



Detection Kit for SARS-CoV-2

AMPIPROBE® SARS-CoV-2 Assay Kit

EUA

IVD

R

The AMPIPROBE® SARS-CoV-2 Assay kit is part of our AMPIPROBE® SARS-CoV-2 Test System. The AMPIPROBE® SARS-CoV-2 Test System, which also includes the AMPIXTRACT® SARS-CoV-2 Extraction Kit and the AMPIPROBE® SARS-CoV-2 Controls Kit, is a multiplex assay system based on real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate specimens) collected from individuals suspected of COVID-19 by their healthcare provider. The AMPIPROBE® SARS-CoV-2 Test System has been authorized by the FDA under an Emergency Use Authorization (EUA).



The AMPIPROBE® SARS-CoV-2 Assay kit is a multiplexed real-time RT-PCR assay that contains two primer and probe sets to detect two regions in the SARS-CoV-2 nucleocapsid (N) gene and one primer and probe set to detect human RNase P (RP) in a clinical sample.

Reliable

Accurate detection of SARS-CoV-2 RNA using our highly optimized AMPIPROBE® technology.

Adaptable

Adaptable to different extraction methodologies and throughput (i.e., GENFLEX®, QIASymphony® SP, and manually).

Affordable

Low-cost alternative to other methods of viral load detection.

Validated

Authorized by FDA's Emergency Use Authorization (EUA).

PERFORMANCE

Sensitivity*: 96.2%

Specificity*: 98.0%

Size: 96 tests

* Percent agreements between the AMPIPROBE® Test System and an FDA-approved EUA test performed on nasopharyngeal swabs.

Automated Extraction,
Amplification and Detection

GENFLEX™ Platform



AMPIPROBE® SARS-CoV-2 Assay Kit

ENZ-GEN215-0096

COMPONENTS FOR 96 TESTS	QUANTITY	STORAGE
AMPIPROBE® RT-PCR Buffer	1.3 mL	-20°C
AMPIPROBE® SARS-CoV-2 Primer/Probe Mix	260 µL	-20°C
AMPIPROBE® RT-PCR Enzyme Mix	130 µL	-20°C
Nuclease-free Water	1 mL	-20°C

AMPIPROBE® SARS-CoV-2 Controls

ENZ-GEN218-0004

The AMPIPROBE® SARS-CoV-2 Controls are designed to be used during the PCR process to ensure an accurate RNA detection and amplification.

COMPONENTS	QUANTITY	STORAGE
AMPIPROBE® SARS-CoV-2 Positive Control	100 µL	-80°C
AMPIPROBE® SARS-CoV-2 Negative Control	100 µL	-80°C
No Template Control (NTC)	100 µL	-80°C

RELATED PRODUCT	
Product Name	Product Number
AMPIXTRACT® SARS-CoV-2 Extraction Kit	ENZ-GEN216

Emergency Authorization Use Only
In Vitro Diagnostic (IVD) Use Only
Prescription/Rx Use Only

The AMPIPROBE® SARS-CoV-2 Test System has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, to perform high complexity tests. The AMPIPROBE® SARS-CoV-2 Test System has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The AMPIPROBE® SARS-CoV-2 Test System 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.

Global Headquarters
ENZO LIFE SCIENCES, INC.
Ph: 800.942.0430
info-usa@enzolifesciences.com

European Sales Office
ENZO LIFE SCIENCES (ELS) AG
Ph: +41 61 926 8989
info-eu@enzolifesciences.com

Belgium, The Netherlands
& Luxembourg
Ph: +32 3 466 0420
info-be@enzolifesciences.com

France
Ph: +33 472 440 655
info-fr@enzolifesciences.com

Germany
Ph: +49 7621 5500 526
info-de@enzolifesciences.com

UK & Ireland
Ph: 0845 601 1488 (UK customers)
Ph: +44 1392 825900
info-uk@enzolifesciences.com

For detailed product information visit us online: www.enzolifesciences.com/coronavirus

In Vitro Diagnostic (IVD) Only. Use under Emergency Use Authorization (EUA) Only. Rx Only.
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