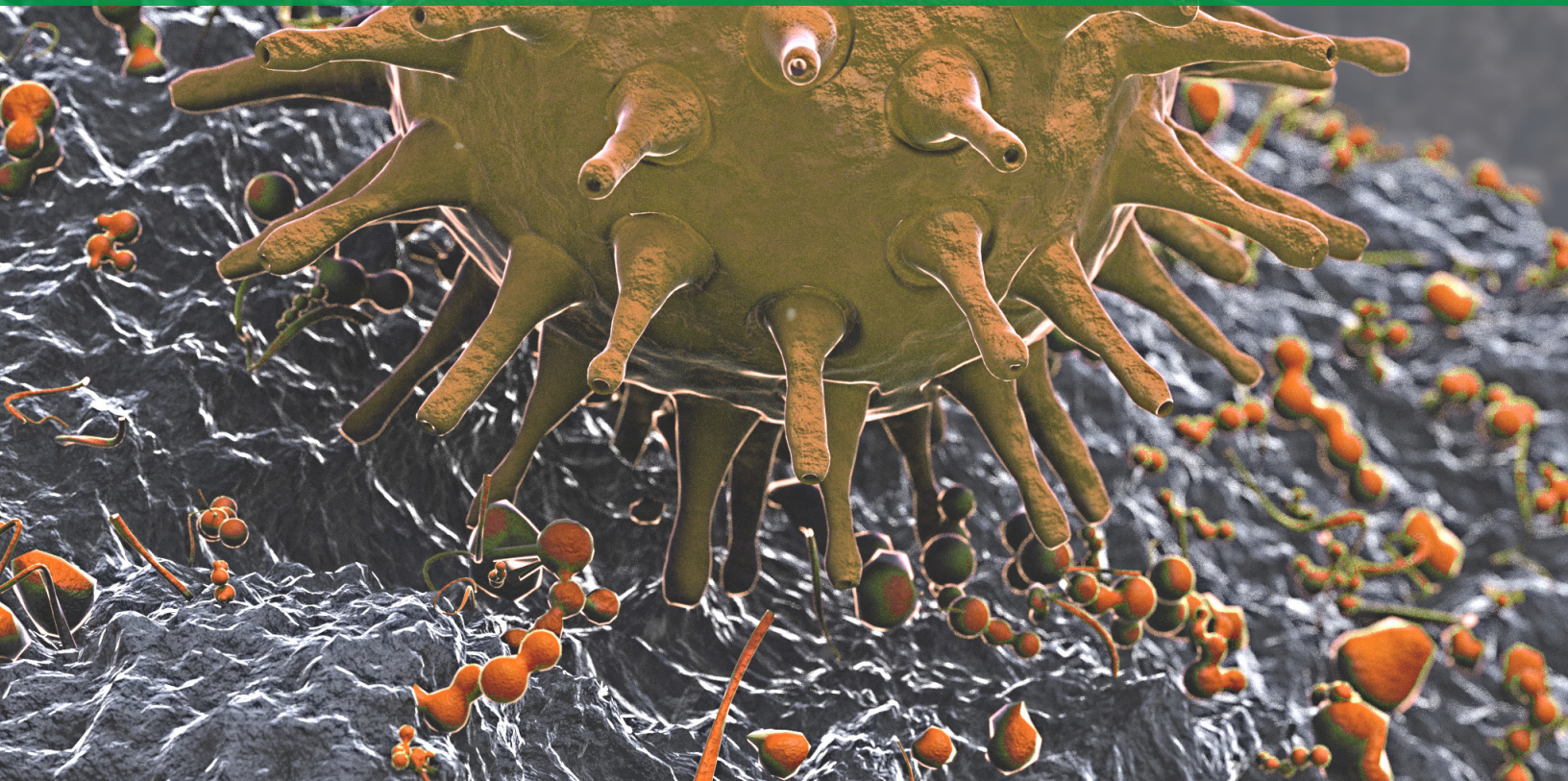


End-to-End Workflow for COVID-19 Detection



Quick SARS-CoV-2 rRT-PCR Kit



ZYMO RESEARCH

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FDA Emergency Use Authorization

Testing for COVID-19 Detection

The *Quick SARS-CoV-2 rRT-PCR Kit* from Zymo Research is intended for the qualitative detection of nucleic acids from SARS-CoV-2 in upper and lower respiratory specimens from patients suspected of COVID-19 by their health care provider. The *Quick SARS-CoV-2 rRT-PCR Kit* is FDA Emergency Use Authorized (EUA) and has been granted with the CE-IVD mark.

Highlights

- No cold-chain required for specimen transportation
- Compatible with automated and manual RNA extraction
- Targets the SARS-CoV-2 nucleocapsid (N) gene and the human RNaseP gene
- Limit of Detection (LoD) of 15 viral genome equivalent copies per reaction (GEC)/rxn
- Simple and fast reaction set-up with results in < 1.5 hours after RNA extraction

The SARS-CoV-2 Testing Workflow Includes:

Sample Collection in DNA/RNA Shield™



Proprietary sample collection technology

- Store the sample at ambient temperature up to 7 days.
- No cold-chain required for shipping.
- Collection devices for upper and lower respiratory tract specimens.

RNA Extraction using Quick-DNA/RNA™ Viral MagBead Kit



Robust nucleic acid purification

- Compatible with manual and automated procedures.
- Automated RNA extraction in < 1 hour using the KingFisher™ Flex Purification System (ThermoFisher Scientific).

SARS-CoV-2 Detection using the Quick SARS-CoV-2 rRT-PCR Kit



SARS-CoV-2 detection system

- Simple reaction set-up in less than 7 minutes: RNA is directly combined with the ready-to-use reaction mix and incubated in the CFX96 Touch Real-Time PCR Detection System (Bio-Rad).
- 100% detection at 15 GEC/rxn.
- Results in < 1.5 hours after extraction.
- Includes CV Mix 1 (for SARS-CoV-2 detection), CV Mix 2 (internal human control), CV Positive Control and No Template Control.

Specifications

1

Specimens collected in DNA/RNA Shield™ are extracted manually or with the automated KingFisher™ Flex Purification System (ThermoFisher Scientific) using the script available at: www.zymoresearch.com/products/quick-sars-cov-2-rrt-pcr-kit



2

Samples are analyzed using the CFX96 Touch Real-Time PCR Detection System (Bio-Rad).



RT-PCR Set-up

Component	Volume per Reaction
CV Mix (1 or 2)	10 µl
Template RNA	10 µl
Total	20 µl

Select **HEX** channel for the detection of SARS-CoV-2 targets (CV Mix 1) and **Quasar 670** for the detection of human target (CV Mix 2).

Data Analysis & Interpretation

Interpret the results based on C_t values

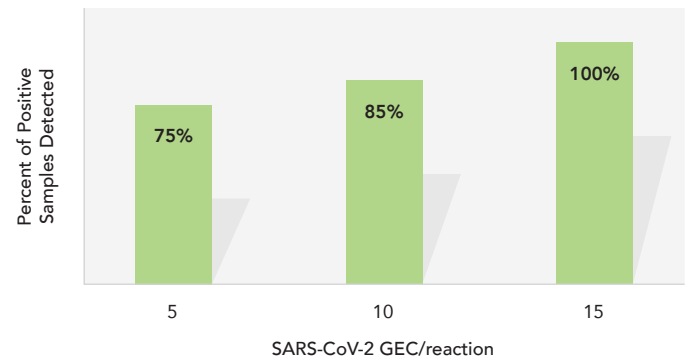
Host Target	Viral Target	Results
+	-	SARS-CoV-2 Negative
+	+	SARS-CoV-2 Positive*
-	+	SARS-CoV-2 Positive*
-	-	Invalid

*A positive result using the Quick SARS-CoV-2 rRT-PCR Kit is considered presumptive for SARS-CoV-2 because it may result from infection by another Sarbecovirus, such as SARS-CoV. Follow-up testing may be performed if differentiation between targets is desired.

3

Performance:

- PPA: 30/30 = 100% (95% CI: 88.7% - 100%)
- NPA: 30/30 = 100% (95% CI: 88.7% - 100%)
- 100% accurate detection as low as 15 GEC/rxn



Ordering Information

	Catalog Number	Product Name	Size
Sample Collection	R1106	DNA/RNA Shield™ Collection Tube w/ Swab (1 ml fill)	10 pack
	R1107		50 pack
	R1108	DNA/RNA Shield™ Collection Tube w/ Swab (2 ml fill)	10 pack
	R1109		50 pack
	R1210	DNA/RNA Shield™ Saliva Collection Kit	1 x 2 ml fill
Sample Purification	R2140	Quick-DNA/RNA™ Viral MagBead Kit	1 x 96 preps
	R2141		4 x 96 preps
SARS-CoV-2 Detection	R3011	Quick SARS-CoV-2 rRT-PCR Kit	100 tests per kit
	R3011-1K		1,000 tests per kit
	R3011-10K		10,000 tests per kit

This test has not been FDA cleared or approved. This test has been authorized by the FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test 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. Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors, and/or stage of infection.

For a complete description of the SARS-CoV-2 testing, refer to the Instruction For Use at www.zymoresearch.com/products/quick-sars-cov-2-rrt-pcr-kit



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