

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



BioFire® COVID-19 Test Kit

A Real-Time PCR Test for the Detection of SARS-CoV-2 RNA in Nasopharyngeal Swabs.

Authorized by the US FDA: March 23, 2020

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



45
minutes

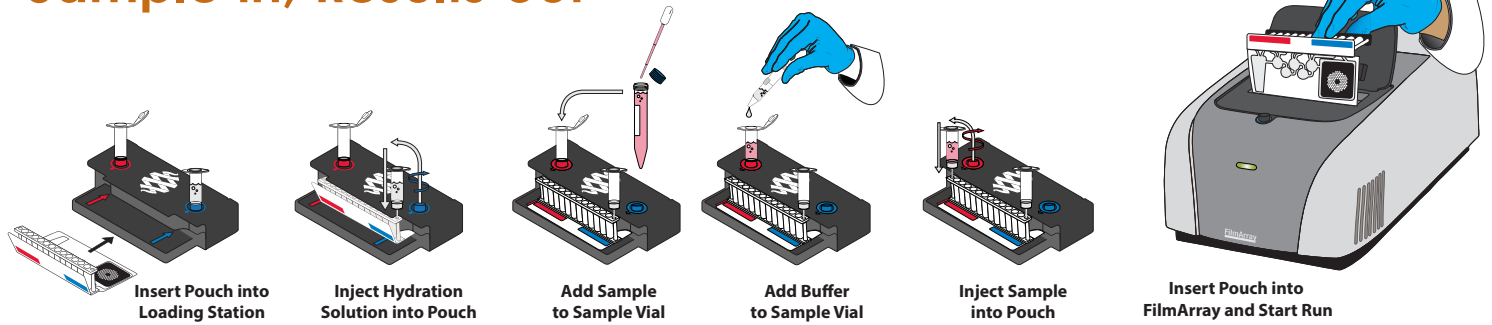
Simple COVID-19 Testing

The easy-to-use, PCR test is performed on the FilmArray® Instrument to detect RNA from the SARS-CoV-2.

- **Fully Automated:** Sample prep, amplification, identification, and reporting.
- **Single Instrument Integration:** Minimal equipment and consumables.
- **Freeze-dried Reagents:** Room temperature stable.



Setting up the Test is Easy – Sample in, Results out



Fully Automated Operation

The FilmArray test contains all the required reagents for sample preparation, reverse transcription-PCR, PCR, and detection in a freeze-dried, room temperature stable format. Prior to a run, the operator injects hydration solution and the unknown sample into the pouch. The FilmArray instrument does the rest.

1. The FilmArray extracts and purifies all nucleic acids from the unknown sample.
2. Next, the FilmArray performs reverse transcription followed by nested multiplex PCR. During this first-stage PCR, the FilmArray performs a single, large volume, multiplexed reaction.
3. Last, individual singleplex second-stage PCR reactions detect the products from the first-stage PCR.

Using endpoint melting curve data, the FilmArray software automatically generates a result for the target.

BioFire® COVID-19 Test Kits

Part No.	423745	423744
Tests per Kit	6 Pack Kit	30 Pack Kit
<ul style="list-style-type: none"> • Sample Type: Nasopharyngeal Swabs in transport media • Freeze-dried in durable plastic pouches • Room temperature storage 		

BioFire® COVID-19 Test External Control Kit

Part No.	423748
Tests per Kit	6 Pack Kit
<ul style="list-style-type: none"> • Freeze-dried in durable plastic pouches • Room temperature storage 	

Easy-to-Read Reporting

www.BioFireDefense.com			
Run Summary			
Sample ID:	Example Report	Run Date:	31 Dec 2019 8:00 AM
Detected:	SARS-CoV-2	Internal Controls:	Passed
Equivocal:	None		
Result Summary			
Viruses			
✓ Detected	SARS-CoV-2		
✓ Detected	SARS-CoV-2a		
✓ Detected	SARS-CoV-2d		
✓ Detected	SARS-CoV-2e		
Run Details			
Pouch:	COVID-19 Test v1.0	Protocol:	NPS2 v3.2
Run Status:	Completed	Operator:	Anonymous
Serial No.:	01234567	Instrument:	FA0000
Lot No.:	012345		

BioFire Defense makes available an external positive assayed quality control kit to monitor the performance of the BioFire COVID-19 Test performed on FilmArray® 2.0 and FilmArray Torch® systems. Evaluation of external controls is recommended prior to using a new shipment or new lot of BioFire COVID-19 Test Kits. This kit may also be used for laboratory verification.



BioFire® COVID-19 Test External Control Kit

The purchase of these products includes a limited, nontransferable instrument license under specific claims of one or more U.S. patents as listed on BioFire Defense's web site (<http://biofiredefense.com/legalnotices>) (the "Web Site") and owned by the University of Utah Research Foundation and/or BioFire. Any kits (i) sold with these products and/or discussed herein may be covered by one or more of the U.S. patents, as listed on the Web Site for the product and (ii) sold herein include a limited, nontransferable license to use the enclosed amount(s) in such kits according to the specified protocols.