Luminex®

NxTAG® CoV Extended Panel (EUA-IVD)

For Use Under Emergency Use Authorization (EUA)

The NxTAG® CoV Extended Panel (NxTAG CoV) is a qualitative, multiplex, nucleic acid test for the detection of SARS-CoV-2 in nasopharyngeal swab samples. Designed for use on the MAGPIX® System, the NxTAG CoV panel detects three separate gene targets to ensure accurate, reliable results.

With the NxTAG CoV panel, you get:

- A highly scalable, cost-effective solution that can process up to 96 samples in approximately 4 hours
- The flexibility to run tests in any combination—use the NxTAG CoV panel to detect SARS-CoV-2, detect 20 other common respiratory pathogens with the NxTAG Respiratory Pathogen Panel (RPP), or run both tests together for a complete picture of a patient's respiratory health
- Detection of 3 virus gene targets, delivering reliable results using SYNCT™ Software

Virus Gene Targets
ORF1ab
N Gene
E Gene

Performance

Target RNA Concentration	Number of Samples tested	SARS-CoV-2-ORF1ab		SARS-CoV-2-N		SARS-CoV-2-E		Overall SARS-CoV-2 Result*	% Positivity
		Mean MDD Value[1]	% Agreement (# Pos or Neg) / Total	Mean MDD Value	% Agreement (# Pos or Neg)/Total	Mean MDD Value	% Agreement (# Pos or Neg)/ Total		
SARS-CoV-2-2xLoD	20	181	95% 19/20[2]	217	100% 20/20	119	100% 20/20	Positive	100%
SARS-CoV-2-3xLoD	5	212	100% 5/5	273	100% 5/5	175.3	100% 5/5	Positive	100%
SARS-CoV-2-5xLoD	5	223	100% 5/5	247	100% 5/5	167	100% 5/5	Positive	100%
NCM (Negative)	30	1	100% 30/30	-2	100% 30/30	-1	100% 30/30	Negative	0%

**Positive result assignment if at least one of three gene targets was detected.*

[1]For each analyte in a sample, the multi-dimension detection (MDD) value is a measure resulting from the subtraction of the sample's noise signal from the analyte's signal. The result is a measure that has been adjusted for the noise within the sample.

[2]A single replicate was negative for ORF1ab, however other gene targets were detected for this replicate, and it was assigned a positive result.

Contrived Samples

The performance of the NxTAG® CoV Extended Panel was evaluated using prospectively collected nasopharyngeal swab (NPS) samples from patients with signs and symptoms of an upper respiratory infection. Data was derived from 30 individual negative clinical samples and 30 contrived positive clinical samples.

Clinical samples were collected and handled by qualified personnel according to the package insert of the collection device. Samples were aliquoted and stored frozen until use. Samples were then confirmed to be negative for respiratory pathogens by a commercially available nucleic acid test for the qualitative detection of microorganisms associated with common respiratory tract infections.

Twenty low-positive contrived samples were prepared at a concentration of 2X LoD of the assay by spiking negative NPS clinical samples with purified SARS-CoV-2 viral genomic RNA. Five moderate-positive contrived specimens were prepared at 3X LoD, and five specimens were prepared at 5X LoD. The positive and negative clinical specimens were tested in a blinded and randomized fashion.

NxTAG® Workflow (Post-Extraction)

Step 1
Add 1-96 extracted samples to pre-plated test wells

Step 2
Integrated multiplex PCR and bead hybridization

Step 3
Read on MAGPIX®

Usage and Targets

The NxTAG® CoV Extended Panel—for use on the Luminex® MAGPIX® Instrument—is an RT-PCR test for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider.

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The NxTAG CoV Extended Panel is for use in US laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-US laboratories.

The NxTAG CoV Extended Panel is only for use under the Food and Drug Administration's Emergency Use Authorization.

Ordering Information

Product Name	Part Number
NxTAG® CoV Extended Panel* Assay and Protocol files	I054C0463 Available Separately+
MAGPIX® System	MAGPIX-XPONENT
NxTAG® Respiratory Pathogen Panel	I051C0447
SYNCT™ Software	CN-SW47

* IVD – Emergency Use Authorization.
+ Contact your Molecular Business Manager, or contact support@luminexcorp.com.

Luminex®
complexity simplified.

orders@luminexcorp.com or support@luminexcorp.com

EUA - In Vitro Diagnostic Use Under Emergency Use Authorization. This test has not been FDA cleared or approved. This test has been authorized by the FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. §360bb-3(b)(1), unless the authorization is terminated or revoked sooner.

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