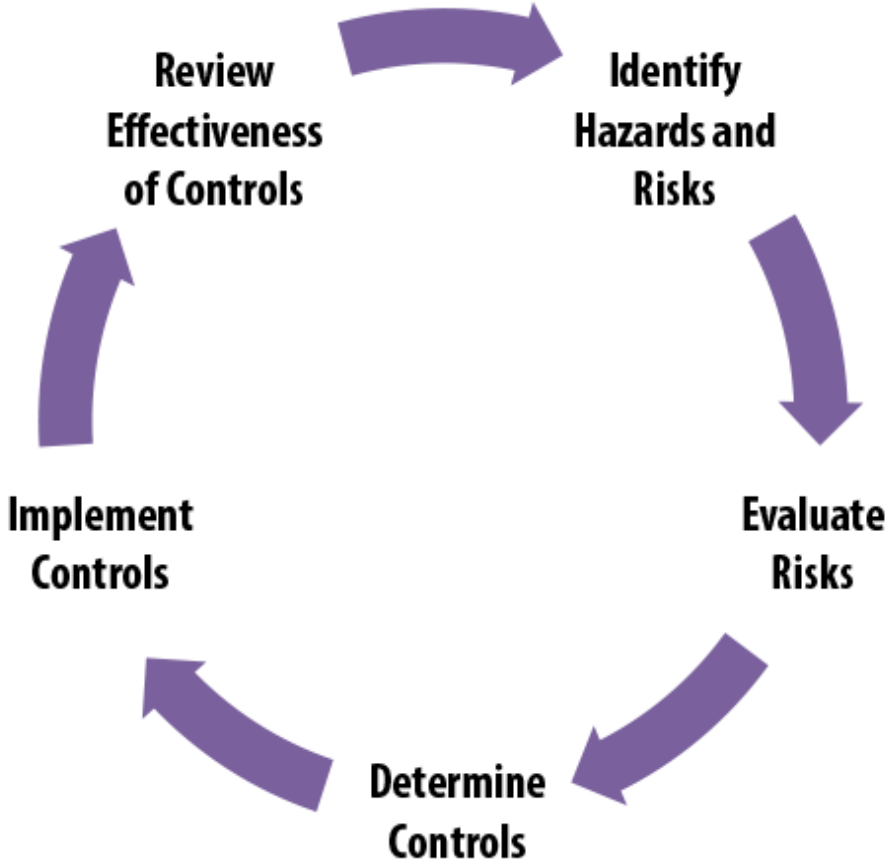
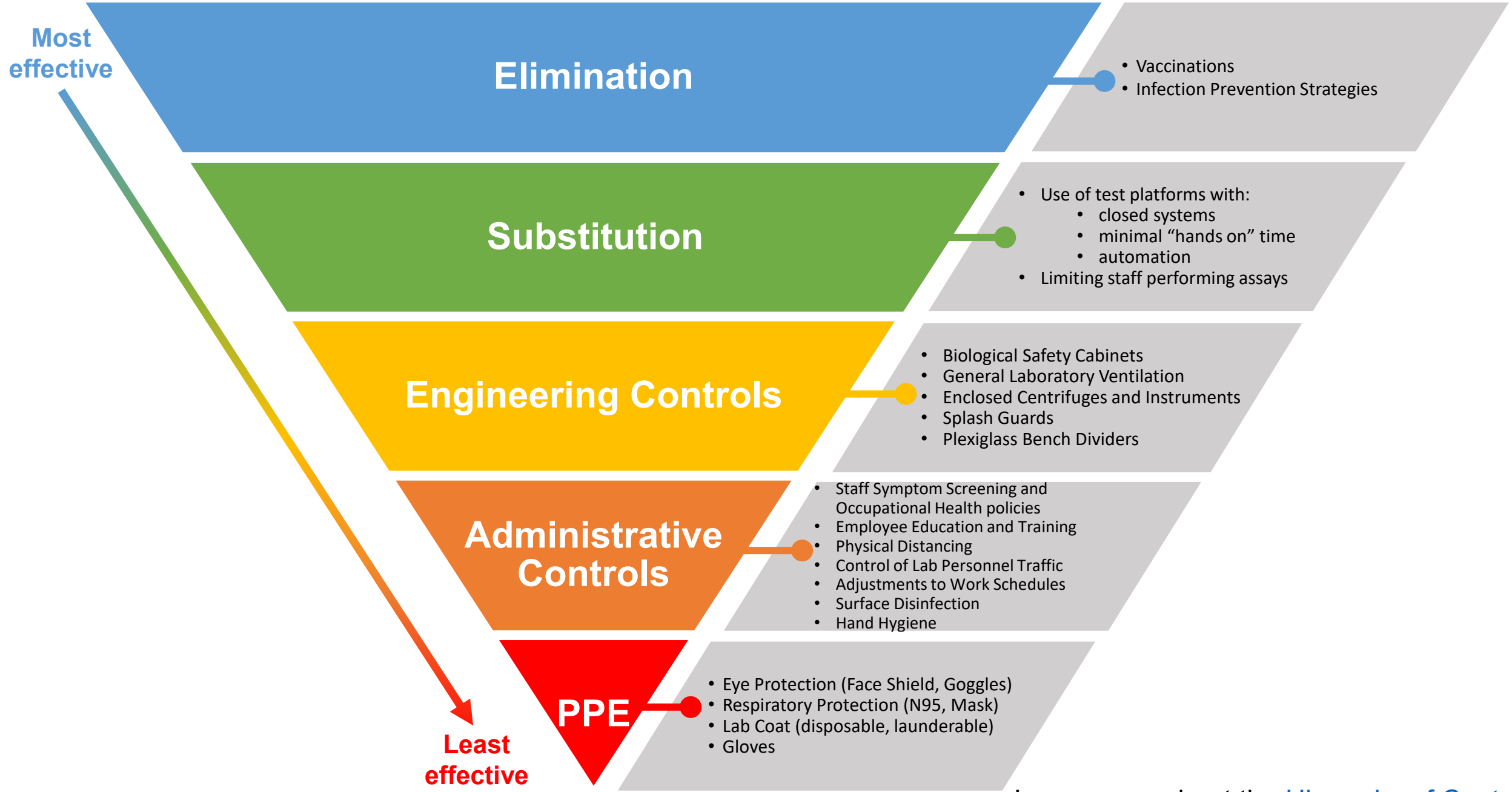
Introduction:

The following module has been created to provide a framework of clinical laboratory considerations in responding to emerging pathogens. This model provides a foundation with which to develop protocols relevant to the pathogen of concern. Strategies may vary based on the mode(s) of transmission, and this tool is not meant to substitute individualized risk assessment.



UCSF Health

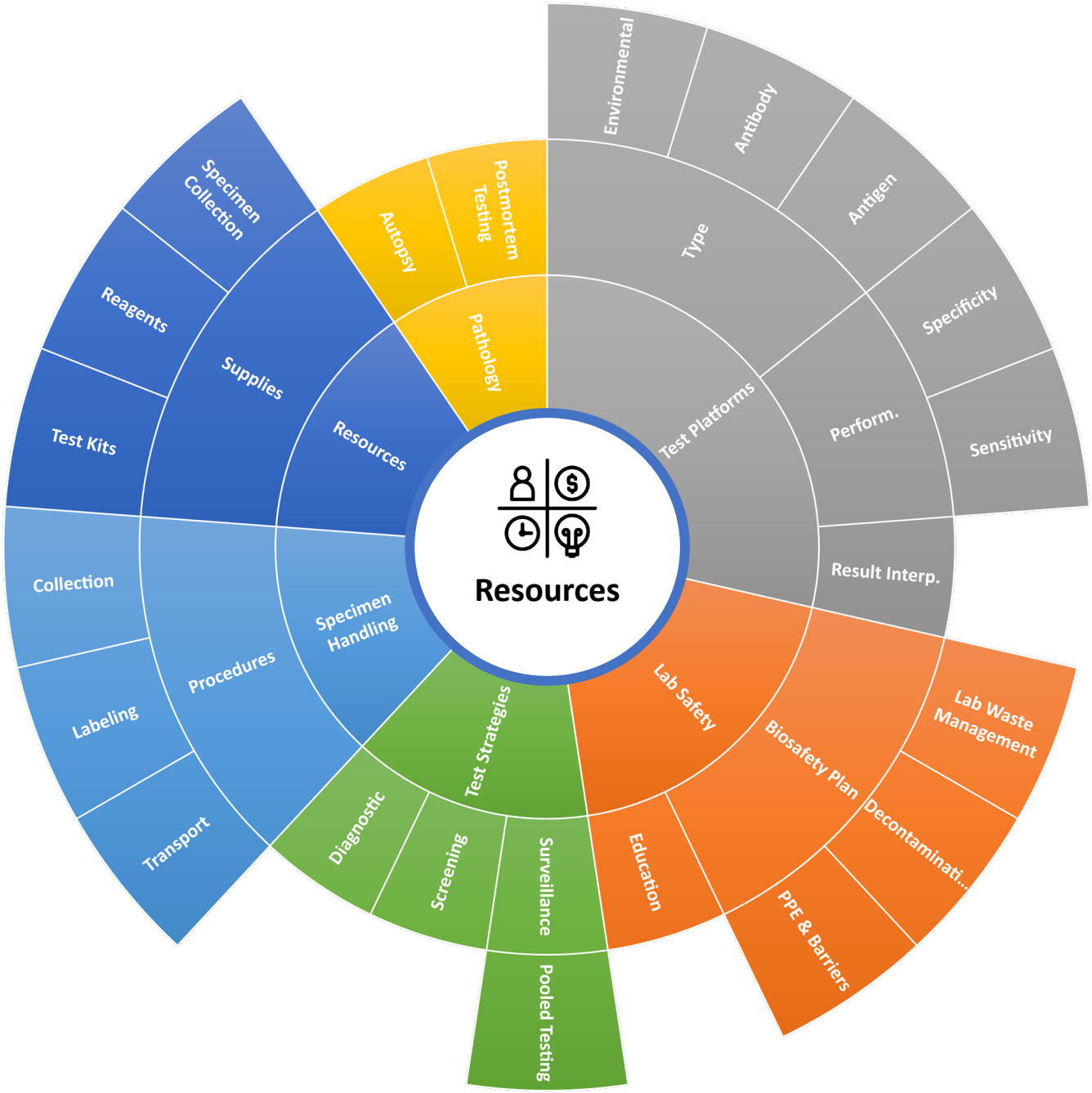
Considerations for Clinical Laboratory: Hierarchy of Controls



Learn more about the Hierarchy of Controls

Considerations for Clinical Laboratory

UCSF Health



Clinical Laboratory leadership to collaborate with stakeholders including Material Services to assess availability of resources:

- **Supplies**
- **Equipment**
- **Staffing** for the following tasks:
  - specimen processing and testing
  - test validation/verification
  - calibration and quality control
  - training and competencies
  - public health reporting

Staffing considerations should include complexity of testing (waived, moderate, high complexity) and type of personnel (MD, RN, CLS, lab technician, other) qualified to perform the test

UCSF Health

Supplies may include but are not limited to the following:

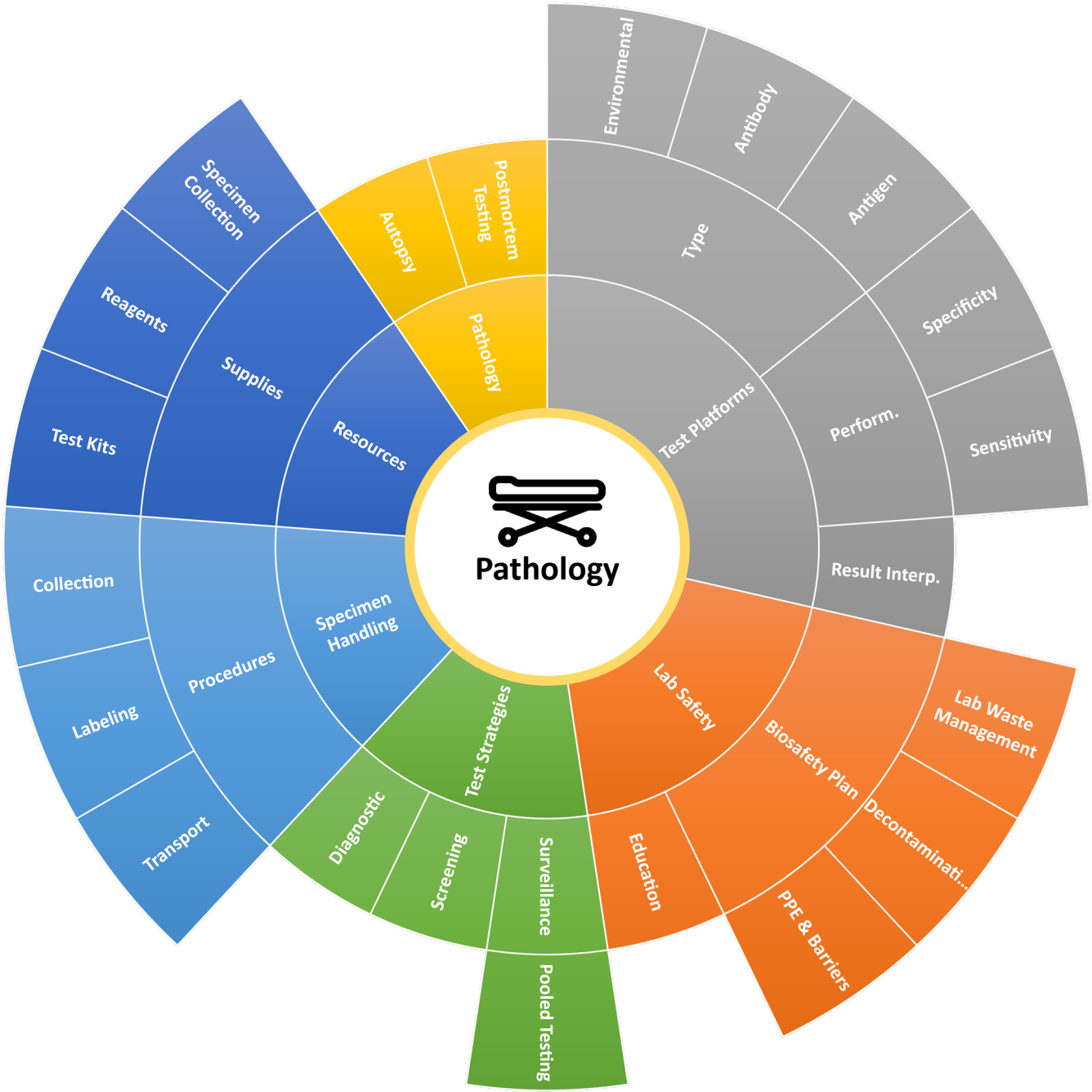
- specimen collection kits
- transport media
- reagents
- test kits
- disposables (pipette tips, loops, etc)

Availability of supplies may be identified as a limiting factor and influence selection of test platform(s)

Equipment may include but is not limited to the following:

- analyzers and test platforms
- refrigerators and freezers
  - storage of reagents, specimens, isolates
- instruments (pipettes, calipers, etc)

UCSF Health



Emerging Pathogen Control Plan to include the following:

Postmortem Testing

- Clinical Laboratory, HEIP, Pathology and Decedent Affairs to collaborate on a process for testing deceased patients (if applicable) to include:
  - Disinfection, labeling of body bag
  - Specimen transport
  - PPE for test collection

Autopsy

- Clinical Laboratory, HEIP, Pathology and Decedent Affairs to collaborate on a process for Autopsy

Mandated Reporting

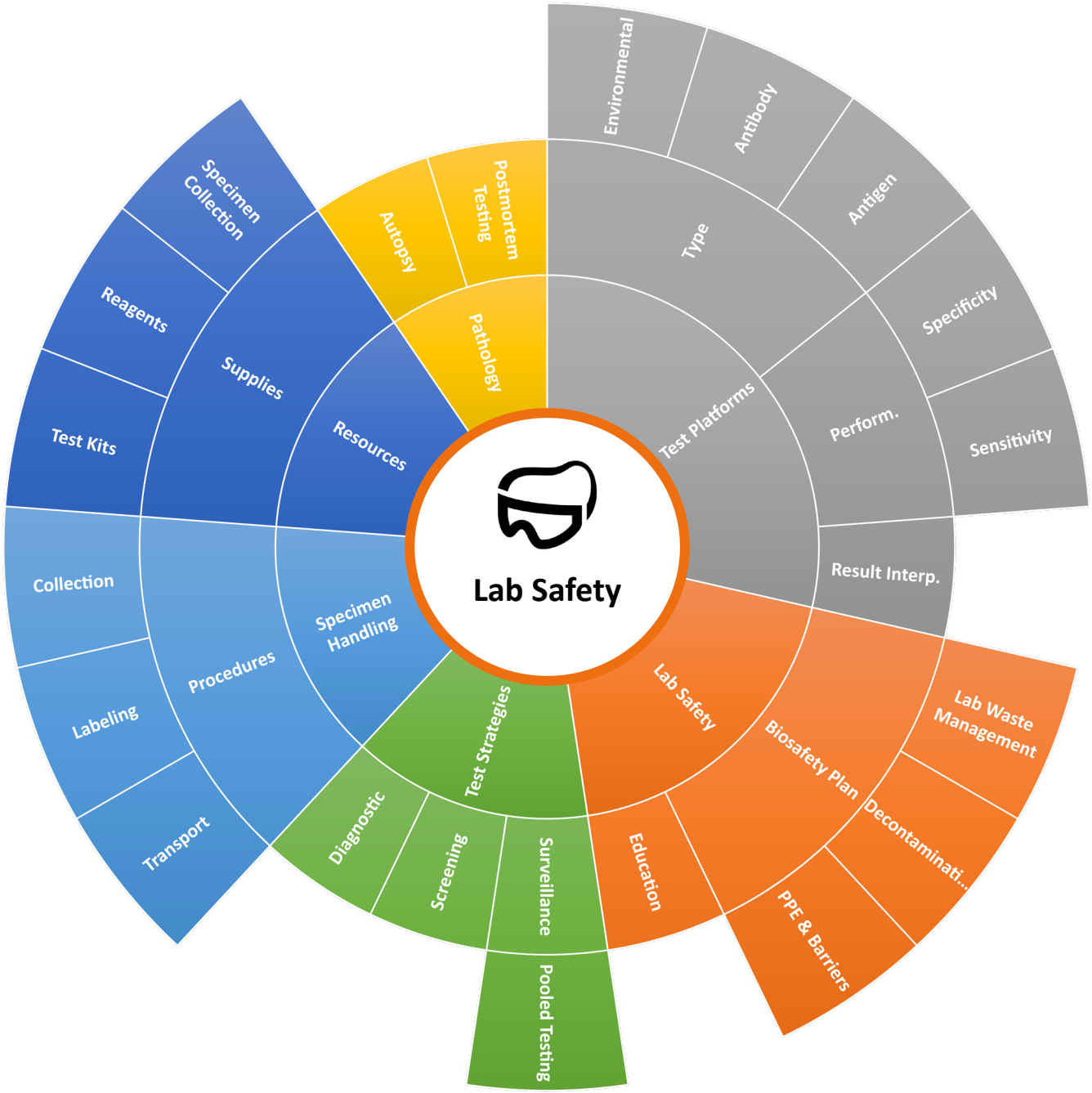
- Determine CDPH and SFDPH recommendations for reporting patient deaths

UCSF Health

Clinical laboratory leadership to engage senior leadership and clinical stakeholders (such as Emergency Department, Perioperative Services, and Birth Center Triage) in **test platform** selection. Consider the following factors in a needs assessment:

- Test volume and throughput
- Turnaround time (TAT), including STAT needs
- Testing types (PCR, antibody, antigen, POCT, environmental)
- Test performance (specificity, sensitivity)
  - Outline process for false positive workup, if applicable
- Result interpretation (including indeterminate and/or invalid results)
- Additional analysis (Strain typing, WGS)
- Point of Care Testing (POCT) and Provider Provided Microscopy (PPM)—refer to UCSF POCT website for additional guidelines

UCSF Health



Consider the necessity of performing a risk assessment for testing of novel pathogens

- **Lab Safety** considerations may include:
  - PPE use, hand hygiene, and barriers
    - based on risk of aerosolization, splash
  - Lab waste management
  - Sharps safety
  - Decontamination
  - Access to eyewash, safety shower, spill kit
  - Employee health, including physical distancing
- Consult the clinical laboratory biosafety plan for complete guidelines
- For exposures, call the UCSF Exposure Hotline at (415) 353-7842
  - UCSF Occupational Health
  - UCSF EH&S

UCSF Health

Senior leadership to consult with Clinical Laboratory on development of clinical workflows inclusive of appropriate **test strategies.** Develop criteria for test acceptance and consider the following factors:

- **Strategies**
  - Diagnostic
  - Screening
  - Surveillance
    - Pooled Testing
- Symptomatic vs Asymptomatic Testing
- Self-Testing vs. Clinician Testing
- Accepted tests and specimen types
  - Based on strategy and clinical scenario
  - Include timing of test relative to procedure or encounter, if applicable

UCSF Health

Specimen Collection

Consider the following based on pathogen and transmission mode(s):

- Use of standard precautions or transmission-based precautions
  - PPE selection
  - ACH and pressurization of room
- Consider training dedicated personnel to perform testing by unit or clinical area
  - In-person training sessions
  - Online education
    - Videos
    - Tip sheets
    - Workflows
    - Modules

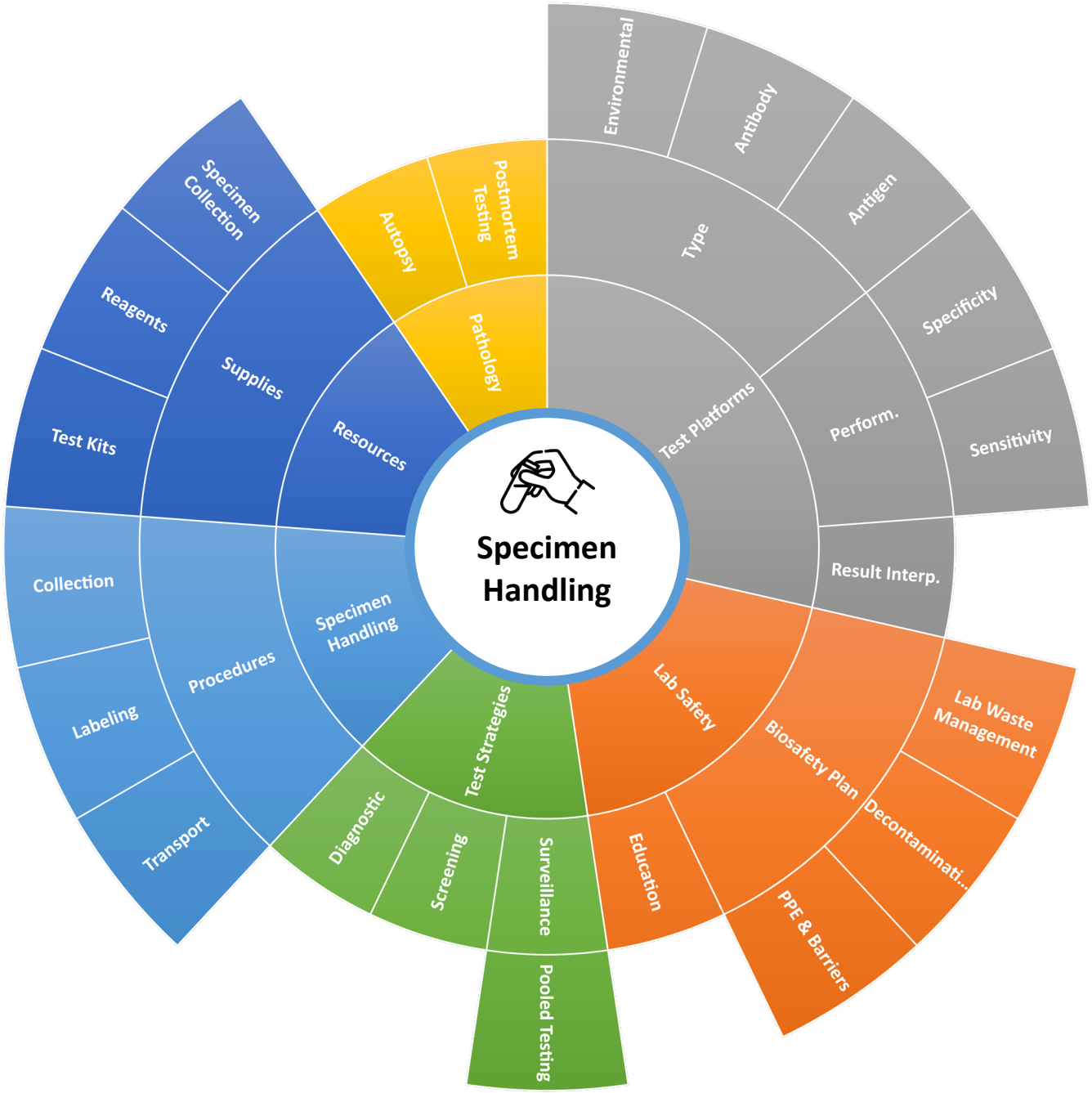
UCSF Health

Specimen Labeling, Packaging, and Transport

Consider the following based on pathogen and transmission mode(s):

- Use of standard (universal) precautions or enhanced precautions
- Safety implications based on transport method (ie: pneumatic tube system, dumbwaiter, courier)
- In-house testing—labeling as “suspected” or “confirmed”, special packaging (ie: double bagging, parafilm, etc)
- Send-out tests—Packaging, labeling, and shipping in accordance with Department of Transportation (DOT) regulations based on category

UCSF Health



Test Result Reporting

Consider the following based on pathogen and transmission mode(s):

- Critical Value and Unit Notification
- Mandated Reporting to Public Health Entities based on CDPH and SFDPH recommendations. Implications for reporting may include but are not limited to:
  - Positive cases
  - Patient deaths
  - Breakthrough vaccine cases
  - Clusters (patient, employee)
  - Specific syndromes associated with pathogen

UCSF Health

Additional Resources

- UCSF Clinical Laboratories
- UCSF EH&S BioSafety
- UCSF Aerosol Transmissible Disease and Exposure Control Plan
- UCSF Bloodborne Pathogens Policy
- Clinical and Laboratory Standards Institute (CLSi) GP36-A “Planning for Laboratory Operations During a Disaster; Approved Guideline”
- World Health Organization (WHO) Laboratory BioSafety Manual
- Occupational Safety and Health Administration (OSHA) Laboratory Safety Guidance
- Outbreak Response and Incident Management: SHEA Guidance and Resources for Healthcare Epidemiologists in United States Acute-Care Hospitals

UCSF Health