

K250324 QIAstat-Dx GI Panel 2 Mini BFeb 28, 2025
23 days to decisionK250324 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k250324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Feb 5, 2025
Decision date	Feb 28, 2025
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	STAT-Dx Life, S.L. (A QIAGEN Company)
Contact	Sonia Pablo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250324/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026