

**K220062 QIAstat-Dx Gastrointestinal Panel 2**May 31, 2024  
872 days to decisionK220062 · Product code: **PCH** · Microbiology  
Source: <https://www.510kdatabase.net/k220062/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Jan 10, 2022
Decision date	May 31, 2024
Days to decision	872 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>QIAGEN GmbH</b>
Location	Hilden, DE
Contact	Stephany Foster Spahr
510(k) history	13 submissions · 13 cleared · 2012-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>QIAGEN Manchester, Ltd.</b>
Contact	Selina Salthouse

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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