



COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)

For professional use



- Result in **15** minutes
- No special equipment is required
- Fast**
- Accurate**
- Simple**
- Convenient**

Stored at 2-30°C

www.bio-kit.com

INTENDED USE

The COVID-19 Antigen Rapid Testing Kit (Colloidal Gold) is used for the qualitative detection of COVID-19 antigen in nasopharyngeal swab (NPS) and oropharyngeal swab (OPS) specimens by colloidal gold immunochromatography assay. It is suitable for the pathogen examination for suspected novel coronavirus-induced pneumonia (COVID-19) patients.

TEST PRINCIPLE

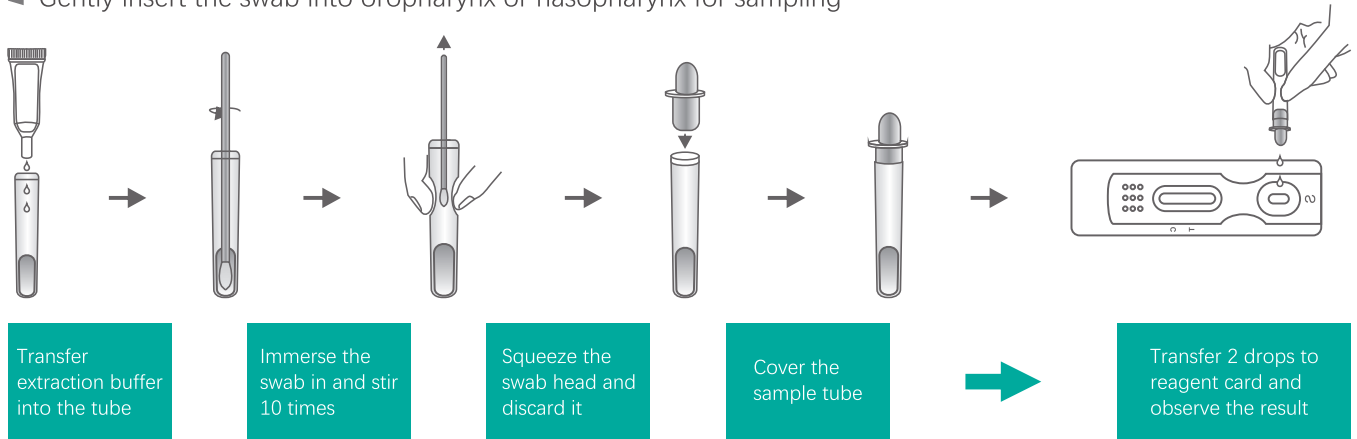
The test kit uses double antibody sandwich technology in colloidal gold immunochromatography - Paired mouse anti-SARS-CoV-2 spike monoclonal antibody pre-coated in the line T, mouse anti-chicken IgY monoclonal antibody pre-coated in the line C.

When the colloidal gold complex reacts with the antigen in specimen, it forms an antigen-antibody reaction. The complex continued to migrate and bound to the second antibody in the detection area (T) and in the quality control area (C) on the nitrocellulose membrane, to develop colored bands.



TEST METHOD

- Balance test materials to room temperature before use
- Gently insert the swab into oropharynx or nasopharynx for sampling



INTERPRETATION OF TEST RESULT

Positive Test

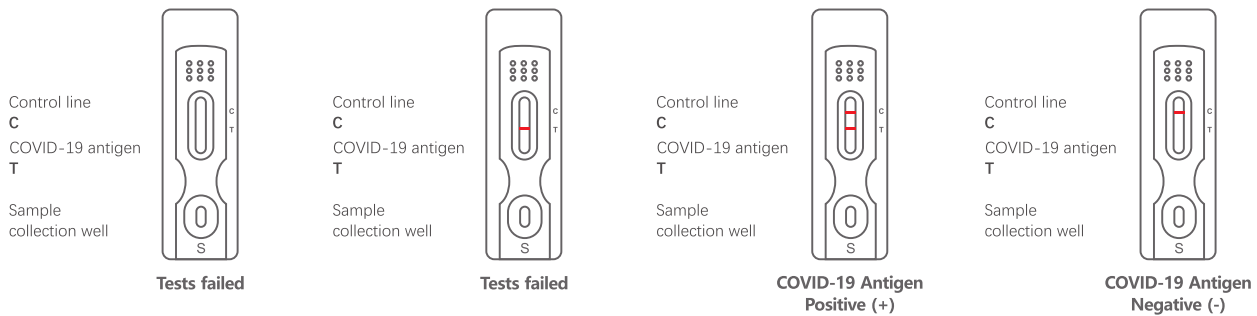
COVID-19 antigen positive (+): Colored bands appear in both of line T and line C in the observation window.

Negative Test

COVID-19 antigen negative (-): A colored band appear in line C only and no colored band develop in line T, indicating that COVID-19 antigen is not detected in the specimen.

Invalid Test

In any case, no colored band appears in line C indicates an invalid assay, possibly due to incorrect test operation or the device is deteriorated and damaged. The test should be re-performed.



CLINICAL PERFORMANCE

A total of 78 PCR negative nasopharyngeal swab (NPS) samples and 46 PCR positive NPS samples were tested using the COVID-19 antigen Rapid Testing kit (Colloidal Gold). The overall PPA is 95.65% and NPA also is 100% for the kit when compared with an approved PCR assay.

COVID-19 antigen tested	Nucleic Acid Tested		Total
	RNA positive	RNA negative	
Ag positive	44	0	44
Ag negative	2	78	80
Total	46	78	124
Overall Positive Percent Agreement	$44/46 \times 100\% = 95.65\%$		
Overall Negative Percent Agreement	$78/78 \times 100\% = 100.00\%$		



<https://en.daangene.com/>

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