

COVID-19 Antigen Rapid Test Kit

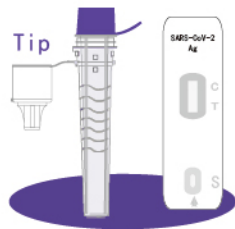
The COVID-19 Antigen Rapid Test Kit is an immunochromatographic intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.



• Test Procedure

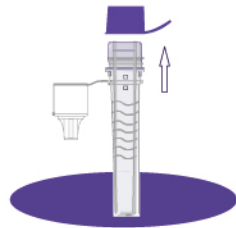
1

Take an extraction tube from the kit and remove a test cassette from the foil pouch by tearing at the notch.



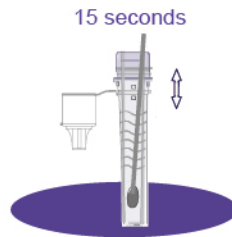
2

Add 10 drops (or 450-550uL) of sample lysis solution into the extraction tube.



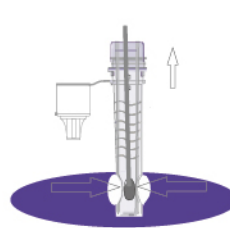
3

Place and soak the patient swab in the sample lysis solution for 15 seconds.



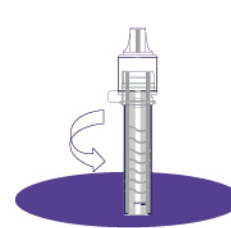
4

While squeezing the tube, specimen Pull the swab out.



5

Firmly attach dropper lid to the top of the extraction tube. Gently invert the tube 5 times.



6

Transfer 2-3 drops (80uL) To the sample well of the test strip. Read the results in 15-20 mins.



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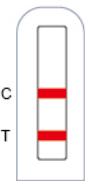
• Components

- 20 x Sterile Swabs
- 20 x Extraction tube
- 2 x Sample Lysis Solution
- 20 x Test Cassette



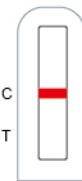
• Result Interpretation

Positive



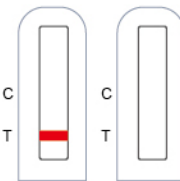
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antigens in the specimen.

Negative



Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antigens does not exist or below the detection limit of the test.

Invalid



No visible colored band appear at control line. The directions may have been followed correctly or test may have deteriorated.

		Clinical diagnosis		
		Positive	Negative	Total
Beier COVID-19 Antigen Rapid Test	Positive	165	1	166
	Negative	6	302	308
	Total	171	303	474

- Sensitivity=96.5%(95% CI: 93.7%~99.3%)
- Specificity=99.7%(95% CI: 99.0% -100%)
- Positive predictive values= 99.4%(95% CI: 98.2% -100%)
- Negative predictive values= 98.0%(95% CI: 96.5%-99.6%)
- Total consistent: 98.5% (95%CI: 97.4%~99.6%)

