FDA 510(k) Premarket Notification

CLEARED

K254032 QIAstat-Dx Gastrointestinal Panel 2

Mar 9, 2026
83 days to decision

K254032 · Product code: **PCH** · Microbiology
Source: https://www.510kdatabase.net/k254032/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Dec 16, 2025
Decision date	Mar 9, 2026
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	QIAstat-Dx GI Panel 2 Mini B&V; QIAstat-Dx GI Panel 2 Mini B

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k254032/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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