

STANDARD Q COVID-19 Ag Test

CE
Cat. No : 09COV30D

STANDARD Q COVID-19 Ag test is the immunoassay for the qualitative detection of specific nucleoprotein antigens to SARS-CoV-2 present in human nasopharynx.

- **Test time** : Within 30 mins
- **Specimen** : Nasopharyngeal swab
- **Storage temperature** : 2-30°C/36-86°F
- **Pack size** : 25Tests/kit



Benefit



Suitable for point of care testing



Room temperature storage



Easy to use



Ready-to-use reagents



Fast results within 30 minutes

Performance Characteristics

[Clinical evaluation]

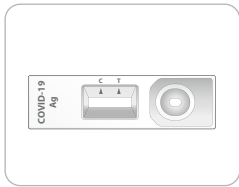
Test were performed according to instructions for use of STANDARD Q COVID-19 Ag Test by using Nasopharyngeal swab specimens. Positive specimen is prepared by spiking inactivated cell (SARS-CoV-2 (2019-nCoV) NCCP 43326/2020 / Korea) into Nasopharyngeal swab specimens with the concentration of $5 \times 10^{3.2}$ TCID₅₀/ml, $2.5 \times 10^{3.2}$ TCID₅₀/ml, $1.25 \times 10^{3.2}$ TCID₅₀/ml. STANDARD Q COVID-19 Ag Test detect the 30 positive contrived specimens and 30 negative specimens correctly.

Spiked concentration of cultured virus	Result
$5 \times 10^{3.2}$ TCID ₅₀ /ml	POS (10/10)
$2.5 \times 10^{3.2}$ TCID ₅₀ /ml	POS (10/10)
$1.25 \times 10^{3.2}$ TCID ₅₀ /ml	POS (10/10)
N/A	NEG (30/30)

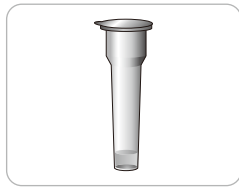


STANDARD Q COVID-19 Ag Test is designed for initial screening only for SARS-CoV-2 infection. If the antigen concentration of the specimen is below the limit of detection of STANDARD Q COVID-19 Ag Test, it may not be detected. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

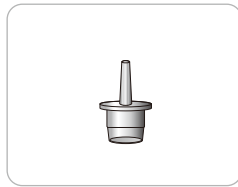
» Contents for the test are all inclusive



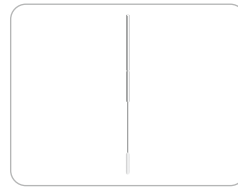
Test device (individually in a foil pouch with desiccant)



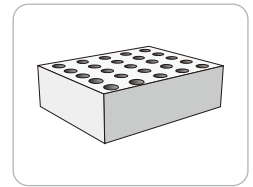
Extraction buffer tube



Nozzle cap

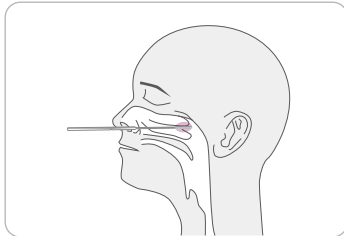


Sterile swab

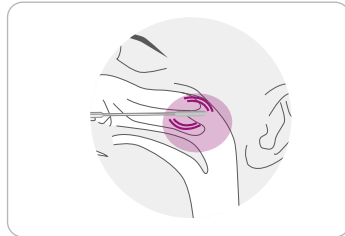


Paper stand

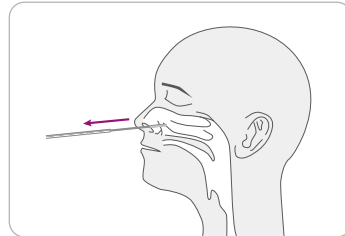
» Test Procedure



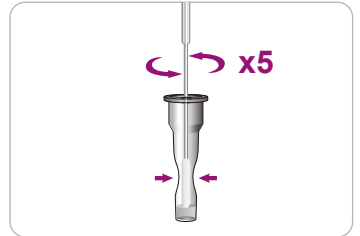
1 Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



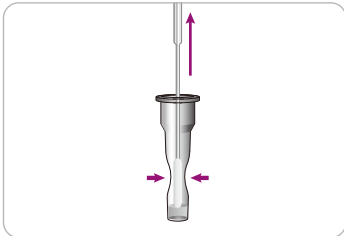
2 Swab over the surface of the posterior nasopharynx.



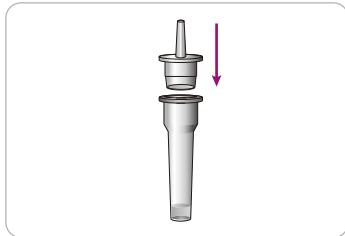
3 Withdraw the sterile swab from the nasal cavity.



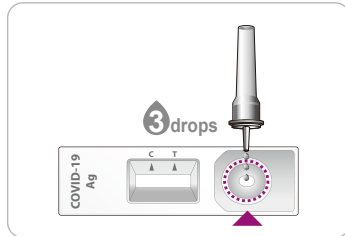
4 Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



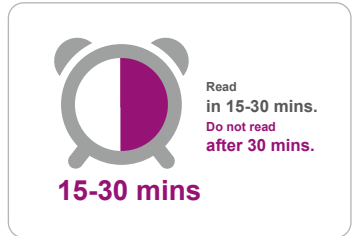
5 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



6 Press the nozzle cap tightly onto the tube.

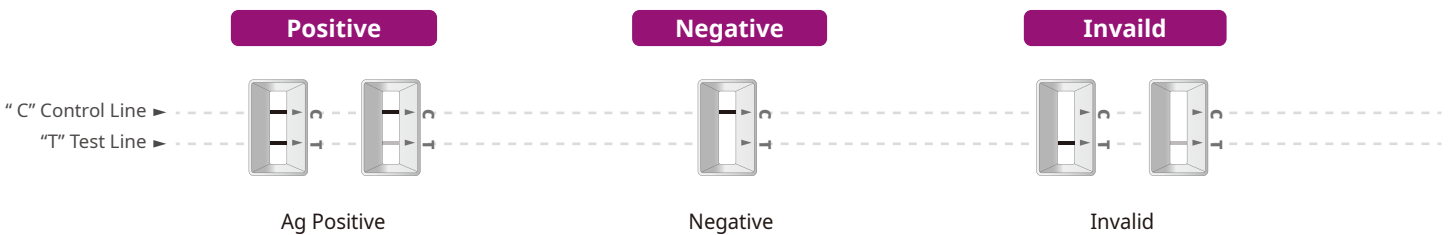


7 Apply 3 drops of extracted specimen to the specimen well of the test device.



8 Read the test result in 15-30 minutes.

» Interpretation of Test Result



» Ordering Information

STANDARD Q COVID-19

Cat. No.	Product	Storage temperature	Tests/kit	Kits/carton	Carton size (W/D/H)
09COV30D	STANDARD Q COVID-19 Ag Test	2-30°C/36-86°F	25	30	550 x 460 x 390 mm
09COV12B	STANDARD Q COVID-19 IgM/IgG Duo Test	2-30°C/36-86°F	20	40	515 x 515 x 370 mm
09COV50G	STANDARD Q COVID-19 IgM/IgG Combo Test	2-30°C/36-86°F	40	40	515 x 515 x 370 mm
10COVC10	STANDARD COVID-19 Ag Control	2-30°C/36-86°F	10	20	155 x 390 x 110 mm
10COVC20	STANDARD COVID-19 IgM/IgG Control	2-30°C/36-86°F	10	20	215 x 390 x 110 mm