PIONEERING DIAGNOSTICS

BIOMÉRIEUX

Strengthen your clinic with point-of-care testing*

Syndromic testing from BioFire lightens the load of infectious disease testing.

BIOFIRE®

BioFire® Respiratory 2.1 Panel

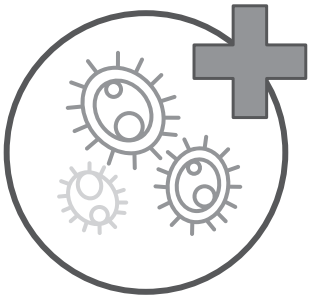
BioFire® Respiratory 2.1-EZ Panel (EUA)*

BioFire® FilmArray® Gastrointestinal Panel

*Includes CLIA waived and CLIA moderate complexity settings

Fast results with just one swab ...done in your clinic.

BioFire's respiratory solutions use a molecular syndromic approach to accurately detect and identify a wide range of pathogens, including SARS-CoV-2. With just two minutes of hands on time and about 45 minutes of runtime, BioFire's respiratory tests can eliminate the need to send samples to a reference lab. The fast turnaround time also means that your patients can potentially have access to their results before the end of their visit.



Respiratory symptoms are among the top complaints for patients in the outpatient setting.[1]

Now you can give patients fast, accurate, and comprehensive answers with the BioFire® Respiratory Panels.

Maximize operational efficiency.

Eliminate process steps and send outs, helping to reduce errors and promote better patient management. Patients tested with the BioFire® FilmArray® Respiratory EZ (RP EZ) Panel experienced shorter appointment times than those tested with rapid antigen tests.[2]

Boost patient satisfaction.

Minimize delays in patient care and reduce return visits. Studies show patients look for speed and convenience when choosing a primary care provider.[3]

77%
of patients prefer clinics with onsite lab services.[3]

67%
of patients would drive up to 20 minutes for a clinic with onsite lab services.[3]

Look beyond COVID-19 and the flu.

Without the right respiratory testing, pinpointing the cause of respiratory symptoms can be a guessing game. A large number of pathogens cause respiratory infections, so tests that only detect influenza or COVID-19 run the risk of missing the real culprit. These tests lack the comprehensiveness of the BioFire Respiratory Panels, which detect and identify 19+ respiratory pathogens, including SARS-CoV-2 and influenza, helping physicians make more informed treatment decisions.

Take the lead in antimicrobial stewardship.

At least
30%
of antibiotics prescribed in the outpatient setting are unnecessary.[7]

Findings show that inappropriate antibiotic usage, including dosage, duration, and inappropriate drug choice, may account for up to 50% of all outpatient antibiotic use.[4-6]

The majority of antibiotics prescribed in these settings are associated with diagnoses of acute respiratory viral infections for which antibiotics are often not recommended or effective.[8]

BioFire® Respiratory 2.1 Panel

FDA De Novo granted!

1 Test. 22 Targets. ~45 Minutes.

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 1
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4
Respiratory Syncytial Virus

BACTERIA

Bordetella pertussis
Bordetella parapertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

Sample Type: Nasopharyngeal swab in transport media or saline

This is a CLIA moderate test to be run on the CLIA moderate BioFire® FilmArray® Torch and BioFire® FilmArray® 2.0 Systems

Overall: 97.1% Sensitivity | 99.3% Specificity[a]
SARS-CoV-2: 98.4% PPA | 98.9% NPA[b]

BioFire® Respiratory 2.1-EZ Panel (EUA)*

1 Test. 19 Targets. ~45 Minutes.

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 pertussis
Bordetella parapertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

Sample Type: Nasopharyngeal swab in transport media

Authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Overall 97.1% Sensitivity | 99.3% Specificity (prospective specimens)[c]
SARS-CoV-2 98.0% Sensitivity | 100% Specificity (archived specimens)[d]
SARS-CoV-2 100% Sensitivity | 100% Specificity (contrived specimens)[e]

*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 diagnostics 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.

[a]Overall performance based on prospective clinical study for the BioFire® FilmArray® Respiratory 2 Panel. Data on file, BioFire Diagnostics.

[b]Overall performance based on prospective SARS-COV-2 clinical study for the BioFire® Respiratory 2.1 Panel in comparison to 3 EUA tests. Data on file, BioFire Diagnostics.

[c]Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel.

[d]Based on the archived specimen study in the BioFire® Respiratory 2.1 (RP2.1) Panel EUA submission.

[e]Based on the contrived specimen study in the BioFire® Respiratory 2.1 (RP2.1) Panel EUA submission.

Improved infectious disease testing from the BioFire® FilmArray® Gastrointestinal (GI) Panel.

Distinguishing possible causes of gastroenteritis in a clinically actionable timeframe can be challenging, especially when overlapping symptoms disguise potential culprits. To further complicate diagnosis, waiting on traditional testing methods can take days, and may not even provide results. Meanwhile, your patients want answers fast. Fortunately, the BioFire GI Panel can help–simultaneously testing for 22 of the most common GI bugs, all in about an hour.

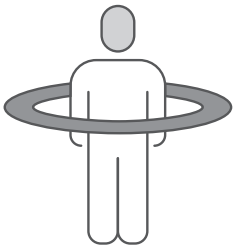
Better testing. Better patient care.

41%

Increase in targeted therapy

Compared to traditional testing, use of the BioFire GI Panel identified 25%-36% more potential pathogens and led to an 84% reduction in time-to-results.[9-12] Additionally, the BioFire GI Panel increased targeted therapy by 41% vs traditional testing.[10] Patients who received the BioFire GI Panel were also 11% less likely to be prescribed antibiotics[11]

Who to test with the BioFire GI Panel?



Individuals at high risk of spreading disease to others and during known or suspected outbreaks.[13]
Patients presenting with:[13,14]

- Dysentery
- Diarrhea with fever, severe abdominal cramps, or signs of sepsis
- Moderate to severe disease
- Symptoms lasting more than seven days
- Immunocompromised patients with diarrhea

BioFire® FilmArray®

Gastrointestinal Panel

1 Test. 22 Targets. ~1 Hour.

BACTERIA

Campylobacter (jejuni, coli, and *upsaliensis)*
Clostridioides (Clostridium) difficile (toxin A/B)
Plesiomonas shigelloides
Salmonella
Vibrio (parahaemolyticus, vulnificus, and *cholerae)*
  Vibrio cholerae
Yersinia enterocolitica
Diarrheagenic *E.coli/Shigella*
  Enteroaggregative *E.coli* (EAEC)
  Enteropathogenic *E.coli* (EPEC)
  Enterotoxigenic *E.coli* (ETEC) *lt/st*
  Shiga-like toxin-producing *E.coli* (STEC) *stx1/stx2*
    E.coli O157
*Shigella/*Enteroinvasive *E.coli* (EIEC)

VIRUSES

Adenovirus F40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus (I, II, IV, and V)

PARASITES

Cryptosporidium
Cyclospora cayetanensis
Entamoeba histolytica
Giardia lamblia

Sample Type: Stool in Cary Blair medium

98.5% Sensitivity | 99.2% Specificity[15]

This is a CLIA moderate test to be run on the CLIA moderate BioFire® FilmArray® Torch and BioFire® FilmArray® 2.0 Systems

Maximize your molecular testing capabilities.

BioFire sets the standard for syndromic infectious disease diagnostics. Our molecular approach to infectious disease diagnostics utilizes multiplex PCR technology. Our test isolates, amplifies, and detects targeted nucleic acids—making it more sensitive than culture. With integrated sample preparation and automated results analysis, the BioFire® FilmArray® System delivers results in about an hour.

BioFire® FilmArray® 2.0 EZ Configuration

Fast. Accurate. Comprehensive.

The BioFire 2.0 EZ Configuration System facilitates rapid near-patient molecular diagnostic testing. It is designed to be used with the BioFire® RP2.1-EZ Panel (EUA)* in CLIA-waived testing sites, including clinics and physician offices. The BioFire 2.0 EZ Configuration System accurately provides results in about 45 minutes with only two minutes of hands-on time.

BioFire® FilmArray® Torch
(for CLIA moderate settings)

The most advanced testing solution yet.

The high-throughput BioFire Torch is a fully integrated, random access system certified to perform CLIA moderate complexity tests, including the BioFire GI and BioFire RP2.1 Panels. The BioFire Torch is scalable to conform to your testing volume needs and provides quick, comprehensive, and accurate results expected from the most advanced testing solution.

biofiredx.com

Call toll free or schedule a demo online:

+1-801-736-6354 ext. 2 | Toll free: +1 800-735-6544 ext. 2

biofiredx.com | sales@biofiredx.com

References

1. Finley, CR et al. Can Fam Physician. 2018;64(11):832-840.
2. Beal SG, et al. Pediatr. Infect. Dis. J. 2020;39(3):188-191
3. Primary Care Consumer Choice Survey, The Advisory Board Company, 2014.
4. CDC. MMWR Morb Mortal Wkly Rep. 2011;60(34):1153-6.
5. Pichichero ME. JAMA. June 19, 2002;287(23):3133-5.
6. Shapiro DJ et al. J Antimicrob Chemother. 2014;69(1):234-40.
7. Fleming-Dutra KE et al. JAMA. 2016;315(17):1864-1873.
8. Pew Charitable Trust Report. Antibiotic Use in Outpatient Settings. 2016.
9. Beal S, et al. J Clin Microbiol. 2018 Jan. 56:1 e01457-17.
10. Cybulski R, et al. Clin Infect Dis. 2018 Nov.13; 67(11):1688-1696.
11. Axelrad J, et al. J Clin Microbiol. 2019 Feb. 57(3) e01775-18.
12. Spina A, et al. Clin Microbiol Infect. 2015 Aug. 21(8):719-28.
13. Riddle M, et al. Am J Gastroenterol. 2016;111(5):602.
14. Shane A, et al. Clin Infect Dis. 2017;65(12):e45–e80.
15. The stated performance is the aggregate of the prospective data from the clinical study.

BFR0001-2721-01