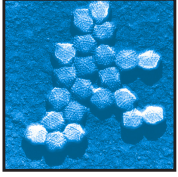


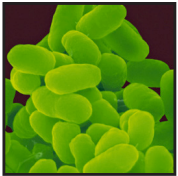
FilmArray Respiratory Panel

1 Test. 20 Respiratory Pathogens. All in about an hour.



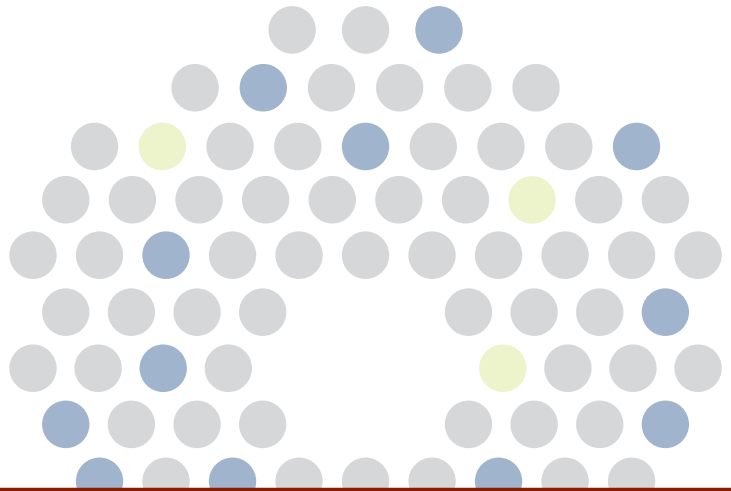
Viruses

- Adenovirus
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus 229E
- Coronavirus OC43
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A
- Influenza A/H1
- Influenza A/H1-2009
- Influenza A/H3
- Influenza B
- Parainfluenza 1
- Parainfluenza 2
- Parainfluenza 3
- Parainfluenza 4
- Respiratory Syncytial Virus



Bacteria

- *Bordetella pertussis*
- *Chlamydomphila pneumoniae*
- *Mycoplasma pneumoniae*



**20
Targets**

Simultaneous Detection of 20 Targets

For In-vitro Diagnostic Use
FDA Cleared | CE IVD Marked

The FilmArray Respiratory Panel tests for a comprehensive panel of 20 respiratory viruses and bacteria. The FilmArray instrument integrates sample preparation, amplification, detection and analysis into one simple system that requires 2 minutes of hands-on time and has a total run time of about 1 hour.

- **Simple:** Two minutes of hands-on time
- **Easy:** No precise measuring or pipetting required
- **Fast:** Turnaround time of about 1 hour
- **Comprehensive:** 20 target respiratory panel



If you are interested in a free, no obligation demonstration of the FilmArray in your laboratory visit www.biofiredx.com or call 1-800-735-6544.

**FREE
Demo!**



Panel Specifications

Sample Handling	Performance Parameters
<ul style="list-style-type: none"> Sample Type: Nasopharyngeal Swab 	<ul style="list-style-type: none"> Hands-on time: Approx. 2 minutes
<ul style="list-style-type: none"> Sample Volume: 300 µL 	<ul style="list-style-type: none"> Run turnaround time: About 1 hour

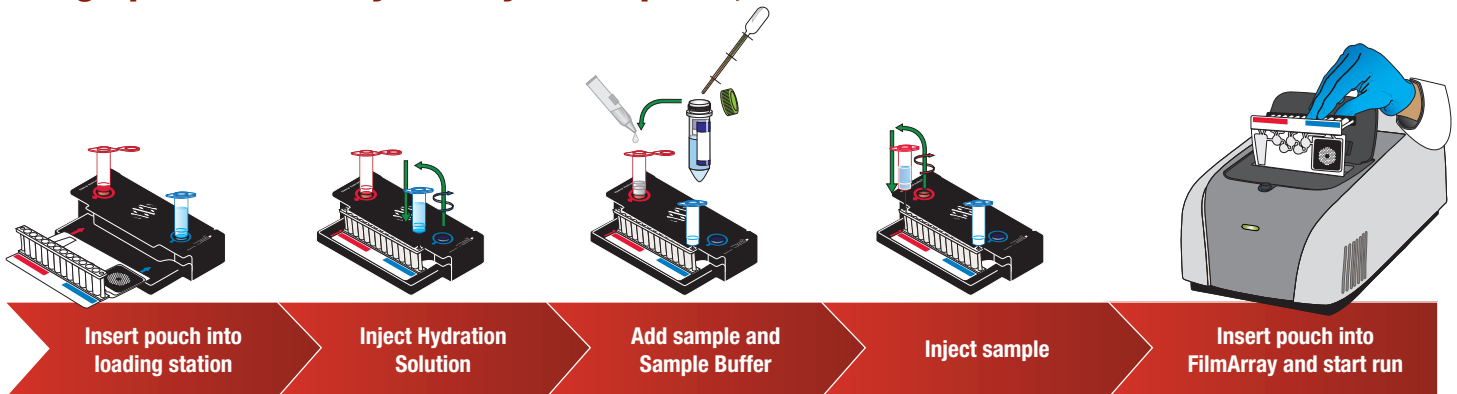
How Does the FilmArray Work?

The FilmArray reagent pouch stores all the necessary reagents for sample preparation, reverse transcription, PCR and detection in a freeze-dried format. Sample is collected in viral transport media. Prior to a run, the user injects hydration solution and sample combined with sample buffer mix into the pouch. The FilmArray instrument does the rest.

First, the FilmArray extracts and purifies all nucleic acids from the sample. Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large-volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first-stage PCR.

Using endpoint melting curve data, the FilmArray software automatically generates a result for each target in a single report.

Setting up the FilmArray is Easy – Sample in, Results out



Clinical Sensitivity and Specificity of the FilmArray Respiratory Pouch

Pathogens	Sensitivity		Specificity
	Prospective	Retrospective	Prospective
Adenovirus	88.9%	100%	98.3%
Coronavirus HKU1	95.8%	n/a	99.8%
Coronavirus NL63	95.8%	n/a	100%
Coronavirus 229E	100%	100%	99.80%
Coronavirus OC43	100%	100%	99.60%
Human Metapneumovirus	94.6%	n/a	99.2%
Human Rhinovirus/Enterovirus	92.7%	95.7%	94.6%
Influenza A	90.0%	n/a	99.8%
Influenza A/H1	n/a	100%	100%
Influenza A/H3	n/a	100%	100%
Influenza A/H1-2009	88.9%*	100%	99.6%
Influenza B	n/a	100%	100%
Parainfluenza Virus 1	100%*	97.1%	99.9%
Parainfluenza Virus 2	87.4%*	100%	99.8%
Parainfluenza Virus 3	95.8%	100%	98.8%
Parainfluenza Virus 4	100%*	100%	99.9%
Respiratory Syncytial Virus	100%	n/a	89.1%
<i>Bordetella pertussis</i>	100%*	94.6%	99.90%
<i>Chlamydomphila pneumoniae</i>	100%*	100%†	100%
<i>Mycoplasma pneumoniae</i>	100%*	84.4%	100%

*Spiked *Chlamydomphila pneumoniae* samples were used to test retrospective sensitivity.

†Due to low prevalence in the prospective study, clinical sensitivity for these pathogens was based on less than 10 positive samples.

The purchase of FilmArray System includes a limited, non-transferable license under U.S. Patent No. 5,871,908, owned by Evotec Biosystems GmbH and licensed to Roche Diagnostics GmbH, to use only the enclosed amount of product according to the specified protocols. No right is conveyed, expressly, by implication, or by estoppel, to use any instrument or system under any claim of U.S. Patent No. 5,871,908, other than for the amount of product contained herein.

The purchase of this product includes a limited, nontransferable instrument license under specific claims of one or more U.S. patents as listed on BioFire Diagnostics' Web site (<http://www.biofiredx.com/LegalNotices/>) (the "Web Site") and owned by the University of Utah Research Foundation and/or BioFire. Any kits sold with this product and/or discussed herein (i) may be covered by one or more of the U.S. patents, as listed on the Web Site for the product and (ii) include a limited, nontransferable license to use the enclosed amount(s) in such kits according to the specified protocols.

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