

# Agilent SARS-CoV-2 qRT-PCR Dx Kit

## Introduction

The Agilent SARS-CoV-2 qRT-PCR Dx kit is a real-time reverse transcriptase PCR (qRT-PCR) *in vitro* diagnostic reagent kit for the qualitative detection of SARS-CoV-2 RNA. Clinical laboratories can easily generate diagnostic results from this single-tube assay. RNA is isolated and purified from nasopharyngeal, nasal, and oropharyngeal swab specimens<sup>1</sup> obtained from individuals suspected of having COVID-19 by their healthcare provider.

The SARS-CoV-2 qRT-PCR Dx kit contains a primer and probe mix that targets the N1 and N2 regions of the SARS-CoV-2 nucleocapsid gene and human RNase P, and includes a synthetic SARS-CoV-2 RNA positive control. The kit has been designed for flexibility across the entire workflow. The open system has been validated with two commercially available RNA extraction products and three real-time PCR systems, including the Agilent AriaDx Real-Time PCR System<sup>2</sup>.

### Efficient, single-tube assay

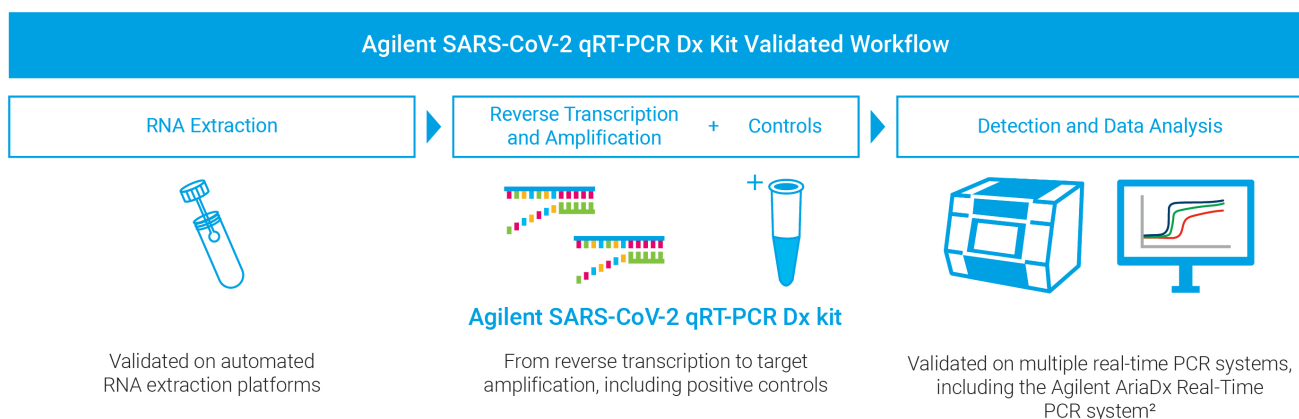
- Single-tube qRT-PCR assay includes 3 targets: N1 and N2 viral targets and human RNase P
- Minimizes use of consumables and maximizes sample throughput per instrument run
- Available as a kit and with an optional stand-alone positive control

### Sensitive, reliable assay for confidence in your test results

- Developed using primer and probe sequences published by the U.S. Centers for Disease Control (CDC)<sup>3</sup>
- Clinically validated and demonstrated with a limit of detection as low as 1.0 copy per  $\mu\text{L}$

### Validated, flexible workflow

- Choose from two automated RNA extraction platforms
- Protocols for established 96-well real-time PCR systems
- Enables easy assay adoption on existing instruments



\*The SARS-CoV-2 qRT-PCR Dx kit can be used with the AriaDx or AriaMx Real-Time PCR System. For countries requiring the use of *In Vitro* Diagnostic instruments, the AriaDx system must be used.

**Figure 1.** Illustration of the Agilent SARS-CoV-2 qRT-PCR Dx kit workflow.



## Order information

Part Number	Product Name	Number of Reactions
K1180A	Agilent SARS-CoV-2 qRT-PCR Dx kit	400
K1180B	Agilent SARS-CoV-2 qRT-PCR Dx Reagents Dx kit	400
K1180C	Agilent SARS-CoV-2 Positive RNA Control Dx kit	8

## Product specifications

SARS-CoV-2 target primer and probes	N1, N2
Internal control	Human RNase P (sample reaction internal control)
Reaction format	Single-tube assay
SARS-CoV-2 viral positive RNA controls	<i>In vitro</i> transcribed N1 and N2 RNA
Primer and probe sequences	Developed using primer and probe sequences published by the U.S. Centers for Disease Control (CDC) <sup>3</sup>
Sample types	Nasopharyngeal, nasal, and oropharyngeal human specimens <sup>1</sup>
Sensitivity	Limit of detection (LoD) as low as 1.0 copy per $\mu$ L
Target specificity	No cross-reactivity with 20 human respiratory pathogens, based on target sequences <sup>4</sup>
Clinical concordance	Up to 100 % positive percent agreement (PPA) and up to 100% negative percent agreement (NPA), based on RNA extraction and real-time PCR methods
Validated RNA extraction systems and reagents	<ul style="list-style-type: none"> <li>MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit with Automated KingFisher Flex system (Thermo Fisher Scientific)</li> <li>QIASymphony DSP Virus/Pathogen Midi Kit with automated Qiasymphony SP (Qiagen)</li> </ul>
Validated real-time PCR instruments	<ul style="list-style-type: none"> <li>AriaDx Real-Time PCR System (Agilent)<sup>2</sup></li> <li>Applied Biosystems 7500 Fast Real-Time PCR System (Thermo Fisher Scientific)</li> <li>CFX96 Touch Real-Time PCR Detection System (Bio-Rad)</li> </ul>
Format	Validated with 96-well plate format systems

<sup>1</sup>The performance of the Agilent SARS-CoV-2 qRT-PCR Dx kit assay was established using nasopharyngeal swab specimen type collected in UTM or VCM transport media. Oropharyngeal swabs, nasal swabs, and mid-turbinate nasal swabs are considered acceptable specimen types for use with the Agilent SARS-CoV-2 qRT-PCR Dx kit assay but performance with these specimen types has not been established.

<sup>2</sup> The SARS-CoV-2 qRT-PCR Dx kit can be used with the AriaDx or AriaMx Real-Time PCR System. For countries requiring the use of In Vitro Diagnostic instruments the AriaDx system must be used.

<sup>3</sup>Centers for Disease Control and Prevention, Division of Viral Diseases. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. CDC/DDID/NCIRD/ Division of Viral (2020), Diseases CDC-006-00019, Revision: 06. <https://www.fda.gov/media/134922/download>

<sup>4</sup>N1 and N2 primer and probe target sequences are identical to CDC protocol. These primer sequences are tested by CDC do not react with related pathogens, disease agents, and normal or pathogenic flora likely to be encountered in a clinical specimen. Cross reactivity is not impacted by mutations circulating virus.

[www.agilent.com/chem/sars-cov-2-qpcr-dx-kit](http://www.agilent.com/chem/sars-cov-2-qpcr-dx-kit)

The Agilent SARS-CoV-2 qRT-PCR Dx kit is CE-IVD marked in accordance with the European Union In Vitro Diagnostic Directive 98/79/EC.

For *In Vitro* Diagnostic Use.  
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This information is subject to change without notice.

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