



DEVICE DETAILS

NAME OF DEVICE	SARS COV 2 ANTIGEN TEST KIT (COLLOIDAL GOLD)
ESTABLISHMENT NAME	EPIC SCIENCE SDN BHD
REGISTRATION NO	IVDC9560522-111517
DEVICE DESCRIPTION	The SARS-CoV-2 Antigen Test Kit is a rapid lateral flow immuno chromatographic sandwich assay to directly detect nucleocapsid protein of SARS-CoV-2 in saliva specimens and diagnosis of SARS-CoV-2 infection. The patient sample is placed in the Sample Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is added into the Test Cassette sample well. And the sample migrates through a test strip, if the SARS-CoV-2 virus antigen is present, a red color line will be showed on the T line. If SARS-CoV-2 viral antigen is absent, there is not a red line will be should on the T line, however, a red line will be always showed on the C line indicating that the reacting system is properly happened.
DEVICE GROUPING TYPE	Family
INTENDED PURPOSE	The SARS CoV-2 Antigen Test Kit is a gold immune-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS CoV-2 saliva specimens directly from individuals who are suspected of COVID 19.
VALIDITY DATE OF REGISTRATION	30-11-2022 - 29-11-2027

MEDICAL DEVICE AUTHORITY

LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
No results found.		