Panodyne®

SARS-CoV-2

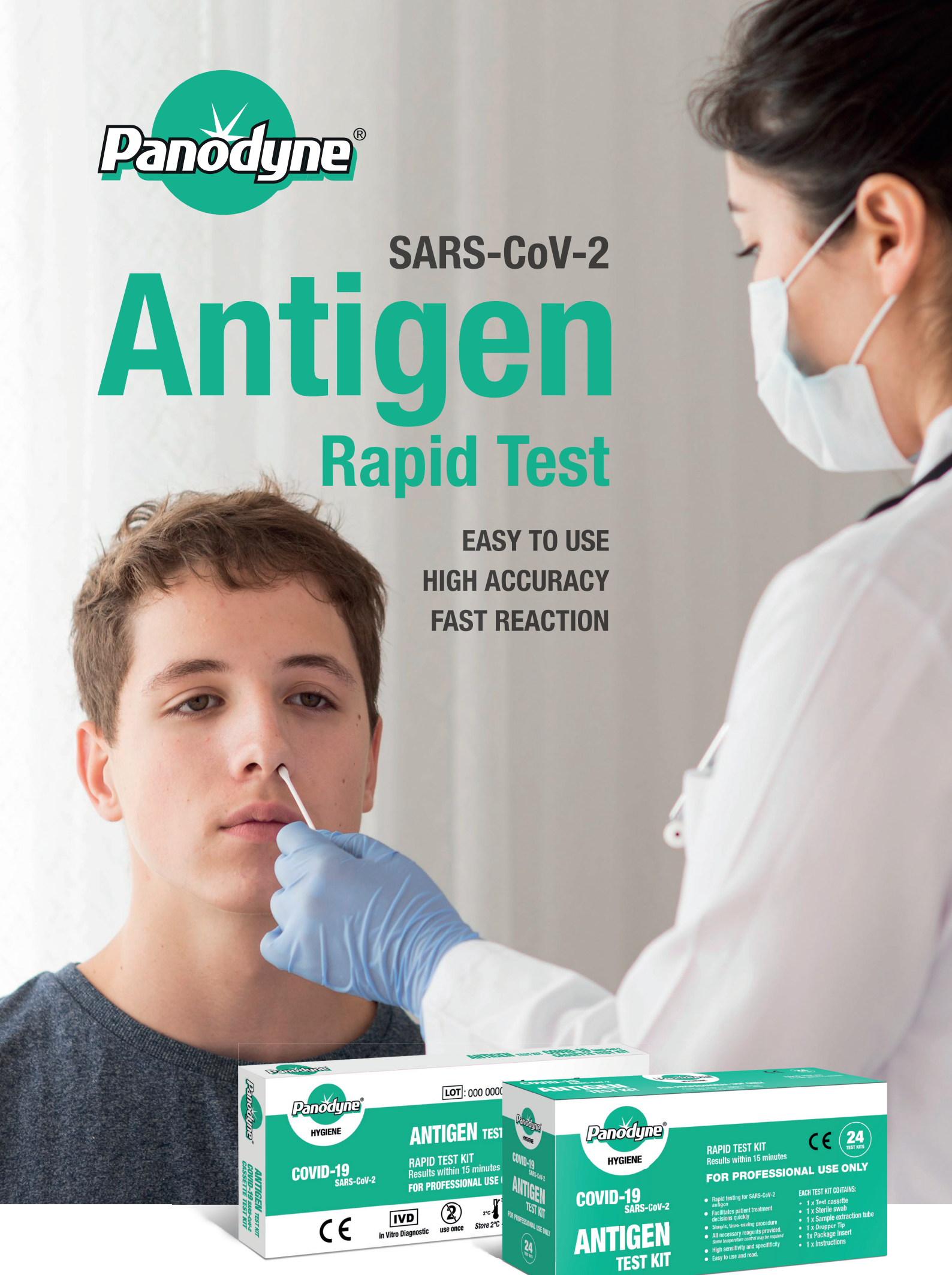
Antigen

Rapid Test

EASY TO USE

HIGH ACCURACY

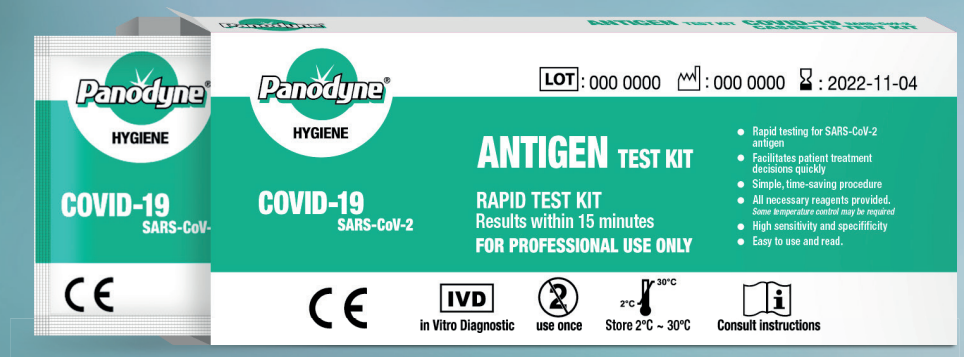
FAST REACTION



For professional use only

SARS-CoV-2 Overview

The novel coronaviruses belong to the β genus. SARS-CoV-2 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.



Benefifits

Rapid testing for SARS-CoV-2 antigen within 15 minutes

Facilitates patient treatment decisions quickly

Simple, time-saving procedure

All necessary reagents provided & no equipment needed. High sensitivity and specifificity

Contents

- 24 Test cassettes
- 24 Sterile swabs
- 24 Sample extraction tube
- 1 Dropper tip
- 1 Package insert

Intended Use

The SARS-CoV-2 Antigen Rapid Test is intended for in vitro qualitative detection to SARS-CoV-2 antigen in human nasopharyngeal swab or oropharyngeal swab samples.

Specification

Information	Time to result	Storage	Shelf life	Specimen type
In detail	15 minutes	2-30℃	**24** months	Nasopharyngeal swab or oropharyngeal swab

Performance Characteristics

SARS-CoV-2 Antigen Rapid Test Performance with Comparator Method (nasopharyngeal swab/oropharyngeal swab)

SARS-CoV-2 Antigen Rapid Test	Comparator Method		Total
	Positive	Negative	
Positive	30	1	31
Negative	33	102	135
Total	3	101	104

PPA: 90.91% (95%CI: 76.43%-96.86%)
NPA: 99.02% (95%CI: 94.66%-99.83%)
OPA: 97.04% (95%CI: 92.63%-98.84%)

EXPLANATION OF TERMS:

PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives

NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives.

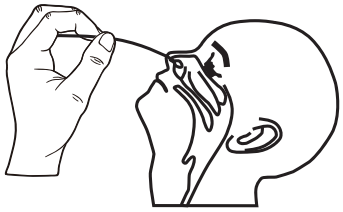
OPA: Overall Percent Agreement = True Positives + True Negatives / Total

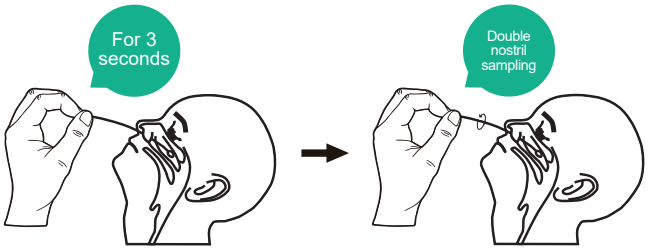
Test Procedure & Interpretation

Specimen collection

Use the nasopharyngeal swab or oropharyngeal swab supplied in the kit.

1. Nasopharyngeal swab collection method:

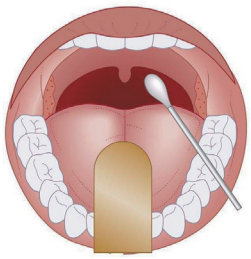


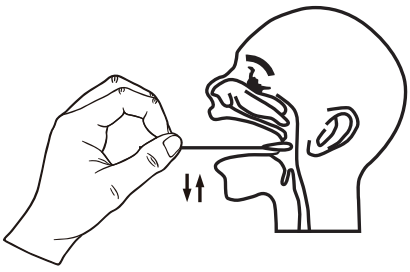


1. The operator holds the swab by the right hand and holds the head of the subject fixedly by left hand. Putting the swab downing backwards the bottom of the nasal cavity and penetrate slowly and gently. Do not overexert to avoid traumatic hemorrhage.

2. When the cusp of the swab touching the paries posterior of the pharyngonasal cavity, letting the swab remain in the place for a few seconds (about 3 seconds) and rotating the swab gently for one cycle, and then remove the swab slowly.

2. Collection method of oropharyngeal swab:





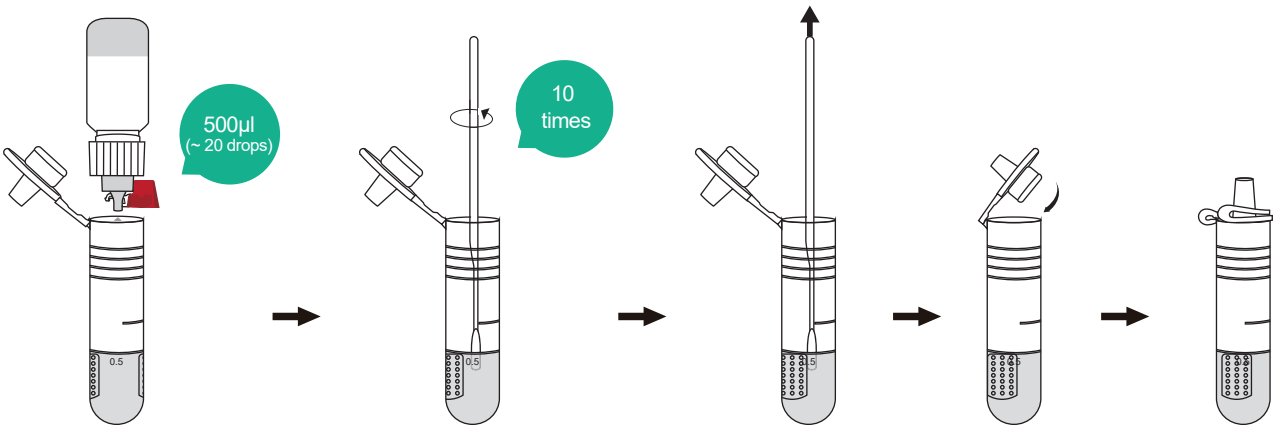
Both sides of the pharyngeal tonsils at least 3 times, up and down the posterior pharyngeal wall at least 3 times

1. The head of the person to be collected is slightly tilted and his mouth is wide open, exposing the pharyngeal tonsils on both sides.

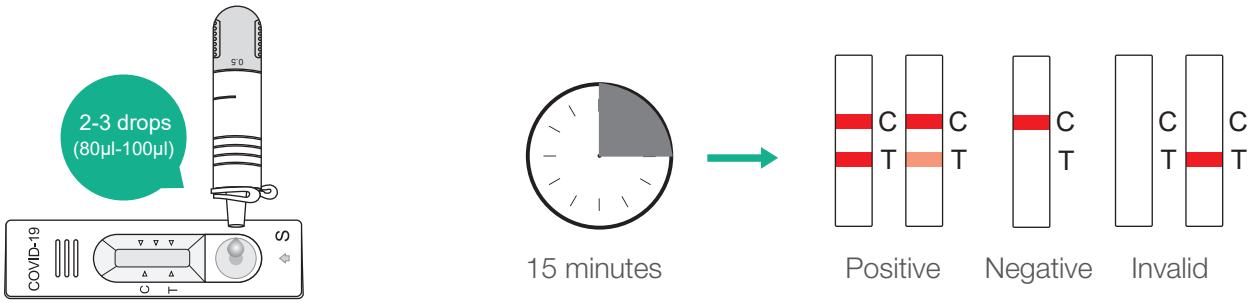
2. Wipe the pharyngeal tonsils on both sides of the person to be collected back and forth with a little force for at least 3 times, and then wipe up and down the posterior pharyngeal wall for at least 3 times.

Sample preparation

Add 500µl (~20 drops) of sample extract to the 0.5 mark of the sampling tube, dip the swab after collecting the sample into the sample extract, make the sample extract fully permeate the swab, rotate and squeeze the swab 10 times, then pull out the swab, and take the stranded liquid as the sample to be tested.



Test procedure & interpretation of results



Ordering Information

Product Description	Time to result	Catalogue No.	Format	Kit Size
SARS-CoV-2 Antigen Rapid Test	nasopharyngeal swab or oropharyngeal swab	-----	Cassette	24 Tests/Kit

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