Evaluation of ROCHE Anti-SARS-CoV-2 ECLIA and comparison with 4 other assays

Edith Sepulchre[1]*, Violeta Stojkovic[1], Henry Paridaens[1], Jean-Marc Senterre[1], Jean-Marc Minon[1]

[1]Department of Laboratory Medicine, CHR Citadelle, Liège, Belgium

Corresponding author: Edith Sepulchre, edith.sepulchre@gmail.com

Objective :

During the current COVID-19 pandemic context, a reliable serological test would be a seductive tool for epidemiologic monitoring. We compared different assays for SARS-CoV-2 antibodies detection on a restricted cohort of patients. We then evaluated the selected method.

Material and method :

In a first time, we compared five serological assays: Euroimmun ELISA (IgG/A), Vircell ELISA (IgG/A+M), DiaSorin CLIA (IgG), Roche ECLIA (total Ig) and Menarini immunochromatographic assay (IgG/M).

In a second time, we evaluated Roche assay's performance on a larger cohort.

Characteristics announced by Roche	
Antigenic target	Nucleocapsid
Positivity COI	>1.0
Sensitivity	100%
Specificity	99.8%
PPV	96.5%
NPV	100%
Antigenic target	Nucleocapsid

PPV: Positive predictive value for a prevalence of 5%. NPV: *Positive predictive value for a prevalence of 5% (1).*

Results :

Fifteen samples from 10 patients were tested with the 5 serological methods. Roche ECLIA appeared as the most effective assay.

Patient	Diagnosis	Onset of symptoms (days)	PCR SARS-CoV-2	Euroimmun IGG	Euroimmun IGA	Menarini IgG	Menarini IgM	DiaSorin IgG	Vircell IgG	Vircell IgA+M	Roche IgG+M
1	SARS-CoV-2	J-5	+	-	+	-	-	-	-	+	+
2	SARS-CoV-2	J-7	+	-	-	-	-	-	+	-	-
2	SARS-CoV-2	J-12	+	+	+	+w	1+	-	+	+	+
2	SARS-CoV-2	J-49	+	+	-	2+	+w	Equiv	+	Equiv	+
3	SARS-CoV-2	NA	ND[1]	-	+	1+	+w	-	Equiv	+	+
3	SARS-CoV-2	NA	ND[1]	+	+	2+	+w	-	+	+	+
4	No infection	NA	-	-	+	-	-	-	+	+	-
4	No infection	NA	-	-	+	-	-	-	+	-	-
4	No infection	NA	-	-	Equiv	-	-	-	+	-	-
5	Other human coronavirus	ND	-	-	-	-	-	-	-	-	-
6	EBV (IgM+G)	ND	-	-	-	-	-	-	-	+	-
7	CMV	ND	-	-	-	-	-	-	-	+	-
8	Mycopasma Pneumoniae	ND	-	-	+	-	-	-	-	-	-
9	Influenza A/B	ND	-	-	-	-	-	-	+	Equiv	-
10	EBV (IgM+G)	ND	-	-	+	-	-	-	-	+	-

Table 1 - Comparison of 5 different serological assays for SARS-CoV-2 antibodies detection

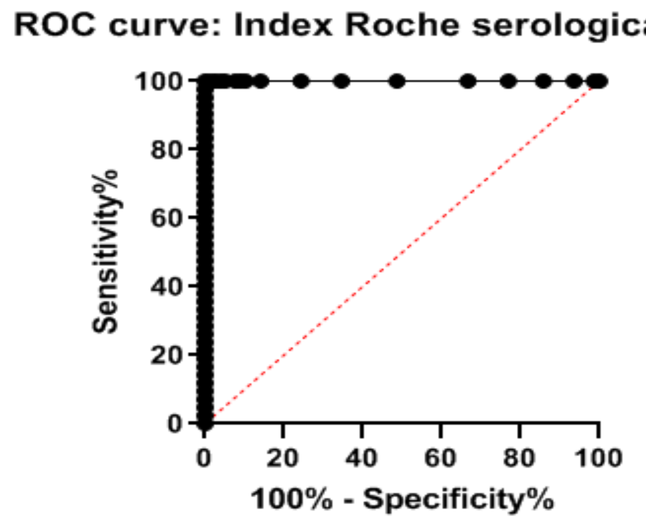
One hundred twenty patients with previous RT-PCR results available were tested with Roche serological assay between 1st march and 29 may 2020.

Among patients with negative serology (COI < 1.0), only one had a previously positive RT-PCR (low viral load, ct=30). He had a serological index value of 0.9, and was finally considered as infected with SARS-CoV2 agent regarding the entire cohort index distribution and clinical informations.

	Positive serology (n=41)	Negative serology (n=79)
Positive PCR (n; %)	26; 63	1; 1
Index (median)	43.3	0.07
Index (IQR)	16.1 – 95.5	0.07 – 0.07

Table 2 – Comparison between Roche Elecsys anti-SARS CoV-2 serology and RT-PCR

A receiver operating characteristics (ROC) curve was established and confirmed the nice performance of this serological test. On basis of our results, a new local COI > 0.54 would enable a specificity and sensitivity of 100%.



AUC	1.0
95% CI	1.0 to 1.0
P value	<0.0001

Figure 1 - ROC curve analysis of Roche serological assay for SARS-CoV-2 antibodies detection

Index values of positive serologies were evaluated according to the time period between positive RT-PCR and serology. In case of multiple RT-PCR for the same patients, the earliest positive result was considered.

Range (weeks)	Index (mean)	Index (median)
<3 w	47.45	19.49
3-9 w	52.31	42.36
>9 w	76.27	85.43

Table 3 – Repartition of positive serologies index values according to the time period between positive RT-PCR and serology.

Anti-SARS-CoV-2 antibodies were detected as soon as 7 days after a positive RT-PCR in some patients, with the highest index values corresponding to a delay period above 9 weeks. The greatest time period was 10 weeks.

Conclusion :

Roche ECLIA assay was validated as an effective tool for serological diagnosis of previous COVID-19 infection. Fast and costless, it could constitute a particularly interesting tool in case of equivocal results, e.g. typical clinical course with negative or absent RT-PCR and for epidemiological monitoring of a wide population group.

Antibodies against COVID-19 agent were detected as soon as 7 days after a positive RT-PCR, and were still detected until 10 weeks. Reduction of antibodies levels and seronegativity after 2 to 3 months have been described in the literature (2), but was not observed in our study due to the short time period.

Optimal timing for serology testing and a local COI remain to be determined on a larger cohort.

References:

1. Interim Guidelines for COVID-19 Antibody Testing. Available at: www.fda.gov
2. Appendix 8: Cases with positive COVID-19 Serology Results and Management of Cases with Multisysystem inflammatory Syndrome in Children (MIS-C) Temporally Associated with COVID-19. Available at: www.health.gov.on.ca