BioSpectrum
the business of Bio & Health Sciences

LumiraDx bags CDSCO approval for COVID-19 antigen test

21 October 2021 | News

Test combines sensitivity with speed and is designed to be used in health care settings to aid with rapid diagnosis of COVID-19

LumiraDx, a next-generation point of care diagnostics testing company based in the UK, has received emergency use approval by the Central Drugs Standard Control Organisation for its SARS-CoV-2 Antigen test for use in India.

The test detects antigen nucleocapsid protein from a nasal swab with results in under 12 minutes from sample application.

In clinical studies, LumiraDx SARS-CoV-2 Antigen test demonstrated a 97.6 per cent positive agreement and 96.6 per cent negative agreement with the PCR test for patients within the first twelve days of symptom, making it one of the fastest, and most sensitive antigen point of care tests currently commercially available.

The LumiraDx SARS-CoV-2 Antigen test is a microfluidic test that runs on the LumiraDx point of care platform which scales down and integrates techniques used in laboratory analysers to provide lab-comparable diagnostic tests on a single point of care instrument.

The platform consists of a small, portable instrument; microfluidic test strip; simple, standardised workflow; and seamless, secure digital connectivity to the cloud and hospital IT systems.