Luminex®

NxTAG® Respiratory Pathogen Panel + SARS-CoV-2 (EUA)

The NxTAG® Respiratory Pathogen Panel + SARS-CoV-2 (NxTAG® RPP + SARS-CoV-2), developed for use on the NxTAG-Enabled MAGPIX® System, is a qualitative test for the detection of nucleic acids from multiple respiratory viruses and bacteria in nasopharyngeal swabs. SARS-CoV-2 RNA and nucleic acids from the other respiratory viral and bacterial organisms identified by this test are generally detectable in a nasopharyngeal swab during the acute phase of infection.

The NxTAG RPP + SARS-CoV-2 Assay offers:

- **Comprehensive Testing:** Detects 19 viral pathogens, including SARS-CoV-2, and 2 bacterial pathogens in a single well, enabling thorough respiratory health analysis.
- **Scalable Throughput:** Process up to 96 samples in less than 3 hours post-extraction, accommodating variable, day-to-day testing demand.
- **Minimal Hands-On Time:** Pre-plated, lyophilized reagents facilitate a simple workflow with just one pipetting step, ensuring an easy fit in any lab's daily routine.

Targets

Viral Targets		Bacterial Targets
Adenovirus	Influenza B	*Chlamydophila pneumoniae*
Coronavirus 229E	Parainfluenza 1	*Mycoplasma pneumoniae*
Coronavirus HKU1	Parainfluenza 2	
Coronavirus NL63	Parainfluenza 3	
Coronavirus OC43	Parainfluenza 4	
Human Bocavirus	Rhinovirus/Enterovirus	
Human Metapneumovirus	Respiratory Syncytial Virus A	
Influenza A	Respiratory Syncytial Virus B	
Influenza A – subtype H1	SARS-CoV-2	
Influenza A – subtype H3		

Performance

The formulation of the NxTAG RPP + SARS-CoV-2 Assay is identical to NxTAG RPP, with the exception of the additional reagents required for the detection of SARS-CoV-2. No changes have been made to the existing NxTAG RPP reagents, reaction conditions, workflow, or software thresholds; therefore, the performance characteristics of NxTAG RPP are still applicable to NxTAG RPP + SARS-CoV-2.

The performance of this device has not been assessed in a population vaccinated against COVID-19.

In silico inclusivity analyses of the oligonucleotide (oligo) sequences for the SARS-CoV-2 ORF1ab and M gene sets were performed against all SARS-CoV-2 sequences available in the GISAID database as of January 3, 2021. The analysis included 230,623 sequences in the amplicon regions of the ORF1ab and M gene oligo sets, including sequences of the United Kingdom strain (B.1.1.7 lineage) and the South Africa strain (501Y.V2 variant). Based on in silico analysis of the percent homology of each oligo sequence to its binding region on each SARS-CoV-2 sequence, it is predicted that NxTAG RPP + SARS-CoV-2 will detect all analyzed SARS-CoV-2 sequences from the GISAID database as of January 3, 2021.

Limit of Detection (LoD) of SARS-CoV-2 Tested with the NxTAG Respiratory Pathogen Panel + SARS-CoV-2

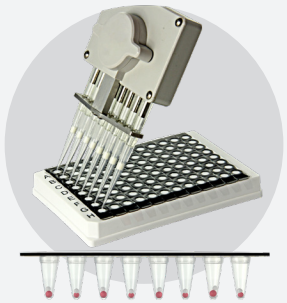
The LoD for SARS-CoV-2 in the NxTAG RPP + SARS-CoV-2 Assay was assessed by testing a serial dilution of heat-inactivated SARS-CoV-2 culture fluid (ATCC VR-1986HK, heat-inactivated virus) in pooled negative nasopharyngeal specimens (Negative Clinical Matrix). The LoD titer for SARS-CoV-2 was defined as the lowest concentration at which ≥95% (≥19/20) of the samples tested generated positive calls. The LoD of the SARS-CoV-2 target in the NxTAG RPP + SARS-CoV-2 Assay is 500 copies/mL.

NxTAG® RPP + SARS-CoV-2 PPA and NPA for the SARS-CoV-2 Target

Sample	Number of Samples Tested	SARS-CoV-2 ORF1ab Gene	SARS-CoV-2 M Gene	SARS-CoV-2 Final Result	% Agreement with Reference Method	
Positive	30	27/30	29/30	30/30	PPA	100%
Negative*	227	227/227	227/227	227/227	NPA	100%

**Negative samples for SARS-CoV-2 are assumed to be negative because they were collected prior to the pandemic and were not tested on the NxTAG® CoV Extended Panel.*

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 the MAGPIX® System.

Usage

NxTAG® Respiratory Pathogen Panel + SARS-CoV-2, for use on the MAGPIX® instrument, is a multiplex nucleic acid RT-PCR test intended for the qualitative detection of nucleic acid from multiple respiratory viral and bacterial organisms, including nucleic acid from SARS-CoV-2, in nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high-complexity tests.

SARS-CoV-2 RNA and nucleic acids from the other respiratory viral and bacterial organisms identified by this test are generally detectable in a nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of the identified organism, but do not rule out co-infection with other pathogens. Laboratories within the United States and its territories are required to report all SARS-CoV-2 positive results to the appropriate public health authorities.

Negative results in the setting of a respiratory illness may be due to infection with pathogens not detected by this test, or lower respiratory tract infection that may not be detected by a nasopharyngeal swab. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

The NxTAG RPP + SARS-CoV-2 Assay is for use by qualified laboratory personnel specifically instructed and trained in the operation of the Luminex MAGPIX instrument and in vitro diagnostic procedures. The NxTAG RPP + SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Ordering Information

Product Name	Part Number
NxTAG® Respiratory Pathogen Panel + SARS-CoV-2*	I056C0468
NxTAG®-Enabled MAGPIX® System	MAGPIX-XPON4.1-CEIVD
SYNCT™ Software	CN-SW47

**IVD – Emergency Use Authorization.*

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.

luminexcorp.com/NxTAG-Respiratory-Pathogen-Panel-SARS-CoV-2/

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