

Validated platforms:

- 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 **

Kit Component

Xfree™ Sample-Ready™ Tube



Supplied by BioGX

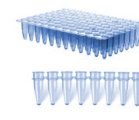
Molecular Grade Water



Purchased separately

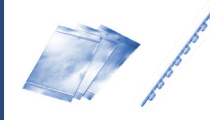
Materials Required

96/384-well PCR Plate or PCR Strip Tubes



Purchased separately

Optical Plate Seals or Tube Caps



Purchased separately

Direct Sample Workflow

Validated Transport Media:

- Saline
- UTM®
- UVT
- VTM
- *ESwab™



Rehydrate with 400 µL of molecular grade water. Dispense Xfree™ reagent (26 x 15 µL) into multi-well plate.

* not validated with pixl™



Add 5 µL of patient sample, pipette up and down once and apply the optical seal or tube caps.



Pulse spin, load into real-time PCR instrument & start run protocol specific for direct sample.

Extracted Sample Workflow

Validated Transport Media:

- Saline
- UTM®
- UVT
- VTM
- *ESwab™



Rehydrate with 400 µL of molecular grade water. Dispense Xfree™ reagent (40 x 10 µL) into multi-well plate.

* not validated with pixl™



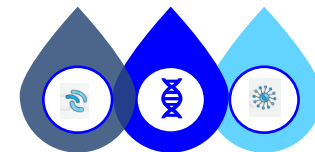
Add 5 µL of extracted RNA, pipette up and down once and apply the optical seal or tube caps.



Pulse spin, load into real-time PCR instrument & start run protocol specific for extracted sample.

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.

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



CE IVD
FDA EUA