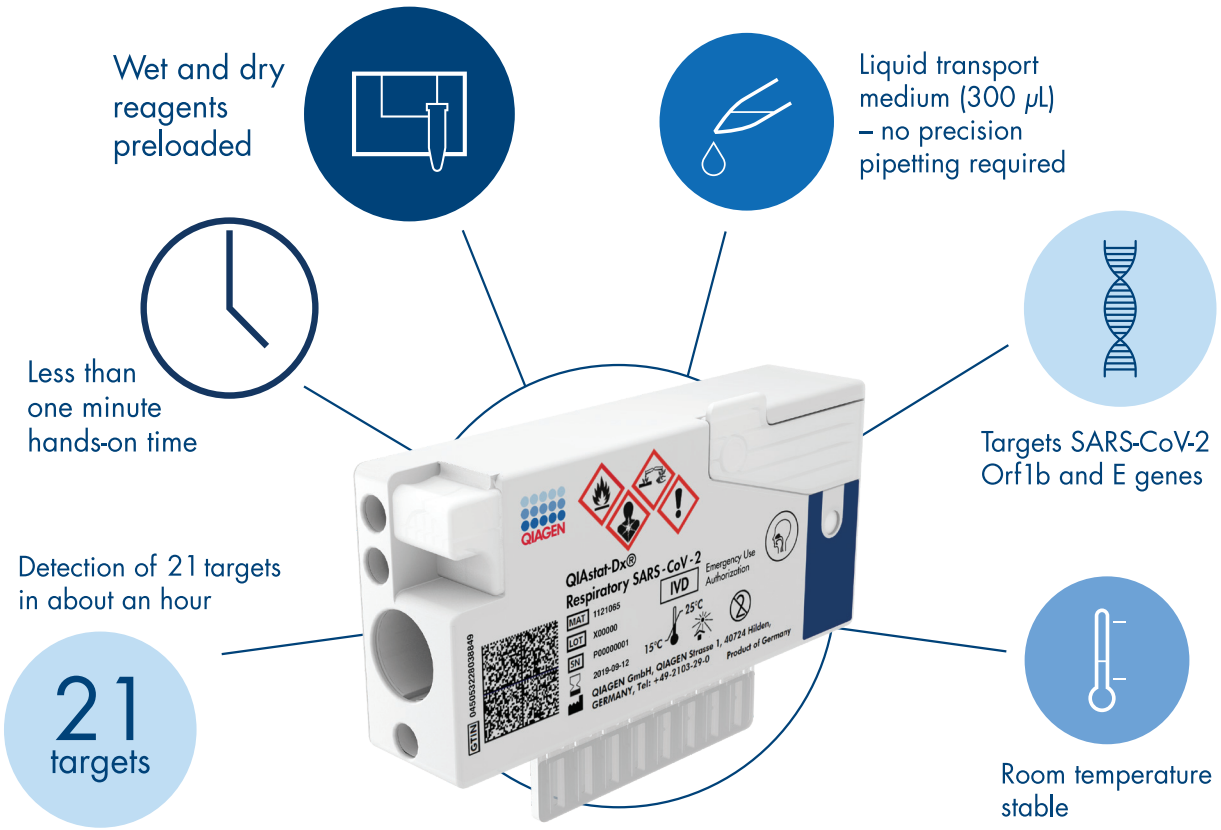
QIAstat-Dx Respiratory SARS-CoV-2 Panel

FDA Emergency Use Authorization

The next generation of syndromic insights

This expanded version of our multiplex respiratory cartridge detects and differentiates* 21 viral and bacterial respiratory targets, including SARS-CoV-2 to support efforts to provide accessible testing to meet the demands of the COVID-19 outbreak.



Bacterial

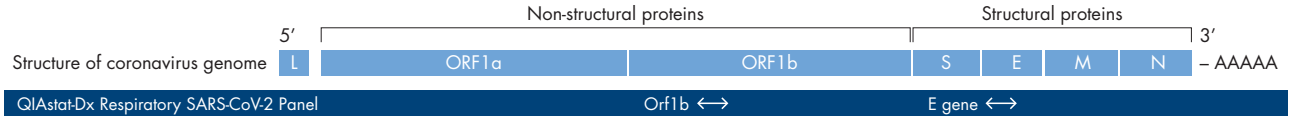
- *Mycoplasma pneumoniae*
- *Chlamydophila pneumoniae*
- *Bordetella pertussis*

Viral

- Influenza A
- Influenza A subtype H1N1/2009
- Influenza A subtype H1
- Influenza A subtype H3
- Influenza B
- Coronavirus 229E
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus OC43
- Parainfluenza virus 1
- Parainfluenza virus 2
- Parainfluenza virus 3
- Parainfluenza virus 4
- Adenovirus
- Respiratory Syncytial virus A/B
- Human Metapneumovirus A/B
- Rhinovirus/Enterovirus*
- **SARS-CoV-2**

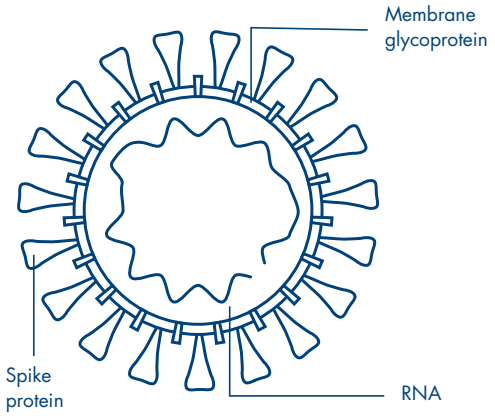
*Enterovirus and Rhinovirus are both detected, but not differentiated, with the QIAstat-Dx Respiratory SARS-CoV-2 Panel (Cat. No. 691223).

QIAstat-Dx Respiratory SARS-CoV-2 Panel – SARS-CoV-2 Targets



The two SARS-CoV-2 gene targets in the QIAstat-Dx Respiratory SARS-CoV-2 Panel were designed using alignment of more than 186 publicly available genomic sequences from the SARS-CoV-2 outbreak, and the two genes are detected with the same fluorescence channel.

1. Orf1b gene (RNA-dependent RNA polymerase region)
2. E gene (envelope protein)



QIAstat-Dx Respiratory SARS-CoV-2 Panel is intended for in vitro diagnostic use under Emergency Use Authorization Only. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.

The QIAstat-Dx Respiratory SARS-CoV-2 Panel has not been FDA cleared or approved;

The QIAstat-Dx Respiratory SARS-CoV-2 Panel has been authorized by FDA under an EUA for use by authorized laboratories;

The QIAstat-Dx Respiratory SARS-CoV-2 Panel has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and

The QIAstat-Dx Respiratory SARS-CoV-2 Panel is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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