

**K243222 BIOFIRE® FILMARRAY® Pneumonia Panel (BIOFIRE Pneumonia Panel)**Nov 6, 2024  
30 days to decisionK243222 · Product code: QDS · Microbiology  
Source: <https://www.510kdatabase.net/k243222/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mers-cov And Common Respiratory Pathogens Semi-quantitative And Quantitative Multiplex Nucleic Acid Detection System (QDS)
Date received	Oct 7, 2024
Decision date	Nov 6, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BIOFIRE® FILMARRAY® Pneumonia Panel plus (BIOFIRE Pneumonia Panel plus)

**APPLICANT**

---

Company	<b>Biofire Diagnostics, LLC (Biomerieux)</b>
Location	Salt Lake City, UT, US
Contact	Karli Plenert
510(k) history	2 submissions · 2 cleared · 2024-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243222/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026