SYNTHGENE RQ005 SARS-COV-2 Nucleocapsid(N) Antigen Rapid Detection Kit User Manual

SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) Instruction manual

Contents

Product Name

SARS-COV-2 Nucleocapsid(N) Antigen Rapid Detection Kit (Colloidal gold method)

REF: RQ005

Packaging specification

1/25/50 Test(s) /kit

Intended use

This product is used to qualitatively detect the SARS-COV-2 Nucleocapsid (N) antigen in human saliva samples in vitro. No instrument required. It can be used for the screening of early infected patients and asymptomatic patients. The test can be performed for professional or self-testing use.

The negative result cannot rule out novel coronavirus infection, and it can not be used alone as a basis for treatment and disease management decisions. The positive result of the antigen test can be used for early triage and rapid management of suspected infected people, but the positive result only indicates the presence of the novel coronavirus N-Protein (Nucleocapsid) in the sample, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by the novel coronavirus. It should be combined with nucleic acid testing, imaging, and other diagnostic information, medical history, and contact history to determine the status of infection. Coronavirus belongs to the order Nidoviridae, and the coronavirus family is divided into three genera of α, β, and γ. α and β are only pathogenic to mammals, and γ mainly causes bird infections. COV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through fecal or oral routes.

Test principle

The binding pad of this test strip was respectively covered with mouse anti-novel coronavirus monoclonal antibody 1 with colloidal gold as the color marker. The detection line (T) on the nitrocellulocellulose membrane was covered with mouse anti-novel coronavirus monoclonal antibody 2 and the quality control line (C) was covered with goat anti-mouse IgG polyclonal antibody. When testing, when the sample to be tested contains the novel coronavirus, it is combined with the colloidal gold-labeled novel coronavirus monoclonal antibody to form an immune complex, which is captured and enriched at the detection line (T) by the reagents fixed on the membrane. The colloidal gold-labeled antibody diffuses to the quality control line (C) area and is captured by the secondary antibody to form a purple-red band in the quality control area.

Main components

1. Test pad: Individually packaged in aluminum foil bags per test. The test pad consists of a sample pad, a gold-labeled pad labeled with a gold-labeled mouse anti-human SARS-COV-2 monoclonal antibody I, nitrocellulose coated with a mouse anti-human SARS-COV-2 monoclonal antibody II, and a goat anti-mouse IgG antibody. It consists of plain film, absorbent paper, plastic backing, and a plastic template.
2. Medical waste bag
3. Instruction manual

Storage conditions and validity

1. Storage conditions: The original packaging should be stored in a dry place at 4~30°C, protected from light, and not freeze.
2. Validity period: 18 months.
3. The reagent should be used as soon as possible within 1 hour after unpacking the aluminum foil bag; it is recommended to use it as soon as possible when the surrounding temperature is higher than 30°C or high humidity.

Sample requirements

1. This product is applicable to human saliva samples.
2. Samples that are heavily contaminated by oral food residues cannot be used for testing this product. Saliva samples are not recommended to be used for testing this product after a large amount of blood is contaminated. If the saliva samples are too viscous, the test results may vary significantly.

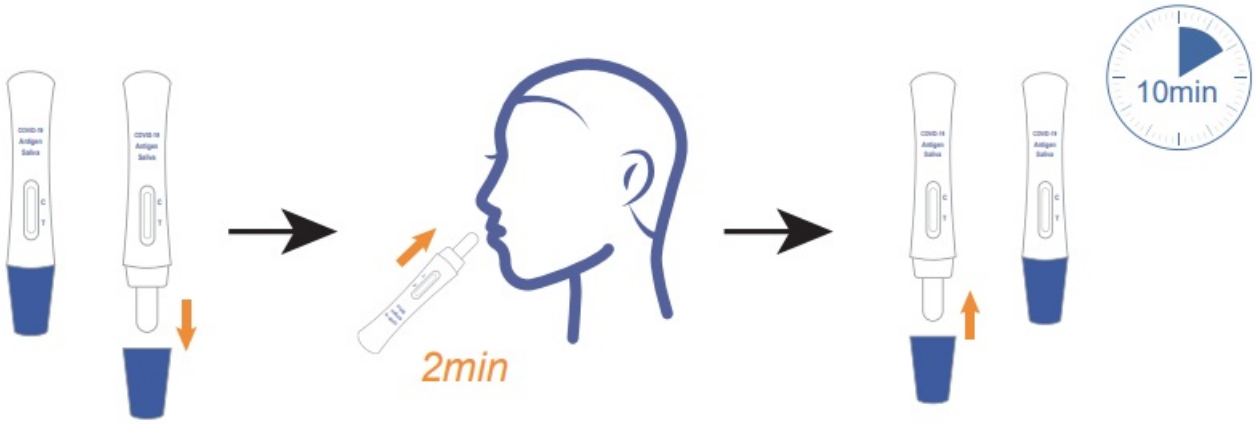
Test method

Please read the instruction manual carefully before testing. Please return all components to room temperature before the test. The test should be performed at room temperature.

Detection steps:

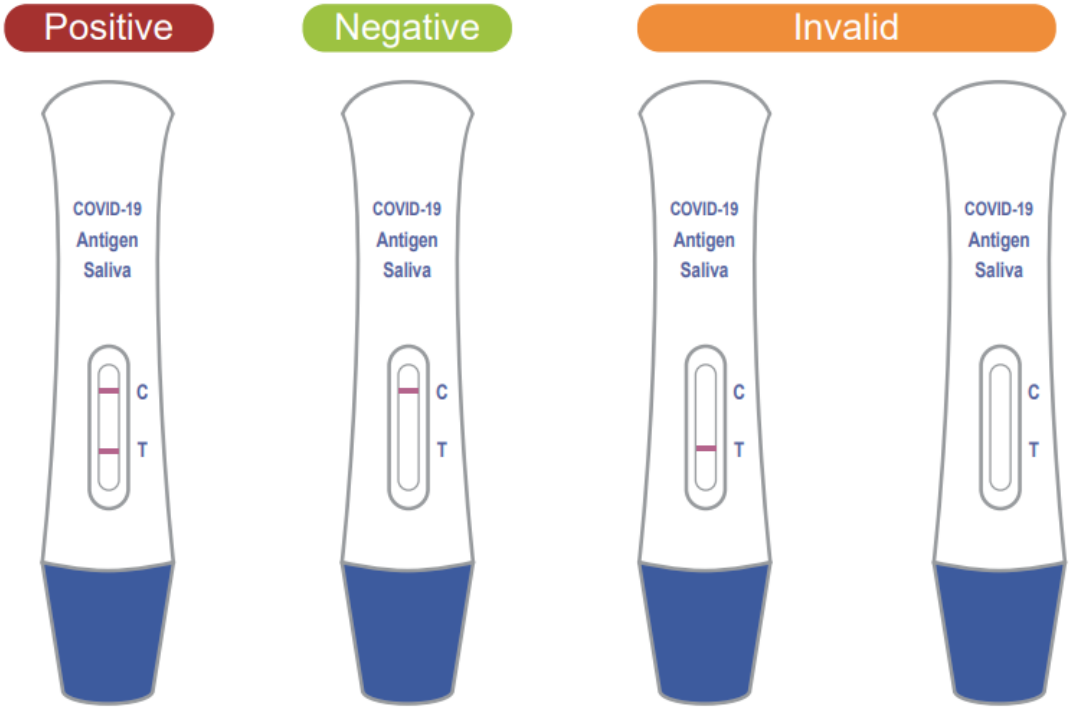
1. After the test pad returns to room temperature, open the aluminum foil bag of the test pad and take out the test pad.
2. Remove the blue cover of the test pad. Put all the water-absorbing parts of the sampler on both sides of the mouth and gently apply it, and finally, press it under the tongue and soak it with saliva. You should salivate naturally until the red line on the control area (C) line is visible. Wait patiently for about 2 minutes to remove it. Cover the blue cover of the test pad.
3. Place the test pad horizontally, and read the displayed result within 10-15 minutes. The result is valid within 15 minutes.

Note: Do not eat, drink or smoke for at least 30 minutes before the test.
The components after use should be treated in strict accordance with the medical waste, pay attention to protection.



Interpretation of test results

1. Positive: Two red bands, the detection area (T) and the control area (C) are both red.
2. Negative: There is no red band in the detection area (T), and a red band appears in the control area (C).
3. Invalid: There is no red band in the control area (C), indicating that the test is invalid, and the test should be re-sampled.



Limitations of test methods

1. This product is only suitable for the detection of human saliva samples. It detects the virus content in the sample extract, regardless of whether the virus is infectious.
   Therefore, the test results of the same sample using this product may not be correlated with the virus culture results.
2. The test pad of this product needs to be restored to room temperature before use. The improper temperature may cause abnormal test results.
3. During the testing process, the test results did not match the clinical results due to insufficient saliva collection samples or improper collection and specimen
   extraction operations.
4. During the use of this product, you need to strictly follow the operating steps of the manual. Improper operating steps and environmental conditions may cause abnormal test results.
5. The positive test result of this product cannot distinguish between SARS-COV and COVID-19.
6. A negative test result of this product cannot rule out the possibility of other pathogens being positive.
7. Negative test results are recommended to be verified with nucleic acid detection reagents to avoid the risk of missed tests.

Performance characteristics

1. Negative coincidence rate: using corporate negative reference products (N1-N20), the results are all negative, and the coincidence rate is 20/20.
2. Positive coincidence rate: tested with positive corporate reference products (P1-P8), the results are all positive, and the coincidence rate is 8/8.
3. Minimum detection limit: Use the company's minimum detection limit reference products S1, S2, S3, S4, S5, S6 for detection, S1-S4 should be positive, S5 can be positive
   or negative, and S6 is negative.

4. Repeatability: R1, R2, and R3 were tested 20 times respectively, and the test results R1 should all be negative, the positive detection rate of R2 should be ≥95%, R3 should all be positive, and the color rendering is uniform without a difference.
5. Differences between batches: Use 3 different batches of kits to detect the reproducible reference products R1, R2, and R3 respectively. R1 should all be negative, the positive detection rate of R2 should be ≥95%, and all R3 should be positive, and There is no obvious difference in color rendering.

Precautions

1. This kit is for scientific research only and is only used for in vitro testing. Please read this instruction carefully before experimenting and strictly follow the operating procedures in the instructions.
2. The collection, storage, and testing of samples should be carried out in strict accordance with relevant guidelines.
3. After the inspection, the remaining samples are preserved and various waste treatments. The waste or remaining samples generated during the inspection process are recommended to refer to the above guidelines. First, diethyl ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, chloroform, and other lipid solvents are used to soak the virus for inactivating, and then the infectious agents are treated according to the above guidelines.

References

1. Lamarre A, Talbot PJ. Effect of pH and temperature on the infectivity of human coronavirus 229E. Canadian Journal of Microbiology. 1989;35(10):972-4.
2. Bucknall RA, King LM, Kapikian AZ, Chanock RM. Studies with human coronaviruses II.Some properties of strains 229E and OC43. Proceedings of the Society for Experimental Biology and Medicine. 1972;139(3):722-7.

Manual approval and revision date
November 18, 2021
Production date and expiration date
See label

LABEL INTRODUCE FOR USER

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n> tests		Date of manufacture
	Manufacturer		Use-by date
EC REP	Authorized representative in the European Community	30°C 4°C	Temperature limit: 4-30 C
CE	CE Marking		Keep dry
	Do not use it if the package is damaged and consult instructions for use		Keep away from sunlight
	Consult instructions for use		Do not re-use
REF	Catalogue number		Biological risks

SYNTHGENE	
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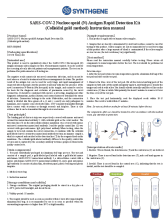
GUARANTEE AND TECHNICAL SUPPORT

If invalid message repeats or need technical support, please contact Synthgene Medical Technology Co., Ltd. Customer Service, and Support Center.

Documents / Resources



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RQ005, SARS-COV-2, Nucleocapsid Antigen Rapid Detection, Antigen Rapid Detection Kit, Antigen Rapid Detection, Rapid Detection