Abbott

Identify COVID-19 potentially contagious people with or without symptoms in 15 minutes to reduce virus spread

Panbio™ COVID-19 Ag Rapid Test Device

FOR EXTERNAL USE

COVID-19 Antigen Test

- **How does it work?**
  - Directly detects presence of the virus, indicating **active infection** (i.e. replication of the virus)
- **Who performs?**
  - Trained healthcare workers, wearing appropriate personal protective equipment (PPE)
- **Where can it be performed?**
  - Any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation
- **Benefits**
  - Enables fast, **decentralized access to direct testing** for the virus, relieving the burden on the laboratory testing system
  - If used for contact tracing, provides an **objective marker to define chains of transmission**

WHO Guidance: Appropriate scenarios for use of Ag RDTs[1]

- **To support outbreak investigations** (e.g. in closed or semi-closed groups including **schools, care-homes, cruise ships, prisons, work-places and dormitories**, etc.)

- In NAAT-confirmed COVID-19 outbreaks, **Ag-RDTs could be used to screen at-risk individuals** and rapidly isolate positive cases (and initiate other contact tracing efforts) and prioritize sample collection from RDT-negative individuals for NAAT.

- To monitor trends in disease incidence in communities, and particularly among **essential workers and health workers during outbreaks** or in regions of widespread community transmission where the positive predictive value and negative predictive value of an Ag-RDT result is sufficient to enable effective infection control

- **Where there is widespread community transmission, RDTs may be used for early detection and isolation of positive cases in health facilities**, COVID-19 testing **centers/sites, care homes, prisons, schools, front-line and health-care workers** and for contact tracing.

- Note that the safe management of patients with RDT-negative samples will depend on the RDT performance and the community prevalence of COVID-19. A negative Ag-RDT result cannot completely exclude an active COVID-19 infection, and, therefore, repeat testing or preferably confirmatory testing (NAAT) should be performed whenever possible, particularly in symptomatic patients.

1. WHO Antigen detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020. https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays

Diagnosis in populations with known risk exposure[1]

The goal of testing within these populations and use cases is to manage the epidemic, in addition to the provision of clinical care where needed

Target populations include:

- Individuals with symptoms
- High-risk populations in areas with confirmed/ suspected outbreak — Elderly, people with comorbidities, and populations in closed settings such as prisons, care homes, etc
- Frontline healthcare workers and essential workers — Symptomatic & Asymptomatic
- Contacts of confirmed cases

1. Africa CDC Interim Guidance Use Rapid Antigen Tests COVID19 Dec 2020. https://africacdc.org/download/interim-guidance-on-the-use-of-rapid-antigen-tests-for-covid-19-response/

Screening in general population with unknown or low exposure risk[1]

The goal is to allow opening of economic and social activities safely while minimizing risk of new outbreaks

- Screening at border points of entry and among in-patients enables early identification of new cases and seeks to prevent new clusters and outbreaks from forming.
- By contrast, testing in educational institutions and workplaces allows for these critical services to remain open and limit the introduction of COVID-19 into these semi-closed settings.

Target populations include:

Travelers crossing borders/points of entry	Teachers, students and administrative staff at educational institutions	Other general populations (e.g. random community screening, surveillance)
Factory workers, government employees and private sector employees at workplaces	In-patients at hospitals admitted for other conditions than COVID-19	

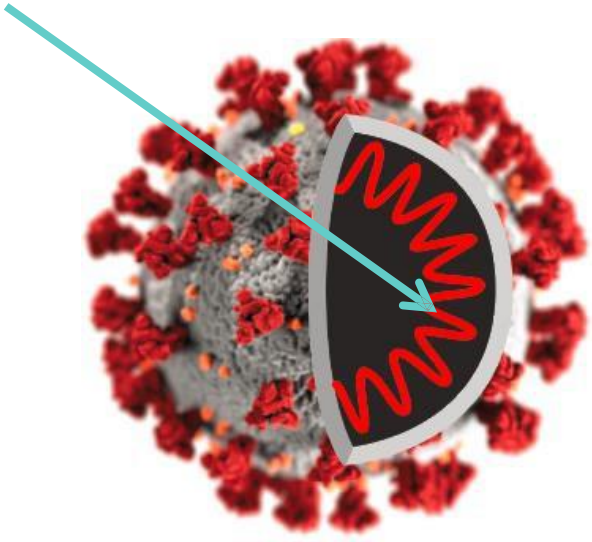
1. Africa CDC Interim Guidance Use Rapid Antigen Tests COVID19 Dec 2020. https://africacdc.org/download/interim-guidance-on-the-use-of-rapid-antigen-tests-for-covid-19-response/

Introducing the Panbio™ COVID-19 Rapid Test Device

Identify COVID-19 potentially contagious people with or without symptoms in 15 minutes

What does the Panbio™ COVID-19 Ag Rapid Test Device detect?

- *In vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)
- Detects nucleocapsid protein inside the SARS-CoV-2 virus



Panbio™ COVID-19 Ag Rapid Test Device Overview

- Mass screening of populations including asymptomatic individuals can quickly **filter out potentially contagious people** and **rebuild a sense of** confidence to gather in workplaces, schools, airports and recreational gatherings.
- **Frequent ongoing screening** in congregate settings reduces risk of infection and informs control measures.[1]
- Patient friendly **self-collected nasal swab** under the supervision of a healthcare professional that minimizes health worker exposure
- Accessible, affordable, easy to deploy, and provides quick, reliable results to **help slow disease spread**.

1. CDC Interim Guidance for Antigen Testing for SARS-CoV-2 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Demonstrated strong performance in suspected and symptomatic patients vs PCR

Nasal sample type

vs Nasal PCR

- Sensitivity: **98.1%**
  (99.0% for samples with Ct values ≤33)
- Specificity: **99.8%**

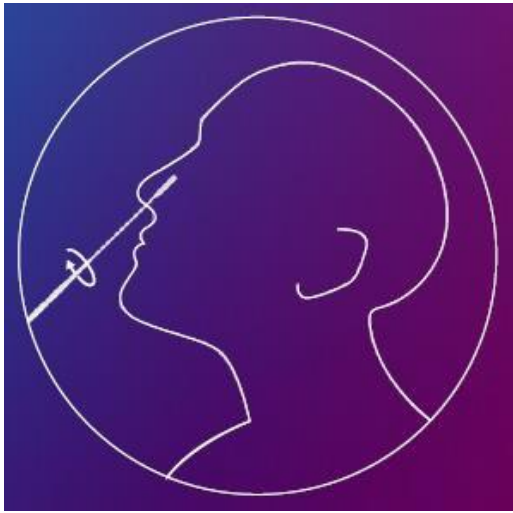
Nasopharyngeal sample type

vs Nasopharyngeal PCR

- Sensitivity: **91.4%**
  (94.1% for samples with Ct values ≤33)
- Specificity: **99.8%**

Nasal sample collection enables scale-up in nontraditional settings

- ~ 2 cm nasal swab insertion depth
- Minimize undesirable reflexes like coughing or sneezing[1]
- Reduce risk of infecting healthcare workers by reducing the duration of the procedure[2]
- Less invasive and less patient discomfort[2] helps overcome patient resistance to procedure
- Lower technical complexity[2]; easier training for staff

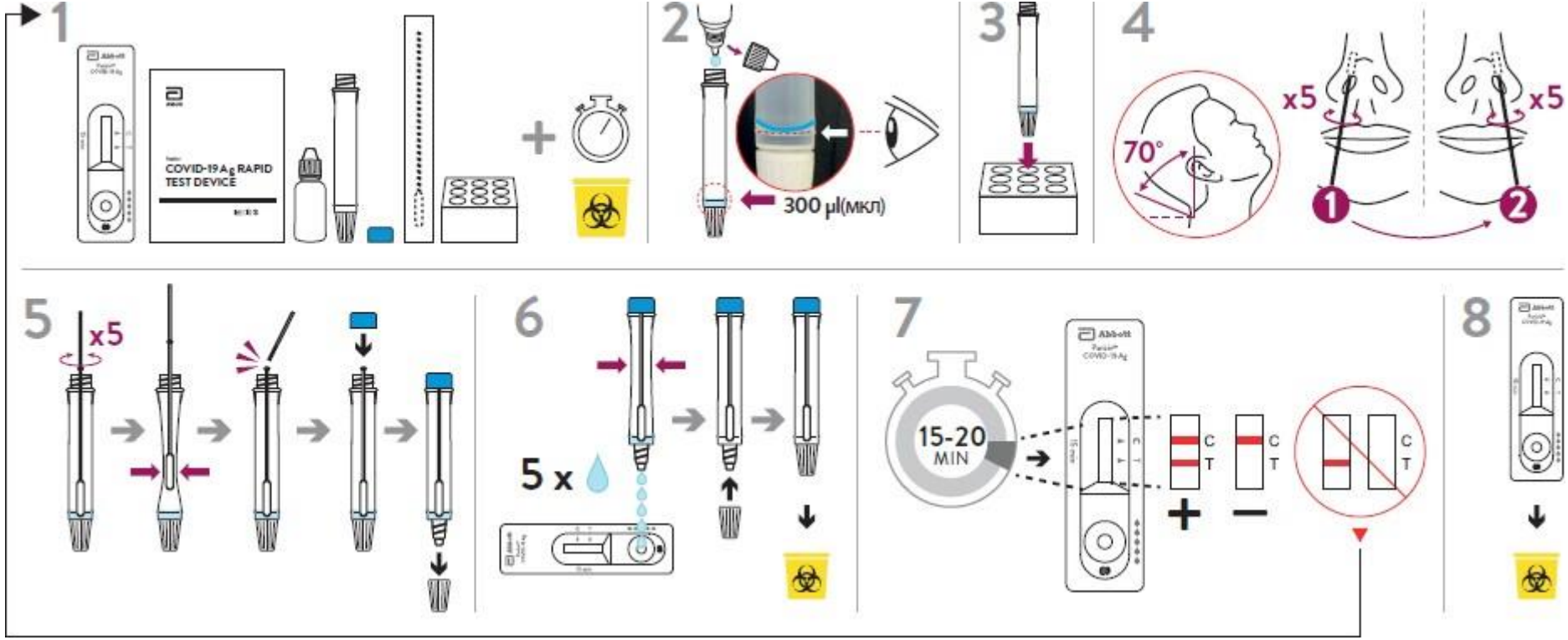


1. Pondaven-Letourmy S, et al. European Annals of Otorhinolaryngology, Head and Neck Diseases. 2020.
2. OASH Office of the Assistant Secretary for Health. COVID-19 Fact Sheet. Nasal Specimen Collection for SARS-CoV-2 Diagnostic Testing 2020.

Patient-friendly **nasal self-collected swab** option minimizes health worker exposure

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

Test Procedure: Nasal



Deploy in workplaces, schools, airports, and recreational gatherings

- Portable format allows fast setup of decentralized community testing sites
- Deploy in lab and non-lab decentralized locations
- Samples are taken and directly applied to test at point of care
- No requirement to ship samples
- Requires no additional instrumentation

Faster Answers for Patients

- Results in 15 minutes, while patients wait
- Enables immediate treatment or isolation measures to minimize transmission
- Fewer follow up calls to patients
- Fast alternative if lab PCR unavailable
- Fewer bottlenecks on throughput

Kit Contents: Everything Needed to Run a Test

Materials Provided

- 25 Test devices with desiccant in individual foil pouch
- 1 Buffer (1 x 9 ml/bottle)
- 25 Extraction tubes
- 25 Extraction tube caps
- 1 Positive control swab
- 1 Negative control swab
- 25 Sterilized nasopharyngeal or nasal swabs for sample collection
- 1 Tube rack
- 1 Quick reference guide
- 1 Instructions for use

Required But Not Provided

- Personal protective equipment (PPE)
- Protective gloves
- Timer
- Biohazard container

Storage Requirements

- 2°C–30°C

Ordering Information: Nasal

- Cat No: 41FK11 (CE, WHO EUL)
- 25 Tests per Kit Box
- CE Mark

Ordering Information: Nasopharyngeal

- Cat No: 41FK10 (CE, WHO EUL)
- 25 Tests per Kit Box
- CE Mark

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 nasopharyngeal or 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.