20-LB-1262-AACC

Comparison of the clinical performance of two serological tests for SARS-CoV-2: Rapid test vs Chemiluminescence – Chilean local experience

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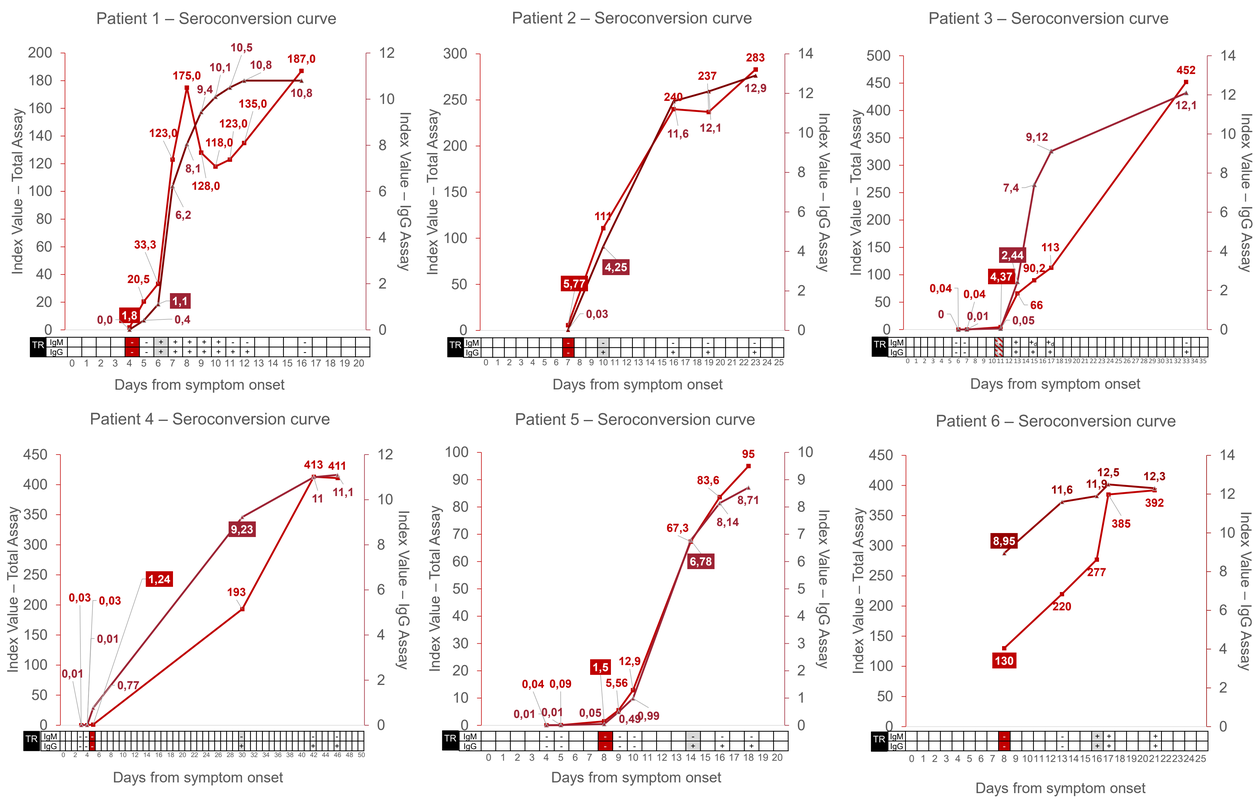
Introduction

The COVID-19 pandemic has been challenging for healthcare institutions across the globe. One key challenge is the accurate diagnosis of the disease. Although Molecular/PCR testing is the gold standard for detection of SARS-CoV-2 in patients, it is not always readily available for public and private clinical laboratories. Beyond access limitations, RT-PCR detection of SARS-CoV-2 from nasal/oropharyngeal swabs and or bronchoalveolar lavage have shown high rates of false negatives[1]. In this scenario antibody detection plays a crucial role in confirming exposure to SARS-CoV-2 and for understanding the timing of immune response. The aim of this study was to show how testing technology impacts clinical characterization of COVID-19 patients admitted in Clinica Redsalud Vitacura.

Materials & Methods

A total of 8 admitted patients to the ICU department at Clinica Redsalud Vitacura were studied and characterized in depth, after a positive diagnosis for SARS-CoV-2 using RT-PCR testing. Since admission, serum samples were taken for serology testing to assess immune response progression at different days from symptoms onset. A total of 51 samples for serology screening for SARS-CoV-2 were obtained and initial testing was performed using HIGHTOP SARS-CoV-2 (COVID-19) IgM/IgG Ab, a lateral flow-based Rapid Test (Hightop Biotech), using whole blood sample tubes. After processing, samples were centrifuged and obtained serums were stored at 4°C. The serum samples were tested using VITROS® Anti-SARS-CoV-2 Total and VITROS® Anti-SARS-CoV-2 IgG assays. We compared results from the rapid tests and VITROS assays for each patient.



This study was supported by Ortho Clinical Diagnostics. PR-10503

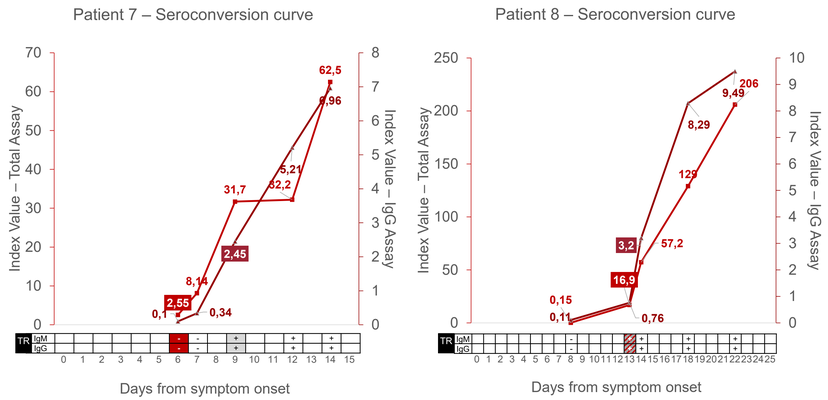


Figure 1. Patient seroconversion profile. : VITROS® Anti-SARS-CoV-2 Total : VITROS® Anti-SARS-CoV-2 IgG – TR: Rapid Test Result / d: weak reaction : 1st Positive sample TR : 1st Positive sample VITROS® Anti-SARS-CoV-2 Total assay : 1st Positive sample VITROS® Anti-SARS-CoV-2 IgG assay (Cut-off value VITROS® assays: ≥1.00)

Results

100% clinical sensitivity was observed at > 8 days from symptom onset with the VITROS antibody assays. At days 15 to 20, we still observed increasing amounts of antibodies, as per index values for total and IgG isotypes, but at a lower rate (Total: 12.8±5.8; IgG: 0.8±0.6), compared to initial days from symptoms onset (Total: 13.8±11.5; IgG: 0.4±0.3) (Figure 1). The VITROS Anti-SARS-CoV-2 Total assay showed earlier detection compared to the rapid tests (Table 1). Once antibodies were detected with the VITROS assays, subsequent draws remained reactive for antibodies for all patients. After detecting antibodies in serial draws for one patient, the rapid test showed a negative result in the last sample drawn 10 days after the first confirmed antibody positive draw (IgG and IgM were both negative).

		Sample 1 (T0)	Sample 2 (T1)	Sample 3 (T2)	Sample 4 (T3)	Sample 5 (T4)	Sample 6 (T5)	Sample 7 (T6)	Sample 8 (T7)	Sample 9 (T8)	Sample 10 (T9)
Patient 1	Rapid test	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (-) IgM	(-) IgG / (-) IgM	(-) IgG / (-) IgM
	VITROS® Anti SARS CoV 2 Total	- (1.76)	- (20.5)	+ (33.3)	+ (123)	+ (175)	+ (128)	+ (118)	+ (123)	+ (135)	+ (187)
	VITROS® Anti SARS CoV 2 IgG	- (0.01)	- (0.41)	+ (1.11)	+ (6.23)	+ (8.05)	+ (9.44)	+ (10.1)	+ (10.5)	+ (10.8)	+ (10.8)
Patient 2	Rapid test	(-) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM					
	VITROS® Anti SARS CoV 2 Total	+ (5.77)	+ (111)	+ (240)	+ (237)	+ (283)					
	VITROS® Anti SARS CoV 2 IgG	- (0.03)	+ (4.25)	+ (11.6)	+ (12.1)	+ (12.9)					
Patient 3	Rapid test	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM weak) IgM	(+) IgG / (+) IgM weak) IgM	(+) IgG / (-) IgM			
	VITROS® Anti SARS CoV 2 Total	- (0.04)	- (0.04)	+ (4.37)	+ (66.0)	+ (90.2)	+ (113)	+ (452)			
	VITROS® Anti SARS CoV 2 IgG	- (0.00)	- (0.01)	- (0.05)	+ (2.44)	+ (7.40)	+ (9.12)	+ (12.1)			
Patient 4	Rapid test	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM				
	VITROS® Anti SARS CoV 2 Total	- (0.03)	- (0.03)	+ (1.24)	+ (193)	+ (413)	+ (411)				
	VITROS® Anti SARS CoV 2 IgG	- (0.01)	- (0.01)	- (0.77)	+ (9.23)	+ (11.0)	+ (11.1)				

		Sample 1 (T0)	Sample 2 (T1)	Sample 3 (T2)	Sample 4 (T3)	Sample 5 (T4)	Sample 6 (T5)	Sample 7 (T6)	Sample 8 (T7)	Sample 9 (T8)	Sample 10 (T9)
Patient 5	Rapid test	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM	(+) IgG / (-) IgM		
	VITROS® Anti SARS CoV 2 Total	- (0.04)	- (0.09)	+ (1.50)	+ (5.56)	+ (12.9)	+ (67.3)	+ (83.6)	+ (95.0)		
	VITROS® Anti SARS CoV 2 IgG	- (0.01)	- (0.01)	- (0.05)	- (0.49)	- (0.99)	+ (6.78)	+ (8.14)	+ (8.71)		
Patient 6	Rapid test	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM					
	VITROS® Anti SARS CoV 2 Total	+ (130)	+ (220)	+ (277)	+ (385)	+ (392)					
	VITROS® Anti SARS CoV 2 IgG	+ (8.95)	+ (11.6)	+ (11.9)	+ (12.5)	+ (12.3)					
Patient 7	Rapid test	(-) IgG / (-) IgM	(-) IgG / (-) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM					
	VITROS® Anti SARS CoV 2 Total	+ (2.55)	+ (8.14)	+ (31.7)	+ (32.2)	+ (62.5)					
	VITROS® Anti SARS CoV 2 IgG	- (0.1)	- (0.34)	+ (2.45)	+ (5.21)	+ (6.96)					
Patient 8	Rapid test	(-) IgG / (-) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM	(+) IgG / (+) IgM					
	VITROS® Anti SARS CoV 2 Total	- (0.15)	+ (16.9)	+ (57.2)	+ (129)	+ (206)					
	VITROS® Anti SARS CoV 2 IgG	- (0.11)	- (0.76)	+ (3.2)	+ (8.29)	+ (9.49)					

Table 1. Comparison of immunity detection profiles using VITROS® SARS-CoV-2 Antibody assays and Rapid test

Conclusion

VITROS® COVID-19 antibody assays have shown usefulness to detect immune response with better performance compared to a rapid test. VITROS® Anti-SARS-CoV-2 Total assay which detects IgA, IgM and IgG antibodies, can detect immune response earlier and could be used to better assess immune response for patients having COVID-19. We were able to detect positive serology as early as 4 days from symptom onset (DSO) for one patient, versus 6 DSO for the rapid test. This study provides further evidence on Chemiluminescent technology, providing trusted results with better performance overall, compared to lateral flow technology when assessing immune response for SARS-CoV-2.

1. Lei, Q, Li, Y, Hou, H-Y, et al. Antibody dynamics to SARS-CoV-2 in asymptomatic COVID-19 infections. Allergy. 2020; 00: 1– 11.