



**NOT FOR
DIAGNOSTIC USE**

BioThreat Panel

DETECTION OF 16 TARGETS IN ONE TEST

BACTERIA

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

VIRUSES

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

TOXIN GENE

Clostridium botulinum
Ricinus communis

Sample Type: Environmental (Swab, Powder, Liquid, Culture, Soil)



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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
Ebola virus 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



**NOT FOR
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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 cayetanensis
Giardia lamblia

VIRUSES

Norovirus GI/GII

Sample Type: Tap Water, Chicken, Beef, Bagged Spinach, Sliced Ham, Weiner, Smoked Salmon Spread, Bagged Shredded Cheddar, Orange Juice, Apple Juice and Oatmeal



FOR IN VITRO
DIAGNOSTIC USE

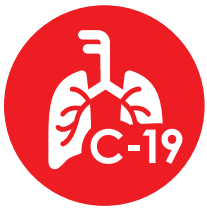
BioThreat-E Panel

Detection of Ebola Zaire virus (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



FOR IN VITRO
DIAGNOSTIC USE

BioFire® COVID-19 Test Kit

A Real-Time PCR Test for the Detection of SARS-CoV-2

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.

Sample Type: Nasopharyngeal Swabs

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.

Warrior Panel

DETECTION OF 6 TARGETS IN ONE TEST

BACTERIA

Bacillus anthracis
Coxiella burnetii
Francisella tularensis
Yersinia pestis

VIRUSES

Ebolavirus spp.
Marburg Marburgvirus

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.



FOR IN VITRO
DIAGNOSTIC USE

Sample Type: Whole Blood, Positive Blood Culture and Sputum

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.
Marburg Marburgvirus
Orthopox viruses
Variola virus
EEE virus
VEE virus
WEE virus

TOXIN GENE

Clostridium botulinum
Ricin communis

TRAINING TARGETS

Bacillus globigii
Bacillus thuringiensis
Saccharomyces cerevisiae



ENVIRONMENTAL
SURVEILLANCE

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