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 fomites/laboratory instruments, 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
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 endospores
  - 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

BIOLOGICAL HAZARD
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?