



EXPLIFY RESPIRATORY PATHOGENS BY NEXT GENERATION SEQUENCING

Limitations

Negative results do not rule out viral, bacterial, or fungal infections. Targeted, PCR-based tests are generally more sensitive and are preferred when specific pathogens are suspected, especially for DNA viruses (Adenovirus, CMV, HHV6, HSV, and VZV), mycobacteria, and fungi.

The analytical sensitivity of this test depends on the cellularity of the sample and the concentration of all microbes present. Analytical sensitivity is assessed using Internal Controls that are added to each sample. Sequencing data for Internal Controls is quantified. Samples with Internal Control values below the validated minimum may have reduced analytical sensitivity or contain inhibitors and are reported as 'Reduced Analytical Sensitivity'. Additional respiratory pathogens to those reported cannot be excluded in samples with 'Reduced Analytical Sensitivity'.

Due to the complexity of next generation sequencing methodologies, there may be a risk of false-positive results. Contamination with organisms from the upper respiratory tract during specimen collection can also occur. The detection of viral, bacterial, and fungal nucleic acid does not imply organisms causing invasive infection. Results from this test need to be interpreted in conjunction with the clinical history, results of other laboratory tests, epidemiologic information, and other available data. Confirmation of positive results by an alternate method may be indicated in select cases.

Validated Organisms

BACTERIA

<i>Achromobacter xylosoxidans</i>	<i>Legionella micdadei</i>	<i>Nocardia puris</i> *
<i>Acinetobacter baumannii</i> *	<i>Legionella pneumophila</i>	<i>Nocardia rhamnosiphila</i> *
<i>Actinomyces graevenitzi</i>	<i>Legionella wadsworthii</i> *	<i>Nocardia takedensis</i> *
<i>Actinomyces israelii</i>	<i>Listeria monocytogenes</i>	<i>Nocardia testacea</i> *
<i>Aggregatibacter actinomycetemcomitans</i> *	<i>Moraxella catarrhalis</i>	<i>Nocardia transvalensis complex</i>
<i>Bordetella parapertussis</i> *	<i>Morganella morganii</i>	<i>Proteus mirabilis</i> *
<i>Bordetella pertussis</i> *	<i>Mycoplasma hominis</i> *	<i>Pseudomonas aeruginosa</i>
<i>Burkholderia cepacia complex</i> *	<i>Mycoplasma pneumoniae</i>	<i>Pseudomonas fluorescens</i> *
<i>Burkholderia gladioli</i> *	<i>Neisseria meningitidis</i>	<i>Pseudomonas fulva</i> *
<i>Chlamydia pneumoniae</i> *	<i>Nocardia abscessus complex</i> *	<i>Pseudomonas luteola</i> *
<i>Citrobacter freundii</i>	<i>Nocardia amamiensis</i> *	<i>Pseudomonas putida</i> *
<i>Citrobacter koseri</i> *	<i>Nocardia aobensis</i> *	<i>Pseudomonas stutzeri</i> *
<i>Corynebacterium pseudodiphtheriticum</i> *	<i>Nocardia beijingensis complex</i> *	<i>Raoultella ornithinolytica</i> *
<i>Eikenella corrodens</i>	<i>Nocardia blacklockiae</i> *	<i>Raoultella planticola</i> *
<i>Enterobacter aerogenes</i> *	<i>Nocardia brasiliensis</i> *	<i>Serratia marcescens</i>
<i>Enterobacter cloacae</i> *	<i>Nocardia carnea</i> *	<i>Staphylococcus aureus</i>
<i>Escherichia coli</i>	<i>Nocardia cyriacigeorgica</i> *	<i>Stenotrophomonas maltophilia</i>
<i>Legionella bozemanii</i>	<i>Nocardia exalbida complex</i> *	<i>Streptococcus agalactiae</i>
<i>Haemophilus influenzae</i>	<i>Nocardia farcinica</i>	<i>Streptococcus anginosus</i>
<i>Haemophilus parainfluenzae</i>	<i>Nocardia ignorata</i> *	<i>Streptococcus constellatus</i>
<i>Klebsiella oxytoca</i> *	<i>Nocardia niigatensis</i> *	<i>Streptococcus dysgalactiae</i> *
<i>Klebsiella pneumoniae</i>	<i>Nocardia niwae</i> *	<i>Streptococcus intermedius</i>



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<i>Legionella anisa</i> *	<i>Nocardia nova complex</i> *	<i>Streptococcus pneumoniae</i> *
<i>Legionella dumoffii</i> *	<i>Nocardia otitidiscaviarum</i> *	<i>Streptococcus pyogenes</i>
<i>Legionella feeleii</i> *	<i>Nocardia paucivorans</i> *	<i>Ureaplasma parvum</i> *
<i>Legionella maceachernii</i>	<i>Nocardia pseudobrasiliensis</i> *	<i>Ureaplasma urealyticum</i>

VIRUSES

Adenovirus A*	Echovirus*	Human Rhinovirus C*
Adenovirus B*	Enterovirus*	Influenza A virus, subtype H1N1
Adenovirus C*	Enterovirus 71*	Influenza A virus, subtype H3N2
Adenovirus D*	Enterovirus D68*	Influenza B virus
Adenovirus E*	Herpes Simplex Virus Type 1	Parainfluenza Virus Type 1
Adenovirus F*	Herpes Simplex Virus Type 2*	Parainfluenza Virus Type 2
Adenovirus G*	Human bocavirus 1*	Parainfluenza Virus Type 3
Coronavirus 229E*	Human bocavirus 2*	Parainfluenza Virus Type 4
Coronavirus HKU1*	Human bocavirus 3*	Parainfluenza Virus Type 5*
Coronavirus NL63	Human bocavirus 4*	Parechovirus*
Coronavirus OC43*	Human herpesvirus 6	Respiratory Syncytial Virus
Coxsackievirus A*	Human metapneumovirus	Varicella Zoster Virus*
Coxsackievirus B	Human Rhinovirus A	
Cytomegalovirus	Human Rhinovirus B*	

FUNGI

Pneumocystis jirovecii

* Validation of these organisms was performed via a computer simulation ('in silico')

The following organisms cannot be differentiated by this test:

Reported	Cannot be differentiated from	Comment
<i>Acinetobacter baumannii</i>	<i>Acinetobacter johnsonii</i>	
<i>Burkholderia cepacia</i> complex	Members of the <i>B. cepacia</i> complex	Members include <i>B. cepacia</i> , <i>B. multivorans</i> , <i>B. cenocepacia</i> , <i>B. stabilis</i> , <i>B. vietnamiensis</i> , <i>B. dolosa</i> , <i>B. ambifaria</i> , <i>B. anthina</i> , <i>B. pyrrocinia</i> , <i>B. ubonensis</i> , <i>B. contaminans</i> , <i>B. seminalis</i> , <i>B. arboris</i> , <i>B. latens</i> , <i>B. lata</i> , <i>B. pseudomultivorans</i> , <i>B. diffusa</i> , <i>B. metallica</i>
<i>Legionella feeleii</i>	<i>Legionella tunisiensis</i> , <i>L. dresdenensis</i> , and <i>L. massiliensis</i>	All three <i>Legionella</i> spp. are environmental organism and have not been reported from clinical specimens.
<i>Pseudomonas fulva</i>	<i>Pseudomonas parafulva</i>	
<i>Pseudomonas stutzeri</i>	<i>Pseudomonas otitidis</i>	