





Anterior Nasal or Nasopharyngeal Swab Sample



Digital Result

TESTING, TESTING AND RE-TESTING BECAUSE IT MATTERS...

- ...to mitigate life-threatening disease.
- ...to prevent community spread and contain the outbreak.
- ...to isolate and quarantine COVID-19 positive cases.
- ...to identify asymptomatic COVID-19 cases.
- ...to avoid rapidly spreading cases from undetected patients.
- ...to test suspected patients with symptoms, moderate or no symptoms.
- ...to test people with close contact with infected patients.
- ...to re-test people under quarantine control.
- ...to differentiate from common cold, flu and allergies.
- ...to take transmission-based precautions.
- ...to test, trace and treat patients.







Affimedix, Inc., a growing Global Medical Device company based in Silicon Valley of California, focuses on R & D, product design, development, manufacturing and marketing of its "Proprietary" Point-Of-Care Tests.

INTENDED USE

TestNOW - **COVID-19 Antigen** Test is an *in vitro* diagnostic Rapid COVID-19 Antigen lateral flow immunoassay for the qualitative detection of SARS-CoV-2 virus antigen in human anterior nares or nasopharynx of individuals suspected of COVID-19 infection. The test is intended for professional and laboratory use only as an aid in the rapid diagnosis of SARS-CoV-2 virus infections with Visual or Digital Result reading.

The test provides preliminary test results. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 disease is suspected in conjunction with other clinical data available to the physician

TestNOW - COVID-19 Ag

The laboratory based RT-PCR are highly accurate in spotting infected people when they are administered properly. However, such tests generally require trained personnel, specific reagents and expensive machines that take hours and days to provide results.

TestNOW - **COVID-19 Ag** is easy to use, costeffective and can be done at point of care in 15 minutes, and could help to rapidly identify people who have high levels of virus - those who are most likely to be infectious to othersand isolate them from the community.

Product Features:

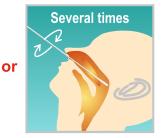
- Point-Of-Care COVID-19 Diagnostic Testing within first week of the onset of symptoms.
- ONE Swab provides flexibility for Anterior Nasal or Nasopharyngeal Samples.
- Results in Just 15 Minutes saving crucial time.
- Results are easy and clear to read Visually or Digitally using RapiRead™CUBE Reader.
- High Clinical Performance:
 - ✓ Sensitivity: 96.1% (vs. RT-PCR-confirmed samples)
 - ✓ Specificity: 99.4%
- Batch Testing with *RapiRead™* CUBE Reader Costefficient and timesaver.
- No special facilities or equipment required; test can be used anytime, anywhere.
- No specialized training required to operate.
- Accurate and reliable with consistent results.
- Room temperature stable.
- Positive and Negative Controls (optional) available for QC.
- Aid accurate diagnosis of Acute and Silent COVID-19 infection

EASY TO USE TEST PROCEDURE

(Consult Instructions for Use for complete procedure)

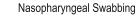




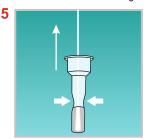


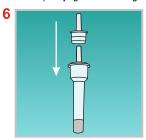


Anterior Nasal Swabbing













Read result at 15 minutes with TWO options:

- 1. Visual interpretation.
- 2. Digital interpretation using *RapiRead*[™] CUBE reader.

CLEAR RESULT INTERPRETATION

(Consult Instructions for Use for Visual or Digital Result Interpretations using *RapiRead*™ CUBE Reader)

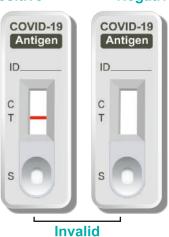
Visual Results







Negative



Digital Results



Positive



Negative







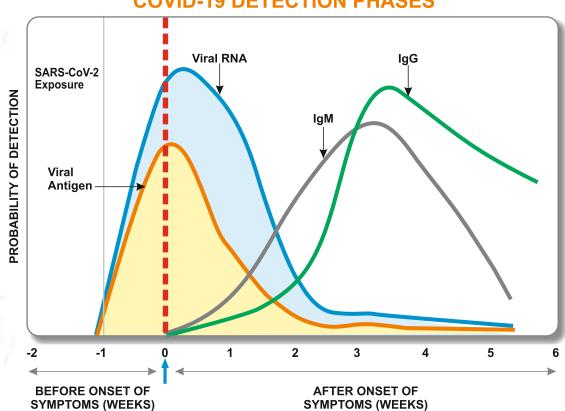
COVID-19 Ag

Simple ● Rapid ● Accurate ● Affordable ● Reliable ● Accessible

Get Answers; Test NOW, Deploy at different Point-of-Care settings:

- Physician offices
- Urgent care facilities
- Pharmacies
- Airport testing
- Employee testing to return to work
- School health clinics
- Assisted Living Facilities
- Hospital facilities to screen Healthcare Personnel (HCP), Patients and Visitors
- Long-term elderly care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations
- Routine follow-up testing (Relax Testing)

COVID-19 DETECTION PHASES







Affimedix, Inc. 3556 Investment Boulevard Hayward, California 94545, USA According to CDC's guidance, COVID-19 antigen test has the best sensitivity from day 1 to day 5 after the onset of symptoms. Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test.



• Approved by Paul Ehrlich Institute (PEI), Germany (a WHO Collaborating Center)

