

(Saliva Test)

COVID-19 ANTIGEN RAPID TEST PEN

NEW



Avoid the discomfort of taking nasopharyngeal sample

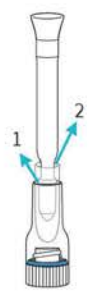
The COVID-19 Antigen Rapid Test Pen is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from saliva samples



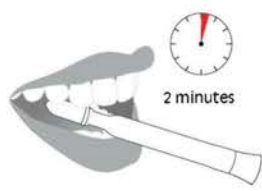
Benefits:

- Easy and fast sampling
- All that is needed to conduct the sample is included
- Portable and can be performed anywhere
- Easy to operate – no special training needed

Test procedure(One Step Test)



① Remove the saliva test pen from its packing



② Place the saliva test pen in the mouth, put the collector of the test device at the root of the tongue (close to the throat), hold for 2 minutes



③ Insert the saliva test pen into the Extraction Buffer vertically



④ Read results at 15 minutes

Clinical Evaluation

Table: COVID-19 Rapid Test vs. RT-PCR

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Rapid Test (Saliva)	Positive	18	2	20
	Negative	2	64	66
Total		20	66	86

Relative Sensitivity: 90.0 % (69.9% ~ 97.2%)*

Relative Specificity: 97.0 % (89.6% ~ 99.2%)*

Overall Agreement: 95.3 % (88.6% ~ 98.2%)*

*95% Confidence Interval

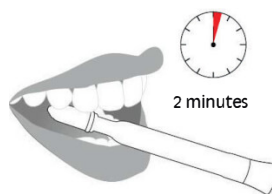
Contents

- Individually packed Saliva Collector with Test Strip
- Individually packed Extraction Buffer
- Package insert

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