

CE

NEW

(Saliva Test)

COVID-19 ANTIGEN RAPID TEST

*Avoid the discomfort of
taking a 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 sampling
- 1-step procedure
- Portable & can be performed anywhere
- Easy to operate, without special training needed
- Reduces the risk of contagion

For in vitro Diagnostic Use Only.

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%)*

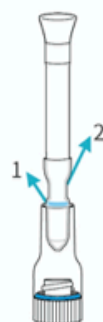
Overall Agreement: 95.3 % (88.6% ~ 98.2%)*

*95% Confidence Interval

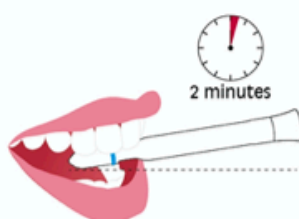
Contents

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

Test procedure(One Step Test)



① Remove the saliva test pen from its packing



② Place the saliva collector in the mouth, hold for 2 minutes



③ Insert the saliva test pen into the Extraction Buffer



15 minutes

④ Read results at 15 minutes