

**K181324 FilmArray Pneumonia Panel plus**Nov 15, 2018  
181 days to decisionK181324 · Product code: **QDS** · Microbiology  
Source: <https://www.510kdatabase.net/k181324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mers-cov And Common Respiratory Pathogens Semi-quantitative And Quantitative Multiplex Nucleic Acid Detection System (QDS)
Date received	May 18, 2018
Decision date	Nov 15, 2018
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biofire Diagnostics, LLC</b>
Location	Salt Lake City, UT, US
Contact	Kristen J. Kanack
Website	<a href="http://www.biofire.com/">http://www.biofire.com/</a>
510(k) history	28 submissions · 24 cleared · 2015-2025

Biofire Diagnostics, LLC specializes in microbiology diagnostic systems for syndromic infectious disease testing. The company, with a manufacturing facility in Salt Lake City, develops rapid molecular diagnostic platforms that detect viruses, bacteria, parasites, yeast, and antimicrobial resistance genes. The BIOFIRE® FILMARRAY® System and BIOFIRE® SPOTFIRE® System deliver results in approximately one hour. Biofire Diagnostics has received FDA 510(k) clearances from total submissions since its first clearance in 2015. The company maintains 100% focus on microbiology devic...

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Device record: <https://www.510kdatabase.net/k181324/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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