

# Gardian Clinical Fact Sheet

## Gardian T3 Clinical Evidence Data

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## Coronavirus

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera:  $\alpha$ ,  $\beta$ ,  $\gamma$  and  $\delta$ . The  $\alpha$  and  $\beta$  genera are only pathogenic to mammals, while  $\gamma$  and  $\delta$  genera mainly cause bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting faecal-oral transmission. Seven kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV, and SARS-CoV-2.

SARS-CoV-2 is one of the most contagious viral pathogens that cause human respiratory tract infections (RTI). Currently, the patients infected by SARS-CoV-2 are the main source of infection. Asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period for SARS-CoV-2 is 1 to 14 days, mostly 3 to 7 days.

The clinical manifestations of SARS-CoV-2 include fever, fatigue, cough, and other symptoms, accompanied by dyspnoea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance. It has also been evidenced that COVID-19 can survive for 27 days on any surface, causing a higher contact risk.

## Variants of Covid

Variant trials have focused on Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Wild type, Omicron (B.1.1.529) and (B.A.2).

The Gardian T3 saliva-based rapid antigen test has been analytically tested, and clinically tested, to validate the research in the following areas of evidence:

Both analytical and clinical trials were conducted with correlating PCR tests to confirm the relationship between CT value, RNA loads, and result outcome as accurate.

Clinical trials to this point have included 830 individuals aged from 4 – 92 years to represent usability and stability. The analytical and clinical trials were conducted independently by the Jiangsu Provincial Centre for Disease Control and Prevention.

Currently, there are 1983 variants of Covid, and it is mutating quicker than the virus lineage can be identified with new variants.

Gardian focuses on having evidence that the Gardian T3 rapid antigen test is capable of detecting the variants of concern prominent in the community. The company is constantly monitoring variants of concern so that research can begin immediately on new variants identified by the World Health Organisation.

## Storage and Shelf Life

As of June 7, 2022, a shelf life of 18 months has been evidenced for Gardian T3 tests. This research was conducted by Medomics and incorporates transport simulation and real-time aging over 18 months. Criteria for this testing includes appearance, positive coincidence rate, negative coincidence rate, Limit of Detection (LoD), and intra-run repeatability.

Extreme temperature testing has also been conducted, and as per most medical devices, it is evidenced to recommend that all kits be maintained and stored out of direct sunlight, and between temperatures of 2-30 degrees Celsius. The tests should also be at room temperature prior to use.

## Food and Drink

A verification report was conducted on common drinks as food is considered too large to create a residue sufficient to affect the test result. Analytical and clinical testing was used to evidence the results.

Black tea, milk, grape juice, orange juice, cola, coffee, cocktails, and Red Bull were the focus fluids for testing. Fluids were tested through direct contact of fluid on the test strip, at 5-minute, 10-minute and 20-minute intervals post fluid consumption.

It was identified that the fluids did not affect the test results.

The recommendation however, is for users to rinse the mouth and wait five minutes prior to testing. Water does not affect the test, so it can be used to help produce saliva to conduct the test if saliva production is proving difficult.