Luminex®

NxTAG®

Respiratory Pathogen Panel (RPP)

1 Patient Sample, 21 Pathogens Tested, Results in <4 Hours

Respiratory tract infections (RTIs) are difficult to identify with costly implications.

A variety of viral and bacterial pathogens are responsible for RTIs.

- Polymicrobial infection has been reported in up to 35% of RTI cases[1]—dual viral, dual bacterial, or mixed viral-bacterial infection.[2]
- Diagnostically, it is difficult to differentiate since there are a large proportion of cases across Europe reported with no pathogen identified.[2]
- Higher rates of co-morbid illness have been linked to patients hospitalized for community acquired pneumonia (CAP) with unknown aetiology.[3]
- "Respiratory tract infection (RTI) involves a variety of viruses and bacteria, which can be conveniently detected by multiplex nucleic acid amplification testing (NAT)."[4]

RTIs are a leading cause of hospitalization, morbidity, and mortality.

- 230,000 people (2.3%) die annually throughout the World Health Organization (WHO) European region due to lower respiratory tract infections (LRTIs).[5]
- Seasonal influenza affects up to 10% of the European population each year, leading to hundreds of thousands of hospitalizations.[6]

RTIs result in high economic cost and productivity loss, and place a significant burden on health care systems.[7]

- An estimated 790,000 disability-adjusted life-years are lost each year across the EU from pneumonia and LRTIs, monetized at €43.5 billion annually.[5]
- Medical costs across Europe, from pneumonia alone, are estimated at €10.1 billion, with an additional €3.6 billion indirect cost from lost work days.[8]

Inappropriate antibiotic prescriptions for RTIs are a target in efforts to reduce the emergence of resistant organisms.[9]

- Up to 90% of RTIs are of viral origin, yet many primary care and outpatient consultations result in a prescription for antibiotics.[10,11]
- Antibiotic resistance is a global health problem contributing to higher treatment cost, prolonged illness, extended hospitalization, and death.[10]
- Pathogen identification is a key component in management of acute respiratory infection outbreaks and pandemic preparedness strategies.[11,12]
- European Society of Clinical Microbiology and Infectious Diseases (ESCMID) guidelines recommend molecular testing for influenza, respiratory syncytial virus (RSV), and atypical pathogens during the winter season.[2]

Same Day Results for 21 of the Most Common Viral and Bacterial Respiratory Pathogens

Quickly identify causal pathogen, avoid inappropriate use of therapeutics, and act fast in response to outbreaks with NxTAG® Respiratory Pathogen Panel—1 Respiratory Sample, 1 Test, 21 Results.

From a single and simple laboratory test, you can get results for 21 of the most common viral and bacterial respiratory pathogens in less than 4 hours. The NxTAG Respiratory Pathogen Panel is a qualitative test intended for the simultaneous detection and identification of nucleic acids from multiple respiratory viruses and bacteria extracted from nasopharyngeal swabs, bronchoalveolar lavages (BALs), nasal and tracheal aspirates, nasal washes, sputum, and throat swabs collected from individuals with clinical signs and symptoms of respiratory tract infection.

NxTAG Respiratory Pathogen Panel

Economic Impact of Respiratory Virus Infections (RVIs)

The economic burden of RVIs is significant. Recent reviews using molecular diagnostic techniques have found RVIs linked to a much larger share of pneumonia cases than previously estimated, up to 50% in some instances.[13] Common acute upper respiratory illnesses also exact a significant economic toll. For example, a 2001 U.S.-based study estimated that noninfluenza, viral respiratory tract illnesses (mostly common colds) cost U.S. $40 billion.[14]

Nucleic Acid Amplification Testing (NAAT) to Support Rapid and Effective Clinical Management of RTIs

The results of a recent study confirm previous findings that the addition of PCR (polymerase chain reaction)-based methods to the conventional microbial techniques improves the yield of aetiological agents significantly and indicate that PCR is not only more rapid than conventional methods, but also more sensitive, both in aetiological diagnosis of CAP and for the detection of respiratory viruses in LRTI allowing clinicians to initiate optimal symptomatic treatment and rational use of antibiotics, adequate antiviral therapy where indicated and optimal infection control. [2]

There was consensus among the group members that the use of NAATs in the routine clinical setting has dramatically changed our approach to the diagnosis of viral respiratory tract infections. Traditional virus detection methods, including RADTs (rapid antigen direct tests), direct fluorescent antibody testing (DFA), and virus culture, can be effective diagnostic tools but are often inferior in assay sensitivity, specificity, time to virus identification, and breadth of pathogen detection compared to NAATs.[15]

RTI Diagnostic Challenges and Clinical Consequences

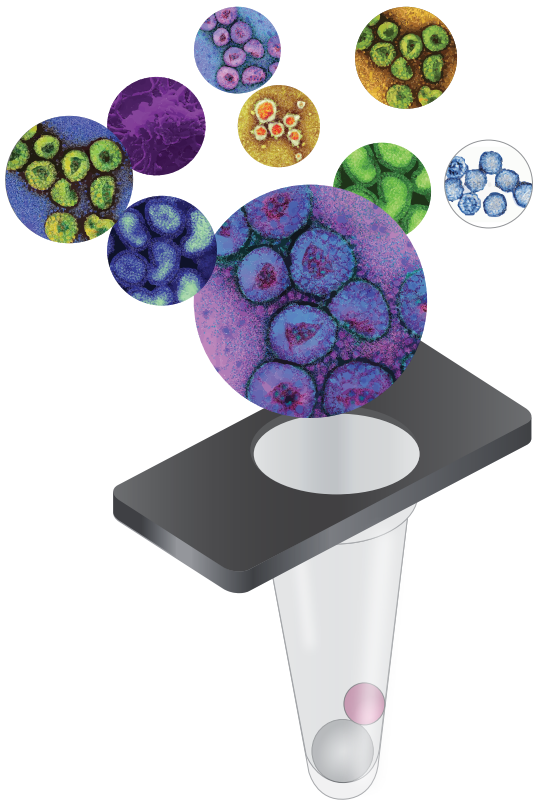
Challenge	Consequence	Solution
Difficult to differentiate between viral and bacterial causative agents	• Risk of improper treatment • Inappropriate use of antibiotics for viral infections. • Complications or secondary bacterial infection from no antibiotic intervention	• NxTAG® RPP simultaneously detects and identifies 18 clinically relevant viral respiratory pathogens, and 3 less common bacterial pathogens • Patient treatment can be optimized
Traditional laboratory methods and single pathogen tests are not able to detect all potentially present pathogens, and results may take days to be reported	• Risk of delayed and/or improper patient treatment • Difficulty in managing time pressured situations, e.g., potential outbreaks	• NxTAG RPP provides high diagnostic yields, and identifies co- or mixed microbial infections for more appropriate patient management • Results in less than 4 hours supports rapid response needs in outbreak management
Current traditional test methodologies lack sensitivity, resulting in low diagnostic yield (e.g., false negatives)	• Incorrect diagnosis resulting in inappropriate antibiotic prescription	• NxTAG RPP takes less than 4 hours, for same-day decision making • NxTAG RPP has high negative and positive percent agreement with existing IVD tests for reliable results*

**Positive and negative percent agreement obtained from clinical trial data, as compared with the CE Marked xTAG® Respiratory Viral Panel (RVP) assay. The individual data are described in the Luminex® NxTAG Respiratory Pathogen Panel Package Insert IVD (CE Marked).* [16]

Comprehensive and Rapid Information

Methods	Test Targets	Turnaround Time	Clinical Performance
Rapid Antigen Direct Tests (RADTs)	• Influenza A, Influenza B, RSV only • Single pathogen per test	15-30 min	Highly variable[15] (generally less sensitive than cell culture)[17]
Direct Fluorescent Antibody Testing (DFA)	• 8 most common respiratory viruses • Single pathogen per test	30-60 min	Dependent on virus and strain[15] (generally less sensitive than cell culture)[17]
Rapid Cell Culture	• 8 common respiratory viruses • Single pathogen per test	1-3 days	Dependent on virus and strain[15]
Traditional Cell Culture	• Broad range of respiratory pathogens • Single pathogen per test	3-7 days	Dependent on virus and strain[15]
Real-Time PCR	• Broad range of pathogens • 1-3 pathogens per test	<4 hours	Good (actual performance depends on pathogen target, individual performance, and number of assays, typically more sensitive than non-molecular methods)
NxTAG® RPP	• Up to 21 viral and bacterial pathogens in a single test	<4 hours	**96.0% and 99.2% positive and negative agreement overall*** (dependent on strain[18], more sensitive than non-molecular methods and highly concordant with comparator assays)

**Overall positive and negative percent agreement as compared to xTAG RVP from clinical trial data described in the NxTAG RPP package insert. Calculations based on data shown in the package insert.[16]*



Designed to Give You Confidence in Your Results

NxTAG Respiratory Pathogen Panel: Clinical Performance (Prospective Sample Set)*

Target (Pathogen)	PPA**		95% CI	NPA***		95% CI
VIRAL						
Influenza A	265/279	95.0%	91.7% - 97.2%	1891/1930	98.0%	97.3% - 98.6%
Influenza A H1	21/21	100.0%	83.9% - 100.0%	2168/2188	99.1%	98.6% - 99.4%
Influenza A H3	209/212	98.6%	95.9% - 99.7%	1942/198	97.7%	96.9% - 98.3%
Influenza B	87/92	94.6%	87.8% - 98.2%	2095/2109	99.3%	98.9% - 99.6%
Respiratory Syncytial Virus A	75/75	100.0%	95.2% - 100.0%	2111/2127	99.2%	98.8% - 99.6%
Respiratory Syncytial Virus B	134/136	98.5%	94.8% - 99.8%	2052/2064	99.4%	99.0% - 99.7%
Coronavirus 229E	21/21	100.0%	83.9% - 100.0%	2175/2188	99.4%	99.0% - 99.7%
Coronavirus OC43	32/33	97.0%	84.2% - 99.9%	2166/2176	99.5%	99.2% - 99.8%
Coronavirus NL63	62/65	95.4%	87.1% - 99.0%	2130/2142	99.4%	99.0% - 99.7%
Coronavirus HKU1	13/14	92.9%	66.1% - 99.8%	2189/2195	99.7%	99.4% - 99.9%
Human Metapneumovirus	137/146	93.8%	88.6% - 97.1%	2032/205	99.1%	98.6% - 99.4%
Rhinovirus/Enterovirus	306/321	95.3%	92.4% - 97.4%	1815/1888	96.1%	95.2% - 97.0%
Adenovirus	21/21	100.0%	83.9% - 100.0%	2153/2188	98.4%	97.8% - 98.9%
Parainfluenza 1	5/5	100.0%	47.8% - 100.0%	2191/2192	99.9%	99.7% - 100.0%
Parainfluenza 2	1/2	50.0%	1.3% - 98.7%	2198/2199	99.9%	99.7% - 100.0%
Parainfluenza 3	21/22	95.5%	77.2% - 99.9%	2162/2179	99.2%	98.8% - 99.5%
Parainfluenza 4	3/5	60.0%	14.7% - 94.7%	2192/2204	99.5%	99.1% - 99.7%
Human Bocavirus	28/29	96.6%	82.2% - 99.9%	2157/2180	98.9%	98.4% - 99.3%
BACTERIAL						
Chlamydophila pneumoniae	0/1	0.0%	0.0% - 97.5%	2208/2208	100.0%	99.8% - 100.0%
Mycoplasma pneumoniae	7/9	77.8%	40.0% - 97.2%	2198/2200	99.9%	99.7% - 100.0%
Legionella pneumophila	0/0	N/A	N/A	2208/2209	99.9%	99.7% - 100.0%

For additional data and complete details, see the Luminex NxTAG Respiratory Pathogen Panel Package Insert IVD (CE Marked).[16]
** *Positive Percent Agreement*
*** *Negative Percent Agreement*

Improve patient outcomes, avoid unnecessary antibiotic prescriptions, and act fast in peak seasons and outbreak situations.

Ask your laboratory for NxTAG RPP and realize the benefits of rapid, easy to perform, flexible (1-96 tests), evidence-based information to support clinical management of RTI patients.

Product Name	Kit Size	Registration Status	Product Number
NxTAG® Respiratory Pathogen Panel	96 tests	CE Marked for IVD Use	I051C0449

Intended Use (CE Marked) [16]

NxTAG Respiratory Pathogen Panel is a qualitative test intended for the simultaneous detection and identification of nucleic acids from multiple respiratory viruses and bacteria extracted from nasopharyngeal swabs, bronchoalveolar lavages (BALs), nasal and tracheal aspirates, nasal washes, sputum, and throat swabs collected from individuals with clinical signs and symptoms of respiratory tract infection.

The test is indicated as an aid in the detection and identification of viral and bacterial agents causing respiratory tract infections in symptomatic adult and pediatric patients, who are either hospitalized, admitted to emergency departments, or who are outpatients with suspected respiratory tract infection.

The NxTAG Respiratory Pathogen Panel is indicated for use with the Luminex MAGPIX® instrument with xPONENT® and SYNCT™ software.

REFERENCES

1. Gutierrez F, Masia M, Rodriguez JC et al. Community-acquired pneumonia of mixed etiology: prevalence, clinical characteristics, and outcome. Eur J Clin Microbiol Infect Dis 2005;24(6):377–83.
2. Woodhead M, Blasi F, Ewig S et al. Guidelines for the management of adult lower respiratory tract infections - full Version. CMI 2011;17:E1-E59.
3. Ewig S, Torres A, Angeles Marcos M et al. Factors associated with unknown aetiology in patients with community acquired pneumonia. Eur Respir J 2002;20:1254–1262.
4. Beckmann C, Hirsch HH. Comparing Luminex NxTAG Respiratory Pathogen Panel and RespiFinder-22 for multiplex detection of respiratory pathogens. J Med Virol 2016 Feb;10.1002/jmv.24492
5. Ambrosino N, Aniwidyaningsih W, Annesi-Maesano I et al. ERS White Book. European Lung White Book (Internet). Cited 2015 July. Available from: http://www.erswhitebook.org/chapters/the-burden-of-lung-disease/
6. Seasonal influenza. European Centre for Disease Prevention and Control (Internet). Cited 2016 March. Available from: http://ecdc.europa.eu/en/healthtopics/seasonal_influenza/Pages/index.aspx
7. Legand A, Briand S, Shindo N et al. Addressing the Public Health Burden of Respiratory Viruses. Future Virology 2013;8(10):953-968.
8. Welte T, Torres A, Nathwani D. Clinical and economic burden of community-acquired pneumonia among adults in Europe. Thorax 2012;67(1):71–79.
9. Interventions to improve appropriate antibiotic use for acute respiratory tract infections. Effective Health Care Program (Internet). Cited on 2016 March. Available from: http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1913
10. Johnston L. Rational use of antibiotics in respiratory tract infections. S Afr Pharm J 2012;79(4):34-39.
11. Berry M, Gamieldien J, Fielding BC. Identification of new respiratory viruses in the new millennium. Viruses 2015;7(3):996-1019.
12. Acute respiratory infections: investigating outbreaks and clusters in schools. Public Health England (Internet). Cited 2016 March. Available from: https://www.gov.uk/government/publications/acute-respiratory-infections-investigating-outbreaks-and-clusters-in-schools
13. Ruuskanen O, Lahti E, Jennings L C, Murdoch D R. Viral pneumonia. Lancet 2011:377(9773);1264–1275.
14. Fendrick AM, Monto AS, Nightengale B, Sarnes M. The economic burden of non-influenza-related viral respiratory tract infection in the United States. Arch. Intern. Med.163(4),487–494 (2003).
15. Scientific Summary of Pandemic Influenza & its Mitigation - Scientific Evidence Base Review. Department of Health (Internet). Cited 2016 March. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215666/dh_125333.pdf
16. Luminex Corporation. NxTAG Respiratory Pathogen Panel (RPP) Package Insert IVD (CE Marked).
17. Leland D S., Ginocchio C C. Role of cell culture for virus detection in the age of technology. Clin Microbiol Rev 2007; 20:49–78
18. Ginocchio C C, McAdam A J. Current Best Practices for Respiratory Virus Testing. J Clin Microbiol 2011;49(9 Suppl): S44–S48.

Luminex®

To learn more, please visit: **www.luminexcorp.com/nxtag**

HEADQUARTERS

UNITED STATES	EUROPE	CANADA	CHINA	JAPAN
+1.512.219.8020	+31.73.800.1900	+1.416.593.4323	+86.21.616.50809	+81.3.5545.7440
info@luminexcorp.com	europe@luminexcorp.com	info@luminexcorp.com	infocn@luminexcorp.com	infojp@luminexcorp.com
www.luminexcorp.com	www.luminexcorp.com	www.luminexcorp.com	www.luminexcorp.com	www.luminexcorp.com

BR1513.0416