



CLA MEDICAL
HUMANISING HEALTHCARE

Registration NO:
IVDC8138125-195331

Medical Device
AUTHORITY
MALAYSIA



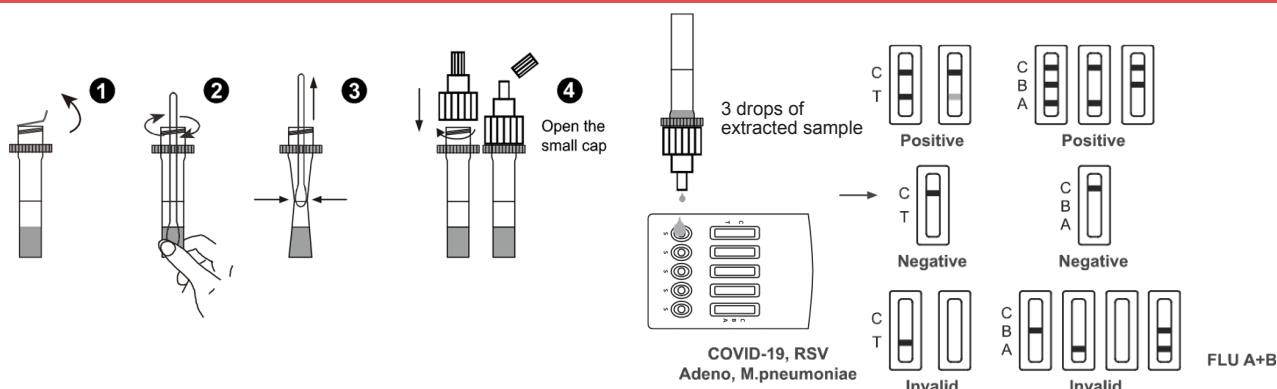
RAPID BIOTEC™

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

INTENDED USE

The Sars-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test Device (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A, Influenza B, Respiratory Syncytial Virus(RSV), Adenovirus and M.pneumoniae antigens present in human nasopharynx.

Operation Diagram



Performance Characteristics

Analytes	Sensitivity	Specificity	Accuracy
SARS-CoV-2	96.4%	99.0%	98.2%
Flu A	95.0%	99.1%	98.4%
Flu B	92.9%	99.1%	98.1%
RSV	94.3%	96.2%	95.9%
Adenovirus	96.9%	98.6%	98.4%
M.pneumoniae	91.8%	98.0%	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-SCIABRSVAPNS20	SARS-CoV-2 / Influenza A+B / RSV / Adenovirus / M. pneumoniae Antigen Combo Rapid Test Device	Nasopharyngeal Swab	20T

For professional in vitro diagnostic use only.

Distributor

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www.clamedical.com.my

MDA Licence No.: MDA-5480-WDP124