
BIOLOGICAL
HAZARD

Emerging Technologies and Safety Implications for Clinical Laboratories

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Disclosures

BioFire Defense, LLC

OpGen, Inc.

Objectives

- Instrument Vulnerability
- Sources of agent transmission
- Descending order of resistance to decontamination/sterilization
- Biosafety/Risk Assessment
- Road Ahead

Overview of Biosafety

- Environmentally Mediated Infection Transmission
  -**air, contaminated <u>fomites/laboratory instruments</u>, aerosols**
- **"Chain of Infection"**
  - pathogen of sufficient virulence
  - relatively high concentration of pathogen (infectious dose)
  - mechanism of transmission of pathogen from the environment to the host
  - host portal of entry
  - susceptible host
- **Decontamination, Cleaning, Sterilization, Disinfection**

Biosafety in Microbiol. And Biomed Lab (BMBL), 5th ed, 2009

GeneXpert

Kiestra™

Copan WASP™

Biomerieux™

FilmArray

SAFETY??

Luminex 100

VersaTREK™

BacT/ALERT 3D

Descending Order of Resistance to Decontamination

Prions

Bacterial Spores (*B. anthracis, C. sporogenes)*

Mycobacteria tuberculosis var *bovis,* NTM

Nonlipid or small viruses (Poliovirus, Coxsackie, Rhinovirus)

Fungi (*Trichophyton, Cryptococcus* spp., *Candida* spp)

Vegetative Bacteria (*P. aeruginosa, S. aureus, Salmonella choleraesuis)*

Lipid or Medium-size viruses (HSV, CMV, RSV, HBV, HCV, HIV, Hantavirus, **Ebola** virus)

BMBL, 2009, 5th ed

Common Sources of Contamination

- Vortexing/Centrifugation
- Opening of tubes (decapping/recapping)
- Inoculation of plates (loops, magnetic beads)/inoculation of broth
- Movement of plates (tracks/conveyor belts); crashing of plates, plates falling off track
- Photographing of plates
- Breaking of pouch
- Compromised tubing
- Puncture of bladder

Decontamination

- Purpose: protect laboratory personnel, environment, individuals who enter laboratory or handles laboratory products away from the laboratory
- Renders an area (space), device, item, or material safe to handle (free from risk of disease transmission)
- Primary objective: reduce level of microbial contamination and eliminate transmission of infection

Miller, J. M., et al., 2012, MMWR, 61 (01)

Microbial Concerns*

- *Bacillus anthracis* (spores)
- *Brucella*
- Biothreat agents
- Hemorrhagic viruses (Ebola)
- Prions
- MRSA
- *Mycobacterium tuberculosis*

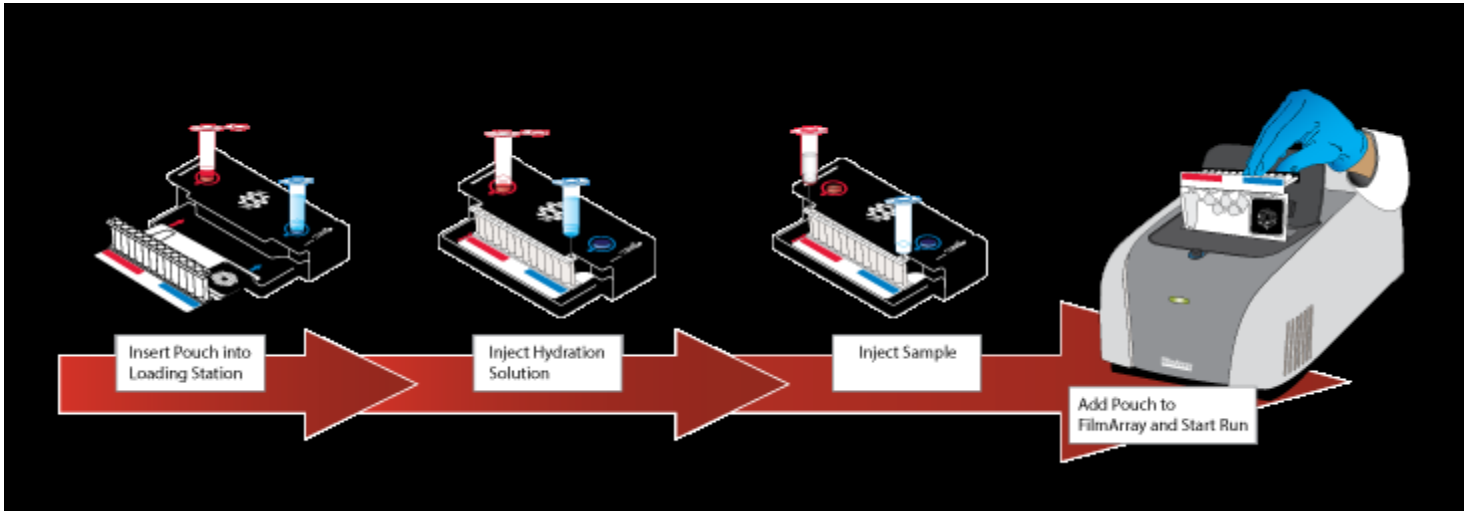
* low infectious dose

Sterilization

- free of all living microorganisms and viruses: everything killed including high quantities of bacterial endo**spores**
    - heat, ethylene oxide gas, hydrogen peroxide gas/vapor, ozone, radiation, formaldehyde gas/vapor
- probability of survival is less than one in one million ("sterility assurance level)

BMBL, 5th ed., 2009

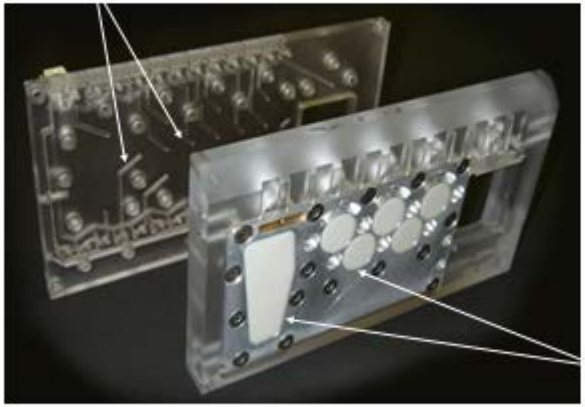
Filmarray: Potential Sources of Contamination



Filmarray: Internal Sources of Contamination

Automated Protocol

Air Channels



- Bladders inflate over blisters to push liquid
- Pistons close channels

Pneumatic Bladders

The Road Ahead

- “Science and science-based evidence should dictate policy on how to decontaminate these instruments. Put all of the pieces together and develop a rational risk-based approach, NOT fear or consequence-based”

  Dr. Mike Loeffelholz, 2015 (CMN)

- Partnership: Scientific community, Industry, Government

Thank You!!

QUESTIONS?