Luminex®

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

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, oropharyngeal, nasal, anterior nasal, and mid-turbinate nasal swabs, nasal aspirates, and nasal wash in UTM™, Liquid Amies (ESwab™), or equivalent.

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

- **Comprehensive Testing:** Detects 23 pathogens, including SARS-CoV-2 (ORF1ab and M gene), in a single tube, enabling the accurate diagnosis and treatment of respiratory illnesses with overlapping symptoms.
- **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 A 2009 H1N1	*Chlamydophila pneumoniae*
Coronavirus 229E	Influenza B	*Legionella pneumophila*
Coronavirus HKU1	Parainfluenza 1	*Mycoplasma pneumoniae*
Coronavirus NL63	Parainfluenza 2	
Coronavirus OC43	Parainfluenza 3	
Human Bocavirus	Parainfluenza 4	
Human Metapneumovirus	Respiratory Syncytial Virus A	
Influenza A	Respiratory Syncytial Virus B	
Influenza A subtype H1	Rhinovirus/Enterovirus	
Influenza A subtype H3	SARS-CoV-2	

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 limit of detection (LoD), analytical reactivity, and specificity (including cross-reactivity) of the panel targets were not impacted by the addition of SARS-CoV-2 to the NxTAG RPP assay.

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.

Based on in silico analysis of each oligo sequence to its binding region in each SARS-CoV-2 sequence, it is predicted that the SARS-CoV-2 sequences available from GISAID as of February 11, 2021—including sequences from the United Kingdom (B.1.1.7), South African (B.1.351 or 20H/501Y.V2), Brazilian (P.1 lineage or 20J/501Y.V3), and Californian (one of five reoccurring mutations that constitute the B.1.429 lineage or CAL20C) variants—are 100% detectable by the NxTAG® Respiratory Pathogen Panel + SARS-CoV-2 Assay.

Clinical Performance of NxTAG® RPP + SARS-CoV-2 Assay for SARS-CoV-2 Target

Sample	Number of Samples Tested	Positive	Negative	% Agreement with Reference Method	
Positive	74*	73	1†	PPA	100.0%
Negative	360	0	360	NPA	99.7%
Total	434	73	361		

**This sample set includes 20 contrived positives in addition to varous upper respiratory specimen types (nasopharyngeal swab (NPS), oropharyngeal swab (OP), anterior nasal swab, and nasal aspirate specimens).*

†This sample was confirmed positive for SARS-CoV-2 via PCR with bidirectional sequencing.

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.

Ordering Information

Product Name	Part Number
NxTAG® Respiratory Pathogen Panel + SARS-CoV-2 (CE-IVD)	I056C0471
NxTAG®-Enabled MAGPIX® System	MAGPIX-XPON4.1-CEIVD
SYNCT™ Software	CN-SW47

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For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions. Please contact Luminex at support@luminexcorp.com to obtain the appropriate product information for your country of residence.

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