Extraction Kit for SARS-CoV-2

AMPIXTRACT® SARS-CoV-2 Extraction Kit

EUA IVD ℞

The AMPIXTRACT® SARS-CoV-2 Extraction Kit is part of our AMPIPROBE® SARS-CoV-2 Test System. The AMPIPROBE® SARS-CoV-2 Test System, which also includes the AMPIPROBE® SARS-CoV-2 Assay 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 AMPIXTRACT® SARS-CoV-2 Extraction Kit is designed for the isolation and purification of SARS-CoV-2 RNA virus from upper respiratory specimen (such as nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate specimens). Its magnetic bead separation technology enables high-quality purification of nucleic acids that are free of proteins, nucleases, and other impurities. The purified nucleic acids are ready for direct use in downstream applications, such as amplification and qualitative detection of SARS-CoV-2 virus.

RNA isolation can be performed with the AMPIXTRACT® SARS-CoV-2 Extraction Kit either manually or via an automated process using Enzo's GENFLEX® platform (contact us for more information).

Effective

RNA isolation using magnetic bead procedure with optimized extraction reagents

Flexible

Compatible with most upper respiratory sample collections

Adaptable

Adaptable to the GENFLEX® (automated) and manual extraction workflows

Validated

Tested to work as part of the EUA-authorized AMPIPROBE® SARS-CoV-2 Test System

Performance

Isolation of RNA in < 1 hour using magnetic bead separation technology with proprietary buffer system

GENFLEX™ Platform

Automated Extraction, Amplification and Detection

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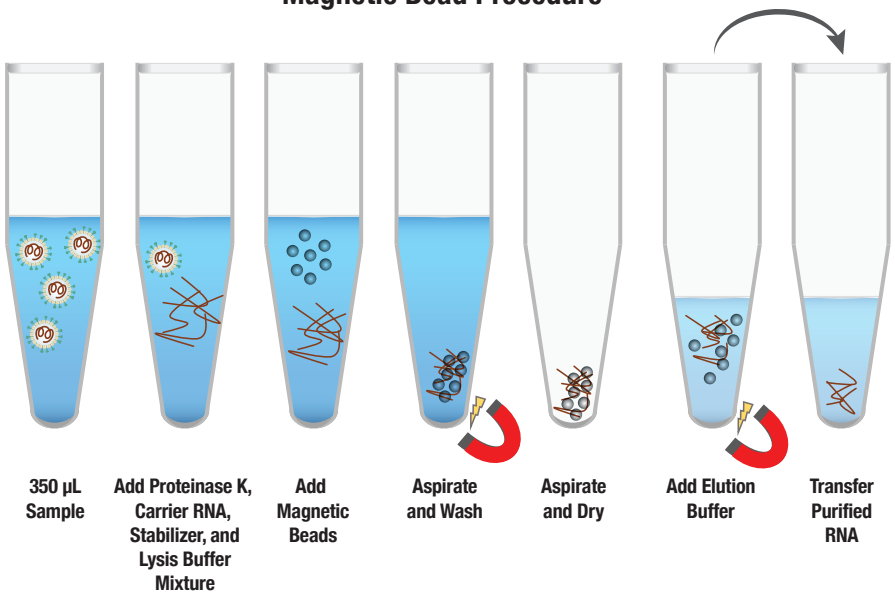
Magnetic Bead Procedure



AMPIXTRACT® SARS-CoV-2 Extraction Kit

COMPONENTS	ENZ-GEN216-0096	ENZ-GEN216-0960
	1 x 96 Well Plate	10 x 96 Well Plate
Wash Buffer	1 x 50 mL	10 x 50 mL
Lysis Buffer	1 x 80 mL	10 x 80 mL
Elution Buffer	1 x 12 mL	10 x 12 mL
Magnetic Beads	1 x 5 mL	10 x 5 mL
PK Dilution Buffer	1 x 9 mL	10 x 9 mL
Stabilizer	2 x 900 µL	20 x 900 µL
Proteinase	1 x 350 µL	10 x 350 µL
Carrier RNA	1 x 1.2 mL	10 x 1.2 mL

RELATED PRODUCTS	
Product Name	Product Number
AMPIPROBE® SARS-CoV-2 Controls	ENZ-GEN218
AMPIPROBE® SARS-CoV-2 Assay Kit	ENZ-GEN215

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.

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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.