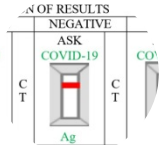


ASK COVID-19 Antibody Rapid Test

Publication by National Taiwan University Hospital (NTUH) :

Four Point-of-Care Lateral Flow Immunoassays for Diagnosis of COVID-19 , J Infect. 2020 Sep;81(3):435-442

Manufacture in Taiwan:
TONYAR BIOTECH. INC.



TFDAEUA No.1096813284

TFDA EUA

	Day 0-7		Day 8-21		After Day 21	
	COVID-19 specimens (n = 61)	Control specimens (n = 194)	COVID-19 specimens (n = 134)	Control specimens (n = 194)	COVID-19 specimens (n = 151)	Control specimens (n = 194)
Roche Elecsys® Anti-SARS-CoV-2 Assay						
Sensitivity, % (95% CI)	39.3 (28.1-51.9)		73.9 (65.9-80.6)		97.4 (93.4-99.0)	
Specificity, % (95% CI)	99.0 (96.3-99.7)		99.0 (96.3-99.7)		99.0 (96.3-99.7)	
Abbott SARS-CoV-2 IgG Assay						
Sensitivity, % (95% CI)	26.2 (16.8-38.4)		75.4 (67.4-81.9)		94.0 (89.1-96.8)	
Specificity, % (95% CI)	97.9 (94.8-99.2)		97.9 (94.8-99.2)		97.9 (94.8-99.2)	
Wondfo SARS-CoV-2 Antibody Test						
Sensitivity, % (95% CI)	39.3 (28.1-51.9)		78.4 (70.7-84.5)		91.4 (85.8-94.9)	
Specificity, % (95% CI)	100.0 (98.1-100.0)		100.0 (98.1-100.0)		100.0 (98.1-100.0)	
ASK COVID-19 IgG/IgM Rapid Test						
Sensitivity, % (95% CI)	39.3 (28.1-51.9)		77.6 (69.8-83.8)		97.4 (93.4-99.0)	
Specificity, % (95% CI)	100.0 (98.1-100.0)		100.0 (98.1-100.0)		100.0 (98.1-100.0)	
Dynamiker 2019-nCoV IgG/IgM Rapid Test						
Sensitivity, % (95% CI)	29.5 (19.6-41.9)		67.2 (58.8-74.5)		90.1 (84.3-94.0)	
Specificity, % (95% CI)	100.0 (98.1-100.0)		100.0 (98.1-100.0)		100.0 (98.1-100.0)	

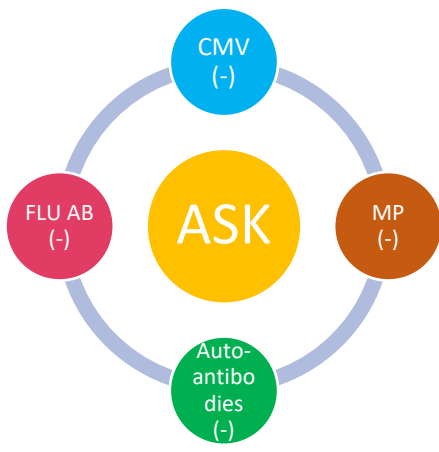
Sensitivity: 97.4%

ASK > D21

Specificity: 100.0 %

ASK > D21

Cohort	No. of specimens tested	No. of specimens with positive results				
		Roche Elecsys® Anti-SARS-CoV-2 Assay	Abbott SARS-CoV-2 IgG Assay	Wondfo SARS-CoV-2 Antibody Test	ASK COVID-19 IgG/IgM Rapid Test	Dynamiker 2019-nCoV IgG/IgM Rapid Test
Total no. of specimens tested	194	2	4	0	0	0
For patients treated between January 31 and May 31, 2020						
Patients with ARI and negative qRT-PCR results on 2 tests, without other confirmed etiologies for ARI	70	0	0	0	0	0
Patients with ARI and negative qRT-PCR results on 2 tests showing the presence of specific etiologies (respiratory tract [antigens] or serum [antibodies])	50	2	2	0	0	0
Coronavirus OC43	2	0	0	0	0	0
Coronavirus 229E	1	0	0	0	0	0
CMV IgG/IgM	7	1 (1.56)	0	0	0	0
CMV IgG/IgM and HSV-IgM	1	0	0	0	0	0
CMV IgG	11	1 (1.42)	1 (1.98)	0	0	0
CMV IgM and HSV-IgM	1	0	0	0	0	0
CMV IgM and HSV-IgM and EBV VCA-IgM	1	0	1 (1.61)	0	0	0
HSV-IgM	1	0	0	0	0	0
EBV VCA-IgM	5	0	0	0	0	0
Mycoplasma pneumoniae IgM	5	0	0	0	0	0
Chlamydia trachomatis IgG	5	0	0	0	0	0
Respiratory syncytial virus (positive antigen test)	2	0	0	0	0	0
Influenza A virus (positive rapid antigen test)	4	0	0	0	0	0
Influenza B virus (positive rapid antigen test)	4	0	0	0	0	0
Patients showing the presence of any specific auto-antibodies	36	0	1 (2.17)	0	0	0



Reference : Multicenter Evaluation of two Chemiluminescence and three Lateral Flow Immunoassays for the diagnosis of COVID-19 and assessment of antibody dynamic responses to SARS-CoV-2 (Manuscript submitted)

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