

Quampas COVID-19 Antigen Test Kit

SARS-CoV-2 Antigen Test Kit



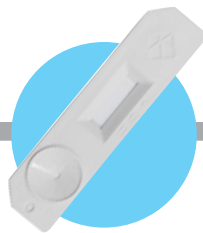
Photos are sample images



This SARS-CoV-2 Antigen Test Kit uses the immunochromatographic method to detect the antigen of the novel coronavirus.

This test kit is suitable for assisting the diagnosis of SARS-CoV-2 infection. No special equipment is needed and test results come out in approximately 15 minutes by simple sample processing.

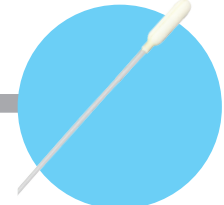
Kit Contents



Test stick



Sample buffer



Nasopharyngeal swab

Specifications

Product name	Quampas COVID-19 Antigen Test Kit
Product code	IQVALF011
Measurement method	Immuno-chromatography
Measurement time	15minutes
Measurement sample	Nasopharyngeal swab
Storage temperature	1°C - 30°C (for 24months)

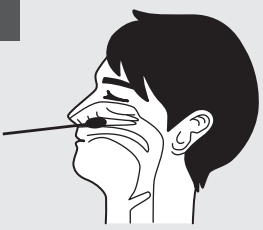
1. The infection of SARS-CoV-2 is not completely ruled out even if the test is negative.
2. For the sample used for the test, please refer to the "Guidelines for testing for novel coronavirus (COVID-19) pathogens, 1st edition" published MHLW of Japan.
3. For the diagnosis, please refer to the latest information released by Japan MHLW and make a comprehensive judgment based on both the test results and clinical symptoms.
4. Please note that when nasal swabs are used as samples, the detection sensitivity tends to be lower than that of nasopharyngeal swabs. Please be careful when collecting the sample.
5. Take necessary protective measures when collecting and handling samples.

[References]

1. The Coronavirus Disease 2019 (COVID-19) Pathogen Detection Manual, ver2.9.1. National Institute of Infectious Diseases, Japan
2. Guidelines for the operation of assay for the novel coronavirus (SARS-CoV-2), 3rd edition, National Institute of Infectious Diseases, Japan
3. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). WHO Kobe Center published in Japanese
4. WHO Website : "Namiug the cojouavijus disease(COVID-19) aud the vijus that causes it"
([https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/understanding-the-novel-coronavirus-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/understanding-the-novel-coronavirus-(covid-2019)-and-the-virus-that-causes-it))
5. Guidelines for testing for novel coronavirus (COVID-19) pathogens, 1st edition, issued on October 2, 2020, MHLW, Japan

Test Protocols

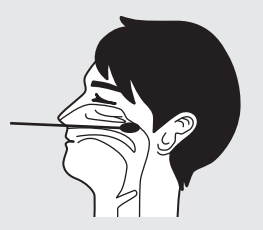
1



Swab Sampling

Insert the swab into the nasal cavity about 2 cm from the edge of the nostril and rotate the swab about 5 times to collect the mucosal epithelial cells.

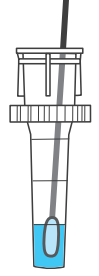
1



Swab Sampling

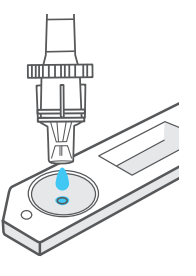
Insert the swab along the turbinate to the nasopharynx and rub it several times to collect the mucosal epithelial cells.

2



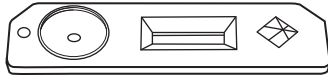
Soak the swab into the sample buffer and suspend it by moving up and down. Remove the swab and attach a nozzle (with filter) onto the top of the tube.

3



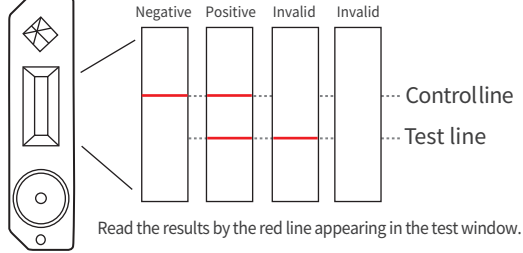
Apply 3 drops (100-150 μL) of the suspension to the sample well of the test stick.

4



Let stand at room temperature for 15 minutes.

5



Read the results by the red line appearing in the test window.

Clinical performance

1) On-site testing at clinical facilities (clinical patients)

		RT-PCR Test		
		Positive	Negative	Total
This kit	Positive	32	1	33
	Negative	10	39	49
	Total	42	40	82

Positive percent agreement : 76%
 Negative percent agreement : 98%
 Overall rates of agreement : 87%

2) On-site testing at clinical facilities (clinical patients)

Virus load in the sample copy/test	Positive samples with this kit/ samples	
	N set 1	N set 2
Less than 10^1	0 / 1	1 / 4
$10^1 \sim 10^2$	1 / 3	0 / 3
$10^2 \sim 10^3$	2 / 3	2 / 2
$10^3 \sim 10^4$	3 / 3	3 / 3
$10^4 \sim 10^5$	5 / 6	5 / 6
$10^5 \sim 10^6$	4 / 6	5 / 7
More than 10^6	17/18	16/17

3) Comparison of the sensitivities among this kit and other kits in artificial samples.

The copy numbers of the virus in test samples were adjusted by spiking the negative nasopharyngeal swab sample to the positive sample.

Copy numbers of virus per test	This Kit	Kit A	Kit B	Kit C
2.8×10^6 copy / test	+	+	+	+
1.0×10^5 copy / test	+	+	-	+
5.0×10^4 copy / test	+	+	-	+
Negative nasopharyngeal swab	-	-	-	-

※ Meanings of the marks in the table: +: Positive, -: Negative, N.D.: No data