



StrongStep®

SARS-CoV-2 Antigen Rapid Test



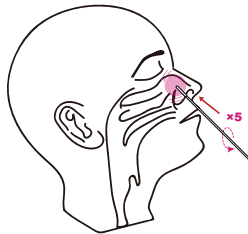
- 20 Individually sealed foil pouch packed test devices
- 2 Dilution Buffer vials (12mL/vial)
- 20 Extraction Tubes
- 20 packs of swab (2 swabs/pack)
- 1 Workstation
- 1 Package insert
- 1 Positive control swab (on request only)

Nasal Swab Sample

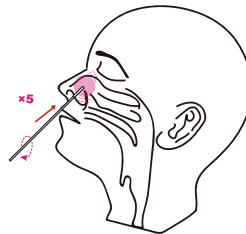
Add 20 drops of Dilution buffer to extraction tube.



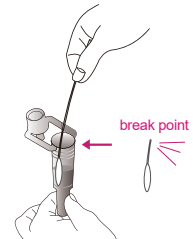
- Insert one swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.



- Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

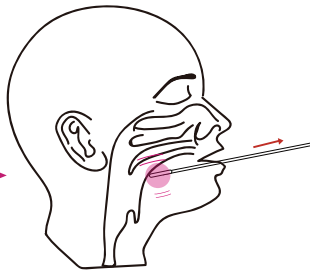
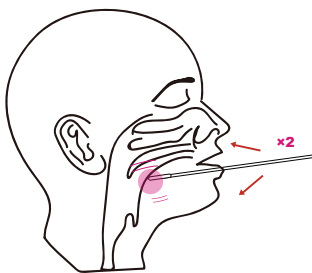


- Put the swab into the extraction tube, break off the swab at the break point, let the swab tip fall into the tube.

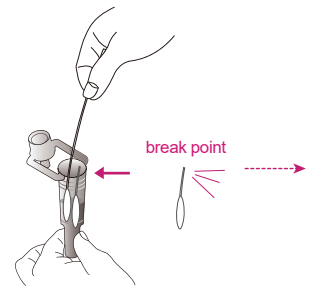


Oropharyngeal Swab Sample

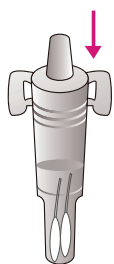
- Ask patient to open mouth and press tongue with tongue depressor if necessary. Use another swab into the oropharynx and scrap left and right side pharynx mucous membrane 2 times.



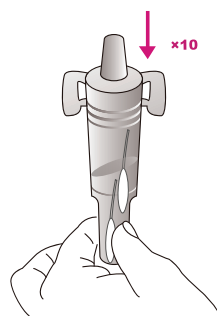
- Put the swab into the extraction tube, break off the swab at the break point, let the swab tip fall into the tube.



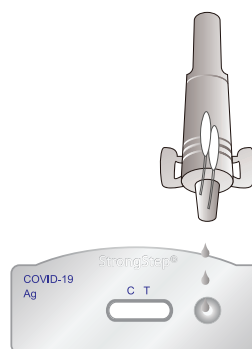
- Cover the cap.



- Mix the solution by squeeze the swab forcefully against the side of the tube for at least ten times (while submerged). Allow the swab to soak in the Extraction Buffer for one minute prior to the next step.



- Remove the test device from the sealed foil pouch. Add 3 drops of specimen solution to round sample well.



- Wait for 15 minutes reading result. Do not interpret the result after 30 minutes.



Result



Positive



Negative



Invalid



- After sampling, it can be tested on site immediately and the result will be given in 15 minutes.
- No auxiliary equipment is required during operation.
- The positive result is of diagnostic value.
- Poor quality of samples may result in false negative.
- Therefore, novel coronavirus pneumonia is not completely excluded by negative results.
- The reagent shall be transported and stored under normal temperature.

Performance

- Positive Percent Agreement: (PPA)= 92.31% (79.13%~98.38%)*
- Negative Percent Agreement: (NPA)= 97.26% (90.45%~99.67%)*
- Kappa: 0.9011(0.8164~0.9858)
- *95% Confidence Interval

PCR Comparator				
StrongStep® SARS-CoV-2 Antigen Rapid Test		Positive	Negative	Total
	Positive	36	2	38
	Negative	3	71	74
	Total	39	73	112