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IDENTIFY POTENTIALLY COVID-19 CONTAGIOUS PATIENTS **WITH OR WITHOUT SYMPTOMS IN 15 MINUTES TO REDUCE VIRUS SPREAD**

PANBIO™ COVID-19 Ag RAPID TEST DEVICE

Patient-friendly nasal self-collected swab option minimises health worker exposure

TESTING USE CASES

Screening asymptomatic individuals	Individuals presenting with symptoms in the last 7 days	Individuals suspected of exposure to COVID-19

AT LEAST 50% OF NEW INFECTIONS ORIGINATE FROM **EXPOSURE TO ASYMPTOMATIC INDIVIDUALS**[1]

Mass screening of populations including asymptomatic individuals can quickly filter out potentially contagious people and **rebuild a sense of safer** workplaces, schools, airports and recreational gatherings.

Frequent ongoing screening in congregate settings reduces the risk of infection and informs control measures.[2]

Clinical data demonstrate that testing with the Panbio™ COVID-19 Ag Rapid Test Device can **effectively identify both symptomatic and asymptomatic individuals** who are contagious.[3]

The Panbio™ COVID-19 Ag Rapid Test Device is **accessible**, **affordable, easy to deploy**, and provides quick, reliable results to help slow disease spread.

PANBIO™ COVID-19 Ag RAPID TEST DEVICE HAS DEMONSTRATED **STRONG PERFORMANCE IN SUSPECTED AND SYMPTOMATIC PATIENTS**

Studies including 508 individuals investigated the performance of the Panbio™ COVID-19 Ag Rapid Test Device using a nasal swab compared to nasal PCR from a population of individuals who were suspected of exposure to COVID-19 or presented with symptoms in the last 7 days.

		NASAL PCR TEST RESULT		
		POSITIVE	**NEGATIVE**	**TOTAL**
PANBIO™ COVID-19 Ag TEST RESULT	**POSITIVE**	102	1	103
	NEGATIVE	2	403	405
	TOTAL	104	404	508

SENSITIVITY	**SPECIFICITY**	**OPA**
98.1% [93.2%; 99.8%]	**99.8%** [98.6%; 100.0%]	**99.4%** [98.3%; 99.9%]

Positive agreement of the Panbio™ COVID-19 Ag Rapid Test Device is higher with samples of Ct values ≤ 30 with a sensitivity of 100.0% (95% CI: 96.0%–100.0%) and Ct values ≤ 33 with a sensitivity of 99.0% (95% CI: 94.5%–100.0%). Patients with Ct values > 30 are no longer contagious.[4-6]

The clinical performance data was also calculated vs nasopharyngeal swab specimens using an FDA EUA RT-PCR reference and has a sensitivity of 91.1% (95% CI: 84.2-95.6%) and specificity of 99.7% (95% CI: 98.6-100.0%).

CI = confidence interval
Ct = cycle threshold
EUA = Emergency Use Authorization
OPA = overall percent agreement
PCR = polymerase chain reaction
RT-PCR = real-time polymerase chain reaction

PANBIO™ COVID-19 Ag RAPID TEST DEVICE DATA DEMONSTRATES THE **POWER OF IDENTIFYING ASYMPTOMATIC INFECTIOUS PEOPLE**

- The purpose of screening asymptomatic individuals is to identify persons who may be contagious so that measures can be taken to prevent further transmission.
- Panbio™ COVID-19 Ag Rapid Test Device performance demonstrated a high positive agreement of 93.8% with PCR in asymptomatic patients with cycle threshold (Ct) values ≤ 30, which correlates with potential contagiousness.
- The Ct value in RT-PCR refers to the number of cycles needed to amplify viral RNA to reach a detectable level. Ct values are inversely related to viral burden; the lower the Ct, the more viral RNA is present, and the higher the Ct, the fewer copies of viral RNA are present in a sample.
- A growing body of scientific literature on the correlation between contagiousness, Ct counts and viral load suggests that at Ct counts in the 30s, the SARS-CoV-2 virus no longer replicates,[7] meaning people are no longer infectious.[4-6]

Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing 483 asymptomatic subjects for SARS-CoV-2

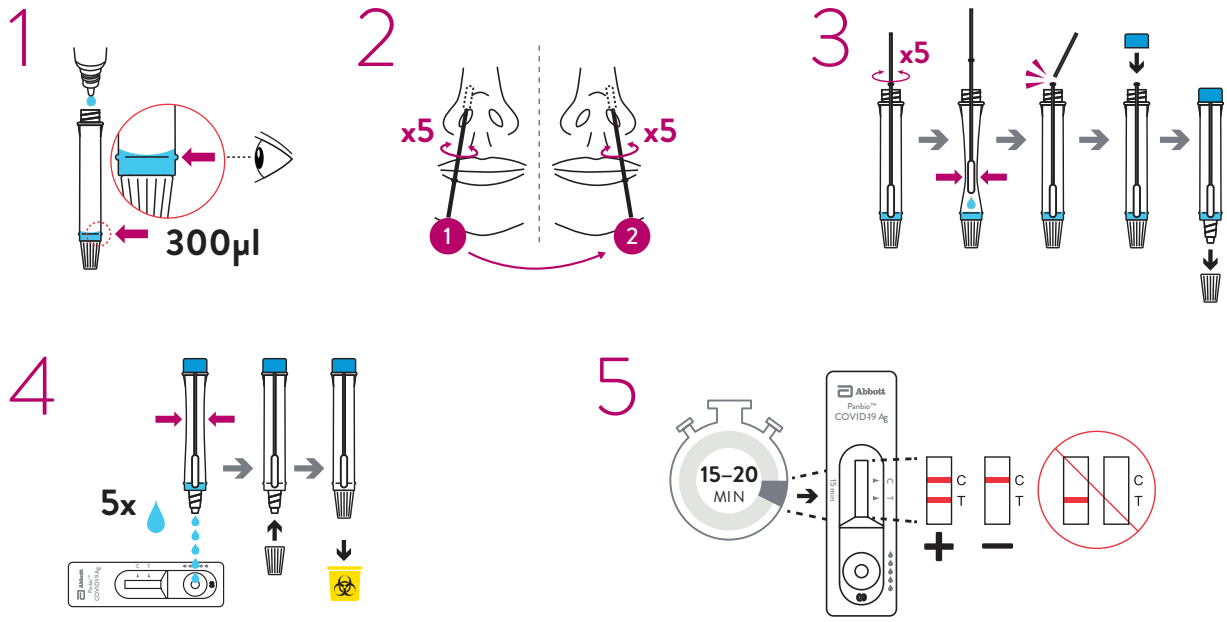
	ALL NASAL PCR POSITIVE SAMPLES (n = 50)	CT VALUES ≤ 33 (n = 40)	CT VALUES ≤ 30 (n = 32)
SENSITIVITY [95% CI]	**66.0%** [51.2%; 78.8%]	**80.0%** [64.4%; 90.9%]	**93.8%** [79.2%; 99.2%]
SPECIFICITY [95% CI]	**100%** (n = 433) [99.2%; 100.0%]		

- Clinical specimens were determined to be positive or negative using an FDA EUA RT-PCR reference method.
- Positive results (n = 50) were stratified by the comparator method Ct counts as a surrogate for the amount of virus present in the clinical sample to help establish the correlation of product performance with viral load levels.
- As presented in the table, the positive agreement increases with lower Ct values. Patients with Ct values > 30 are no longer contagious.[4-6]

PATIENT-FRIENDLY, SELF-COLLECTED NASAL SWAB **MINIMISES HEALTH WORKER EXPOSURE**

- Patients can perform sample self-collection with nasal swab, supervised by a trained professional.
- Health workers can maintain distance during the sample collection procedure, which minimises their personal exposure.
- Self-collection offers a more comfortable patient experience and feeling of control during the sampling procedure.

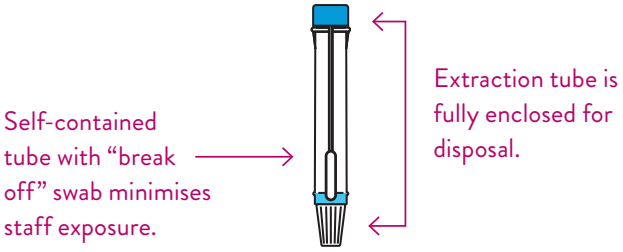
SIMPLE TEST PROCEDURE



Consult Instructions for Use for complete procedure.

BIOHAZARD RISK-REDUCTION FEATURES

Reduce the risk of facility contamination and health worker exposure.



SPECIFICATIONS

- **TEST TIME:** 15 MINUTES
- **STORAGE:** 2°C–30°C
- **SAMPLE TYPE:** NASAL SWAB

INTENDED USE: Panbio™ COVID-19 Ag Rapid Test Device is an *in vitro* diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal 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 (NASAL)

CATALOG NUMBER:	• 41FK11 (CE)
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 Nasal Swabs for Sample Collection • 1 Tube Rack • 1 Quick Reference Guide • 1 Instructions for Use

FOR MORE INFORMATION, CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE OR VISIT GLOBALPOINTOFCARE.ABBOTT

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Product not available in all countries. Not approved for sale in New Zealand. Consult your local Abbott representative for availability in your country.

1. Johansson et al. SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. *JAMA Netw Open*. 2021;4(1):e2035057.
2. Centers for Disease Control and Prevention. Interim Guidance for Antigen Testing for SARS-CoV-2. 2020.
3. Panbio COVID-19 Ag Rapid Test Device Instructions for Use.
4. Centers for Disease Control and Prevention. Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance). 2020.
5. Centers for Disease Control and Prevention. Duration of Isolation and Precautions for Adults with COVID-19. 2020.
6. Bullard, et al. Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples. *CID*. 2020; November 15, 2020;71(10). doi:10.1093/cid/ciaa638.
7. La Scola B, et al. Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards. *Eur J Clin Microbiol Infect Dis*. June 2020;39(6):1059-1061.

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