
Nano
Repro

NanoRepro SARS-CoV-2 Antigen Rapid Test

Medical relevance	In December 2019, the novel respiratory disease caused by coronavirus, which is known as Covid-19 emerged. The disease COVID-19 and the pathogen *SARS-CoV-2* which triggered the epidemic in the People 's Republic of China was previously unknown and was considered as local outbreak. Soon after its global spread, it was declared a pandemic by the **WHO** on March 11, 2020. A few patients infected have developed severe pneumonia, pulmonary oedema, ARDS, or multiple organ failure and have died. **Following symptoms may appear between 2 to 14 days after exposure:** • shortness of breath • having a cough that gets more severe over time • a low-grade fever that gradually increases in temperature **How it spreads** The virus is thought to be transmitted or spread mainly from person-to-person. such as: • People being in close contact with infected one. ➢ Through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. So, it is very important to detect the infected person, in order to minimize the transmission rate.
Intended use	The NanoRepro SARS-CoV-2 Antigen Rapid Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens.
Intended User	The sample collection by anterior nasal swab is suitable for lay person use. Test is designed for lay person use.
Test principle	This kit is an immunochromatography assay. According to the gold immunochromatographic test principle, double antibody sandwich method was used to detect SARS-CoV-2 antigen in the samples. When there is virus antigen presence in the sample, the antigen binds with the corresponding colloidal gold monoclonal antibody and the coated monoclonal antibody at the detection line to form a compound and then condenses into a red band, indicating a positive result. If there is no antigen in the sample, complex cannot be formed at the detection line, and no red band is shown, indicating negative result. If SARS-CoV-2 viral antigen is absent, there is not a colored line will be shown on the T line, however, a line will be always shown on the C line indicating that the reaction system is properly occurred.

	Interpretation of results: 1. The test result is positive if a light- to dark red line appears in the control panel (C) and a light or dark red line in the test field (T). 2. The test result is negative if a light- to dark red line appears in the control panel (C) and no red line in the test field (T). 3. If no control line (C) or a test line (T) can be seen, the test is not performed correctly and invalid.
Kit components	**(1pcs/Kit) Provided materials:** ➢ 1 x Test cassette ➢ 1 x Sample tube prefilled with sample extraction buffer ➢ 1 x Swab ➢ 1x Instruction for use **Material required but not provided:** 1 timer **(5 pcs/Kit) Provided materials:** ➢ 5 x Test cassettes ➢ 5 x Sample tube prefilled with sample extraction buffers ➢ 5 x Swabs ➢ 1x Tube stand ➢ 1x Instruction for use **Material required but not provided:** 1 timer **(20 pcs/Kit) Provided materials:** ➢ 20 x Test cassettes ➢ 20 x Sample tube prefilled with sample extraction buffers ➢ 20 x Swabs ➢ 1x Tube stand ➢ 1x Instruction for use **Material required but not provided:** 1 timer
Performance	
Detection limit	30 $TCID_{50}$/mL
Sensitivity	97.33%
Specificity	99.33%
Run-time	15 min
Storage and Stability	
Storage stability	24 months
Storage temperature	The test kit can be stored between 2°C and 30°C in a sealed pouch until the expiry date.