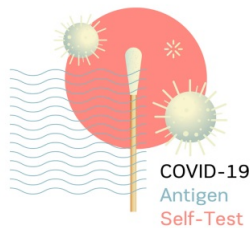## Germany Government Approves Covid-19 Antigen Self-Test for Lay Persons



The German Federal Office for Drugs and Medical Devices (BfArM) has given temporary special approval for self-administration of the CLINITEST Rapid COVID-19 Antigen Self-Test by lay persons. Moreover, the regular conformity assessment procedure for CE marking for self-administration by lay persons has been initiated. The test had already received a CE mark for use by healthcare professionals.

When used as part of a comprehensive mitigation strategy, the CLINITEST Rapid COVID-19 antigen test can serve as an effective tool to help communities identify infected individuals and isolate outbreaks. The manufacturer states that this test has sensitivity of 97.25% and a specificity of 100%, thereby helping to contain the spread of the virus.

In the wake of the large number of infections and huge demands on medical facilities and staff, this announcement comes as a relief. The test, which is easy to use with visual instructions, does not require any laboratory instruments or special laboratory staff to assist. Results are available within 15 minutes.

In order to assess the ease of use, a group of 50 people without medical training performed the test on themselves, by taking a swab from the nasal cavity. With the help of visual instructions for use, they confirmed the usability.

## Using the Test

The test is carried out by doing a nasal or a nasopharyngeal swab. Visual instructions help the user through five different steps whereby a swab is taken from both nostrils, which is then dipped in a reagent, dissolving a specific protein from the surface of the virus. This liquid is poured into a well in the test cassette. After approximately 15 minutes, the liquid flows into the view window of the cassette and becomes visible by a dash. One can see if the test is negative or positive by the position and number of lines indicated, or whether something was done incorrectly during the test procedure. In such a case, the test must be repeated.

The instructions indicate how to proceed once the test result is available. For example, a negative test result, which is only a snapshot, does not release the tester from Covid-19 related safety measures that are currently in effect. This test can be used on individuals with or without COVID-19 symptoms.

"The CLINITEST COVID-19 Antigen Self-Test offers users high flexibility in performing the test with very good quality results," said Christoph Pedain, Head of Point of Care Diagnostics at Siemens Healthineers.

This test will be distributed through selected channels. The personal use of this test - currently time-limited until 30 June 2021 - is also permitted in Austria.

Source:

Siemens Healthineers

Published on : Fri, 26 Mar 2021