

**K183597 QIAstat-Dx Respiratory Panel**May 18, 2019  
148 days to decisionK183597 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k183597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Dec 21, 2018
Decision date	May 18, 2019
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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