Laboratory Support and Biosafety in Specimen Handling in the Management of EVD
Objectives:

• To discuss the supportive POC diagnostic testing for patient management

• To discuss the biosafety guidelines in the handling of specimens
Outline:

I. Laboratory Support
   - Recommended laboratory tests for clinical management of EVD cases
   - Recommended testing platform for specimens from EVD cases

II. Biosafety in Specimen Handling
   - Proper use of PPE
   - Proper specimen handling during processing and testing
   - Disinfection of the work area
What are the recommended laboratory tests?

• RITM recommends use of solely POC (point of care) testing to minimize exposure

• Patient Management
  - POC blood chemistry, hemoglobin, hematocrit
  - coagulation parameters (PT/INR)
  - electrolytes

• Diagnostic Work-up
  - EVD confirmatory testing (RT-PCR, ELISA)
  - *Malaria thick blood film (trained microscopist)
Point of Care Testing System
## Point of Care Testing System Comparison

<table>
<thead>
<tr>
<th></th>
<th>i-STAT</th>
<th>Piccolo Express</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power source</strong></td>
<td>2 lithium batteries (approx. 350-400 test)</td>
<td>AC 220 V</td>
</tr>
<tr>
<td><strong>Warranty</strong></td>
<td>2 years (parts and services)</td>
<td>2 years (Parts and services)</td>
</tr>
</tbody>
</table>
| **Composition of purchased item per unit** | 1 i-STAT Analyzer  
1 Martel printer  
1 External Simulator  
1 Operation Manual  
6 pcs. Additional 9V Lithium battery  
Thermal Paper Roll  
1 Pipettor  
1 box PT/INR cartridge (24 pcs.)  
1 box Chem 8 (25 pcs.)  
Free Software upgrade  
Free on-site Training | 1 Piccolo Express analyzer  
0.1 cc Minipipette  
Disposable tips with rack (96’s)  
Operation Manual  
1 Power cord and Supply  
Thermal Paper Roll  
Software interface driver  
1 box Metlac 12 cartridge (10 pcs.)  
2 demo disc  
Free Training  
Extra air filter |
| **Control**             | Level 1, 2, 3 (chem 8)  
Level 1 & 2 (PT/INR)                                                   | Internal Control Only                             |
<table>
<thead>
<tr>
<th></th>
<th>iSTAT</th>
<th>Piccolo Express</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (H x W x D)</td>
<td>23.48 cm × 7.68 cm × 7.24 cm</td>
<td>32.4 cm × 15.2 cm × 20.3 cm</td>
</tr>
<tr>
<td>Turn-Around-Time of results</td>
<td>5-10 mins</td>
<td>10-12 mins</td>
</tr>
<tr>
<td>Cartridge storage</td>
<td>2° to 8° C</td>
<td>2° to 8° C</td>
</tr>
<tr>
<td>Type of specimen used</td>
<td>Heparinized blood (Na/Lithium)</td>
<td>Lithium Heparin only</td>
</tr>
<tr>
<td>Sample volume</td>
<td>PT:20 µL Chem 8 65 µL</td>
<td>100 µL</td>
</tr>
<tr>
<td>Printer</td>
<td>Separate printer</td>
<td>Built-in Printer</td>
</tr>
<tr>
<td>Price (machine)</td>
<td><strong>Php. 800,000</strong></td>
<td><strong>Php. 750,000</strong></td>
</tr>
<tr>
<td>Cartridges</td>
<td>Available test</td>
<td>Packaging</td>
</tr>
<tr>
<td>------------</td>
<td>----------------</td>
<td>-----------</td>
</tr>
<tr>
<td>i-STAT</td>
<td>Chem 8+</td>
<td>Na, K, Cl, iCa, BUN, Crea, TCO2, Glucose, Hgb, Hct</td>
</tr>
<tr>
<td>PT/INR</td>
<td>Prothrombin Time and INR</td>
<td>24 pcs per box</td>
</tr>
<tr>
<td>CG 8+</td>
<td>Na, K, iCa, Hct, Hgb, Glucose, pH, PCO2, PO2, TCO2, HCO, BEecf, sO2</td>
<td>25 pcs per box</td>
</tr>
<tr>
<td>G3+</td>
<td>pH, PCO2, PO2, TCO2, HCO, BEecf, sO2</td>
<td>25 pcs per box</td>
</tr>
</tbody>
</table>
What is the recommended laboratory set-up
Temporary “Point of Care” Laboratory

- Specimens from PUIs/EVD Suspect Cases must not be processed and tested in the hospital’s general clinical laboratory.
- A temporary “point of care” laboratory adjacent to or near the isolation rooms of PUIs/EVD suspect cases.
- The temporary “point-of-care” laboratory shall have the following minimum required equipment:
  - Biosafety cabinet type II - calibrated and validated
  - Dedicated pipettors
  - Dedicated handheld Point-of-care testing system (e.g., i-STAT or equivalent)
  - Autoclave

- The temporary “point-of-care” laboratory shall have dedicated supplies and reagents for testing, specimen packaging and transport, spill management as well as waste management.
Biosafety in Specimen Handling
Personal Protective Equipment

- All staff processing and performing routine diagnostic tests must wear the following appropriate personal protective equipment:
  - Attire under PPE: Scrub suit with dedicated washable footwear; No personal items (e.g., cellphone, jewelry, etc.)
  - Double layer of nitrile gloves with extended cuffs
  - Disposable Full face shield
  - Disposable coverall
  - N95 respirator OR Powered Air Purifying Respirator (PAPR)
  - Fluid resistant or impermeable boots
**BASIC REQUIREMENTS FOR ENSURING STAFF SAFETY IN SPECIMEN COLLECTION, HANDLING, PROCESSING AND TESTING OF SAMPLES FROM PUI’S AND EVD SUSPECT CASES**

<table>
<thead>
<tr>
<th>SPECIMEN COLLECTOR</th>
<th>LABORATORY PROCESSING AND TESTING PERSONNEL</th>
<th>EQUIPMENT</th>
<th>SUPPLIES AND REAGENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum training and skill requirements:</td>
<td>Minimum training and skill requirements:</td>
<td>• Functional and certified Biosafety Cabinet Type II</td>
<td>• Supplies and reagents dedicated for routine testing of PUIs or EVD Suspect cases.</td>
</tr>
<tr>
<td>• Phlebotomy</td>
<td>• Good laboratory practices</td>
<td>• Dedicated handheld point-of-care testing system (e.g., i-STAT or equivalent)</td>
<td>• Supplies dedicated for waste management, such as sharps container, trash bags, trash bins, etc.</td>
</tr>
<tr>
<td>• Biosafety</td>
<td>• Biosafety</td>
<td>• Autoclave</td>
<td></td>
</tr>
<tr>
<td>• Donning and doffing of Personal Protective Equipment</td>
<td>• Donning and doffing of Personal Protective Equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Use of Biosafety Cabinet</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Use of Point-of-Care system (e.g., i-STAT or equivalent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• **Aerosol Generating Procedures**
  • **Limit** activities that may **generate** aerosols to pipetting (POC)

**Decontamination of Patient’s Sample**
• All potentially contaminated liquid and solid materials should be appropriately sterilized before disposal.
Disinfection of Work Surfaces

- Disinfection should be done promptly after completing work on the surface.

- Work surfaces should be treated with a 1:100 dilution of 5.25% household bleach with contact time of at least 10 minutes.