DEVICE DETAILS

NAME OF DEVICE	SARS-COV-2 ANTIGEN RAPID TEST (SELF-TESTING)
ESTABLISHMENT NAME	TRANSLAB (M) SDN BHD
REGISTRATION NO	IVDC4131022-107253
DEVICE DESCRIPTION	The SARS-CoV-2 Antigen Rapid Test (Self-Testing) is a lateral flow chromatograhic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens. Test results are read visually at 15-30 minutes based on the presence or absence of the colored lines. To serve as a procedural control, a colored line will always appear in the control line region indicating that sufficient specimen volume was added and membrane absorption has occurred.
DEVICE GROUPING TYPE	Family
INTENDED PURPOSE	The SARS-CoV-2 Antigen Rapid Test (Self-Testing) is a lateral flow test for the qualitative detection of the antigen from SARS-CoV-2 in nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. It does not differentiate between SARS-CoV and SARS-CoV-2.
VALIDITY DATE OF REGISTRATION	03-11-2022 - 02-11-2027

LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
No results found.		