Xfree™ COVID-19 Direct RT-PCR

Direct Sample. Extraction-Free. *Simple yet Superior.*

Xfree

Laboratories across the world are struggling to keep up with the increasing demand of reliable and fast COVID-19 testing. The shortage of testing reagents, supplies, and longer test turnaround times have crippled the efficiency and capabilities of labs all over the world. *Xfree™* COVID-19 RT-PCR from BioGX enables laboratories to overcome these challenges with a groundbreaking extraction-free, high-throughput Direct RT-PCR test for the detection of SARS-CoV-2 coronavirus.

Multi-Platform, High-throughput COVID-19 Testing

High-Throughput

Capacity of 6,000 tests per day
96 to 384 test results in 80 minutes

Highly Accessible

Validated on Applied Biosystems™ 7500 Fast Dx, QuantStudio™ 5, Bio-Rad CFX96 & CFX384 Touch™
Ships anywhere at ambient temperature

Simple & Efficient

Complete Lyophilized Test in a Single Vial
No other reagent required

Sensitive & Cost Effective

No sample preparation
Direct sample addition
Broad coverage of sample types

Intended Use

The *Xfree™* COVID-19 Direct RT-PCR* is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in nasopharyngeal and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider. Results are for the identification of SARS-CoV-2 RNA. The *Xfree™* COVID-19 assay includes two controls; (i) RNase P detection serves as an endogenous Sample Processing Control (SPC) and (ii) integrated RNA to serve as Internal Amplification Control (IAC) for reverse-transcription and PCR.

The product has been validated for use with direct patient sample addition to the rehydrated master mix or for use with purified nucleic acid using a validated magnetic bead or silica column nucleic acid extraction method. The sample types of Nasopharyngeal swab, Nasal swab, Mid-turbinate swab, Oropharyngeal swab transported in Copan ESwab™, Copan UTM®, BD UVT, VTM and dry swab (resuspended in saline) have been validated for both direct sample and nucleic acid extracted sample workflows. Additionally, Nasopharyngeal wash/aspirates and Nasal aspirates (0.85% saline) have been validated for both direct sample and nucleic acid extracted sample workflows.

*Detection of SARS-CoV-2 (N1) and human RNase P utilize identical primers and probes sequences as in US CDC EUA Test.

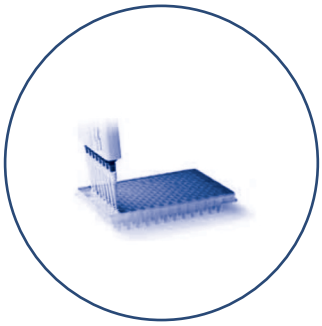
Extraction-Free Direct Sample Workflow

Xfree™ COVID-19 is a complete test in a single vial, lyophilized in the trusted BioGX Sample-Ready™ format. The user would simply Just Add Water™, the patient sample, and run the test on a validated real-time PCR instrument.

JUST ADD WATER

Rehydrate and dispense reagent into multi-well plate

SAMPLE ADDITION



Add patient sample and apply seal

RUN PROTOCOL

Spin pulse, load plate and start run

Clinical Concordance

BioGX *Xfree™* COVID-19 Direct RT-PCR and FDA recommended comparator method clinical concordance study.

QuantStudio™ 5 Direct Sample Addition	FDA recommended comparator method	
Xfree™ COVID-19 Direct RT-PCR	Positive	Negative
Positive	57	0
Negative	3*	35
Positive Percent Agreement (95%CI)	95.0% (86.3-98.3%)	
Negative Percent Agreement (95%CI)	100.0% (90.1-100.0%)	

*The three direct samples with discordant results were identified as positive by the comparator method with Ct values between 37.6 & 40.5.

Product Details:

When placing an order or making an inquiry, please reference these details:

***Xfree™* COVID-19 Direct RT-PCR • REF: 500-003-XMP**

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories
This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens
The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

BioGX
Molecular Made Easy

CE IVD • FDA EUA

Contact Details:
North America • info@biogx.com • +1.205.250.8055
International • eu@biogx.com • +31.20.893.4261

Just Add Water, Sample-Ready and Xfree are trademarks of BioGX.