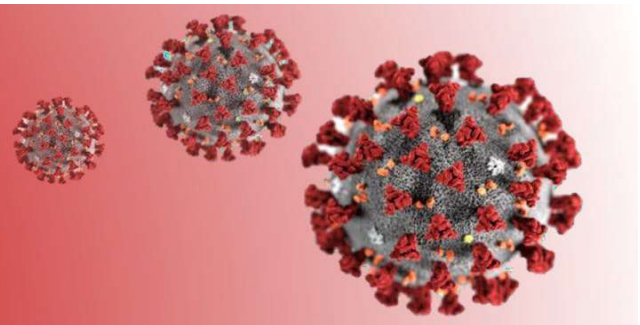
FDA 510(K) CLEARED



Nano-Check™ COVID-19 Antigen Test

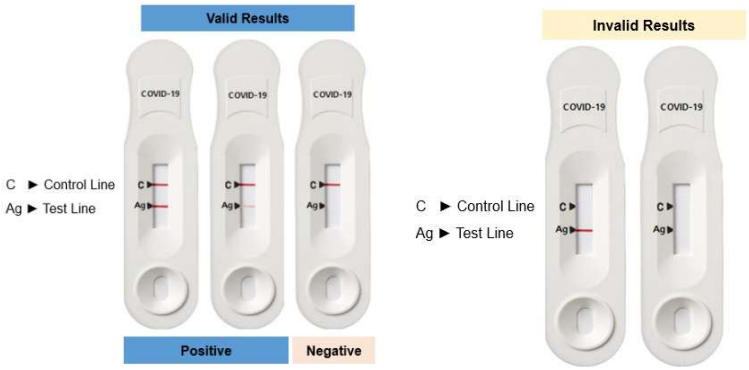
FIRST PROFESSIONAL FULLY FDA APPROVED, VISUAL READ COVID ANTIGEN TEST AVAILABLE ON THE MARKET!

The Nano-Check™ COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the rapid, qualitative detection of SARS-CoV-2 nucleoprotein protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 4 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Nano-Check™ COVID-19 Antigen Test and followed up with a molecular test.

- No Age restriction (Suitable for children uder 2)
- Sensitivity: 83.67%, Specificity 99.62%
- Reproducibility: 98%
- Rapid results in 15 minutes
- No equipment required
- SARS-CoV-2 Virus detection
- Storage condition (2°C -30°C)

SARS-CoV-2 Variant	Strain	LoD	% Positive
Wild	2019-nCoV/USA-WA1/2020, Gamma-irradiated	7.0×10^{2} $TCID_{50}$/mL (3.5×10^{1} $TCID_{50}$/swab)	95%
Omicron	hCoV-19/USA/MD-HP20874/2021, Heat Inactivated	1.95×10^{2} $TCID_{50}$/mL (9.8×10^{1} $TCID_{50}$/swab)	95%
Delta	USA/PHC658/2021, UV Inactivated	5.21×10^{2} $TCID_{50}$/mL (2.6×10^{1} $TCID_{50}$/swab)	95%

Interpretation



Positive: If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive. Repeat testing is not needed for individuals with a positive result.

Negative: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes COVID-19 was not detected in the sample.

Note: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours or followed up with a molecular test.

Invalid: If a control (C) line is not visible, the test is not valid. Re-test with a new swab and a new test cassette. If the problem persists, please call at +1-855-297-7877.

CE

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Please email : orders@aliuspr.com

ND Nano-Ditech Corporation

Clinical performance

Table 1. Comparison Result with Comparator RT-PCR method

Nano-Check™ COVID-19 Antigen Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	123	2	125
Negative	24	521	545
Total	147	523	670
Positive Percent Agreement (PPA) = (123/147) x 100% = 83.67% (95% CI: 76.86% - 88.78%)			
Negative Percent Agreement (NPA) = (521/523) x 100% = 99.62% (95% CI: 98.62% - 99.90%)			

Table 2. Positive Results by Age Group

Age Group	Comparator RT-PCR method		
	# of Specimen Tested	# of Positive Specimen	Prevalence (%)
≤ 5 years	23	3	13.04
6 to 21 years	144	12	8.33
22 to 60 years	400	100	25.00
≥61 years	103	32	31.07
Total	670	147*	21.94
**: Nano-Check™ COVID-19 Antigen Test yielded positive results for 3 samples in the age group below 5 years old, 8 samples in the age group of 6 to 21 years, 85 samples in the age group of 22 to 60 years, and 27 samples in the age group over 61 years.*			

Table 3. Positive Results Stratified by Days Post-Symptom Onset

Days Post Onset	RT-PCR Positive	Nano-Check™ COVID-19 Antigen Test Positive	Positive Rate (%)
0-1	23	17	73.91
0-2	69	54	78.26
0-3	113	91	80.53
0-4	147	123	83.67

Order information

Catalog No.	Product Name	Sample Types	Package	Storage Condition	Shelf Life
ND-MD8147	Nano-Check™ COVID-19 Antigen Test	Nasal Swab	20 tests/box	2°C -30°C	14 months

***NANO CHECK COVID 19 Antigen test is the first visual read antigen test exclusively for moderate and high complexity laboratories to be granted approval for marketing (510K) by the FDA. Alius Scientific is pleased to be the first company to bring this to our market, proving our commitment to bring the most up to date solutions that comply with regulatory requirements.