Laboratory Testing and Safety

Presented by:
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Funded by ASPR & CDC
Learning Objectives

Identify safe procedures for specimen collection
  • Patient bedside

Describe safe procedures for specimen transport
  • Both in-house and off-site

Recognize safe procedures for laboratory testing
  • In-patient care unit and outside the unit

Know recommended PPE
  • Vary based on location and type of activities
• Understand role of point-of-care testing

• Be familiar with processes for lab waste management and handling spills

• Describe criteria for Ebola virus testing

• Realize the need for a site-specific risk assessment to determine hazards and to mitigate risk.
Learning Objectives (continued)

• For Assessment Hospitals
  • Understand importance of timely diagnostics
  • Ensure patient care is not compromised during assessment

• Recognize the need for lab testing prior to availability of Ebola test results

• For Treatment Centers
  • Recognize the need for optimal patient management
Multiple parts

- Follow Blood borne Pathogen Standard
- Risk Assessment and Mitigation
- Specimen Collection and Transport
- Equipment and Point-of-Care Instrumentation
- Preventing Splash or Needlestick Exposure
- Cleaning and Disinfecting
- Handling Spills and Decontamination
- Waste Management
- PPE
OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) as amended pursuant to the 2000 Needlestick Safety and Prevention Act

- …is a regulation that prescribes safeguards to protect workers against health hazards related to bloodborne pathogens.

- …has provisions dealing with exposure control plans, engineering and work practice controls, hepatitis B vaccination, hazard communication and training, and recordkeeping.

- ...(is a) standard (that) imposes requirements on employers of workers who may be exposed to blood or other potentially infectious materials such as certain tissues and body fluids.
Risk of acquiring Ebola through laboratory testing
  • Low but not zero

Risk assessment performed to mitigate risks
  • Engineering controls
  • Administrative practices
  • Work practices
  • Appropriate PPE

To minimize risk
  • Limit staff
  • Evaluate and segregate equipment used
Laboratory Safety

Carefully consider the decision to test in a hospital lab
  •  Check with equipment manufacturers regarding…
    •  Warranties
    •  Repair/disinfection procedures

OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)
  •  All U.S. laboratories that collect, handle, or test human specimens
    •  Compliance mandatory
Site Specific Risk Considerations

- Specimen management and transport
- Equipment hazards
- BSC certification and operation safe
- Decontamination procedures
- Infectious waste management
- Laboratory design
- Engineering controls and safety equipment
- Laboratory communication protocols
- Laboratory entry and exit procedures
- PPE selection and use
- Facility ventilation and filtration
- Employee medical surveillance and exposure response
- Safe sharps handling
- Personnel safety training and competencies
Laboratory Safety
Risk Assessment

Identify hazards associated with known or potentially infectious agent
  • Activities performed
  • Likelihood of exposure
  • Consequences of personnel exposure

Goal of risk assessment
  • Determine exposure risk and the means to mitigate these risks
    • Generation of aerosols, sprays, splashes, or spills
Laboratory Safety
Risk Assessment

Considerations for a site-specific risk assessment

- Specimen path through the laboratory
- Identification of potential exposure risks
  - Evaluate work processes, procedures and tasks

Means to mitigate these risks

- Engineering controls
- Administrative controls (including work practices)
- Appropriate PPE
Laboratory Safety
Risk Mitigation

Based on the risk assessment

• Engineering Controls
  • Biosafety cabinet
  • Sealed centrifuge rotors
  • Sharps containers
  • Laboratory ventilation
  • Anterooms

• Administrative controls
  • Training
  • SOPs
  • Institutional policies
  • Safe work practices
  • Medical surveillance

• Appropriate personal protective equipment (PPE)
Laboratory Safety
Risk Mitigation

Other strategies

• Use point-of-care testing
• Limit laboratory staff
• Segregate equipment
• Test in dedicated space
Laboratory Safety
Risk Mitigation

Test in dedicated space
Laboratory Safety

PPE

Proper donning and doffing

- Laboratory staff must be trained
- Strict adherence to protocols essential

Use dependent on work performed

- More PPE
  - Direct contact with patient
- Less PPE
  - Specimen transport within facility
- Laboratory testing
  - Protect bare skin and mucous membranes (eyes, nose, mouth)
Laboratory Safety

PPE
More NOT always necessary

- Reduced visibility, dexterity, sensory perception and mobility
- Heat stress and fatigue
- Discomfort causes distraction

N-95 respirator

- Annual fit testing and medical clearance required
- Some cannot wear N-95 respirators
- Facial hair may compromise seal
- Changes in facial structure can compromise seal
Laboratory Safety
PPE for Specimen Collection

Clinically stable PUI **without** bleeding, vomiting, or diarrhea

- PPE at a minimum:
  - Face shield
  - Surgical face mask
  - Impermeable gown
  - Two pairs of gloves

Clinically unstable PUI with bleeding, vomiting, or diarrhea or confirmed Ebola patient

- Additional PPE recommended
Laboratory Safety
Specimen Collection for Ebola Screen

Wear appropriate PPE

• Disposable gloves
• Solid-front fluid-resistant or fluid-impermeable wrap-around gown
• Surgical mask to cover nose and mouth
• Eye protection
  • Full face shield or
  • Goggles / Safety glasses with side shields
Laboratory Safety
Specimen Collection for Ebola Screen

Use appropriate collection container

- Whole blood collection
  - EDTA preferred
  - Also acceptable
    - Sodium polyanethol sulfonate
    - Citrate
    - Clot activator

Do not separate serum or plasma from 1° collection container

- Performed only in the approved laboratory

Other specimens

- May be submitted after consultation with CDC
Safe Laboratory Testing
Manipulating Specimens

Use certified biosafety cabinet i.e. Class II-A2

Use manufacturer-installed safety features

• Reduce likelihood of exposure

Wear appropriate PPE

• Disposable gloves
• Solid-front fluid-resistant or fluid-impermeable wrap-around gown
• Surgical mask to cover nose and mouth
• Eye protection
  • Full face shield or
  • Goggles / Safety glasses with side shields
Laboratory Safety
Prepare Specimen for Transport

Pre-plan route from site-of-care to laboratory
  • Avoid high-traffic areas

Don proper PPE when packaging

Decontaminate outside of specimen container
  • Before removing from site-of-care
  • Use appropriate disinfectant

Place specimen in a durable, leak-proof 2°C container
  • Comply with 29 CFR §1910.1030)
Before removing from site-of-care

- Decontaminate outside of specimen transport container
- Use an approved disinfectant

Hand carry specimen to lab

- DO NOT use pneumatic tube system
- Consider using a buddy system
Laboratory Safety
Off-Site Transport

- Ebola virus classified by the DOT as a Category A infectious substance
  - Package and transport in accordance with the DOT’s Hazardous Materials Regulations and International Air Transport Association Dangerous Goods Regulations

- Individuals packaging and shipping infectious substances must be trained and certified
  - DOT requires every three years
  - IATA requires every two years

- Requires specific UN-certified packaging, labels, marking, and documentation
Laboratory Safety
Off-Site Transport

Use triple packaging system

• 1° container
  • Sealed and wrapped with absorbent

• 2° container
  • Watertight, leak-proof

• Outer rigid shipping container
Laboratory Safety
Off-Site Transport

- Watertight Primary Plastic Receptacle*
- Infectious Substance
- Absorbent Packing Material (for liquids)
- Cap
- List of Contents
- Itemized List of Contents:
- Watertight Secondary Packaging
- Rigid Outer Packaging
- Infectious Substance Label
- Proper Shipping Name and UN Number
- UN Package Certification Mark
- Shipper or Consignee Identification
- Cross Section of Closed Package
- Closure requires positive means of ensuring leakproof seal
- Infectious Substance
- Absorbent Packing Material

*If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them.
To manage testing for a PUI

- CDC and PHL can provide guidance
  - Test selection
  - Sources for additional tests
Laboratory Testing
Clinical Care and Differential Diagnosis

Assessment hospitals should consider how to safely perform the following tests (if indicated)

- CBC, differential, platelet count
- Electrolytes, calcium, magnesium, BUN, creatinine, glucose
- Liver enzymes (AST, ALT), total bilirubin
- Coagulation testing (especially prothrombin time)
- Blood culture
- Malaria smear (or rapid test)
- Rapid Influenza virus
- Rapid Respiratory Syncytial virus (RSV) and other respiratory viruses
- Rapid group A strep
- Urinalysis (screening test, not requiring centrifugation)
May need to identify other approaches to patient management

- Empiric treatments, alternative diagnostic strategies

Blood typing ➤
<table>
<thead>
<tr>
<th>Test</th>
<th>Order Code</th>
<th>Tube type</th>
<th>performed at (Instrument)</th>
<th>Centrifugation (NPHL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amylase</td>
<td>AMY</td>
<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
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<td>BL2 level</td>
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<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
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<td>Blood culture</td>
<td>BLDCU</td>
<td>Plastic Aerobic Bacite Bottle</td>
<td>NPHL Lab</td>
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<td>Blood Gas arterial</td>
<td>POCC13</td>
<td>Heparinized blood gas syringe</td>
<td>BCU lab (Istat)</td>
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<td>Blood Gas venous</td>
<td>POCC14</td>
<td>4.5 ml green top PST</td>
<td>BCU lab (Istat)</td>
<td>No</td>
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<td>Blood type</td>
<td>ABORH</td>
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<td>BCU lab (slide forward type)</td>
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<td>Basic metabolic panel</td>
<td>BMET</td>
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<tr>
<td>CBC with automated diff</td>
<td>CBCP</td>
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<td>CBC with manual diff</td>
<td>CBCM</td>
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<td>Cortisol</td>
<td>CORTS</td>
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<td>Creatine Kinase Total</td>
<td>CK</td>
<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
<td>Yes</td>
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<td>C-Reactive protein</td>
<td>CRP</td>
<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab</td>
<td>No</td>
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<td>DIC screen (see note below)</td>
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<td>3 ml lavender top</td>
<td>Hospital Core lab (Sysmex)</td>
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<tr>
<td>NOTE: Lab will provide platelet count and examination of peripheral smear for schistocytes to be used in conjunction with coag results from BCU lab</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Drug Study experimental</td>
<td>No test code</td>
<td>5ml lavender (Qty 1) top OR 3ml lavender (Qty 2)</td>
<td>BCU lab or NPHL Lab</td>
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<td>Fe/Ferritin/TIBC</td>
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<td>Sputum Culture</td>
<td>HPT</td>
<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
<td>Yes</td>
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<tr>
<td>HIV</td>
<td></td>
<td>5 ml red top</td>
<td>BCU lab (Istat)</td>
<td>No</td>
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<td>Ionized Ca(STAT CHEMS+)</td>
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<td>4.5 ml green top PST</td>
<td>BCU lab (Istat)</td>
<td>No</td>
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<tr>
<td>Lactic Acid</td>
<td></td>
<td>5 ml grey top</td>
<td>Hospital Core lab (DXC)</td>
<td>Yes</td>
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<td>Lipase</td>
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<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
<td>Yes</td>
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<td>Magnesium</td>
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<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
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<tr>
<td>Malaria</td>
<td>MALP</td>
<td>3 ml lavender top</td>
<td>Hospital Core lab</td>
<td>No</td>
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<tr>
<td>Phosphorus</td>
<td>PO4</td>
<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
<td>Yes</td>
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<tr>
<td>Prealbumin</td>
<td>PAB</td>
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<td>Hospital Core lab</td>
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<tr>
<td>PT/PTT</td>
<td>Coagulation Panel</td>
<td>1.8 ml or 2.7 ml blue top</td>
<td>BCU lab (Hemocron)</td>
<td>No</td>
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<tr>
<td>Reticulocyte Count</td>
<td>RETCT</td>
<td>3 ml lavender top</td>
<td>Hospital Core lab (DXI)</td>
<td>No</td>
</tr>
<tr>
<td>Sputum Culture</td>
<td>SPUCU</td>
<td>Not applicable</td>
<td>NPHL lab</td>
<td>No</td>
</tr>
<tr>
<td>Standard Ca++</td>
<td>CA</td>
<td>5 ml gold top SST tube, or 4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
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<td>Troponin</td>
<td>TROP</td>
<td>4.5 ml green top PST</td>
<td>Hospital Core lab (DXI)</td>
<td>Yes</td>
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<tr>
<td>Urine Culture</td>
<td>URNCU</td>
<td>Not applicable</td>
<td>NPHL lab</td>
<td>No</td>
</tr>
<tr>
<td>Urine electrolytes</td>
<td>UNA, UKS, UCS</td>
<td>BD Urinalysis Plus conical tube</td>
<td>NPHL lab</td>
<td>No</td>
</tr>
</tbody>
</table>

SST Top, Serum Separator Tube; Green PST Top, Lithium heparin Plasma Separator Tube; Lavender Top, EDTA lithium citrate; Grey Top, Fluoride oxalate; Blue, sodium citrate.
Laboratory Testing
Assessment Hospital Expectations

Provide a timely and minimum menu of tests

- CBC, glucose, potassium, malaria, influenza, liver function

Ensure patient care is not compromised

- Prior to availability of Ebola laboratory testing results

Note

- In the U.S., most PUIs will not have EVD
  - Another etiology more likely
- Timely ID of other etiologies essential
  - Provide appropriate patient care
Consult with jurisdictional public health official

Obtain blood specimen when patient meets criteria for a PUI

- Elevated body temperature or subjective fever

OR

- Any Ebola-compatible symptoms, including severe headache, fatigue, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage

AND

- An epidemiological risk factor within the 21 days preceding onset of symptoms
Presumptive Ebola testing

- >50 Laboratory Response Network (LRN) labs

Using a commercial Ebola virus test

- Also submit paired specimen to an LRN-approved lab or CDC

Confirm all positive Ebola test result at the CDC

EZ1 Real-Time RT-PCR
ABI 7500 Fast, Emergency Use Authorization
Laboratory Testing
Assessment Process

To perform Ebola virus testing

- Patient meets criteria for Person Under Investigation (PUI)

If PUI symptoms present <3 days

- Negative test result may be a false negative
- Collect a 2nd sample 72 h after symptom onset
  - To definitively rule out EVD
Some laboratory equipment may **not** be appropriate

- May generate an aerosol
- Recommended disinfectants
  - May affect instrument’s performance
  - Void manufacturer’s warranty

Currently CDC and FDA are working with manufacturers to assess and resolve safety issues of laboratory equipment
Laboratory Equipment
Point-of-Care Tests

When POC instruments are used

- Clinical laboratory director
  - Must ensure compliance with CLIA regulations
  - Waived vs non-waived testing
  - Testing meets intended use as approved by the FDA

When intended use excludes testing of critical patient

- Considered off-label use
- Must establish performance specifications and validate before use
Laboratory Equipment
Point-of-Care Tests

Before POC instruments used
  - Establish performance specifications and validate

Place in a location to contain splashes or potential aerosols
  - Biosafety cabinet available
    - Ensure airflow is not compromised by overloading
  - BSC not available
    - Use other safety equipment

Train staff to include hands-on use of the POC instrument
  - With PPE on

Ensure ongoing competence through periodic drills and proficiency testing (PT) sample evaluations
### Clinical Chemistry

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckman-Coulter</td>
<td>DxC880i</td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td>iSTAT</td>
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<tr>
<td>Abaxis</td>
<td>Piccolo Xpress</td>
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</table>

### Hematology

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sysmex</td>
<td>XN 9000</td>
</tr>
<tr>
<td>Sysmex</td>
<td>pocH 100i</td>
</tr>
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</table>

Listing for information only and not intended as an endorsement of these instruments or practices, nor should this be considered a complete list of all test instruments that may be acceptable.
Instrument or Methods Used

**Coagulation**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITC</td>
<td>Hemochron Signature Elite</td>
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<tr>
<td>F. Hoffman-La Roche</td>
<td>CoaguChek</td>
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</tbody>
</table>

**Microbiology**

<table>
<thead>
<tr>
<th>Test</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Culture</td>
<td>Plastic bottle/manual monitoring method</td>
</tr>
<tr>
<td>Malaria</td>
<td>Smear fixed in methanol for 15-30 mins</td>
</tr>
<tr>
<td></td>
<td>Alere BinaxNOW</td>
</tr>
<tr>
<td>Ebola virus testing</td>
<td>Biofire FilmArray*</td>
</tr>
</tbody>
</table>

Listing for information only and not intended as an endorsement of these instruments or practices, nor should this be considered a complete list of all test instruments that may be acceptable.

If testing is done on the BioFire, also send a sample to the LRN laboratory for testing.
Don proper PPE

Use EPA-registered hospital disinfectants

• With label claim for use against a non-enveloped virus

Follow product label use directions

Perform routine cleaning and disinfection of the lab

• PPE doffing area
• Work surfaces
• Equipment
Equipment Decontamination

- Use EPA-registered hospital disinfectants
  - Label claim for use against a non-enveloped virus

- Consult in advance with equipment manufacturer(s):
  - Select appropriate disinfectants for use
  - Prepare equipment for repairs/maintenance
Steam sterilization will inactivate Ebola virus

- If properly ....
  - operated,
  - maintained, and
  - monitored.

When autoclave is not available

- Contact a licensed external waste contractor to...
  - transport,
  - treat and
  - dispose.
- Permits are required and other restrictions may apply
Waste management requirements vary by state

- Check local and state regulations associated with disposal of biohazards

Waste generated from a PUI or patient with confirmed EVD

- NOT subject to Select Agent regulations UNLESS viable Ebola virus is intentionally isolated from that waste
Are hospitals/laboratories that treated the patient able to retain patient specimens confirmed for EVD?

“Once patient care for the select agent infection has concluded, specimens become subject to the select agent regulations unless they are destroyed within seven calendar days of the conclusion of patient care.”

Oct 14, 2015
Handling Spills

Follow basic principles for blood/body substance spill management
  • Outlined in OSHA’s Bloodborne Pathogens Standard

Develop policies and procedures to handle spills

Practice on the procedures to handle spills
Handling Spills

CDC guideline recommendations
- Remove bulk spill material
- Clean site
- Disinfect site with effective disinfectant

Other recommendations
- Limit staff involved in cleanup
- Develop protocols for safely remediating spills containing broken glass

Ensure staff are trained and wear recommended PPE
- Protection against exposure of cleaning chemicals, contamination, and splashes

Materials used for cleanup are treated as infectious
- Dispose in biohazard waste container
Summary

1. Do not delay laboratory testing during patient evaluation and prior to definitive patient status.

2. A site-specific risk assessment is critical to determine hazards and to implement controls to reduce risk.

3. Adherence to the OSHA Bloodborne Pathogens Standard is required.
4. Recommended PPE will vary based on location and activities performed.

5. Staff training is critical for all aspects of handling patient specimens.

6. Individuals packing and shipping infectious substances must be trained and certified.
Ultimate goal.....provide for optimal management of the patient in an environment that is safe for employees.
Introducing the complete Ebola HAZMAT suit solution. Now available in Designer Darth.

www.truckdrivingschoolsinfo.com
Questions to Facilitate Decision Making

Is the specimen contained within a closed chamber throughout testing?

Even if the specimen remains contained within a closed chamber, has an evaluation been performed to determine if the manufacturer’s safety features effectively protect operators from exposure to aerosols or sprays?
If the specimen container is opened during processing, have potential routes of exposure to the operator been identified and have engineering controls and/or PPE been implemented?

Does the instrument test system employ wash and decontamination solutions to adequately inactivate bloodborne pathogens, including Ebola virus?
Does the manufacturer’s instruction manual provide hazard warnings and PPE guidance?

Have the potential exposure routes associated with handling and transport of the instrument’s on-board waste collection been identified and PPE evaluated and implemented?
How close is the instrument to other operations in the laboratory?
Are there instructions for cleaning and decontaminating the instrument, including track systems?

Do recommended disinfectants meet the EPA requirements for inactivating non-enveloped viruses?
What are the size and operational requirements of the entire test system? (Consider the instrument’s environmental operating requirements to include temperature, humidity, and proper reagent storage e.g., refrigerator or freezer).

Does the “Intended Use” statement of the device labeling allow for testing critically ill patients? (FDA has not approved the use of some devices for testing critically ill patients.)
If the instrument is placed inside a BSC, will it compromise the proper BSC operation and protective functions e.g., air flow?

Is the instrument difficult to operate while wearing required PPE?

Is the instrument easily decontaminated?


