SAND2014-0802P

Laboratory Results

11 February 2014

Objectives

- Assess and analyze findings and determine possible causes for results
- Recognize additional data needs for interpreting laboratory results
- Understand basic levels of complexity in tests

International
BIOLOGICAL THREAT REDUCTION

Types of Tests

- Presumptive
  - Initial test suggests presence of agent
- Confirmatory
  - Indicated presence of agent
  - Recognized as valid
- Qualitative
  - Presence or absence of agent

    Positive/negative

    Color change
- Quantitative
  - Result is a value

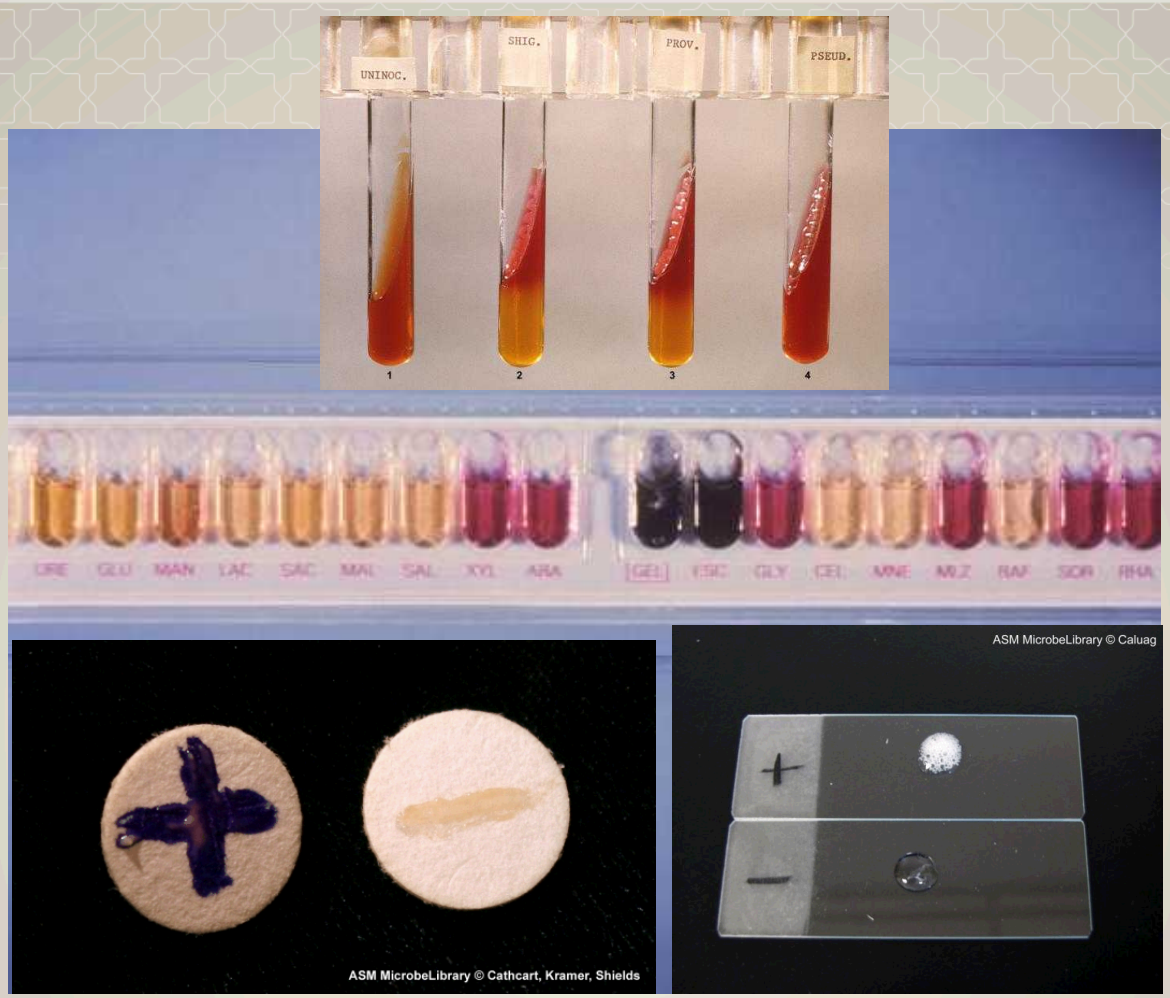
    amount of agent present

International
BIOLOGICAL THREAT REDUCTION

Laboratory testing

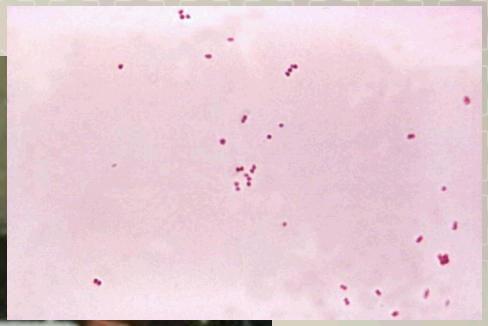
- Additional lab confirmation is strongly suggested for rapid tests
- Laboratory tests can be complex and labor intensive
  - Most require an idea of suspected agent
  - Result interpretation
    - False positives
    - False negatives
    - Positive and negative controls
- Instrument limitations

International
BIOLOGICAL THREAT REDUCTION



Conventional methods

Biochemical reactions

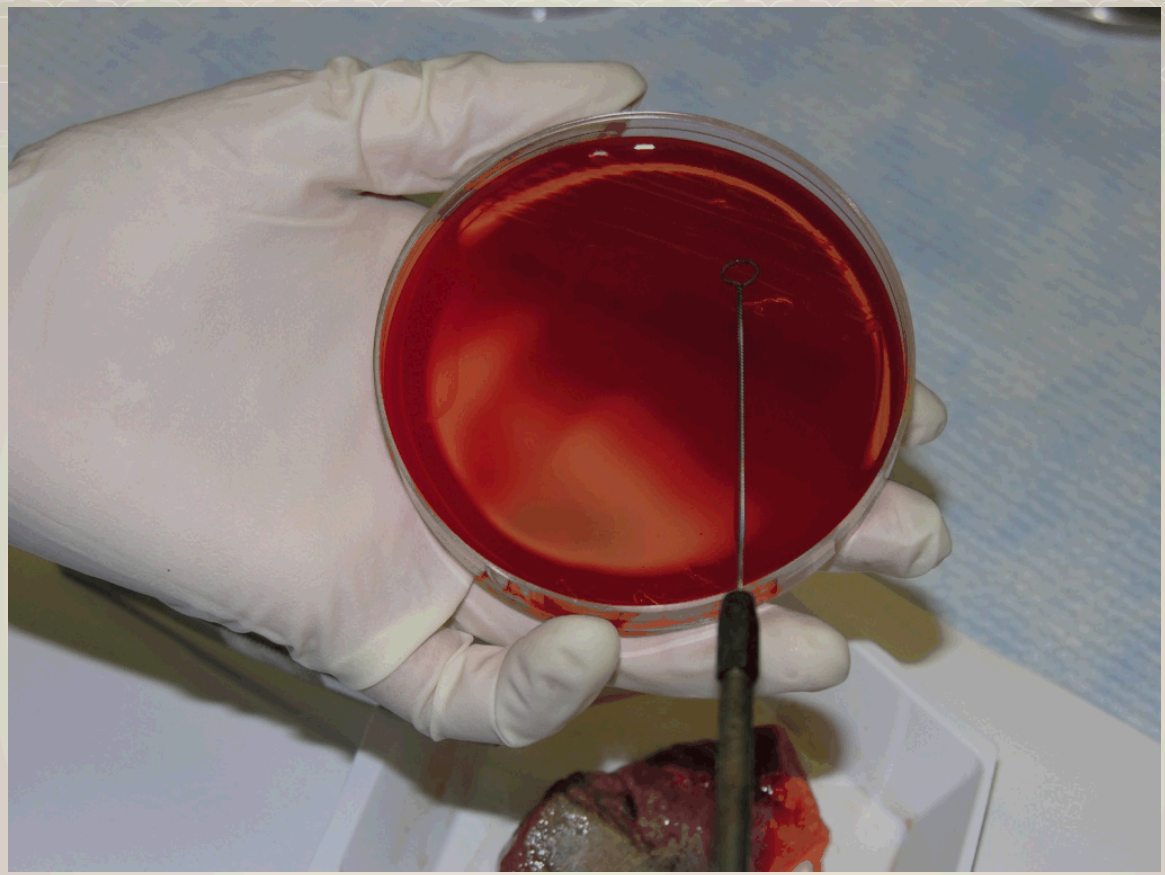


Conventional methods

Microscopy: Gram stain

UNITED STATES CENTRAL COMMAND

International BIOLOGICAL THREAT REDUCTION

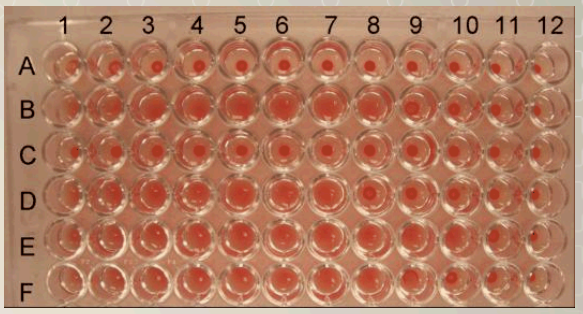


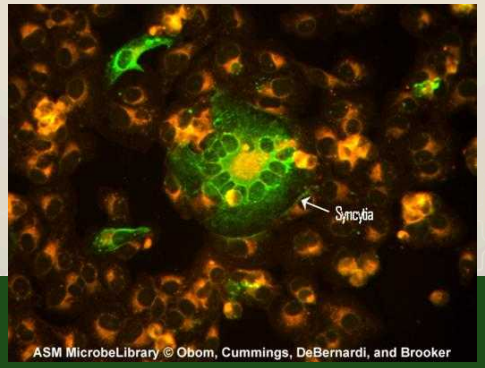
Conventional methods

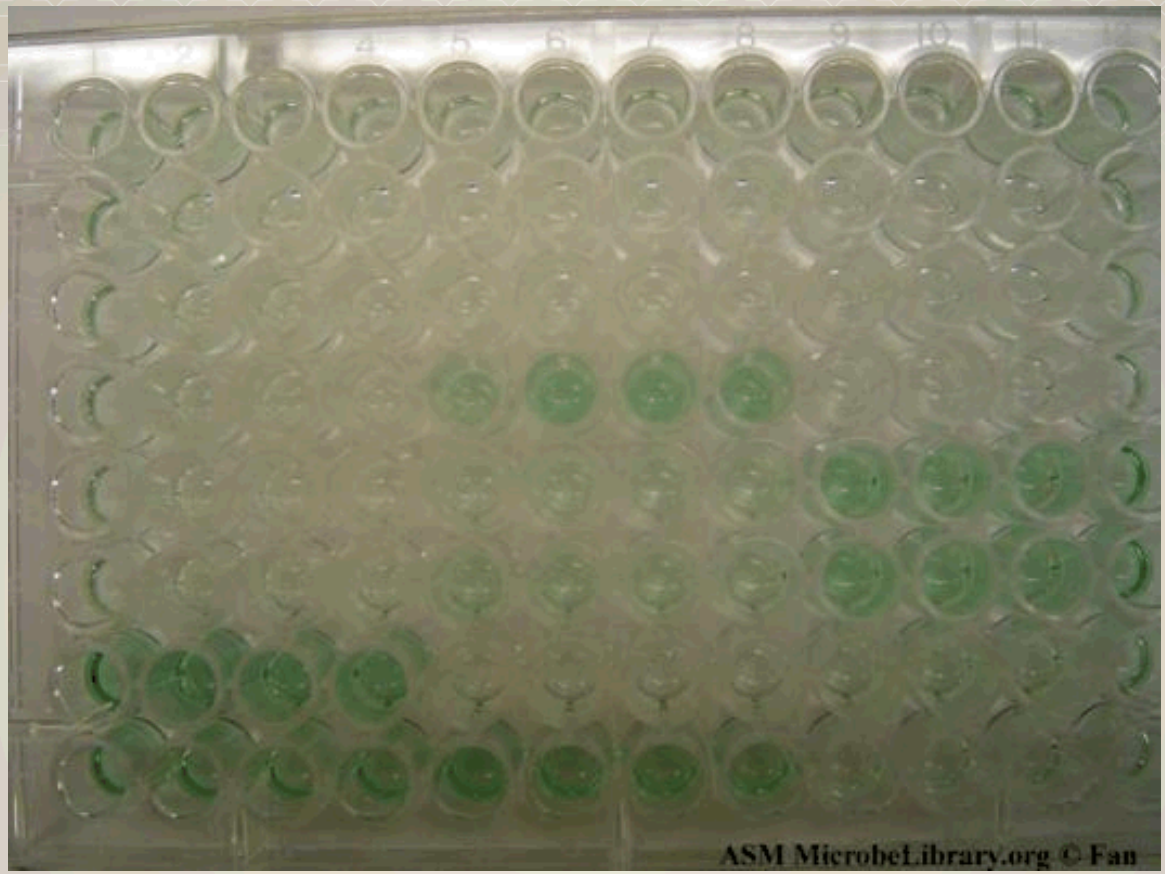
Bacterial culture

Immunoassays

- Serological testing
  - Agglutination
  - Precipitation
  - Complement fixation
  - Neutralization
  - Immunofluorescence

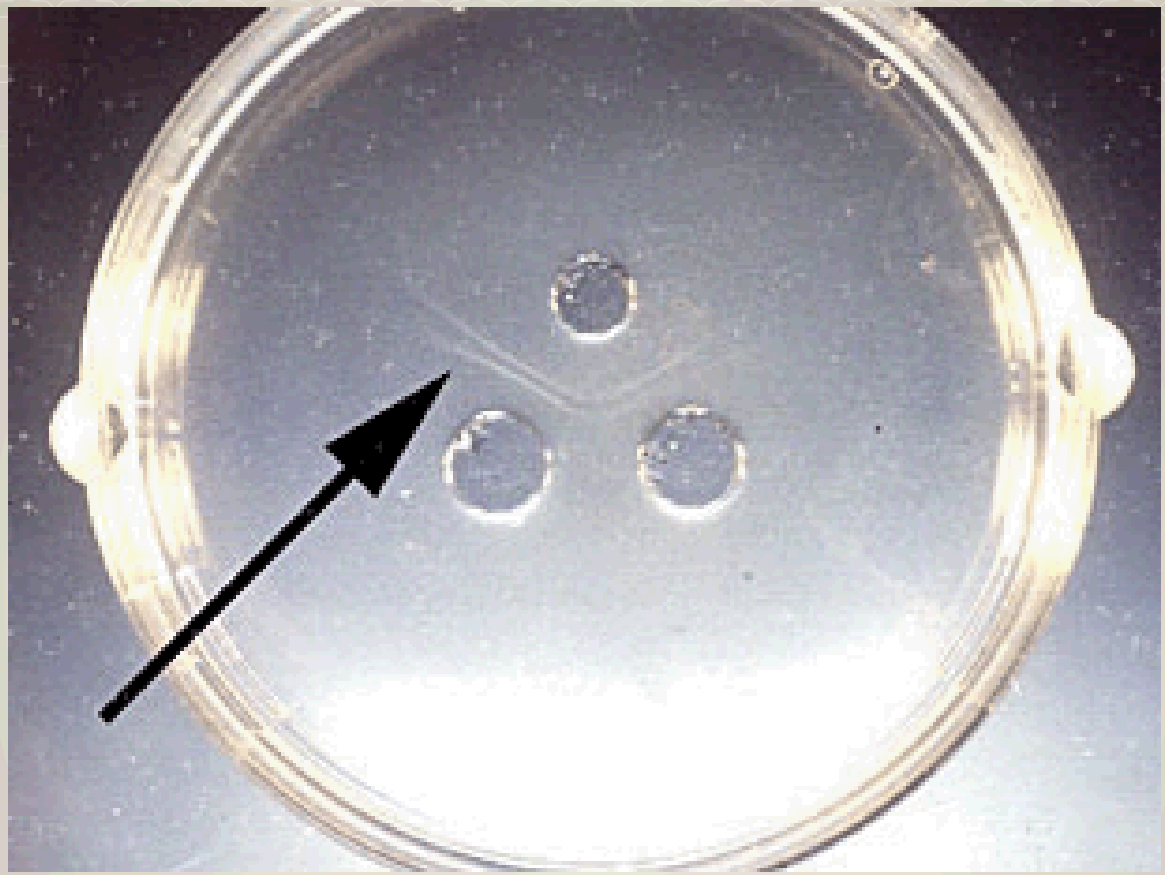






Immunoassays

Enzyme linked immunosorbent assays



Immunoassays

Agar gel immunodiffusion (AGID)

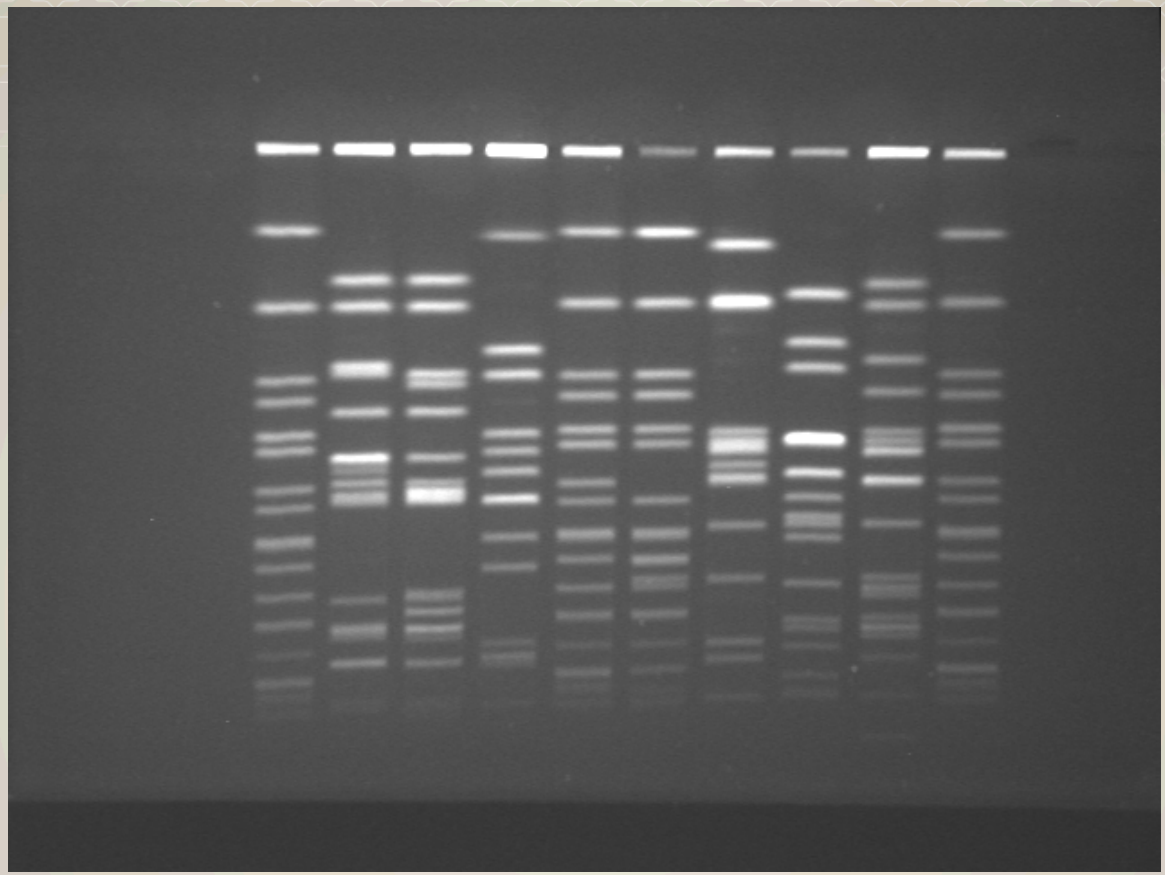
Molecular biological methods

- Nucleic acid probes
- Nucleic acid amplification
- Polymerase chain reaction
- Direct sequencing

International
BIOLOGICAL THREAT REDUCTION

PCR

Cartridge PCR



PCR

Gel product

Tests for foodborne illness

- Culture
  - Isolation of bacteria
- PCR
  - Pulsed-field gel electrophoresis (PFGE)

International
BIOLOGICAL THREAT REDUCTION

Tests for Influenza and Respiratory Viruses

• Rapid tests	• Insensitive, non-specific
• Direct fluorescent antigen specific	• Rapid, less sensitive
• Shell vial culture	• Sensitive
• Roller tube culture	• Sensitive, slow
• Real time qPCR/RT-PCR	• Sensitive, slow
• Pyrosequencing	• Expensive
• Flow through microsphere array	• Rapid, expensive

International
BIOLOGICAL THREAT REDUCTION

Discussion

Laboratory capacity and confidence in results in important when to detect and manage biological incidents.

What capabilities exist for clinical diagnostic, forensic, and biodefense laboratories?

- National level laboratories
- Regional level laboratories
- District level laboratories
- Hospitals
- Healthcare clinics

Define the role filled by external laboratories

International
BIOLOGICAL THREAT REDUCTION

Review

- Test results may require additional information to interpret
- Rapid tests may not detect all positive cases
- More complex test methods require additional resources including: infrastructure, equipment, training, and consumables

Questions?

International
BIOLOGICAL THREAT REDUCTION