



CLA MEDICAL
HUMANISING HEALTHCARE

Registration NO:
IVDC8769824-189134

Medical Device
AUTHORITY
MALAYSIA



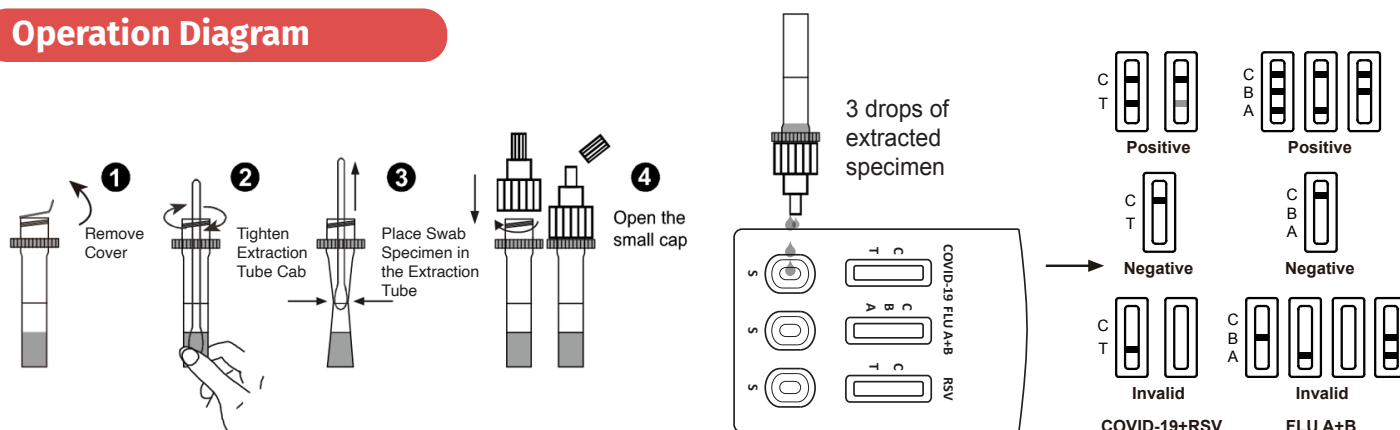
RAPID BIOTECTM

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

INTENDED USE

The SARS-CoV-2 / Influenza A+B / RSV Antigen Combo Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) antigens present in human nasopharyngeal swab specimen or nasal swab specimen.

Operation Diagram



Performance Characteristics

Analytes	Specimen	Sensitivity	Specificity	Accuracy
SARS-CoV-2	Nasopharyngeal Swab	97.0%	99.0%	98.0%
Flu A		95.0%	99.1%	98.4%
Flu B		92.9%	99.1%	98.1%
RSV		94.3%	96.2%	95.9%

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-COVIRCS20	SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test Device	Nasopharyngeal Swab	20 T

For professional in vitro diagnostic use only.