



## DEVICE DETAILS

NAME OF DEVICE	LYHER NOVEL CORONAVIRUS (COVID-19) ANTIGEN TEST KIT (COLLOIDAL GOLD) SELF-TEST KIT
ESTABLISHMENT NAME	TEDA WELLNESS SOLUTIONS SDN BHD.
REGISTRATION NO	IVDC7175523-119360
DEVICE DESCRIPTION	The immune colloidal gold technique is used in the assay to detect antigens (N-protein) of Covid-19. The reagent binding pad is coated with the SAR-COV-2 monoclonal antibodies which is labelled with colloidal gold maker, respectively. A nitrocellulose membrane in the area of a strip is coated with anSARS-COV-2 antibodies. The quality control area within the nitrocellulose membrane is coated with goat anti-mouse IgG antibodies. When testing, the antibodies against COVID-19 form immuno-complexes with the antigen (n-protein) of the virus in the specimen to be tested. As a result chromatography, immuno-complexes moved along the membrane and will be captured by the anti-SARS-COV-2 antibodies coated in the test area to form a visible line with red color (T-line) . The free colloidal gold marker or immune complexes continue to move forward and specifically bind to the goat anti-mouse antibody coated in the quality control area to form a visible line (C line). If the specimen does not contain the antigen of Covid-19, no test will be show, only quality control line (C line) will appear.
DEVICE GROUPING TYPE	Family
INTENDED PURPOSE	The Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) is an in vitro immunoassay. The assay is for the direct and qualitative detection of antigen (N-protein) of SARS-COV-2 from oral fluid (saliva/sputum) sepcimens. The kit is for in vitro diagnostic use. The kit is used for self-testing.
VALIDITY DATE OF REGISTRATION	23-02-2023 - 22-02-2028

## LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
No results found.		