



IVD For In Vitro Diagnostic Use Under an Emergency Use Authorization

Information Sheet

2 Minutes Hands-on-Time. Results in about 45 Minutes.

RT-PCR Test for the Detection of SARS-CoV-2



45
minutes
to results

Initially Authorized by the US FDA: March 23, 2020

- 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; and
- 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

BioFire COVID-19 Test v1.1

In about 45 minutes with 2 minutes of hands-on time, this test performs nested multiplexed RT-PCR intended for the qualitative detection of SARS-CoV-2 RNA in samples from individuals suspected of COVID-19 by their healthcare provider.

BIOFIRE® SHIELD™ Control Kit for the BioFire® COVID-19 Test v1.1

The BIOFIRE SHIELD assayed quality controls are available for use with the BioFire COVID-19 Test v1.1 and may be used to monitor test quality control and to perform test verifications according to laboratory procedures. These controls reduce the risk of false positive results due to contamination by using distinct melting temperature to provide results.

BioFire COVID-19 Test Specifications

Kit	BioFire COVID-19 Test v1.1
Part No	423745 (6 Pack Test); 423744 (30 Pack Test)
Sample Types	<ul style="list-style-type: none"> • Upper Respiratory Swab Specimens • Lower Respiratory Specimens • Saliva Specimens Collected without Preservatives • Pooled Samples for up to 8 Upper Respiratory Specimens (DOD use only)
	<ul style="list-style-type: none"> • Freeze-dried in durable plastic pouches • Room temperature storage

External Control Kit Specifications

Kit	BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test v1.1
Part No	424062
Tests per Kit	6 Positive External Control Vials

Sample Swab Kit Specifications

Kit	BioFire® COVID-19 Test Sample Swab Kit (Used for Lower Respiratory Specimen Testing)
Part No	424063
Swabs per Kit	32 Swabs