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
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.
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

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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