

COVID-19

Antigen Rapid Test (Saliva Test)

Faster! Simpler! Less Invasive!
Double the Testing Capacity of Laboratory!



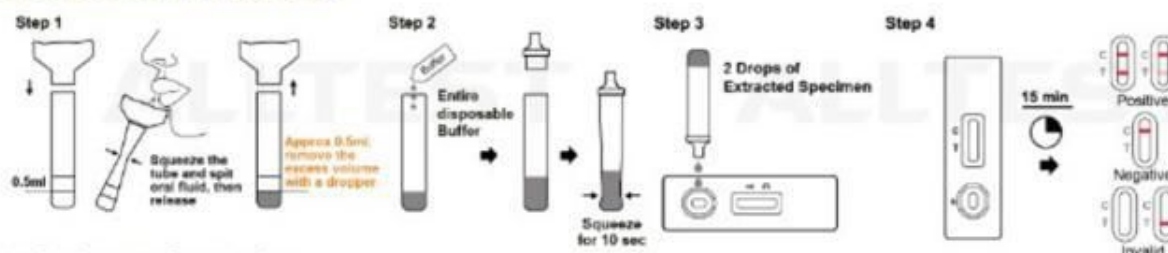
* Research shows that the SARS-CoV-2 virus is stable in oral fluid for long periods of time at warm temperatures. COVID-19 Antigen Rapid Test (Oral Fluid) is a screening test for the qualitative detection of SARS-CoV-2 antigens in oral fluid specimens from individuals with suspected SARS-CoV-2 infection.



A Comparison of COVID-19 Antigen Rapid Test (Oral Fluid) and Nucleic Acid Test

Items	COVID-19 Antigen Rapid Test	RT-qPCR
Application	COVID-19 Screening	COVID-19 Screening and Diagnosis
Detection	SARS-CoV-2 Antigen in Oral Fluid	SARS-CoV-2 Nucleic Acid in nasopharyngeal (NP) swab, oropharyngeal (OP) swab and sputum, etc.
Testing Time	15 minutes	1-3 hours
Suitability for Field Use/ Small Labs	Suitable for field use and for resource-poor setting	Complex with trained technicians and highly temperature sensitive test kits, making field use difficult.
Need for Well-equipped laboratory	Can be performed by minimally trained health professionals	Needs well-equipped laboratory including testing equipment as well as high end refrigerator capable of storing certain items.
Result Interpretation	Simple Visual Interpretation	Complex machine-read results
Advantage in detection	1. Faster 2. Simpler specimen collection 3. Less training required	Higher sensitivity and accuracy

Convenient Procedure



Ordering Information

Cat.No.	Product	Format	Specimen	Pack	CE Status
ICOV-802	COVID-19 Antigen Rapid Test	Cassette	Oral Fluid	20T	CE

**HOSPITAL SUNGAI BULOH
SELANGOR**

Performance of ALLTEST COVID-19 Antigen Rapid Test (Oral Fluid)

Intended Use

The COVID-19 Antigen Rapid Test (Oral Fluid) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in oral fluid specimens from individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.

Manufacturer

Hangzhou AllTest Biotech Co., Ltd.

#550, Yin Hai Street, Hangzhou Economic & Technological Development Area, Hangzhou, Zhejiang, 310018, P.R. China.

Test Principle

The COVID-19 Antigen Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human oral fluid specimen. SARS-CoV-2 nucleocapsid protein antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 nucleocapsid protein antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 nucleocapsid protein antibody in the test line region. If the specimen contains SARS-CoV-2 Antigens, a coloured line will appear in the test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no coloured line will appear in the test line region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating the proper volume of specimen has been added and membrane wicking has occurred.

Test Kit

The evaluation was carried out using this kit with the lot number of ATCOV2103212-S, and the expiry date was on 2023-03.

Instrument Used

Timer

Reagent and Sample Preparation, Result Interpretation

Kindly refer to product package insert in the attachment

Sample Used

Known Positive Sample = 30

Known Negative Sample = 30



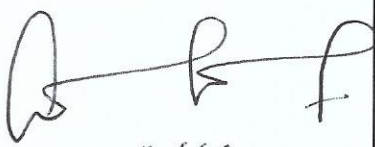
Total samples used for analysis = 60

Performance Analysis

Test		Tested Kit Assay		Interpretation
		Positive	Negative	
HSgB In-house Panel	SARS-CoV2 Positive (COVID-19)	28	2	Sensitivity = 93.3%
	SARS-CoV2 Negative (COVID-19)	0	30	Specificity = 100%

Comments

The positive panels were selected among saliva samples that had been tested positive using our COVID-19 RT-PCR test system and the Ct values were less than 26. As for the negative panels, known negative saliva samples confirmed by our COVID-19 RT-PCR test system were used.

Test performed by	Reviewed by	Approved by
 11/06/2021	 14/6/2021	 14/6/21
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