

ENVIRONMENTAL SURVEILLANCE PANELS

These FilmArray Panels are designed for environmental testing, food and beverage screening, and research use.



NOT FOR
DIAGNOSTIC USE

FilmArray® BioThreat Panel

DETECTION OF 16 TARGETS IN ONE TEST

BACTERIA

Bacillus anthracis
Brucella melitensis
Burkholderia mallei / *pseudomallei**
Coxiella burnetii
Francisella tularensis
Rickettsia prowazekii
Yersinia pestis

VIRUSES

Ebola virus (Zaire)
EEE virus
Marburg virus
Orthopox virus
Variola virus
VEE virus
WEE virus

TOXIN-ENCODING GENES

Clostridium botulinum
Ricinus communis

Sample Type: Environmental (Liquid, Powder, and Surface Swabs)

*The *Burkholderia mallei* / *pseudomallei* assay may be cross-reactive with other *Burkholderia* species.



NOT FOR
DIAGNOSTIC USE

FilmArray® Food & Water Panel

DETECTION OF 15 TARGETS IN ONE TEST

BACTERIA

Campylobacter (*jejuni*, *coli*, and *upsaliensis*)
Salmonella
Vibrio (*parahaemolyticus*, *vulnificus*, and *cholerae*)
Vibrio cholerae
Yersinia enterocolitica

DIARRHEAGENIC E. COLI / SHIGELLA

Enteraggregative *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)

PARASITES

Cryptosporidium
Cyclospora cayentanensis
Giardia lamblia

VIRUSES

Norovirus GI/GII

Sample Type: Food and Beverage Samples (Example: Tap Water, Chicken, Beef, Bagged Spinach, Sliced Ham, Weiner, Smoked Salmon Spread, Bagged Shredded Cheddar, Orange Juice, Apple Juice, and Oatmeal)

RESEARCH USE ONLY PANEL

This FilmArray Panel is designed for research use only.



NOT FOR
DIAGNOSTIC USE
FOR RESEARCH
USE ONLY

FilmArray® Global Fever Panel - RUO

DETECTION OF 19 TARGETS IN ONE TEST

BACTERIA

Bacillus anthracis
Francisella tularensis
Leptospira spp.
Salmonella enterica serovar Typhi
Salmonella enterica serovar Paratyphi A
Yersinia pestis

VIRUSES

Chikungunya virus
Crimean-Congo hemorrhagic fever virus
Dengue virus
Ebolavirus spp.
Lassa virus
Marburg marburgvirus
West Nile virus
Yellow fever virus
Zika virus

PROTOZOA

Leishmania spp.
Plasmodium spp.
Plasmodium falciparum
Plasmodium vivax/ovale

Sample Type: Whole Blood

IVD PANELS

These BioFire FilmArray Panels are designed for clinical samples of individuals with signs and/or symptoms that are outlined in their specific Instructions for Use.



FOR IN VITRO
DIAGNOSTIC USE

BioFire® Global Fever Panel

DETECTION OF 6 TARGETS IN ONE TEST

BACTERIA

Leptospira spp.

VIRUSES

Chikungunya virus
Dengue virus

PROTOZOA

Plasmodium spp.
Plasmodium falciparum
Plasmodium vivax/ovale

Sample Type: EDTA Whole Blood

CLIA Complexity: Moderate

BIOFIRE® SHIELD™ Control Kit for the BioFire Global Fever Panel

BIOFIRE SHIELD Controls are available for use with the BioFire Global Fever Panel and may be used to monitor test performance and perform test verifications according to laboratory procedures.



FOR IN VITRO
DIAGNOSTIC USE

BioFire® Global Fever Special Pathogens (SP) Panel

DETECTION OF 16 TARGETS IN ONE TEST

BACTERIA

Bacillus anthracis
Francisella tularensis
Leptospira spp.
Yersinia pestis

PROTOZOA

Leishmania spp.
Plasmodium spp.
Plasmodium falciparum
Plasmodium vivax/ovale

VIRUSES

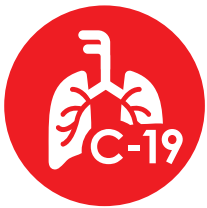
Chikungunya virus
Crimean-Congo hemorrhagic fever virus
Dengue virus
Ebola virus spp.
Lassa virus
Marburgvirus
West Nile virus
Yellow fever virus

Sample Type: EDTA Whole Blood

CLIA Complexity: High

BIOFIRE® SHIELD™ Control Kit for the BioFire Global Fever SP Panel

BIOFIRE SHIELD Controls are available for use with the BioFire Global Fever Special Pathogens Panel and may be used to monitor test performance and perform test verifications according to laboratory procedures.



FOR IN VITRO
DIAGNOSTIC USE
UNDER AN
EMERGENCY USE
AUTHORIZATION

BioFire® COVID-19 Test

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

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.

Sample Type: Upper Respiratory Swab Specimens, Lower Respiratory Specimens, Saliva Specimens Collected without Preservatives, Pooled Samples for up to 8 Upper Respiratory Specimens (DOD use only)

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

BIOFIRE SHIELD Controls are available for use with the BioFire COVID-19 Test and may be used to monitor test performance and perform test verifications according to laboratory procedures.



FOR IN VITRO
DIAGNOSTIC USE
UNDER AN
EMERGENCY USE
AUTHORIZATION

FilmArray® BioThreat-E Test

Detection of Ebola virus (species *Zaire ebolavirus*, detected in the West Africa outbreak in 2014)

AUTHORIZED BY THE US FDA: OCTOBER 25, 2014

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization for use by CLIA Moderate and High Complexity Laboratories;
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) and 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 the emergency use of in vitro diagnostics for detection of Ebola Zaire virus under section 564(b) (1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Sample Type: Whole Blood and Urine

DOD CONTROLLED PANELS

These FilmArray Panels are manufactured solely for use by United States Department of Defense laboratories, and laboratories designated by the Department of Defense.



FOR IN VITRO
DIAGNOSTIC USE

FilmArray® NGDS Warrior Panel

DETECTION OF 6 TARGETS IN ONE TEST

BACTERIA

Bacillus anthracis
Coxiella burnetii
Francisella tularensis
Yersinia pestis

VIRUSES

Ebolavirus spp.
Marburg marburgvirus

Sample Type: Whole Blood, Positive Blood Culture, and Sputum



NOT FOR
DIAGNOSTIC USE
ENVIRONMENTAL
SURVEILLANCE

FilmArray® Sentinel Panel

DETECTION OF 19 TARGETS IN ONE TEST

BACTERIA

Bacillus anthracis
Brucella melitensis
Brucella spp.
Burkholderia spp.
Burkholderia pseudomallei
Coxiella burnetii
Francisella tularensis
Rickettsia prowazekii
Yersinia pestis

VIRUSES

Ebolavirus spp.
EEE virus
Marburg marburgvirus
Orthopoxviruses
Variola virus
VEE virus
WEE virus

TOXIN-ENCODING GENES

Clostridium botulinum
Ricinus communis

TRAINING TARGETS

Bacillus globigii
Bacillus thuringiensis
Saccharomyces cerevisiae

Sample Type: Powder; Surface Swab; Soil; Sand; Mammalian Blood; Food; Liquids: Culture Medium, Aerosol Collection Buffer, Surface Water; Vectors: Flea, Tick, Louse, and Mosquito

The Warrior and Sentinel Panels are controlled for export under the International Traffic in Arms Regulations (ITAR), administered by the U.S. Department of State, Directorate of Defense Trade Controls (DDTC) and may not be exported or transferred to any foreign national without prior approval of the DDTC.

BioFire has delivered more than 10 million pouches throughout the world helping to make the world a safer and healthier place.

10+
MILLION
POUCHES

