

# **SCALE UP COVID-19** ANTIGEN TESTING

RAPID TEST DEVICE

- For patients suspected of current COVID-19 infection
- Rapid answers for patients: test results in 15 minutes
- Reliable, high performance\*
  - Sensitivity: 91.4% (94.1% for samples with Ct values ≤33)
  - Specificity: 99.8%
- Deploy at point of care in a variety of settings
- Accessible solution enables large-scale testing



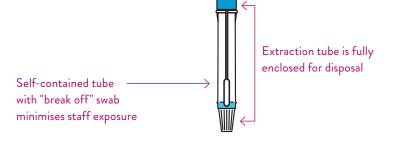






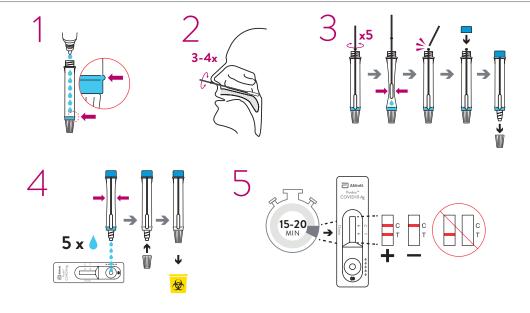
# **BIOHAZARD RISK** REDUCTION FEATURES

Reduce the risk of facility contamination and healthcare worker exposure.



## TEST PROCEDURE

Consult Instructions for Use for complete procedure.



#### PERFORMANCE\*

• SENSITIVITY: 91.4% (94.1% for samples with Ct values ≤33)

• **SPECIFICITY**: 99.8%

 CLINICAL STUDY POPULATION: 585 individuals, including 140 PCR-positives and 445 PCR-negatives

## SPECIFICATIONS

• TEST TIME: 15 MINUTES • STORAGE: 2°C-30°C

• CE MARK

• SAMPLE TYPE: Nasopharyngeal swab

INTENDED USE: An in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

#### ORDER INFORMATION

- PANBIO™ COVID-19 AG RAPID TEST DEVICE
- CONTENTS: 25 Test Devices, 1 Buffer (9 mL/bottle), 25 Extraction Tubes, 25 Extraction Tube Caps, 1 Positive Control Swab, 1 Negative Control Swab, 25 Sterilized Nasopharyngeal Swabs for Sample Collection, 1 Tube Rack, 1 Quick Reference Guide,







