalence of seropositivity on assay performance. Scenarios with increasing population prevalence (x-axis) are shown for each RDT. PPV (Positive Predictive value) and NPV (Negative predictive value) expressed in percentage (y axis) have been calculated using VassarStats (http://vassarstats.net/). Zones for which both PPV and NPV are above 90% (red zone) or above 95% (green zone) are indicated.




RDT 4
Percentage
Prevalence
PPV
NPV
PPV and NPV > 95%
0.15
0.39
PPV and NPV > 90%
0.08
0.58
RDT 5
Percentage
Prevalence
PPV
NPV
PPV and NPV > 90%
0.25
0.53
RDT 6
Percentage
Prevalence
PPV
NPV
PPV and NPV > 90%
0.16
0.36


RDT 7
Percentage
Prevalence
PPV
NPV
PPV and NPV > 90%
0.43
0.60


RDT 8
Percentage
Prevalence
PPV
NPV


RDT 9
Percentage
Prevalence
PPV
NPV
PPV and NPV > 95%
0.25
0.51
PPV and NPV > 90%
0.14
0.69

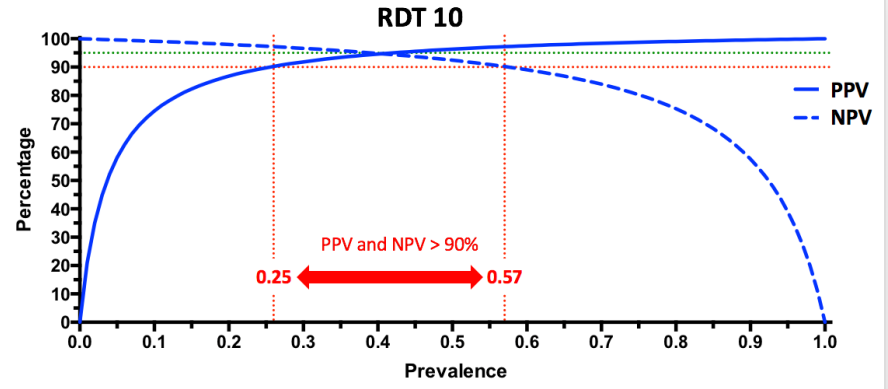

RDT 10
Percentage
Prevalence
PPV
NPV
PPV and NPV > 90%
0.25
0.57

Table S1: Immunoassay kit and manufacturer information

	RDT 1	RDT 2	RDT 3	RDT 4	RDT 5	RDT 6	RDT 7	RDT 8	RDT 9	RDT 10
Name	**NG-Test IgG-IgM COVID-19**	**Anti-SARS-CoV-2 Rapid test**	**Novel Coronavirus (2019-nCoV) Antibody IgG/IgM Assay Kit**	**NADAL COVID-19 IgG/IgM Test**	**Biosynex COVID-19 BSS**	**2019-nCoV Ab Test**	**2019-nCoV IgG/IgM**	**COVID-19-CHECK-1**	**Finecare SARS-CoV-2 Antibody Test**	**Wondfo SARS-CoV-2 Antibody Test**
Manufacturer	**NG Biotech SA, Guipry, France**	**Autobio Diagnostics Co, Ltd, Zhengshou, China**	**Avioq Bio-tech Co, Ltd, Shandong, China**	**Nal Von Minden Co, Ltd, Moers, Germany**	**Biosynex SWISS SA, Fribourg, Switzerland**	**Innovita (Tangshan) Biological Technology Co, Ltd, Hebei, China**	**Biolidics Co, Ltd, Mapex, Singapore**	**Vedal Lab SA, Alençon, France**	**Wondfo Biotech Co, Ltd, Guangzhou, China**	**Wondfo Biotech Co, Ltd, Guangzhou, China**
Catalogue No./manufacturer Ref	NGB-COV-W23-002	RTA0202	------	COV20030034	SW40005	------	CBB-F015016-B1	200081-4-2-3L	W276	W195
Lot number tested	200414-01	21C22-J01	20200201	243001	COV20040003	20200402	V5020032352	23040-46	F27614309AD	
Product description										
Antibody detection	IgG-IgM	IgG-IgM	IgG-IgM	IgG-IgM	IgG-IgM	IgG-IgM	IgG-IgM	IgG-IgM	Total Ab	IgG/IgM 1 test,1 line
Antigens *	NP, SP	------	------	------	------	NP, SP	------	------	------	------
Detection conjugate	Coloidal gold	Coloidal gold	Coloidal gold	Coloidal gold	Coloidal gold	Coloidal gold	Coloidal gold	Coloidal gold	Fluorescent conjugate	Coloidal gold
Type of reading	Visual	Visual	Visual	Visual	Visual	Visual	Visual	Visual	UV automatic reader	Visual
Format	cassette with single lane and different band for IgG and IgM	cassette with separate lane for IgG and IgM	cassette with single lane and different band for IgG and IgM	cassette with single lane and different band for IgG and IgM	cassette with single lane and different band for IgG and IgM	cassette with separate lane and different band for IgG and IgM	cassette with single lane and different band for IgG and IgM	cassette with single lane and different band for IgG and IgM	cassette with single lane and single band for both IgG and IgM	cassette with single lane and single band for both IgG and IgM
Specifications										
Sample type	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma	WB/Serum/Plasma
Sample volume	10µL	5µL	10µL	5µL (S, P), 10µL (WB)	10µL	10µL	20µL	10 µL	10µL	10 µL
Pipette for sample volume provided	Not provided but system integrated to device for direct transfer for Capillary WB	Not provided	transfert system, lancet	Not provided	Plastic disposable pipettes	Not provided	Not provided	Not provided	pipette tips and tubes of detection buffer	Not provided
Diluent volume	2 drops	60µL	2 drops (50-70µL)	2 drops	2 drops (80 µL)	2 drops (80 µL)	3 drops	3 drops (100 µL)	------	2-3 drops
Diluant bottle format	1.5 mL	4,5 mL	4.5 mL	3 mL	------	5 mL	5 mL	3 mL	25 tubes of detection buffer	
Time to result	15 min	15-20 min	15 min	15 min	20 min	15 min	10 min	10-15 min	10 min	15 min
Limit Of Detection	------	------	------	3,4 ng/mL (IgG), 210 ng/mL (IgM)	------	------	------	------	------	------
Interference reported	None reported	None reported	None reported	None reported	SARS-CoV Ab, Rheumatoid Factors, MERS-CoV Ab	None reported	------	None reported	None reported	None reported
Cross -reactivity reported on IFU	None reported	None reported	None reported	None reported	None	None	------	None reported	None reported	None reported
Shelf-life (months)	24 m	12 m	18 m	24 m	24 m	18 m	24 m	12 m	12 m	12 m
Storage temperature (°C)	2-30°C	2-30°C	4-30°C	2-30°C	2-30°C	4-30°C	4-30°C	2-30°C	4-30°C	4-30°C
Package size	5 test/ box	20 test/box	20 test/box	10 test/bags	25 test/box	40 test/box	50 test/box	20 test/box	25 test/box	20 test/box
Controls	Internal control line	Internal control line	Internal control line	Internal control line	Internal control line	Internal control line	Internal control line	Internal control line	Internal control line	Internal control line
Performance notes	------	Some band smearing	------	------	------	Some band smearing	------	------	------	------
Regulatory approval										
IVD Certification	CE-IVD	CE IVD, Chinese FDA-EUA,	CE IVD, Chinese FDA-EUA,	CE-IVD	CE-IVD	CE IVD, Chinese FDA-EUA,	CE-IVD	CE-IVD	CE, Chinese FDA-EUA, Taiwan FDA	CE, Chinese FDA-EUA, Taiwan FDA
Pictures of the Kit content										
Kit Acquisition for study	Provided by supplier Free of charge	Purchased from supplier	Provided by supplier Free of charge	Purchased from supplier	Purchased from supplier	Purchased from supplier	Purchased from supplier	Purchased from supplier	Provided by supplier Free of charge	Provided by supplier Free of charge

Table S2. Detail results obtained with the 254 sera of COVID negative patients

Tests	Rheumatoid factor		Hyper IgG		Hyper IgM		Sera with TPHA +		Other coronavirus		Other			Malaria		Total		
	TN[a]	FP	TN	FP	TN	FP	TN	FP	TN	FP	TN	FP	NI	TN	FP	n	TN	FP
RDT 1	3	0	6	0	3	0	94	1G[b]	11	0	128	1MG	0	5	0	252	250	2
RDT 2	3	0	6	0	3	0	89	5M + 2G + 1MG	11	0	122	3M + 2G +1MG	1	5	0	254	239	14
RDT 3	0	2M +1MG	5	0	2	1MG	86	2M + 1G + 1MG	10	1MG	121	2G + 2MG	0	ND	ND	238	224	14
RDT 4	3	0	6	0	3	0	97	0	11	0	127	2G	0	5	0	254	252	2
RDT 5	3	0	5	0	3	0	92	1M + 1G	10	0	124	2M + 3G	0	4	1M	249	241	8
RDT 6	3	0	6	0	2	1G	95	1M	10	1G	129	0	0	4	1MG	253	249	4
RDT 7*	3	0	5	0	2	1G	12	2M	10	1G	41	2G	0	ND	ND	79	73	6
RDT 8	3	0	4	1G	1	2G	72	10M + 4G + 6MG	8	2G	95	24M + 6G + 4MG	0	4	1M	247	187	60
RDT 9	3	0	6	0	2	1T	96	1T	11	0	127	2	0	2	0	251	247	4
RDT 10	3	0	5	1T	2	1T	94	3T	10	1T	126	3	0	5	0	254	245	9

[a] TN, True negative ; FP, False positive; NI, Not interpretable; ND, Not determined
[b] M = IgM, G = IgG, MG = IgM + IgG, T= Total Ig
*Only part (79/254) of the collection was tested due to a limited number of tests received

Table S3. Usability of the ten RDTs

RDTs	1	2	3	4	5	6	7	8	9	10
Clarity of instruction for user										
Manufacturer instructions	Very clear	Very clear	Clear	Very clear	Very clear	Very Clear	Clear	Very Clear	Clear	Clear
Presence of pictures, schemas	methods and results	methods and results	methods and results	methods and result	methods and results	methods and results	results only	results only	none	methods only
Technical complexity										
Technical complexity	Very easy	Easy	Very easy	Very easy	Very easy	Very easy	Very easy	Very easy	Easy	Very easy
Number of steps	3	3	3	3	3	3	3	3	3	3
Exact measurements or volumes for specimens	No (Drop)	Yes (µl)	No (Drop)	Yes (µl)	Yes (µl)	Yes (µl)	No (Drop)	Yes (µl)	Yes (µl)	Yes (µl)
All equipment present in the kit to use test	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No
Easy to identify the well to deposit the sample	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Easy to identify the well to deposit buffer	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Results interpretation										
Easiness of results interpretation	Very easy	Very easy	Very easy	Very easy	Very easy	Difficult	Very easy	Very easy	Very easy	Very easy
Reading type	Visual	Visual	Visual	Visual	Visual	Visual	Visual	Visual	Visual	Visual
Time to results (min)	<15	< 15	<15	<15	<15	<15	<15	<15	<15	15-20
Packaging, legal information										
T° storage conditions available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Product reference available	Yes	Yes	No	Yes	Ye	No	Yes	Yes	Yes	Yes
Single sealed package	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pouch dessicant	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes