

**K233100 QIAstat-Dx® Respiratory Panel Plus**May 10, 2024  
227 days to decisionK233100 · Product code: **QOF** · Microbiology  
Source: <https://www.510kdatabase.net/k233100/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Sep 26, 2023
Decision date	May 10, 2024
Days to decision	227 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	Autumn Collasius
510(k) history	13 submissions · 13 cleared · 2012-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qiagen</b>
Contact	Melissa Mahall

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233100/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026