NOW AVAILABLE

THE BIOFIRE® RESPIRATORY 2.1-EZ (RP2.1-EZ) PANEL IS NOW AUTHORIZED BY THE FDA UNDER AN EMERGENCY USE AUTHORIZATION (EUA).

BioFire® Respiratory 2.1-EZ (RP2.1-EZ) Panel (EUA)* with SARS-CoV-2

1 Test. 19 Targets. ~45 Minutes.

Quickly identify SARS-CoV-2, along with 18 additional viral and bacterial pathogens that are common causes of respiratory illness. Many respiratory illnesses present with nearly indistinguishable symptoms. The BioFire RP2.1-EZ Panel (EUA) provides rapid answers on a comprehensive menu of pathogens to give physicians confidence in their treatment decisions.

The BioFire RP2.1-EZ Panel (EUA) was developed for use with the CLIA-waived BioFire® FilmArray® 2.0 EZ Configuration System.

Overall: 97.1% sensitivity | 99.3% specificity (prospective specimens)[1]
SARS-CoV-2: 98.0% sensitivity | 100% specificity (archived specimens)[2]
SARS-CoV-2: 100% PPA | 100% NPA (contrived specimens)[3]

BioFire RP2.1-EZ Panel (EUA) Menu

VIRUSES

Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza A/H1
Influenza A/H3
Influenza A/H1-2009
Influenza B
Parainfluenza Virus
Respiratory Syncytial Virus

BACTERIA

Bordetella pertussis
Bordetella parapertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

Part Number

423833	BioFire RP2.1-EZ Panel (EUA), 30 Tests

For more information, visit **biofiredx.com**

1. Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel.
2. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel (EUA) submission.
3. Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel (EUA) submission.

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 and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

BIOFIRE® BY BIOMÉRIEUX

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