Xfree™ COVID-19 Direct RT-PCR

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

Multi-Platform, High-Throughput COVID-19 Testing

Complete Lyophilized Test in a Single Vial
No other reagent required

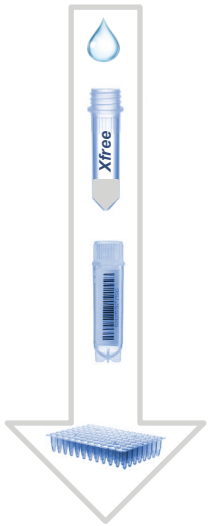
High-Throughput Workflow
Process more samples in less time

No sample preparation at all
Direct sample addition

Includes two sets of controls
RNase P gene detection as SPC
RNA IAC as RNA amplification control

Sample-to-Answer in 3 Easy Steps

1. **JUST ADD WATER**
2. **ADD PATIENT SAMPLE**
3. **SEAL & RUN RT-PCR**



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.

Specimen Types: 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)

CE IVD

FDA EUA

Validated on

Applied Biosystems™ 7500 Fast Dx
QuantStudio™ 5 (96 and 384-well)
Bio-Rad CFX96 Touch™ & CFX384 Touch™
Bio Molecular Systems MIC
pixl™ Real-Time PCR Platform **

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

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.

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