

K250080 QIAstat-Dx Respiratory Panel PlusAug 27, 2025
226 days to decisionK250080 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k250080/>**SUBMISSION DETAILS**

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	Jan 13, 2025
Decision date	Aug 27, 2025
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	QIAstat-Dx Respiratory Panel Mini

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	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.netDevice record: <https://www.510kdatabase.net/k250080/> 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 13, 2026