PIONEERING DIAGNOSTICS

BIOMÉRIEUX

The BioFire® Respiratory 2.1-EZ (RP2.1-EZ) Panel (EUA)[1]

1 Test. 19 Pathogens. ~45 Minutes.

BioFire RP2.1-EZ Panel (EUA) Targets

VIRUSES

Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Coronavirus 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

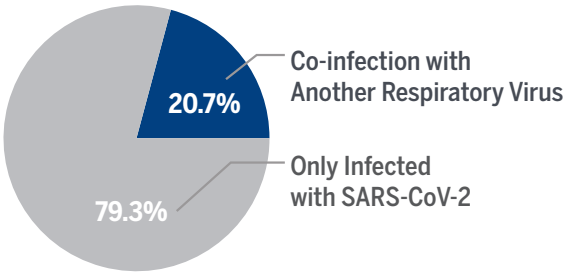
BACTERIA

Bordetella parapertussis
Bordetella pertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

COVID-19 and the Value of the Syndromic Approach

Study results suggest higher rates of co-infection between SARS-CoV-2 and other respiratory pathogens than previously reported. In some cases, as many as 20% of COVID-19 patients have co-infections with another respiratory virus.[2] Respiratory symptoms are similar and overlapping; and unlike targeted respiratory tests, BioFire's syndromic respiratory panel can provide fast, comprehensive answers.

Co-infection for SARS-CoV-2 Positive Patients[2]

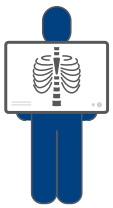


BIOFIRE®

Knowing the Pathogen Matters

Inform Clinical Decisions

Approximately 50% of respiratory pathogens detected by the BioFire® FilmArray® Respiratory EZ (RP EZ) Panel are not detectable by rapid antigen testing due to the limited number of pathogens.[3]



Reduce Unnecessary Testing

Comprehensive answers from the BioFire RP EZ Panels may result in a reduction of additional testing, including expensive send-out tests.

Reduce Appointment Length

Pediatric patients tested with the BioFire RP EZ Panels experienced shorter appointment times than those tested with rapid antigen tests.[3]

Help Guide Antimicrobial Stewardship Programs

Use of the BioFire RP EZ Panels has been shown to reduce antibiotic use by identifying respiratory viruses in a clinically actionable timeframe.[3]

BioFire RP EZ Panels resulted in avoidance of antibiotics in 11% of pediatric patients tested.[3]

Panel Specifications

Sample Type: Nasopharyngeal swab in transport media	**Sample Volume:** 0.3 mL
Overall Performance: 97.1% sensitivity and 99.3% specificity (prospective specimens)[4] **SARS-CoV-2 Performance:** 98.0% sensitivity and 100% specificity (archived specimens)[5], 100% PPA and 100% NPA (contrived specimens)[6]	**Hands-On Time:** approximately 2 minutes
Storage Conditions: All kit components stored at room temperature (15-25 ˚C)	

Part Number

BioFire® Respiratory 2.1-EZ (RP2.1-EZ) Panel (EUA) Kit (30 Pouches): 423883

References

1. 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. This test 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 authorization is terminated or revoked sooner.
2. Kim, D et al. (2020) JAMA doi:10.1001/jama.2020.6266.
3. Beal S, et al. (2020) Pediatr Infect Dis J. 39(3):188-191.
4. Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel.
5. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission.
6. Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission.

Contact Us

Phone: +1-801-736-6354 x 2558
Email: sales@biofiredx.com
biofiredx.com

BIOMÉRIEUX

BIOFIRE®

BFR0001-2679-01