

Clinical Study Report of Linkcare Bioscreening COVID-19 IgM/IgG Seroscreening Kit

Performed by the laboratory of the Servei Andorrà de Salut

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Participants:

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Introduction

Linkcare Bioscreening COVID-19 IgM/IgG seroscreening kit is a lateral flow chromatographic immunoassay for the qualitative determination of SARS-CoV-2's IgM and IgG antibodies in human whole blood (from vein or fingertip), serum or plasma. For professional in vitro diagnostic use only.

The test devices contain:

- Conjugate pad: recombinant SARS-CoV-2 antigen labeled with colloidal gold which linked FITC, FITC antibody and quality control antibody gold marker.
- NC membrane: coated with two detection lines (IgG line and IgM line) and one quality control line (C line).
The IgM line coated with mouse anti-human IgM monoclonal antibody detects the SARS-CoV-2 IgM antibody.
The IgG line coated with mouse anti-human IgG monoclonal antibody detects the SARS- CoV-2 IgG antibody.
The C line coated with quality control antibody.

Goals

Stablish the clinical performance of Linkcare Bioscreening COVID-19 IgM/IgG Rapid Test with 187 clinical samples SARS-CoV-2 TMA validated test from Hospital Nostra Senyora de Meritxell.

Method

Instruments and Materials

Test: Linkcare Bioscreening SARS-CoV-2 IgM/IgG seroscreening kit manufactured by Nantong Egens Biotechnology Co., Ltd.

Samples

Total 187 serum samples were used in this comparison study. All the samples have been tested by SARS-CoV-2 RT-PCR and CT, and the concentration distribution of result is as follows.

SARS-CoV-2 clinical sample (by RT-PCT&CT)	Quantity
Negative (samples from 2019)	68
Positive (infection time 1 week)	38
Positive (infection time 2 weeks)	20
Positive (infection time 3 weeks)	26
Positive (infection time >3 weeks)	35
TOTAL	187

Table 1: Concentration distribution of SARS-CoV-2 clinical specimen tested by RT-PCR&CT

Procedure

- Take out the test kit and leave it at room temperature for 30 at least minutes.
- Remove the test cassette from the foil pouch.
- Place the cassette on a clean and level surface.
- Apply 10µL of whole blood/serum/plasma onto the sample well of the test device with a pipette, then add 2 drops of buffer (approximately 80 µL) and start the timer.

- Read the result after 10 minutes.
- Two observers read the results in doubtful cases.

Interpretation of Test Results

Positive result:

- The SARS-CoV-2 IgM antibody is detected if the quality control line C and the detection line IgM are both colored, and the detection IgG line is not colored, that means the SARS-CoV-2 IgM antibody is positive.
- The SARS-CoV-2 IgG antibody is detected if the quality control line C and the detection IgG line are both colored, and the detection IgM line is not colored, that means the SARS-CoV-2 IgG antibody is positive.
- The SARS-CoV-2 IgG and IgM antibodies are detected if the quality control line C, the detection line IgM and IgG are both colored, that means both the SARS-CoV-2 IgG and IgM antibodies are positive.

Negative result:

There is only a quality control line C is colored, IgG and IgM detection lines are not colored, the SARS-CoV-2 IgM/IgG antibody is not detected, meaning the result is negative.

Invalid result:

The quality control line C is not colored, no matter whether the detection line IgG/IgM is colored or not, the result is invalid and needs to be tested again.

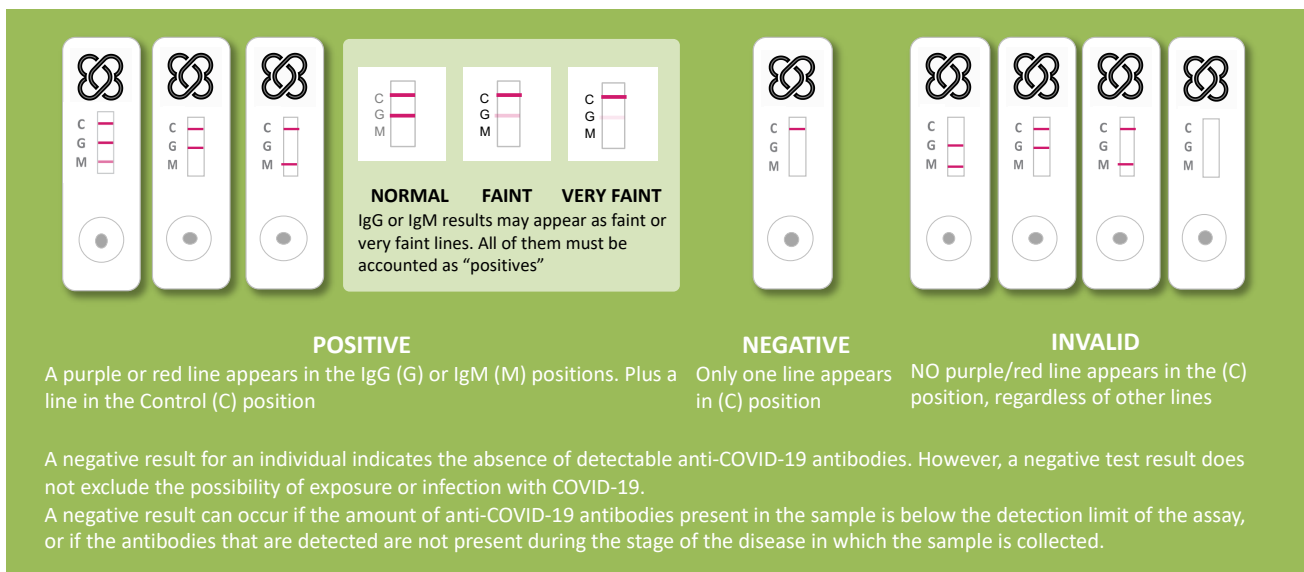


Figure 1: Reading each assay result

Results and Conclusions

Combined results

Combined Specificity: 99%

Combined Sensitivity: 96%

Accuracy (after 1st week): 99%

Combined after 1st week	n	Antibody (G i/o M)			
		NEGATIVE	POSITIVE	IgG/IgM	IC 95%
TOTAL	149				
POSITIVE SAMPLES (RT-PCR)	81	1	80	99%	97-100 % SENSITIVITY
NEGATIVE (2019)	68	65	3	96%	92-99 % SPECIFICITY
VPN	98%				
VPP	96%				

Including also first week disease samples:

Combined including 1st week	n	Antibody (G i/o M)			
		NEGATIVE	POSITIVE	IgG/IgM	IC 95%
TOTAL	187				
POSITIVE SAMPLES (RT-PCR)	119	15	104	87%	83-92 % SENSITIVITY
NEGATIVE (2019)	68	65	3	96%	93-99 % SPECIFICITY
VPN	81%				
VPP	97%				

Detailed results (After first week)

Detailed after 1st week	n	NEGATIVE				POSITIU			
		IgG-	IgM-	IgG+	IgM+	IgG	IC 95%	IgM	IC 95%
TOTAL	149								
PCR POSITIVA	81	3	13	78	68	96%	93-99 %	84%	78-90 % SENSIB
NEGATIUS (2019)	68	66	66	2	2	97%	94-100 %	97%	94-100 % SPECIF
VPN	96%		84%						
VPP			98%		97%				

Breakdown by disease onset week

Clinical performance of negative sample			
Negative Cases (blood samples 2019)	Negative coincidence rate (SARS-CoV-2 IgM)	Negative coincidence rate (SARS-CoV-2 IgG)	Negative coincidence rate (Total)
68	66 (97%)	66 (97%)	66 (97%)

Clinical performance of positive sample (1 st week)			
Positive Cases (By PCR)	Positive coincidence rate (SARS-CoV-2 IgM)	Positive coincidence rate (SARS-CoV-2 IgG)	Positive coincidence rate (Total)
38	20 (53%)	20 (53%)	20 (53%)

Clinical performance of positive sample (2 nd week)			
Positive Cases (By PCR)	Positive coincidence rate (SARS-CoV-2 IgM)	Positive coincidence rate (SARS-CoV-2 IgG)	Positive coincidence rate (Total)
20	17 (85%)	20 (100%)	20 (100%)

Clinical performance of positive sample (3 rd week)			
Positive Cases (By PCR)	Positive coincidence rate (SARS-CoV-2 IgM)	Positive coincidence rate (SARS-CoV-2 IgG)	Positive coincidence rate (Total)
26	22 (85%)	25 (96%)	25 (96%)

Clinical performance of positive sample (>3 rd week)			
Positive Cases (By PCR)	Positive coincidence rate (SARS-CoV-2 IgM)	Positive coincidence rate (SARS-CoV-2 IgG)	Positive coincidence rate (Total)
35	29 (83%)	33 (94%)	33 (94%)

Clinical performance of all positive samples			
Positive Cases (By PCR)	Positive coincidence rate (SARS-CoV-2 IgM)	Positive coincidence rate (SARS-CoV-2 IgG)	Positive coincidence rate (Total)
119	86 (72%)	98 (82%)	98 (82%)

Testing data

nom Omega	G	M	COMBI	PCR	Interval	COVID
1953104	N	N	N	-	-	NEGATIVE
1953224	N	N	N	-	-	NEGATIVE
1964585	N	N	N	-	-	NEGATIVE
1964586	N	N	N	-	-	NEGATIVE
1965012	N	P	P	-	-	NEGATIVE
1975944	N	N	N	-	-	NEGATIVE
1975945	N	N	N	-	-	NEGATIVE
1975951	N	N	N	-	-	NEGATIVE
1975952	N	N	N	-	-	NEGATIVE

nom Omega	G	M	COMBI	PCR	Interval	COVID
1975953	N	N	N	-	-	NEGATIVE
1975954	N	N	N	-	-	NEGATIVE
1975955	N	N	N	-	-	NEGATIVE
1975956	N	N	N	-	-	NEGATIVE
1975957	N	N	N	-	-	NEGATIVE
1975963	N	N	N	-	-	NEGATIVE
1975965	N	N	N	-	-	NEGATIVE
1978711	N	N	N	-	-	NEGATIVE
1978739	N	N	N	-	-	NEGATIVE
1978745	N	N	N	-	-	NEGATIVE
1981363	N	N	N	-	-	NEGATIVE
1981365	N	N	N	-	-	NEGATIVE
1981377	N	N	N	-	-	NEGATIVE
1984085	N	N	N	-	-	NEGATIVE
1984096	N	N	N	-	-	NEGATIVE
1984097	N	N	N	-	-	NEGATIVE
1984125	N	N	N	-	-	NEGATIVE
1984129	N	N	N	-	-	NEGATIVE
1984131	N	N	N	-	-	NEGATIVE
1984133	P	P	P	-	-	NEGATIVE
1984134	N	N	N	-	-	NEGATIVE
1984336	N	N	N	-	-	NEGATIVE
1984337	N	N	N	-	-	NEGATIVE
1984749	N	N	N	-	-	NEGATIVE
1984760	N	N	N	-	-	NEGATIVE
1984778	N	N	N	-	-	NEGATIVE
1984779	N	N	N	-	-	NEGATIVE
1984780	N	N	N	-	-	NEGATIVE
1984782	N	N	N	-	-	NEGATIVE
1984783	N	N	N	-	-	NEGATIVE
1984784	N	N	N	-	-	NEGATIVE
1984785	N	N	N	-	-	NEGATIVE
1984787	N	N	N	-	-	NEGATIVE
1984789	N	N	N	-	-	NEGATIVE
1984791	N	N	N	-	-	NEGATIVE
1984796	N	N	N	-	-	NEGATIVE
1984799	N	N	N	-	-	NEGATIVE

nom Omega	G	M	COMBI	PCR	Interval	COVID
1984800	N	N	N	-	-	NEGATIVE
1984803	N	N	N	-	-	NEGATIVE
1984806	N	N	N	-	-	NEGATIVE
1984812	N	N	N	-	-	NEGATIVE
1984814	N	N	N	-	-	NEGATIVE
1984815	N	N	N	-	-	NEGATIVE
1984817	N	N	N	-	-	NEGATIVE
1984820	N	N	N	-	-	NEGATIVE
1984821	N	N	N	-	-	NEGATIVE
1984827	N	N	N	-	-	NEGATIVE
1984828	N	N	N	-	-	NEGATIVE
1984830	N	N	N	-	-	NEGATIVE
1984831	N	N	N	-	-	NEGATIVE
1984834	N	N	N	-	-	NEGATIVE
1984835	N	N	N	-	-	NEGATIVE
1984836	N	N	N	-	-	NEGATIVE
1984838	N	N	N	-	-	NEGATIVE
1984840	N	N	N	-	-	NEGATIVE
1986021	N	N	N	-	-	NEGATIVE
1986159	N	N	N	-	-	NEGATIVE
1986166	P	N	P	-	-	NEGATIVE
1987306	N	N	N	-	-	NEGATIVE
1938020	P	P	P	P	2nd week	POSITIVE
1938027	P	P	P	P	After 3rd week	POSITIVE
1938044	P	P	P	P	After 3rd week	POSITIVE
1938056	P	P	P	P	After 3rd week	POSITIVE
1938188	N	N	N	P	1st week	POSITIVE
1969099	P	N	P	P	1st week	POSITIVE
1969100	P	N	P	P	2nd week	POSITIVE
1969221	P	P	P	P	2nd week	POSITIVE
2006260	P	P	P	P	After 3rd week	POSITIVE
2008705	P	P	P	P	2nd week	POSITIVE
2031003	P	P	P	P	1st week	POSITIVE
2031005	P	P	P	P	1st week	POSITIVE
2031021	P	P	P	P	1st week	POSITIVE
2031022	P	N	P	P	2nd week	POSITIVE
2032034	P	P	P	P	2nd week	POSITIVE

nom Omega	G	M	COMBI	PCR	Interval	COVID
2032041	P	P	P	P	2nd week	POSITIVE
2032053	P	P	P	P	3rd week	POSITIVE
2032060	P	P	P	P	After 3rd week	POSITIVE
2032061	P	P	P	P	After 3rd week	POSITIVE
2032071	N	N	N	P	1st week	POSITIVE
2032096	P	P	P	P	3rd week	POSITIVE
2032124	P	P	P	P	3rd week	POSITIVE
2032135	P	P	P	P	2nd week	POSITIVE
2032138	P	P	P	P	2nd week	POSITIVE
2032148	P	P	P	P	2nd week	POSITIVE
2032195	P	N	P	P	After 3rd week	POSITIVE
2032208	P	N	P	P	After 3rd week	POSITIVE
2032299	P	P	P	P	After 3rd week	POSITIVE
2032301	P	N	P	P	After 3rd week	POSITIVE
2032317	P	P	P	P	3rd week	POSITIVE
2032331	P	P	P	P	2nd week	POSITIVE
2032336	P	P	P	P	3rd week	POSITIVE
2032337	P	P	P	P	3rd week	POSITIVE
2032338	P	P	P	P	3rd week	POSITIVE
2032350	P	N	P	P	3rd week	POSITIVE
2032441	N	N	N	P	1st week	POSITIVE
2032446	N	N	N	P	1st week	POSITIVE
2032499	N	N	N	P	1st week	POSITIVE
2032522	N	N	N	P	1st week	POSITIVE
2032526	P	P	P	P	1st week	POSITIVE
2032534	N	N	N	P	1st week	POSITIVE
2032535	P	P	P	P	2nd week	POSITIVE
2032538	P	P	P	P	1st week	POSITIVE
2032551	P	P	P	P	1st week	POSITIVE
2032566	P	P	P	P	2nd week	POSITIVE
2032577	P	P	P	P	2nd week	POSITIVE
2032587	P	N	P	P	1st week	POSITIVE
2032589	P	P	P	P	2nd week	POSITIVE
2032687	P	N	P	P	2nd week	POSITIVE
2034579	P	P	P	P	After 3rd week	POSITIVE
2035629	P	P	P	P	After 3rd week	POSITIVE
2038040	P	P	P	P	1st week	POSITIVE

nom Omega	G	M	COMBI	PCR	Interval	COVID
2038044	N	N	N	P	1st week	POSITIVE
2038059	P	P	P	P	1st week	POSITIVE
2038071	N	N	N	P	1st week	POSITIVE
2038077	N	N	N	P	1st week	POSITIVE
2038090	P	P	P	P	2nd week	POSITIVE
2038151	P	P	P	P	1st week	POSITIVE
2038155	N	N	N	P	1st week	POSITIVE
2038157	N	P	P	P	1st week	POSITIVE
2038164	P	P	P	P	3rd week	POSITIVE
2038196	P	P	P	P	After 3rd week	POSITIVE
2038204	P	P	P	P	3rd week	POSITIVE
2038209	N	N	N	P	1st week	POSITIVE
2038235	P	P	P	P	3rd week	POSITIVE
2038262	P	P	P	P	3rd week	POSITIVE
2038266	P	P	P	P	3rd week	POSITIVE
2038283	P	N	P	P	After 3rd week	POSITIVE
2038290	P	P	P	P	After 3rd week	POSITIVE
2038293	P	P	P	P	After 3rd week	POSITIVE
2038319	P	P	P	P	3rd week	POSITIVE
2038321	P	N	P	P	After 3rd week	POSITIVE
2038363	P	N	P	P	1st week	POSITIVE
2039231	P	P	P	P	1st week	POSITIVE
2039946	P	N	P	P	1st week	POSITIVE
2039964	P	N	P	P	1st week	POSITIVE
2040770	P	N	P	P	After 3rd week	POSITIVE
2040791	P	P	P	P	After 3rd week	POSITIVE
2040866	P	P	P	P	After 3rd week	POSITIVE
2041091	N	N	N	P	1st week	POSITIVE
2041103	N	N	N	P	1st week	POSITIVE
2041105	P	P	P	P	1st week	POSITIVE
2041134	P	P	P	P	1st week	POSITIVE
2041166	P	P	P	P	1st week	POSITIVE
2041178	P	P	P	P	2nd week	POSITIVE
2041185	P	P	P	P	2nd week	POSITIVE
2041226	P	P	P	P	3rd week	POSITIVE
2041238	P	P	P	P	3rd week	POSITIVE
2042559	N	P	P	P	1st week	POSITIVE

nom Omega	G	M	COMBI	PCR	Interval	COVID
2042561	N	P	P	P	1st week	POSITIVE
2042591	P	N	P	P	1st week	POSITIVE
2042652	P	P	P	P	2nd week	POSITIVE
2042688	N	P	P	P	1st week	POSITIVE
2042824	N	P	P	P	After 3rd week	POSITIVE
2043203	P	P	P	P	After 3rd week	POSITIVE
2044508	P	P	P	P	After 3rd week	POSITIVE
2044517	P	P	P	P	3rd week	POSITIVE
2044519	P	P	P	P	3rd week	POSITIVE
2044683	P	P	P	P	After 3rd week	POSITIVE
2044711	P	P	P	P	After 3rd week	POSITIVE
2044714	P	P	P	P	After 3rd week	POSITIVE
2044722	P	P	P	P	After 3rd week	POSITIVE
2044727	P	P	P	P	3rd week	POSITIVE
2044811	P	P	P	P	After 3rd week	POSITIVE
2044834	P	P	P	P	After 3rd week	POSITIVE
2044879	P	P	P	P	3rd week	POSITIVE
2044904	P	P	P	P	After 3rd week	POSITIVE
2044907	P	P	P	P	After 3rd week	POSITIVE
2044918	P	P	P	P	After 3rd week	POSITIVE
2044927	P	P	P	P	After 3rd week	POSITIVE
2044928	P	P	P	P	1st week	POSITIVE
2044945	P	N	P	P	3rd week	POSITIVE
2044970	P	P	P	P	3rd week	POSITIVE
2044973	N	N	N	P	3rd week	POSITIVE
2044980	P	N	P	P	3rd week	POSITIVE
2044987	N	P	P	P	After 3rd week	POSITIVE
2045278	P	P	P	P	3rd week	POSITIVE
2045777	P	P	P	P	3rd week	POSITIVE
2048488	P	P	P	P	After 3rd week	POSITIVE