

## K243496 MycoMEIA Aspergillus Assay

Aug 1, 2025  
262 days to decision

K243496 · Product code: **NOM** · Microbiology  
Source: <https://www.510kdatabase.net/k243496/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Galactomannan, Aspergillus Spp. (NOM)
Date received	Nov 12, 2024
Decision date	Aug 1, 2025
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Pearl Diagnostics, Inc.</b>
Location	Baltimore, MD, US
Contact	Irina Baburina
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k243496/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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