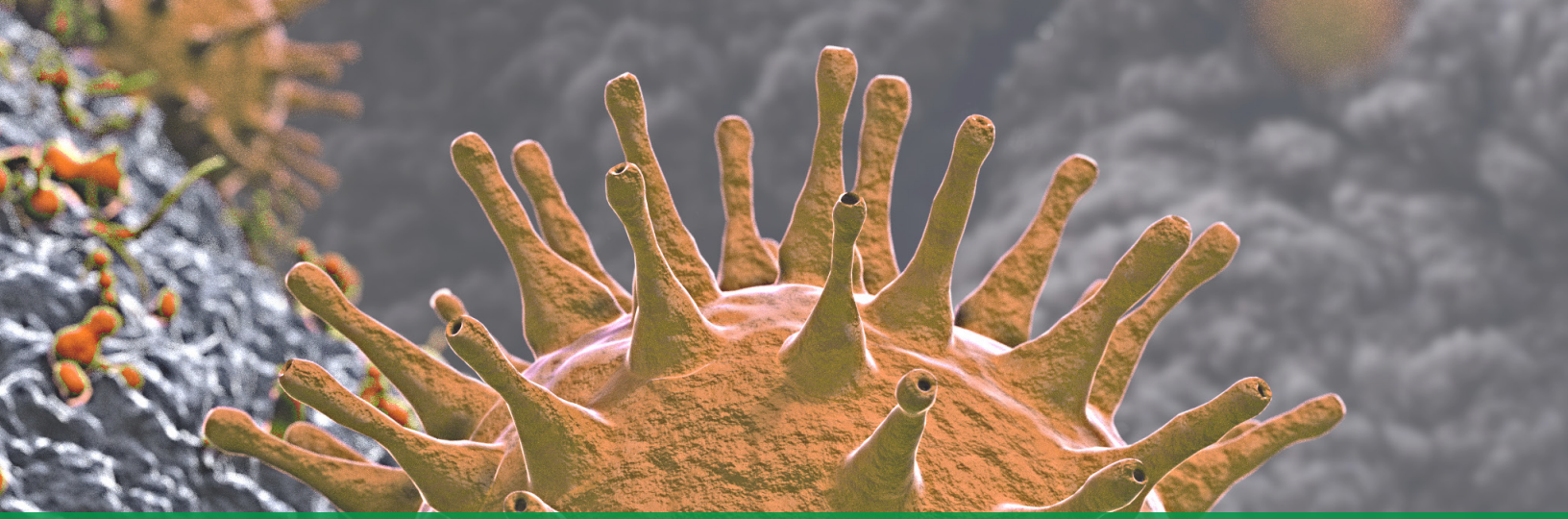
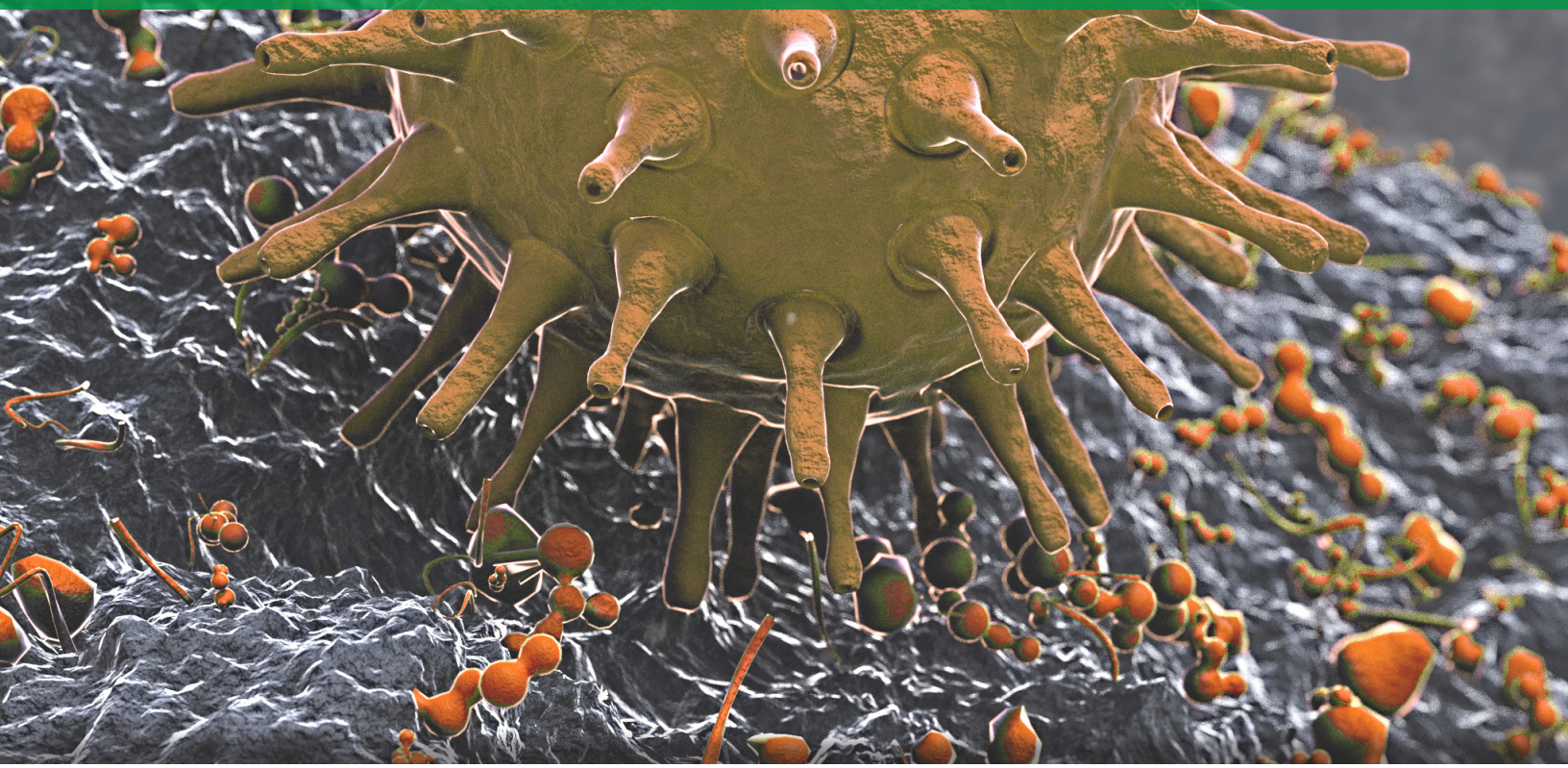


End-to-End Workflow for COVID-19 Detection



Quick SARS-CoV-2 rRT-PCR Kit

ZYMO RESEARCH

The Beauty of Science is to Make Things Simple®

FDA Emergency Use Authorization

Zymo Research Testing for COVID-19 Detection

The *Quick* SARS-CoV-2 rRT-PCR Kit is an FDA Emergency Use Authorized (EUA) real-time RT-PCR test 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.

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

Zymo Research SARS-CoV-2 Testing 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

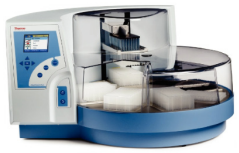
SARS-CoV-2 detection system

- Simple reaction set-up: 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) Template RNA	10 µl 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

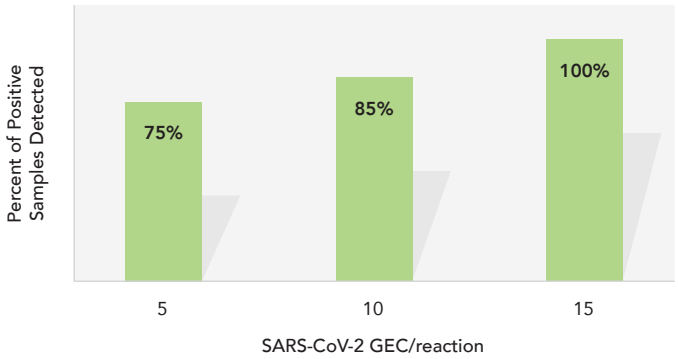
Host Target	Viral Target	Results
+	-	SARS-CoV-2 Negative
+	+	SARS-CoV-2 Positive*
-	+	SARS-CoV-2 Positive*
-	-	Invalid

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