

K243813 QIAstat-Dx GI Panel 2 Mini B&VJan 8, 2025
28 days to decisionK243813 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k243813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Dec 11, 2024
Decision date	Jan 8, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	QIAGEN GmbH
Location	Hilden, DE
Contact	Autumn Collasius
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Qiagen
Contact	Colleen Adams

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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