



DEVICE DETAILS

NAME OF DEVICE	NEWGENE COVID-19 ANTIGEN DETECTION KIT
ESTABLISHMENT NAME	MALAYSIAN DIAGNOSTICS CORPORATION SDN BHD
REGISTRATION NO	IVDC5384922-101425
DEVICE DESCRIPTION	The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibody against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device.
DEVICE GROUPING TYPE	Family
INTENDED PURPOSE	The COVID-19 Antigen Detection Kit is intended for rapid detection of SARS-CoV-2 nucleocapsid protein in human nasal swab and saliva samples. This product is suitable for people with symptoms similar to COVID-19, like cough, fever, fatigue and etc., to assist the early diagnosis of SARS-CoV-2 infection. It can also be used to test people without COVID-19 symptoms to regularly monitor their health status. For self-test use / Suitable for non-professionals to conduct self-test.
VALIDITY DATE OF REGISTRATION	15-08-2022 - 14-08-2027

LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
No results found.		