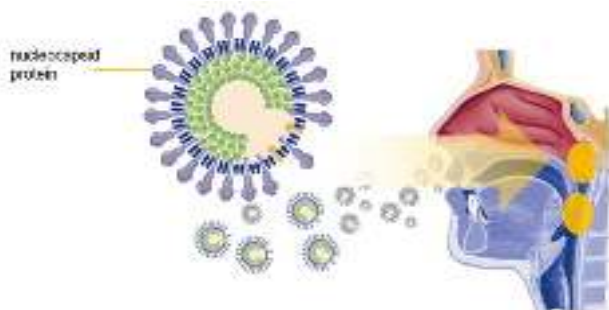
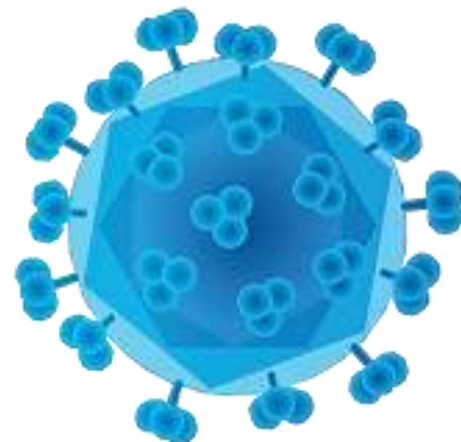


COVID-19 Antigen Rapid Test (Colloidal Gold)

COVID-19 comprehensive screening and monitoring

Coronaviruses belong to a large family of potentially harmful RNA viruses. In humans, they are known to be involved mainly in respiratory infections ranging from the common colds to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The recently discovered coronavirus, SARS-CoV-2, causes coronavirus disease COVID-19, a significant global health problem.



Most of the time the COVID-19 viral particles are present in the nose and nasopharynx of infected individuals. Many infected individuals will develop clinical signs, many will remain without symptoms.

Intended Use

The COVID-19 Antigen Rapid Test is intended for the qualitative detection of SARS-CoV-2 virus, particularly its nucleocapsid protein, in the samples obtained from the nasopharyngeal (NP) and nasal (NS) swabs. Test is recommended for individuals with the clinical symptoms, especially within the first seven days of their onset. Test is also recommended for asymptomatic individuals with suspected COVID-19 disease, or for the COVID-19 epidemiological situation evaluation.

Recommended Target Groups for Testing:

High Risk Individuals

People with obvious clinical symptoms, with or without positive nucleic acid test.

Individuals with Suspicion of the Disease

Family members or close contacts of positive individuals

Susceptible Individuals

Elderly people, children, immune compromised and chronically ill individuals

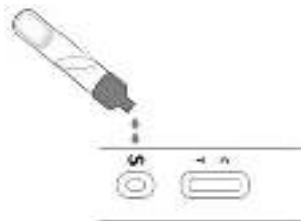
Follow Up Individuals

Positive, or sick, individuals with the need to monitor the progress of the disease and recovery

Testing Process:



1. Collect the sample from the nose or nasopharynx using the swab



3. Place 2 drops of the solution from the test tube (cca 90 µl) into the sample area of the cartridge



2. Transfer all the extraction buffer to the reagent tube and place the collection swab with the sample to the reagent tube. Mix carefully but thoroughly to avoid the aerosol formation. Remove the swab and cap the tube with the adapter.

Wait 3-15 minutes



Positive



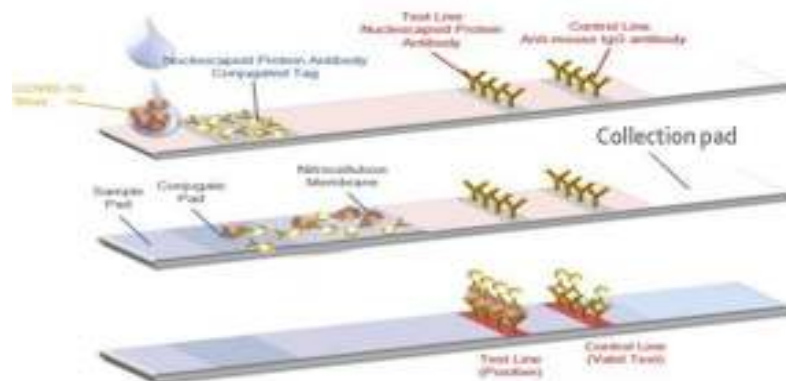
Negative



Invalid

4. Wait 3-15 minutes for the results

Principle of the Test:



As the sample moves through the test cartridge the virus particles are conjugated with the mouse anti-SARS-CoV-2 antibodies and subsequently with the anti-mouse IgG antibodies. The formed conjugate is visualized in the form of the red line in the testing area (T). The color line appears in the control area (C) also, if the test was running correctly.



Results Interpretation:

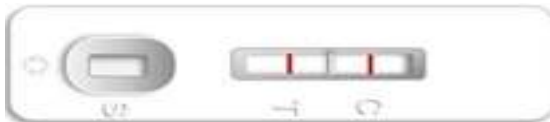
1. Negative Result

Only the line in the control area (C) is visible. The line in the test area (T) is not present. No SARS-CoV-2 virus was detected



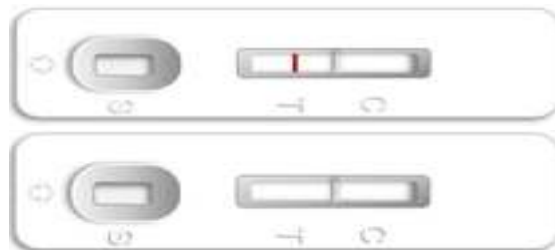
2. Positive Result

Both lines, in the test area (T) and control area (C) are present. The SARS-CoV-2 virus was detected and the test result is positive



3. Invalid Result

If no line is visible in the control area (C), the test is invalid, regardless of the line presence in the test (T) area. The test did not run properly and needs to be repeated.



Rapid Test vs. RT PCR Test – Comparison

Parameter	Rapid Test	RT-PCR Test
Duration of the test	3-15 minutes	3-4 hrs
Test requirements	Easy to perform, portable	Complex test requiring specialized equipment and trained personnel
Convenience	Doesn't require sophisticated set up, can be performed in small labs, in patient rooms, no special equipment needed	Requires highly specialized equipment and trained personnel. Prone to human error. More appropriate in larger hospital settings.

Product Advantages :

Early Detection

Positive test indicates early stages of the infection

Efficiency

Fast and reliable; test results available within 15 minutes

Safety

Easy to perform, low chances for (cross) contamination



Package Specification

Catalog Number

CoV19-Ag

Package Size

- 1 Test/kit
- 20 Test/kit

Content of the Kit

- Test Cartridge (1x)
- Extraction Buffer (300 µl) (1x)
- Reagent Tube with the Adapter (1x)
- Swab
- Instruction for Use

Required, but not provided: Protective gear – gloves, goggles, shield, lab coat and timer



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