

The Participant Self-test Records

Informed Consent Form

Novel Coronavirus 2019-nCoV Antigen Test Self-test Informed Consent Form

**Product: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
(Anterior nasal swab)**

You will be invited to participate in a clinical study of an in vitro diagnostic product. The following items describe the test background, methods, possible risks, benefits, and rights of this test product. Please be careful before participating in the clinical study read. The information provided to you in this informed consent form can help you decide whether to participate in this clinical study to ensure that you fully understand the relevant content.

Background of the Study : This kit is used for in vitro qualitative determination of novel coronavirus antigen. It is used as rapid investigation for suspected cases of novel coronavirus, can also be used as a reconfirmation method for nucleic acid detection in discharged cases. This test is also for self-test in non-healthcare settings (such as Individual's home or certain non-traditional sites such as offices, sporting events, airports, schools etc.) by individuals and results are for the detection of 2019-nCoV antigen. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for 2019-nCoV by a healthcare provider is necessary.

Product operation method: Please strictly refer to the product manual to complete the test and record the test result.

Risks and discomfort: This test product is an in vitro diagnostic product and does not have contact with the human body during the testing process. Therefore, there will be no risks and side effects during use.

Potential benefits: Most people can accurately detect whether they are infected with the novel coronavirus after using this product. However, due to personal operating errors and physical differences, the detection accuracy of this product cannot reach 100%, so the diagnosis results of professional medical institutions are still required.

Cost: Participation in this research is free.

Rights: Participation in this research is voluntary. You choose whether to participate in this trial, or withdraw at any time without discrimination or retaliation.

Confidentiality: All personal privacy-related information participating in this research will be kept strictly confidential and will not be disclosed to the outside world. Research data may be published in scientific journals, but no personal identification information will be listed.

Please read the above content carefully. If you have understood the content of the notice and agreed to the inoculation, please sign to confirm!

Receiver's signature: _____

5.1.2e

Age: _____

5.1.2e

Date: 2021.02.06

Inspection Record		
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