

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



Easy to use



Fast results within 30 minutes



Room temperature storage



Ready-to-use reagents

» 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.

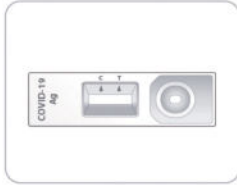
Spiked concentration of cultured virus	Result
$5 \times 10^{3.2}$ TCID ₅₀ /ml	POS (10/10)
$2.5 \times 10^{3.2}$ TCID ₅₀ /ml	POS (10/10)
$1.25 \times 10^{3.2}$ TCID ₅₀ /ml	POS (10/10)
N/A	NEG (30/30)



NOTE

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)



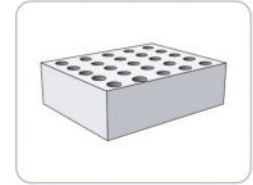
Extraction buffer tube



Nozzle cap

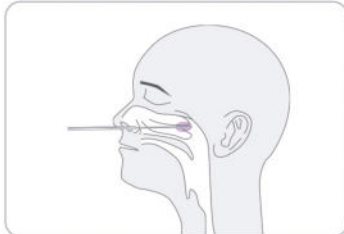


Sterile swab

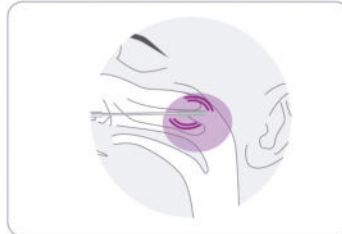


Paper stand

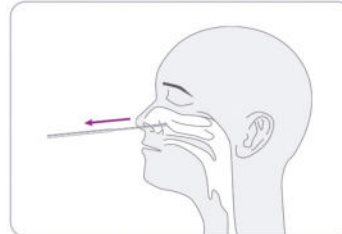
» Test Procedure



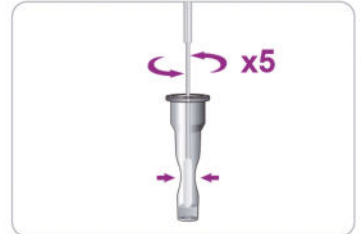
1 Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



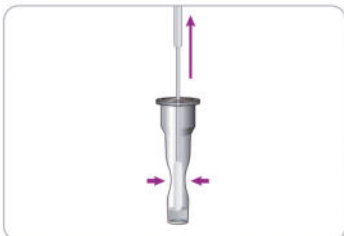
2 Swab over the surface of the posterior nasopharynx.



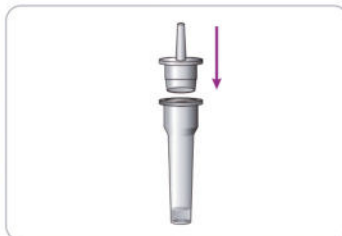
3 Withdraw the sterile swab from the nasal cavity.



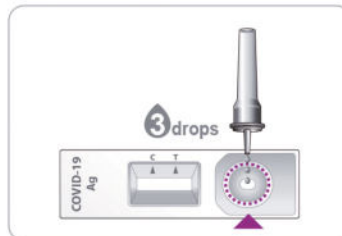
4 Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



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.

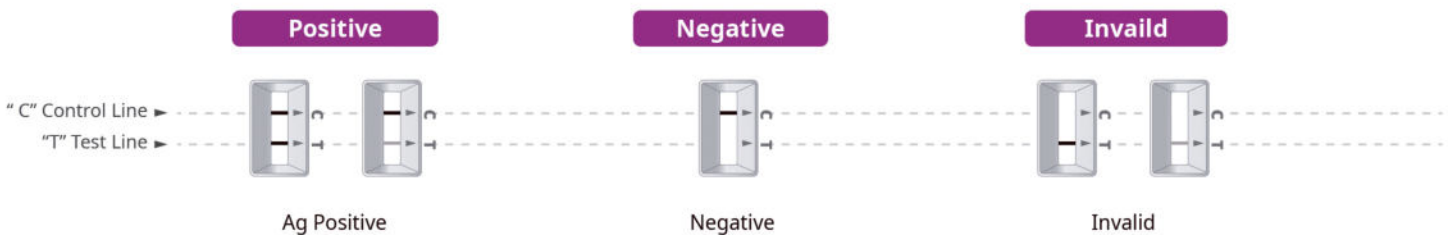


7 Apply 3 drops of extracted specimen to the specimen well of the test device.



8 Read the test result in 15-30 minutes.

» Interpretation of Test Result



Test sensitivity

The STANDARD Q COVID-19 Ag Test showed 84.38% of sensitivity.

Table 1. Summary of the sensitivity of the STANDARD Q COVID-19 Ag Test compared to PCR.

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	27	0	27
	Negative	5	0	5
	Total	32	0	32
Sensitivity		84.38% (27/32, 95% CI, 67.21% - 94.72%)		

Test specificity

The STANDARD Q COVID-19 Ag Test showed 100% of specificity.

Table 2. Summary of the specificity of the STANDARD Q COVID-19 Ag Test compared to PCR.

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	0	0	0
	Negative	0	170	170
	Total	0	170	170
Specificity		100.00% (170/170, 95% CI, 97.85% - 100%)		