Xfree™ COVID-19 Direct RT-PCR

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

Xfree

Laboratories across the world are looking for a high quality, cost effective, low resource and simple way to perform COVID-19 PCR testing. In these times of fast turnaround, limited staff and variable demand, BioGX offers Xfree™ COVID-19 Direct RT-PCR to enable labs 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

Process more samples in less time
Up to 384 results in 80 minutes

Highly Accessible

Validated on ABI 7500 Fast Dx, QuantStudio™ 5 (96 and 384-well), Bio-Rad CFX96 & CFX384 Touch™, Bio Molecular Systems MIC, and pixl™ Real-Time PCR Platform †
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

† *pixl™ Real-Time PCR Platform manufactured by Anitoa Biotechnology and distributed by BioGX*

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™ (not validated with pixl™), 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.

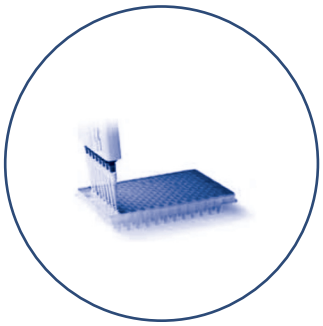
Extraction-Free Direct Sample Workflow

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

** *Refer to current Instructions For Use Manual for complete Intended Use Statement*

*** *Detection of SARS-CoV-2 (N1) and human RNase P utilize US CDC designed primers and probes sets*

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.

CE IVD • FDA EUA

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