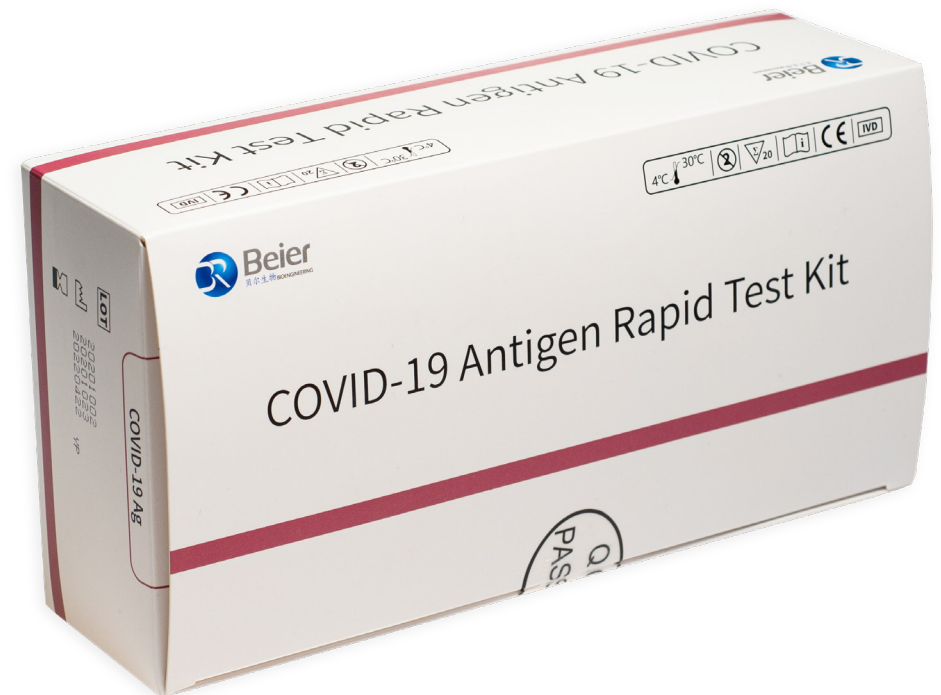# COVID-19 ANTIGEN RAPID TEST KIT
REF: BSD400

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.
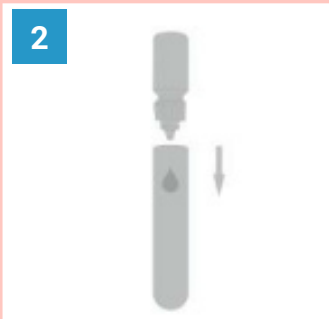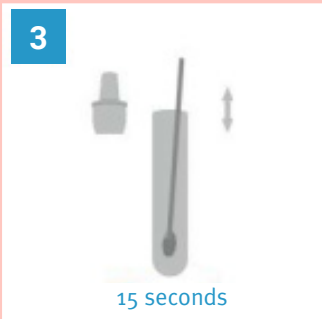
TEST PROCEDURE

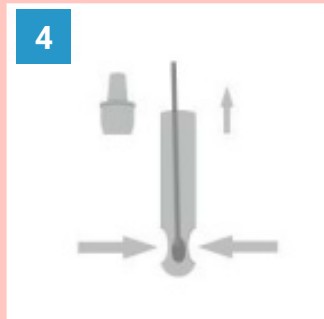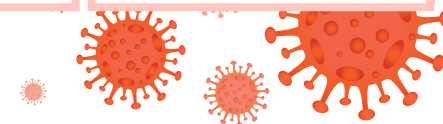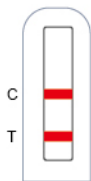|					
1. Take an extraction tube from the kit and remove a test cassette from the foil pouch by tearing at the notch.	2. Add 10 drops (or a single package) of sample lysis solution into the extraction tube.	3. Place and soak the patient swab in the sample lysis solution for 15 seconds.	4. While squeezing 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 (80µl) to the sample well of the test strip. Read the results in 15~20 mins.

	Clinical Diagnosis (PCR)		
	Positive	Negative	Total
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%)

COMPONENTS

1. 20 Sterile Swabs
2. 20 Extraction tube
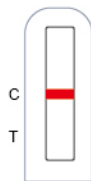3. 20 Single package Sample Lysis Solution (450μL)
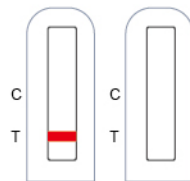4. 20 Test Cassette

RESULT LNTERPRETATION

POSITIVE

Colored bands appear at both test line (T) and control line (C). Not 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.