Luminex

NxTAG® Respiratory Pathogen Panel v2 (CA-IVD)

The NxTAG® Respiratory Pathogen Panel (RPP) v2 is a multiplex, real-time polymerase chain reaction-based test, that qualitatively detects nucleic acid from 2 bacterial and 20 viral pathogens, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), from naso-pharyngeal swab (NPS) samples in universal transport medium (UTM™), MicroTest™ M4RT™, or viral transport media (VTM).

Panel-based respiratory testing results can help to reduce hospitalization time and unnecessary or prolonged antibiotic courses.[1] While respiratory illnesses often present with similar symptoms, panel-based assays like NxTAG RPP v2 offer an advantage to clinicians looking to identify the causative pathogen(s) underlying a patient's symptoms. With 22 respiratory targets differentiated and scalable throughput, included and scalable throughput, you can count on this assay to support testing even when sample volumes surge.

Designed for use on the NxTAG®-Enabled MAGPIX® System, this assay was designed to keep pace with virus evolution and is the enhanced, second-generation version (v2) of the original NxTAG RPP.

1. Making Sense of Respiratory Viral Panel Results. ASM (Internet). Cited February 2023. Available from: https://asm.org/Articles/2020/March/Making-Sense-of-Respiratory-Viral-Panel-Results.

The NxTAG® Respiratory Pathogen Panel v2 Assay offers

- **Comprehensive Detection of Respiratory Pathogens:** Detects 2 bacterial and 20 viral pathogens, including SARS-CoV-2 (ORF1ab and M gene) in a single test, enabling accurate diagnosis and patient treatment.
- **Scalable Throughput:** Process up to 96 samples in less than 3 hours post-extraction, accommodating variable, day-to-day testing demands.
- **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.

Performance

Limit of Detection (LoD) for SARS-CoV-2

The development of version 2 focused on overall improved performance and the addition of the SARS-CoV-2 targets. The LoD for SARS-CoV-2 is 500 copies/mL (Strain: USA-WA 1/2020).

Targets

Viral Targets		Bacterial Targets
Adenovirus	Influenza A subtype H3	*Chlamydophila pneumoniae*
Coronavirus 229E	Influenza B	*Mycoplasma pneumoniae*
Coronavirus HKU1	Parainfluenza 1	
Coronavirus NL63	Parainfluenza 2	
Coronavirus OC43	Parainfluenza 3	
Human Bocavirus	Parainfluenza 4	
Human Metapneumovirus	Rhinovirus/ Enterovirus	
Influenza A	RSV A	
Influenza A subtype H1	RSV B	
Influenza A subtype 2009 H1N1	SARS-CoV-2	

Summary of the Comparative Clinical Performance of the NxTAG® RPP v2 Assay

Pathogen	PPA*		NPA*	
	TP / (TP+FN)	%	TN / (TN+FP)	%
Virus				
Adenovirus	31/33	93.9%	1261/1264	99.8%
Coronavirus 229E	12/12	100%	1284/1285	99.9%
Coronavirus HKU1	30/32	93.8%	1265/1265	100%
Coronavirus NL63	30/30	100%	1268/1268	100%
Coronavirus OC43	30/30	100%	1263/1267	99.7%
Human bocavirus	8/8	100%	1416/1419	99.8%
Human Metapneumovirus	30/30	90%	1265/1267	99.8%
Influenza A	39/39	100%	1257/1258	99.9%
Influenza A subtype H1	0	N/A	1296/1297	99.9%
Influenza A subtype 2009 H1N1	29/30	96.7%	1267/1267	100%
Influenza A subtype H3	9/9	100%	1288/1288	100%
Influenza B	30/30	100%	1267/1267	100%
Parainfluenza 1	30/30	100%	1266/1267	99.9%
Parainfluenza 2	30/30	100%	1267/1267	100%
Parainfluenza 3	35/35	100%	1262/1262	100%
Parainfluenza 4	15/16	93.8%	1281/1281	100%
Rhinovirus/Enterovirus	112/115	97.4%	1155/1182	97.7%
RSV A	30/30	100%	1265/1267	99.8%
RSV B	0	N/A	1297/1297	100%
SARS-CoV-2	65/66	98.5%	1354/1361	99.5%
Bacteria				
Chlamydophila pneumoniae	14/14	100%	1282/1283	99.9%
Mycoplasma pneumoniae	48/52	92.3%	1245/1245	100%

**Additional details are available in the Package Insert.*

Influenza A and B inclusivity was assessed with sequences available from the GISAID database between January 1, 2017 and January 6, 2022. The assay oligos for influenza A, influenza A H1, influenza A H3, and influenza B are predicted to have 100% inclusivity against the analyzed sequences.

We are continuously monitoring the GISAID database SARS-CoV-2 Variants of Concern sequences. Please go to **https://www.luminexcorp.com/covid19-testing-solutions/** and select "Click here" to view the results of our *in silico* inclusivity analysis.

Workflow

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

Step 2
Run multiplex PCR and bead hybridization.

Step 3
Read on the NxTAG®-Enabled MAGPIX® System.

Ordering Information

Product Name	Part Number
NxTAG® Respiratory Pathogen Panel v2 CA-IVD (96 tests)	I055C0465
NxTAG®-Enabled MAGPIX® System	MAGPIX-XPON4.1-CEIVD

Luminex®
A DiaSorin Company

orders@luminexcorp.com or support@luminexcorp.com

luminexcorp.com/NxTAG-RPP/

HEADQUARTERS
UNITED STATES
+1 512 219 8020
info@luminexcorp.com

EUROPE
+31 73 800 1900
europe@luminexcorp.com

CANADA
+1 416 593 4323
info@luminexcorp.com

CHINA
+86 21 8036 9888
infocn@luminexcorp.com

JAPAN
+81 3 5545 7440
infojp@luminexcorp.com

SS535205