

Antigen Test Kit



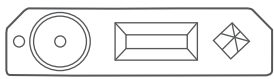
Application Survey and research on the novel coronavirus antigen

The detection performance of nasal discharge as a sample is currently under study. Please be aware that its performance is not necessarily guaranteed.

- This product is not IVD and is intended for research use only.
- NOT for diagnostic and therapeutic purposes.

This kit is a research immunochromatographic kit for detecting the antigen of the novel coronavirus. No measuring device is needed and test results come out in approximately 15 minutes by simple sample processing.

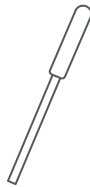
Kit contents



Test stick
x1



Nozzle
x1



Swab
x1



Sample buffer
x1



Sample collection sheet
x1

※If this product has been refrigerated, please take it out of the refrigerator and leave it for at least 30 minutes to allow it reach the room temperature before use.

※Use the test stick within 30 minutes after opening.

※Be careful not to fall over after opening the sample buffer.

Specifications

- Product name QuaResearch COVID-19 antigen test kit
- Product code RCVLF011
- Measurement method Immunochromatography
- Measurement sample Nasal discharge

- Storage temperature 2~28°C
- Quality Assurance Period 12 months after manufacture


※ The expiration date (Exp.) is printed on the outer box.

※ Please use immediately after opening the test stick.

- Be sure to read the instructions for use before use.
- Be sure to check the latest protocol on the following website before use.
<https://www.cellspect.com/>
- This product is intended for research use (scientific studies, learning, and education). Please use it at the user's own responsibility.
- Store this product at 2~28°C, away from direct sunlight.
- Please keep this product out of reach of young children.
- Proper infection prevention should be taken by individuals.
- Use the included sampler. When using other sampling instruments, the user should verify and determine whether the desired observation value can be obtained.
- When sampling and handling nasal or nasopharyngeal swabs, make sure to check the requirements based on regulations and guidelines. Make sure that medical professionals use them appropriately. We are not responsible for any events that occur during this operation.
- Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

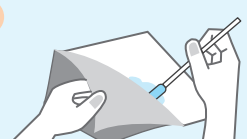
Test Protocol (For nasal discharge)

1



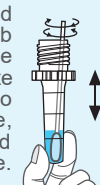
Place the sample collection sheet on your nose and blow your nose.

2



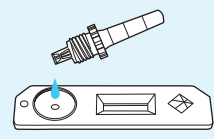
After confirming that the amount of nasal discharge is adequate, use a swab to collect nasal discharge.

3



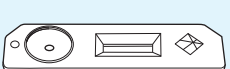
Immerse the swab into the sample buffer and lightly pinch the swab head from the outside of the container. Rotate the swab from side to side 10 times or more, and move it up and down 20 times or more.

4




Hold the tube at the middle part and add 3 drops of the sample buffer to the sample well of the test stick.

5



Let stand at room temperature for 15 minutes.

6



Test window

- C Control line [C]
- T2
- T1 Test line [T1]

※ T2 is NOT used in this kit

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

※ Judgment should be made 15 minutes after the sample is dropped.

※ Do not use a test stick that has passed the judgment time because the result may change due to dryness, etc.

※ If there is no red line in the Test Line [C], it may be due to the problem of measurement or the quality of the reagent. Retry the test with a different test stick.

※The pictures are sample images. The appearance of the product is subject to change without notice.

Main specifications and performance

1 Performance

Sensitivity, accuracy, and within-run reproducibility studies using positive (0.5 ng/test) and negative (sample processing fluid) controls meet the following specifications.

(1) Sensitivity

Positive controls are correctly identified as "positive" in the results.

(2) Accuracy

When positive and negative controls are tested, positive controls are detected and negative controls are undetected.

(3) Within-run reproducibility

When three positive and three negative controls are tested, all positive controls are detected and all negative controls are undetected.

2 Detection limit

The detection limit of this product is 0.1 ng/test.

3 Results of cross reactivity tests

(1) Viruses other than SARS-CoV-2

Influenza Type A virus protein, Flu A protein (NP Antigen)
Influenza Type B protein (TOKIO)

(2) Other coronaviruses

coronavirus (HCoV-229E) Nucleoprotein
coronavirus (HCoV-OC43) Nucleoprotein
coronavirus (HCoV-HKU1) Nucleoprotein

No cross-reactivity was observed in any of the above (1) and (2).

4 Measurement example

(The following are the test results by our company and are not guaranteed in all cases.)

The positive agreement rate of this product with the viral load in positive samples by RT-PCR.

Virus load (copy / 5 μ L)	Positive samples for this product	
	N set 1	N set 2
Less than 10 ¹	0/0	0/0
10 ¹ ~10 ²	2/6	2/9
10 ² ~10 ³	2/11	3/12
10 ³ ~10 ⁴	5/11	6/10
10 ⁴ ~10 ⁵	6/8	6/7
10 ⁵ ~10 ⁶	8/8	12/12
More than 10 ⁶	30/30	24/24

Note) The ratio of the results consistent with RT-PCR results is 91% in the samples containing 1,000 copies/5 μ L or more RNA (N Set 2, estimated value).

5 Interfering substances/agents

In the hemoglobin addition test, there was no effect up to a concentration of 0.3 g/dL in the sample.

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 : "Naming the coronavirus disease (COVID-19) and the virus that causes it"
([https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(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

◆Manufacturer and Seller: Cellspect Co., Ltd

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※QuaResearch is the name of reagent kit of CellSpect Co., Ltd

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