

**K243759 BIOFIRE Blood Culture Identification 2 (BCID2) Panel  
(RFIT-ASY-0147 (30 pack) RFIT-ASY-0148 (6 pack))**Dec 20, 2024  
14 days to decisionK243759 · Product code: **PEN** · Microbiology  
Source: <https://www.510kdatabase.net/k243759/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Dec 6, 2024
Decision date	Dec 20, 2024
Days to decision	14 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	Karli Plenert
Website	<a href="http://www.biofiredx.com/">http://www.biofiredx.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...