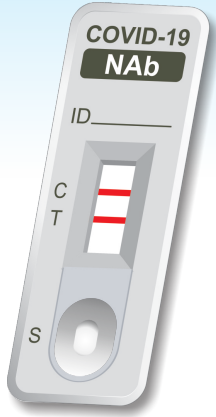


HOW LONG AM I PROTECTED POST COVID-19 VACCINATION DURING GLOBAL PANDEMIC?



COMPANION DIAGNOSTIC (CDx) FOR COVID-19 VACCINES: ANSWERING THE QUESTION OF VACCINES LONGEVITY

MEASURE AND MONITOR NEUTRALIZING ANTIBODY (NAb) TITER TO KNOW YOUR PROTECTIVE IMMUNITY IN 15 MINUTES



COVID-19 NAb



FIRST Rapid COVID-19 Neutralizing Antibody (NAb) "Quantitative" Whole Blood Test

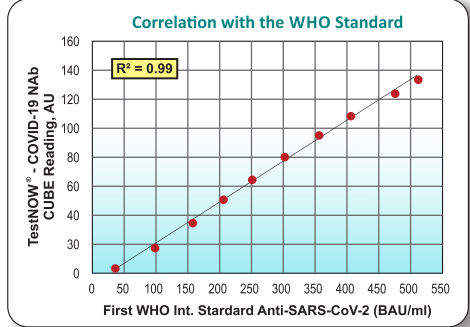
DIGITAL RESULT

BECAUSE COVID-19 NAb TITER MATTERS...

- ...to resume normal life.
- ...to check the efficacy of COVID-19 Vaccines.
- ...to identify people with protective immunity.
- ...to measure rising and falling levels of NAb longitudinally.
- ...to monitor long-term immunity from COVID-19.
- ...to assess immune response after SARS-CoV-2 infection.
- ...to recognize right convalescent plasma donors for therapy.
- ...to predict who might be immune if the virus comes back.
- ...to check if the world population has achieved herd immunity.
- ...to identify the need for booster shot if NAb's wane over time.

WHO Standardized

TestNOW® - COVID-19 NAb has been standardized against "First WHO International Standard for anti-SARS-CoV-2 Immunoglobulins" (NIBSC Code: 20/136)





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 NAb is an *in vitro* Rapid “Sandwich” immunochromatography test for the “Quantitative” detection of circulating functional Neutralizing Antibodies (NABs) Titer against SARS-CoV-2 that block the interaction between the Receptor Binding Domain (RBD) of the viral Spike Protein (S) with the Angiotensin Converting Enzyme-2 (ACE2) cell surface receptor of human cell.

TestNOW® - COVID-19 NAb Test detects Neutralizing Antibodies (NAB) in finger-prick whole blood, serum or plasma that neutralize the RBD-ACE2 interaction post COVID-19 vaccination or SARS-CoV-2 infection. Clinical study has shown that serum IgG against RBD best correlates with virus-neutralizing activity and disease severity*.

What are Neutralizing Antibodies (NABs)?

Not all antibodies are neutralizing. Neutralizing Antibodies (NABs) are a subgroup of IgG antibodies which “Specifically” bind to RBD (the major neutralizing determinant for Coronavirus) of S protein and block the viral infection.

Why are Neutralizing Antibodies (NABs) so important?

NABs inactivate the entry of invading Coronavirus in human cells by neutralizing the RBD-ACE2 interaction, thus providing protective immunity against COVID-19 infection and possible re-infection.

Can I catch Coronavirus after getting fully Vaccinated?

NO COVID-19 vaccine is 100% effective; therefore, odds are low. A very small number of fully vaccinated people have been infected with the coronavirus, called “breakthrough infections”. If you do get infected after your vaccination, your case is likely to be asymptomatic or mild infection.

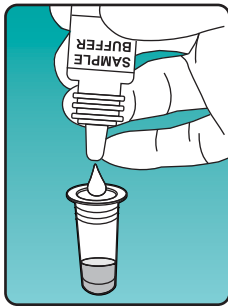
Product Features:

- Detects NAb Titer that blocks RBD-ACE2 interaction.
- Quick Quantitative test in 15 minutes.
- Test requires just 10µl of finger-prick blood.
- Digital results in 3 seconds.
- Results in WHO recommended standardized Binding Antibody Unit (BAU)/ml.
- Sensitivity: 99.17% (vs. RT-PCR and Reference NAB ELISA Test).
- Specificity: 98.67%
- Excellent correlation with “First WHO International Standard for anti-SARS-CoV-2 Immunoglobulins” ($R^2 = 0.99$).
- Limit of Detection (LOD): 25 – 50 BAU/ml (Test Lot dependent).
- Accurate and reliable with consistent results.
- Batch Testing with **RapiRead™** CUBE Reader – Cost-efficient and timesaver.
- No special facilities, equipment or training required; test can be used anytime, anywhere.
- COVID-19 NAb Controls available (optional).

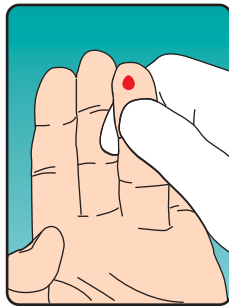
* Kuniaki Saito et al. Comparative Analysis of Antigen-Specific Anti-SARS-CoV-2 Antibody Isotypes in COVID-19 Patients; J Immunol May 15, 2021, 206 (10) 2393-2401

EASY TO USE TEST PROCEDURE WITH UniSampler™ DEVICE

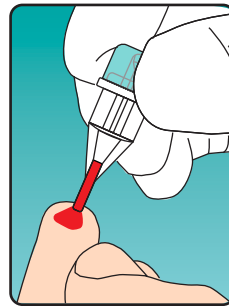
(Consult Instructions for Use for complete procedure)



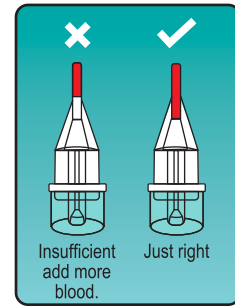
Add 5 Drops into the Tube.



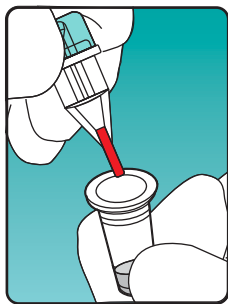
Use a Lancet to draw Finger-prick Blood.



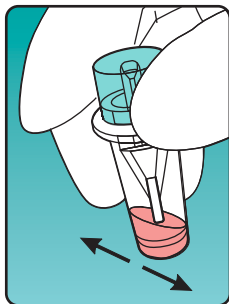
Gently touch the tip of Blood Collector to Blood droplet. Capillary action will fill 10µl blood and stop.



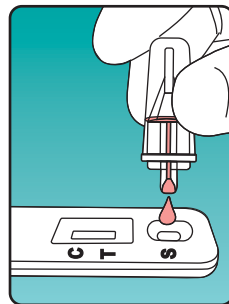
Insufficient add more blood. Just right



Insert Blood Collector into Tube and push firmly.



Shake vigorously and mix completely.



Remove Cap and add 3 drops.



Read result at 15 minutes Using **RapiRead™** CUBE Reader.

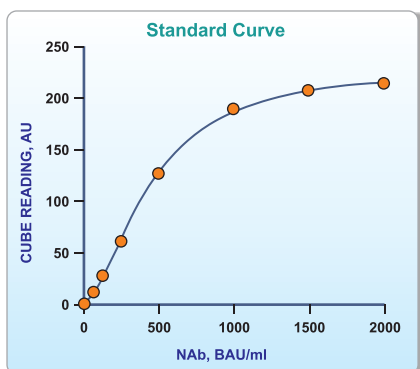
CLEAR RESULT INTERPRETATION

(Consult Instructions for Use for Digital Result Interpretations using **RapiRead™** Cube Reader)

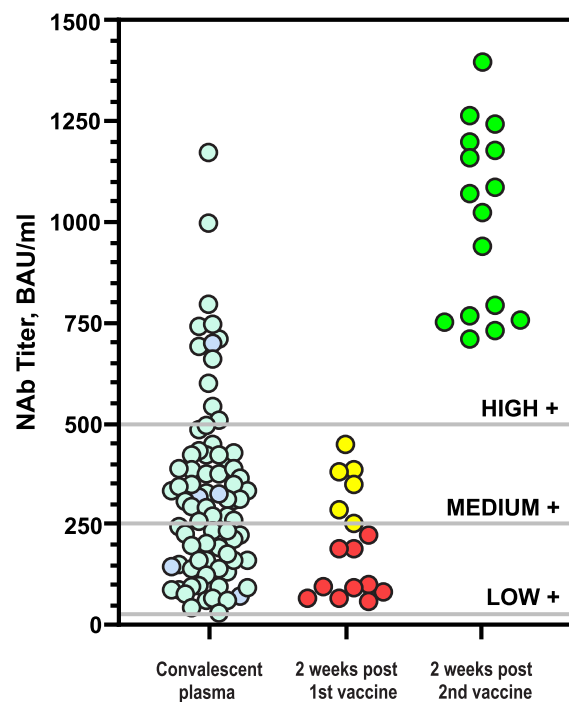


Based on Neutralizing Antibody (NAb) level, the Titer is displayed as a Numeric Value in BAU/ml followed by Result with an audible beep signal:

NAb Titer Range	Result
• < 30 BAU/ml	NEGATIVE
• ≥ 30 - < 250 BAU/ml	LOW +
• ≥ 250 - < 500 BAU/ml	MEDIUM +
• ≥ 500 BAU/ml	HIGH +



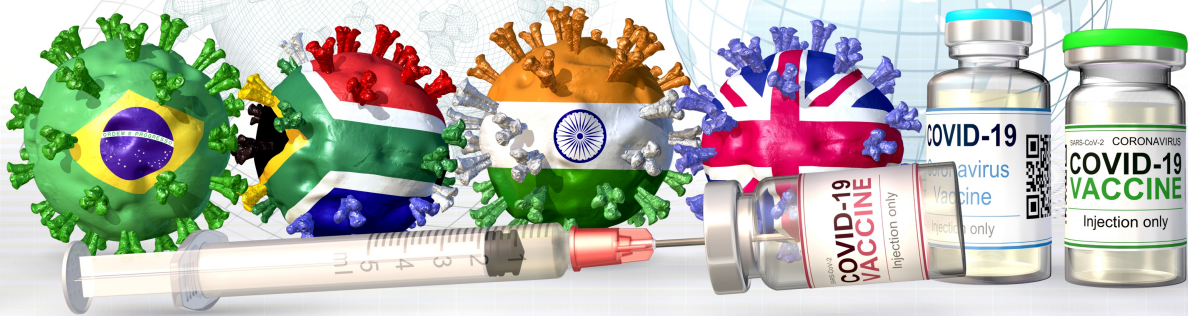
Progression of NAb response in SARS-CoV-2 infected patients and 2 weeks post 1st and 2nd shots of Pfizer / Moderna vaccines tested with TestNOW® – COVID-19 NAb





COVID-19 NAb

YOUR IDEAL COMPANION DIAGNOSTIC (CDx) FOR COVID-19 VACCINES
MEASURE & MONITOR YOUR PROTECTIVE IMMUNITY DURING PANDEMIC



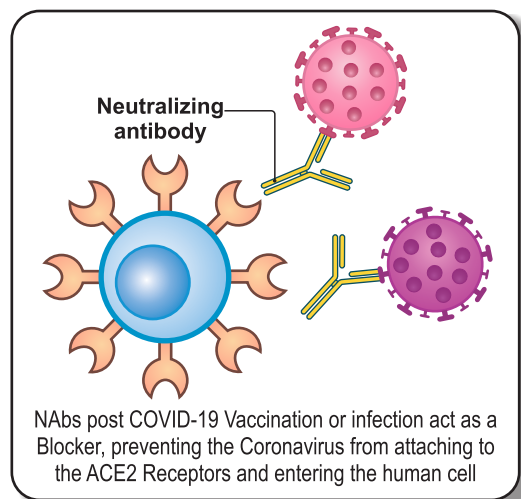
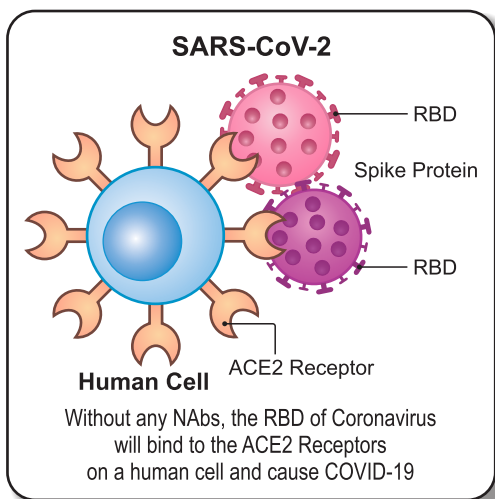
🌟 **Simple** 🌟 **Rapid** 🌟 **Quantitative** 🌟 **Accurate** 🌟 **Affordable** 🌟 **Reliable** 🌟 **Accessible**

Get your Protective Immunity Answer & Assurance; Test NOW, Deploy at any Point-of-Care settings:

- Essential Workers
- Front-line Healthcare personnel
- People with Underlying Medical Conditions
- Older Adults
- Teachers and School Staff
- Childcare Providers
- Workplace
- Business organizations
- Military Personnel
- Agricultural Workers
- Pregnant Women
- Convalescent Plasma Donors

Anyone who has received COVID-19 vaccine can be tested with **TestNOW® - COVID-19 NAb Test**. Periodic testing is required to track persistent or declining NAb titers to check vaccine efficacy and advice need for booster immunization.

How do you get Immunity Protection with Neutralizing Antibodies (NABs)?



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Email: info@affimedix.com
www.affimedix.com

*...Supporting Communities for
COVID-19 Diagnostic Testing.*



Anytime, Anywhere!

TRACK the VAX...Immunity Monitoring made Simple!