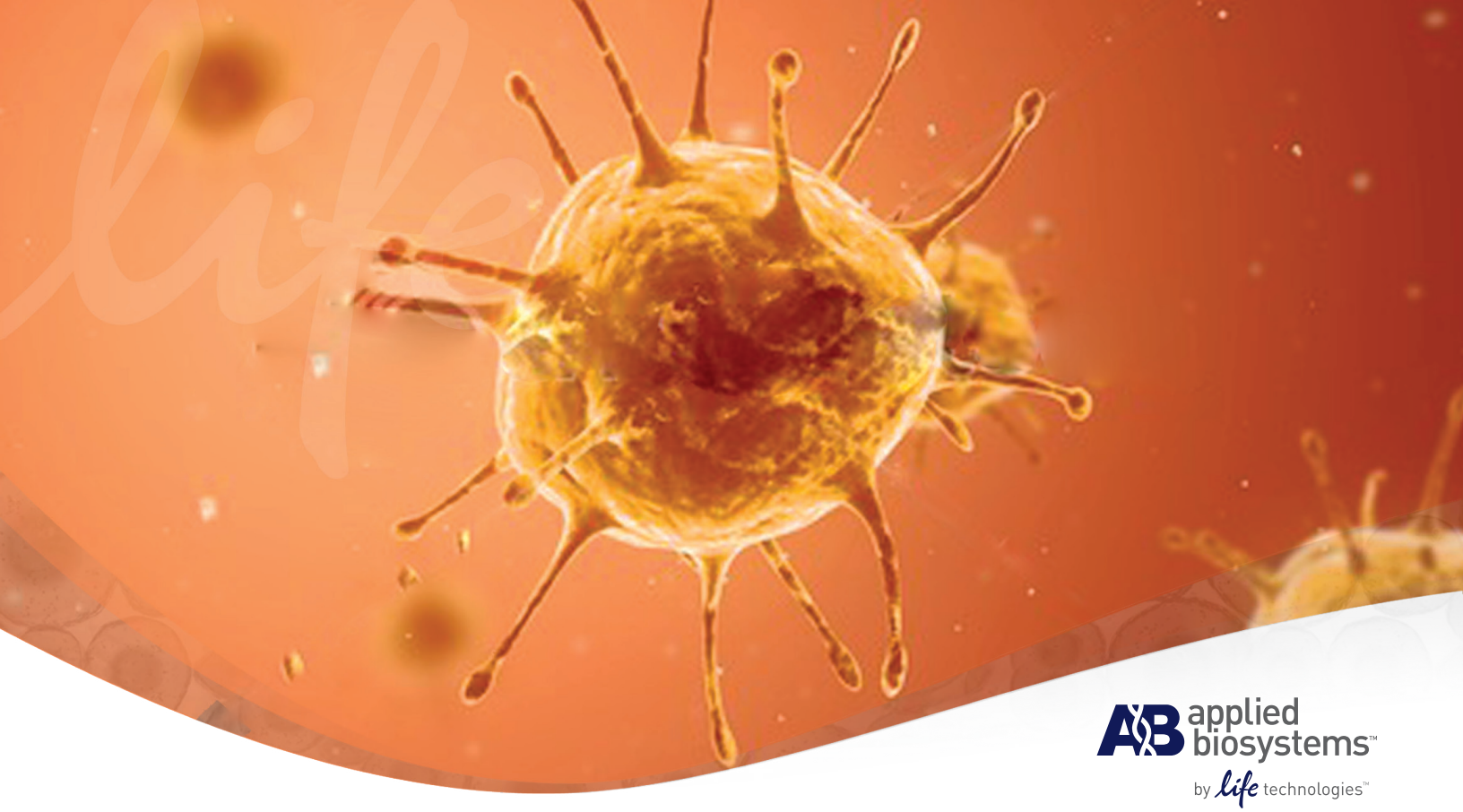


applied biosystems™
by life technologies™

Broad Spectrum Molecular Diagnostics for Respiratory Pathogens

TrueScience™ RespiFinder® Pathogen and Viral Identification Panels CE IVD

Rapid Analysis for Critical Infection

- Broad spectrum—detect presence of up to 15 viral and 4 bacterial pathogens with one panel
- Rapid test—diagnostic result available typically within 8 hours of nucleic acid isolation
- Clarity of results—differentiate up to 19 different pathogens, with a single patient report
- Minimal hands-on time—multiplex assay may reduce pipetting and sample transfer steps

Detect Multiple Pathogens—One Tube, One Patient Sample

Acute respiratory tract infection (RTI) is prevalent in adults and children and is of significant concern in immunocompromised patients. Both viruses and bacteria can cause acute RTI, and the number of potential causative agents is large. To further complicate diagnosis, a single patient can carry more than one infection. Rapid molecular diagnostic tests have the potential to detect and differentiate many serious pathogens, helping to reduce prescriptions for broad spectrum antibiotics.

TrueScience™ RespiFinder® Pathogen and Viral Identification Panels are multiplex PCR–based tests that can detect and differentiate up to 14 RNA viruses, 1 DNA virus, and 4 bacterial strains in a single tube (Table 1, back cover). The assay utilizes a reverse transcription PCR (RT-PCR)–based probe ligation technique that is rapid, sensitive, and accurate. Test results can be obtained typically within 8 hours of nucleic acid isolation. And because they are CE IVD–marked, you can be confident that *TrueScience*™ RespiFinder® Panels are designed to support the demanding needs of clinical environments by delivering unsurpassed data quality scientists and clinicians expect.

life technologies™

Broad Spectrum Molecular Diagnostics

The *TrueScience*™ RespiFinder® Pathogen and Viral Identification Panels clearly indicate the presence of up to 19 targets in a single reaction, from a single patient sample. The assay differentiates the presence of multiple pathogens in the patient sample, allowing physicians to reduce the time to treatment by accurately diagnosing a broad spectrum of viruses and bacteria.

Simple Workflow

The *TrueScience*™ RespiFinder® Panels have a simple workflow, which starts with the combined reverse transcription and PCR pre-amplification of isolated total nucleic acids (RNA and DNA). Subsequently, probe hybridization, ligation, and amplification are performed (Figure 1). The result is a powerful multiplex assay that provides data lab directors and clinicians can easily interpret.

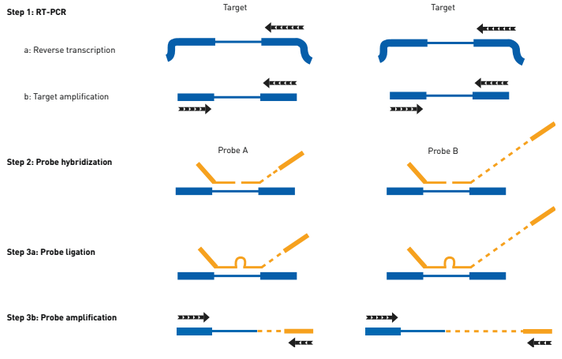
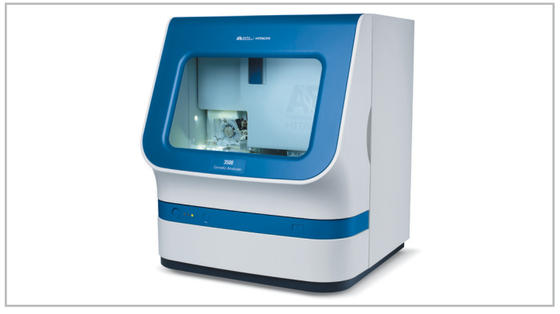


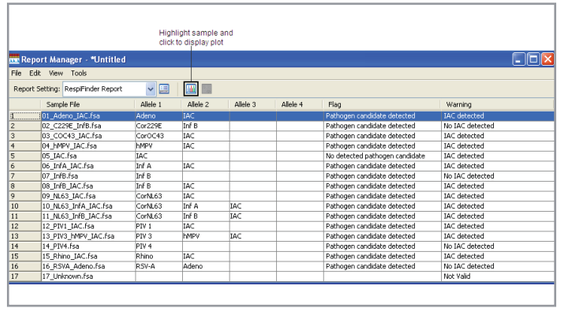
Figure 1. Pathogens Are Identified Using RT-PCR Followed by Probe Hybridization and Amplification.
RNA and DNA purified from clinical samples are amplified using RT-PCR and then hybridized to probe pairs that are specific to each pathogen in the panel. Pathogens are identified by the lengths of the fragments produced.



Accurate Detection

After the PCR amplification with the *TrueScience*™ RespiFinder® Panel, pathogen detection proceeds on an Applied Biosystems® Genetic Analyzer, including the multicapillary systems such as the 3500 Series and 3130 Series Genetic Analyzers.

The state-of-the-art 3500 Series Genetic Analyzers integrate seamlessly into your work environment, enabling ease of use without sacrificing reliability. Hands-on time is reduced by providing preformulated, load-and-run consumables, which helps reduce the possibility of mixing and handling errors.



	Sample File	Allele 1	Allele 2	Allele 3	Allele 4	Flag	Warning
1	01_Adeno_IAC.fsa	Adeno	IAC			Pathogen candidate detected	IAC detected
2	02_C229E_InfB.fsa	Cor229E	Inf B			Pathogen candidate detected	No IAC detected
3	03_COC43_IAC.fsa	CorOC43	IAC			Pathogen candidate detected	IAC detected
4	04_hMPV_IAC.fsa	hMPV	IAC			Pathogen candidate detected	IAC detected
5	05_IAC.fsa	IAC				No detected pathogen candidate	IAC detected
6	06_InfA_IAC.fsa	Inf A	IAC			Pathogen candidate detected	IAC detected
7	07_InfB.fsa	Inf B				Pathogen candidate detected	No IAC detected
8	08_InfB_IAC.fsa	Inf B	IAC			Pathogen candidate detected	IAC detected
9	09_NL63_IAC.fsa	CorNL63	IAC			Pathogen candidate detected	IAC detected
10	10_NL63_InfA_IAC.fsa	CorNL63	Inf A	IAC		Pathogen candidate detected	IAC detected
11	11_NL63_InfB_IAC.fsa	CorNL63	Inf B	IAC		Pathogen candidate detected	IAC detected
12	12_PIV1_IAC.fsa	PIV 1	IAC			Pathogen candidate detected	IAC detected
13	13_PIV3_hMPV_IAC.fsa	PIV 3	hMPV	IAC		Pathogen candidate detected	IAC detected
14	14_PIV4.fsa	PIV 4				Pathogen candidate detected	No IAC detected
15	15_Rhino_IAC.fsa	Rhino	IAC			Pathogen candidate detected	IAC detected
16	16_RSVA_Adeno.fsa	RSV-A	Adeno			Pathogen candidate detected	No IAC detected
17	17_Unknown.fsa						Not Valid

Clear Results

Applied Biosystems® GeneMapper® Software v4.1 completes fragment analysis with a simple and easy-to-interpret analysis package for reporting results (Figure 2). Pathogen identification is conveniently called out in the GeneMapper® Software report. In addition to reporting the presence of multiple pathogens, GeneMapper® Software can also streamline the creation of a full patient sample report, which can be easily printed or transferred electronically.

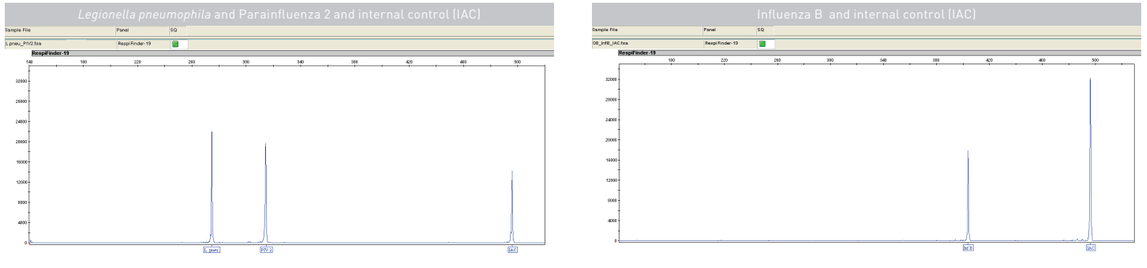


Figure 2. GeneMapper® Software v4.1 Delivers Accurate, Simple Analysis of the Fragments Generated With the *TrueScience*™ RespiFinder Panels.

Ordering Information

Product	Description	Part No.
TrueScience™ RespiFinder® 15 Viral Identification Panel	Detects 14 RNA viruses and 1 DNA virus	4460381
TrueScience™ RespiFinder® 19 Pathogen Identification Panel	Detects 14 RNA viruses, 1 DNA virus, and 4 bacteria	4460382
GeneScan™ 600 LIZ™ Size Standard	Internal size standard for reproducible amplicon sizing of samples analyzed with *TrueScience*™ RespiFinder® Pathogen and Viral Identification Panels	4366589

Pathogens Identified by the *TrueScience*™ RespiFinder® Panels		
	RespiFinder® 15 Viral Identification Panel	RespiFinder® 19 Pathogen Identification Panel
Influenza A	X	X
Influenza B	X	X
Influenza A H5N1	X	X
RSV A	X	X
RSV B	X	X
Adenovirus	X	X
Rhinovirus	X	X
Coronavirus 229E	X	X
Coronavirus NL63	X	X
Coronavirus OC43	X	X
Parainfluenza 1	X	X
Parainfluenza 2	X	X
Parainfluenza 3	X	X
Parainfluenza 4	X	X
Human Metapneumovirus	X	X
Bordetella pertussis		X
Chlamydophila pneumoniae		X
Mycoplasma pneumoniae		X
Legionella pneumophila		X
Internal Control	X	X

Table 1. Pathogens Identified by the *TrueScience*™ RespiFinder® Panels.

For more information, please visit us online at www.appliedbiosystems.com/respifinder.

CE IVD

The *TrueScience*™ RespiFinder® Pathogen and Viral Identification Panels meet the requirements of the In Vitro Diagnostic Medical Device Directive. Not for sale in the USA. Not cleared by SFDA in China.

The *TrueScience*™ RespiFinder® 19 Pathogen Identification Panel and *TrueScience*™ RespiFinder® 15 Viral Identification Panel are qualitative multiparameter tests intended to simultaneously detect and identify common respiratory pathogens from purified total nucleic acids.

The input sample is total nucleic acids extracted and purified from nasopharyngeal swabs, nasal aspirates, sputum, and bronchoalveolar lavages (BAL) from patients suspected of respiratory tract infections. Preparation of clinical samples is a separate process from the scope of the panels; use suitable methods or products to handle specimens and extract and purify nucleic acids.

The *TrueScience*™ RespiFinder® Identification Panels aid in the diagnosis of respiratory tract infection when used in conjunction with other clinical and laboratory findings. Negative results do not necessarily indicate absence of viral or bacterial respiratory tract infection; negative results should not be used as the sole basis for diagnosis, therapy, or other treatment decisions. Positive results do not exclude co–infection with other pathogens. The pathogen(s) detected may not be the definite cause of disease. Other laboratory testing and assessment of clinical presentation must be included in the final diagnosis. Performance characteristics were established with validated EQA panels from www.qcmd.org. The product is for use by laboratory professionals, and it is intended for use with certain instruments and data analysis software from Applied Biosystems.

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