

# DHS/NIST Workshop – BioFire Defense Overview

15 June 2021



# FilmArray - Simple, Easy, Fast

- Automated
- Integrated Sample Preparation
- Multiple Genetic Targets
- Automatic Analysis
- 45 Minutes
- Clinical and Environmental
- >10,000 Systems in US Clinical Use



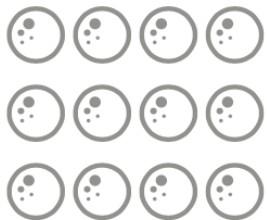
# BioFire Syndromic Approach

Syndromic testing is a symptom-driven grouping of pathogens into a rapid test that maximizes the chance of getting the right answer to a doctor

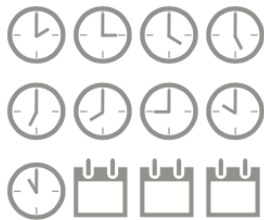
## Traditional Testing



One sample



Multiple tests ordered

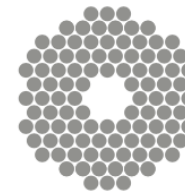


Results take hours to days

## Syndromic Testing



One sample



One comprehensive test



Takes about an hour for results

# FilmArray® Panels – BioFire Defense



BioThreat Panel  
Environmental  
2010



Sentinel Panel  
US DoD Only  
Environmental  
2018



Food & Water Panel  
Environmental  
2019



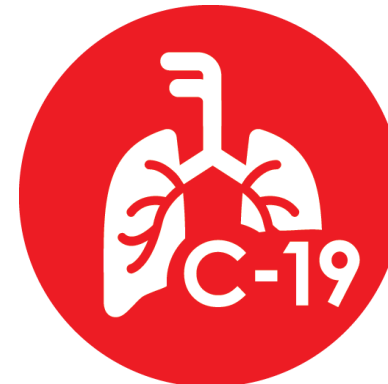
Mycoplasma Panel  
Environmental  
2020



Warrior Panel  
US DoD Only  
2017



Global Fever Panel  
2020

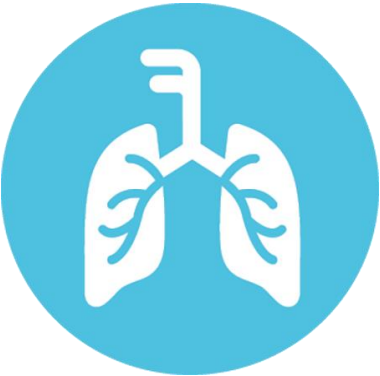


COVID 19-Test  
FDA EUA  
2020



BioThreat-E  
FDA EUA  
2015

# BioFire Diagnostics FilmArray® Panels



RP Panel  
FDA-cleared 2011

RP2.1 Panel  
FDA-cleared 2021  
Includes SARS-CoV-2



BCID Panel  
FDA-cleared  
2013



GI Panel  
FDA-cleared  
2014



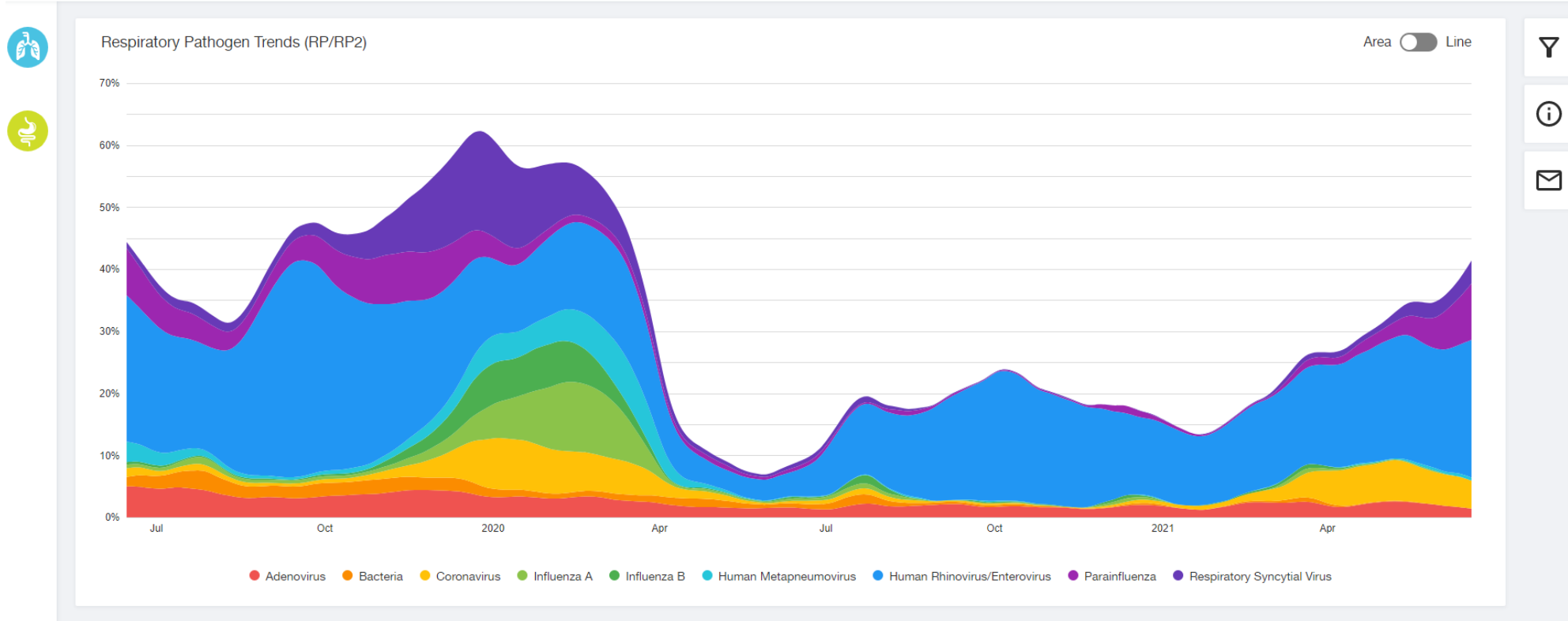
ME Panel  
FDA-granted  
2015



Pneumo Panel  
FDA-cleared  
2018

# Data Tracking - TRENDS

BIO FIRE<sup>®</sup> Syndromic Trends



BIO FIRE<sup>®</sup>  
BY BIOMERIEUX  
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<https://www.syndromictrends.com>

Information Proprietary to BioFire Defense - Confidential

# COVID-19 Response

- Developed EUA Test for US DoD
  - 7 Different Gene Target (3 Currently Used)
  - Sample Types –
    - Upper and Lower Respiratory
    - Saliva In Development
  - Transport Media – Validated Multiple Types
  - 510k Clearance Package Submitted
  - 300 genomic copies/ml Sensitivity in [Wastewater](#)
    - Same Sensitivity as Clinical Upper Respiratory Samples
- Shipped Hundreds of Systems to US Gov. in Response to Pandemic
- Increased Production Capacity 300%
- Delivered >1M Tests to US Government

# Questions

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