



CLA MEDICAL
HUMANISING HEALTHCARE

Registration NO:
IVDC8329524-186894

Medical Device
AUTHORITY
MALAYSIA



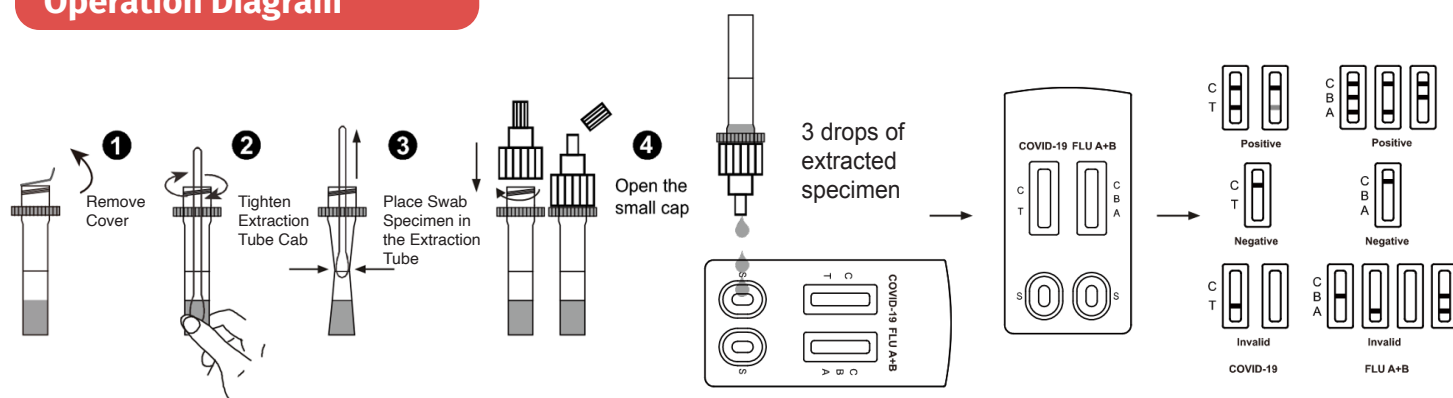
RAPID BIOTEC™

Sars-CoV-2/ Influenza A+B Antigen Combo Rapid Test Device (Nasopharyngeal Swab)

INTENDED USE

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A and Influenza B virus antigens present in human nasopharynx.

Operation Diagram



Performance Characteristics

Analytes	Specimen	Sensitivity	Specificity	Accuracy
SARS-CoV-2	Nasopharyngeal Swab	97.6%	99.7%	99.1%
Flu A		94.7%	98.2%	97.7%
Flu B		93.0%	97.7%	97.0%

Materials Provided

- Test Devices
- Workstation
- Sterile Swabs
- Package Insert
- Specimen Collection Tubes with Extraction Buffer
- Procedure card

Products Advantages

- Easy specimen collection
- Fast results in 15 minutes
- Easy visual interpretation
- Simple operation
- High accuracy

Ordering Information

Cat.no.	Product	Specimen	Kit Size
D-COVID1	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device	Nasopharyngeal Swab	1 T
D-COVID20	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Device	Nasopharyngeal Swab	20 T

For professional in vitro diagnostic use only.