



DEVICE DETAILS

NAME OF DEVICE	ALLTEST COVID-19 ANTIGEN TEST ORAL FLUID SELF TESTING
ESTABLISHMENT NAME	GLOBAL SCIENCE SDN BHD
REGISTRATION NO	IVDC4160422-97856
DEVICE DESCRIPTION	The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
DEVICE GROUPING TYPE	IVD Test Kit
INTENDED PURPOSE	The COVID-19 Antigen Rapid Test (Oral Fluid) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 in human oral fluid. This test is designed for home use ¹ with self-collected oral fluid samples from symptomatic individuals who are suspected of being infected with COVID-19. The COVID-19 Antigen Rapid Test (Oral Fluid) obtain a preliminary results only, the final confirmation should be based on clinical diagnostic results.
VALIDITY DATE OF REGISTRATION	19-07-2022 - 18-07-2027

MEDICAL DEVICE AUTHORITY

LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
No results found.		