

SOP: Blood Extraction for Ebola Virus Disease

1. OBJECTIVE:

This documents the process of blood extraction and labelling of samples for Ebola virus disease (EVD) test requests.

2. SCOPE:

The specimen collection described includes only blood for EVD laboratory examination. This work instruction describes the procedures in the performance of the test, including detailed steps, biosafety considerations, including proper donning and doffing of PPE and responsibilities of staff concerned.

3. POLICY/PRINCIPLE:

3.1. POLICIES:

3.1.1. The hospital laboratory is committed to provide quality and timely clinical laboratory services that satisfy the customers' requirements.

3.1.2. The procedures will be performed in accordance with the patient's rights and institute policy on patient confidentiality and autonomy.

3.1.3. Only qualified or trained personnel shall perform procedures in this process.

3.1.4. SAFETY PRECAUTIONS:

3.1.4.1. All procedures will comply with RITM Laboratory Biosafety Manual guidelines and the Interim Guidelines on Specimen Collection, Packaging, and Transport for Ebola virus disease version 4.

3.1.4.2. DO NOT ENTER THE PATIENT AREA IF YOU DO NOT HAVE ALL PROTECTIVE GEAR ON.

3.1.4.3. Always have a buddy system (or in pairs) and a safety officer when performing the procedures.

3.1.4.4. The responsibilities must be clear to all staff involved in the performance of the procedures.

3.1.4.5. Proper grooming should be strictly observed.

3.1.4.5.1. Wear hairband/hair pin to prevent hair fall.

3.1.4.5.2. Remove earrings, watches, rings, necklace, bracelets ID badges.

3.1.4.5.3. Secure eyeglasses by taping it to the bridge of the nose.

3.1.4.6. Check all PPE for defects.

3.1.4.7. Make sure that all staff who will use the N95 respirator had a documented fit test.

3.1.4.8. Alert the Infection Control Committee for any untoward incidence or breach in the procedures.

3.1.4.9. Always make sure the availability and sufficiency of all materials.

3.2. PRINCIPLE:

Ebola is spread through direct contact (e.g., through broken skin or through mucous membranes of the eyes, nose, or mouth) with blood or body fluids of a person who is sick with Ebola or with objects (e.g., needles, syringes) that have been contaminated with the virus. The incubation period ranges from 2-21 days.

Ebola virus is detected in blood only after onset of symptoms, most notably fever. It may take up to 3 days post-onset of symptoms for the virus to reach detectable levels. Virus is generally detectable by real-time RT-PCR during the acute phase and ELISA IgM/Antigen detection from 3-10 days post-onset of illness. Optimally, specimens should be taken when symptomatic patient/suspected Ebola patient reports to the healthcare facility.

It is important that hospital and laboratory staff responsible for the collection, packaging and transport of specimens for confirmatory testing are aware of the biosafety and biosecurity considerations and infection control guidelines in order to minimize the risk of infection with EVD.

4. SUPPLIES/MATERIALS/EQUIPMENT:

PPE Storage and Donning Area

PPE

Rubber boots – leak-proof, knee-high, correct size

Cover-all – Kleen-GARD

N95 respirator

Gloves (preferably nitrile – inner gloves and high cuff surgical – outer gloves)

Goggles – anti-fog

Apron – preferably one that is easy to untie

Hair net/Hair pin/Head band

Anti-fog spray

Shoe/Foot cover -

Checklist of materials

Mirror – full-length

Sterilium/alcohol-based hand rub

Time log in

HOT ZONE/PATIENT ROOM

Extraction kit in a ziplock bag

Tubes – EDTA – violet top tube – ELISA Ag detection

Na+/ Li+ heparin – green top tube – blood chem

whole blood – red top tube – PTINR

whole blood with serum separator - yellow top tube – PCR/ELISA IgM/Ag detection)

vacutainer with flashback needle or with butterfly needle

needle adapter

tourniquet

cotton balls

alcohol swab

Micropore

Paper towels/gauze

Sterilium/alcohol based hand rub

0.5% Sodium hypochlorite – freshly prepared; refer to Annex for the preparation

Spill Kit

Sharps container

Biohazard bag

Marker/pen -permanent
Tube rack
Scissors

For pediatric patients:
Blanket/towels for wrapping child during extraction

PPE Removal Area

Disinfectant – 0.5% sodium hypochlorite solution and Sterilium or 0.05% sodium hypochlorite solution
Biohazard bag
Extra gloves

5. DEFINITION OF TERMS AND ACRONYMS:

5.1. TECHNICAL TERMS:

- 5.1.1. Yellow top tube – tube without preservative but with serum separator
- 5.1.2. Violet top tube – tube with EDTA preservative
- 5.1.3. Green top tube – tube with sodium heparin preservative
- 5.1.4. Red top tube – plain tube
- 5.1.5. PPE Storage and Donning Area - this is an area outside the Ebola patient room (e.g., a nearby vacant patient room, a marked area in the hallway outside the patient room) where clean PPE is stored and where medical technologist/nurse/safety officer can don PPE before entering the patient's room. This is a CLEAN AREA.
- 5.1.6. Hot zone or Patient Room -this is a single-patient room. The door is kept closed. Any item or healthcare worker exiting this room should be considered potentially contaminated.
- 5.1.7. PPE Removal Area - this is an area in proximity to the patient's room (e.g., anteroom or adjacent vacant patient room that is separate from the clean area) where healthcare workers leaving the patient's room can doff and discard their PPE assisted and supervised by the safety officer (trained observer).

5.2. ACRONYMS:

- 5.2.1. PPE: Personal Protective Equipment
- 5.2.2. EDTA: Ethylenediaminetetraacetic acid
- 5.2.3. EVD: Ebola Virus Disease
- 5.2.4. ELISA: Enzyme Linked Immunosorbent Assay
- 5.2.5. IgM: Immunoglobulin M
- 5.2.6. RITM: Research Institute for Tropical Medicine

6. RESPONSIBILITY:

- 6.1.** The Head of the lab is aware of the process and provides the necessary resources to fully implement and maintain test quality.
- 6.2.** The Laboratory Heads ensure that laboratory personnel performing this procedure are qualified, trained and proficient as evidenced in her certificate of attendance to the Ebola Training conducted by RITM.

- 6.3. The Laboratory heads are responsible for reviewing checklist of materials and case investigation forms, identifying possible errors, and taking corrective actions.
- 6.4. The medical technologist and his/her "buddy" (preferably a fellow medical technologist) ensure that procedures are followed accordingly and are responsible for the proper collection of blood specimens from suspected cases of EVD.
- 6.5. It is the role of the "buddy" to:
 - 6.5.1. Observe for and assist the staff in case of breach in infection control procedures.
 - 6.5.2. Make sure that infection control practices are observed at every step.
 - 6.5.3. Remind the person of the next step.
 - 6.5.4. Make sure no breach in protocol arises.
 - 6.5.5. Reports any breach in protocol.
- 6.6. The safety officer ensures that procedures are followed accordingly and is responsible for the proper donning and doffing of PPE of the medical technologist and the buddy. .
Specifically, the tasks of the safety officer are the following:
 - help prepare the sample for transport
 - assist with putting on the personal protective equipment
 - informs the nurse-on-duty when the phlebotomist and his/her buddy are ready for blood extraction

7. REFERENCES:

- 7.1. **JOURNALS/BOOKS/WORLD WIDE WEB:** CDC Blood Extraction Manual

8. PROCEDURE:

Pre-analytic Phase (PPE and DONNING OF PPE Area)

A designated Assistant/safety officer wearing gloves should be available to help the phlebotomist and his/her assistant outside the patient room.

1. Perform hand hygiene with Sterilium/70% alcohol/0.05% sodium hypochlorite.
2. Ensure that all materials are available as listed in the checklist.
3. Assemble equipment for collecting blood:
 - 2 sets of laboratory sample tubes for blood collection
 - o vacuum- extraction blood tubes with rubber screw caps: EDTA (violet), lithium heparin (green), and red and yellow tubes
 - 2 sets of blood sampling systems (safety lock, gauge 23 needle and syringe system, winged butterfly system-gauge 23cc (vacuum extraction) or winged butterfly system (syringe))
 - 2 Tourniquets (single-use, disposable)
 - Skin antiseptic solution: 70% alcohol
4. Assemble equipment for preventing infections:
 - Long-sleeved, disposable coverall suit
 - a plastic apron for tasks where contact with blood or body fluid could happen
 - Face protection: "goggles and N95 respirator"
 - Surface disinfectant: 0.5% sodium hypochlorite
 - Personal Protective Equipment (PPE):
 - o Pairs of disposable gloves (non-sterile, ambidextrous, single layer)
 - o Two pairs of high cuff surgical gloves (2nd layer)
 - o Puncture resistant footwear/rubber boots:

- Disposable overshoes/ shoe cover secured around the shoes to prevent direct contact with ground and infected bodily fluid spills

For waste management materials:

- Leak-proof and puncture resistant sharps container – placed in patient room
 - Leak-proof infectious waste bags: for disposable material (destruction)
5. Pre-label all the sample containers with the complete name, age, sex and date of collection.
 6. Perform hand hygiene.
 7. Put on all personal protective equipment (PPE) in proper sequence:
 - 7.1. Wear rubber boots.
 - 7.2. Wear shoe cover.
 - 7.3. Put on nitrile gloves (1st layer).
 - 7.4. Wear the disposable cover-all. Make sure that everything is all covered.
 - 7.5. Wear the N95 respirator.
 - 7.6. Do the fit check by pinching the metal and do breathe in/out.
 - 7.7. Put on the hood, making sure that it covers the skin.
 - 7.8. Put goggles on. Double check the strap. All adjustments shall be done at this point.
 - 7.9. Wear the disposable apron and tie the knot in such a way that it can easily be removed.
 - 7.10. Wear the 2nd layer high cuff surgical gloves.
 - 7.11. Check your partner or buddy for the completeness/correctness of wearing PPE.
 - 7.12. Check the availability of all materials needed.

Analytic Phase (BLOOD EXTRACTION – Patient’s Room)

1. Identify and prepare the patient. Introduce yourself to the patient and explain what you will do with the blood sample and why. Make sure that this is the correct patient from whom you wish to take the blood sample.
NOTE: If the EVD suspect is a pediatric patient, wrap the child with a blanket or towel. The “buddy” is responsible for restraining the pediatric patients or adult patients who are vomiting.
2. Apply a tourniquet around the arm. Tie approximately 4–5 finger widths above the selected site.
3. Ask the patient to form a fist so that the veins are more prominent.
4. Select the site. Palpate the area; locate a vein of good size that is visible, straight and clear. The vein should be visible without applying a tourniquet.
5. Disinfect the area where you will put the needle with an alcohol swab. Wait 30 seconds for the alcohol to dry. DO NOT touch the site once disinfected.
6. When using vacuum extraction system with holder, insert the blood collector tube into the holder.
7. Anchor the vein by holding the patient’s arm and placing a thumb BELOW the place where you want to place the needle. DO NOT touch the disinfected site. DO NOT place a finger over the vein to guide the needle.
8. Draw at least 2ml of blood for each tube.
9. Once sufficient blood has been collected (minimum 2ml), release the tourniquet BEFORE withdrawing the needle.
10. Withdraw the needle gently. Give the patient a clean gauze or dry cotton wool ball to press gently on the site.
11. Put needle DIRECTLY into leak-proof and puncture resistant sharps container. Do not recap.
12. Remove blood collector tube from holder and put into rack.
13. Disinfect the blood holder tray and rack.

14. Take the blood tube from the tray .Place in a ziplock all the blood tubes.
15. Disinfect the ziplock containing the blood tubes.
16. Put the wrapped tube of blood into the plastic leak- proof packaging container. Be careful not to touch outside of leak-proof plastic tube with gloves.
17. Perform hand hygiene.
18. Exit the patient room.
19. Place the specimens in a sturdy, biohazard transport container.

Post-analytic (DOFFING OF PPE Area)

The safety officer ensures the proper doffing of PPE.

1. Doff PPE as described in ICC Guideline and Procedures of doffing PPE.
2. Exit the area.
3. Alert the laboratory staff in charge for the packaging and transport of the specimens to the hospital Clinical Laboratory for i-STAT analysis.

SOP: Blood chemistry and PT/INR analyses using i-STAT machine

1. OBJECTIVE:

This documents the proper use of i-STAT machine for blood chemistry and PT/INR analysis of suspected EBOLA cases. It describes the procedural steps of performing the i-STAT analyzer and cartridges for quantitative chemistry point of care testing.

2. SCOPE:

This includes only blood for EVD laboratory examination. This work instruction describes the principles and procedures in the performance of the test, including detailed steps, , biosafety considerations and responsibilities of staff concerned.

3. POLICY/PRINCIPLE:

3.1. POLICIES:

- 3.1.1. The hospital laboratory is committed to provide quality and timely clinical laboratory services that satisfy the customers' requirements.
- 3.1.2. The procedures will be performed in accordance with the patient's rights and institute policy on patient confidentiality and autonomy.
- 3.1.3. Only qualified or trained personnel shall perform procedures in this process.
- 3.1.4. Proper coordination with hospital authorities regarding the schedule of blood extraction and testing should be in place.
- 3.1.5. **SAFETY PRECAUTIONS:**
 - 3.1.5.1. All procedures will comply with RITM Laboratory Biosafety Manual guidelines and the Interim Guidelines on Specimen Collection, Packaging, and Transport for Ebola virus disease version 4.
 - 3.1.5.2. DO NOT ENTER THE PATIENT AREA IF YOU DO NOT HAVE ALL PROTECTIVE GEAR ON.
 - 3.1.5.3. Always have a buddy system (or in pairs) and a safety officer when performing the procedures.
 - 3.1.5.4. The responsibilities must be clear to all staff involved in the performance of the procedures.
 - 3.1.5.5. Proper grooming should be strictly observed.
 - 3.1.5.5.1. Wear hairband/hair pin to prevent hair fall.
 - 3.1.5.5.2. Remove earrings, watches, rings, necklace, bracelets ID badges.
 - 3.1.5.5.3. Secure eyeglasses by taping it to the bridge of the nose.
 - 3.1.5.6. Check all PPE for defects.
 - 3.1.5.7. Make sure that all staff who will use the N95 respirator had a documented fit test.
 - 3.1.5.8. Alert the Infection Control Committee for any untoward incidence or breach in the procedures.
 - 3.1.5.9. Always make sure the availability and sufficiency of all materials.
 - 3.1.5.10. Specimen collection and processing should be planned ahead of time and should be timed during non-peak hours in the laboratory.

3.1.5.11. BSC must be located a specified distance from lab doors, operable windows, supply diffusers, and other sources of air movement. : Any laboratory staff involved in manipulating, processing or testing of non-inactivated specimens should do so in a certified Biological Safety Cabinet Class II with enhanced precautions.

3.2. PRINCIPLE:

The i-STAT system incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable handheld analyser, a cartridge with the required tests and 100 ul of blood will allow the laboratory staff to view quantitative results for blood gas, chemistry and coagulation test in approximately 2 minutes.

4. SUPPLIES/MATERIALS/EQUIPMENT:

Biological Safety Cabinet (BSC) Class II – calibrated, certified
i-STAT machine (printer, cartridges, scanner)
Discard bag with stand
Pipettor – 200 ul
Pipet tips – long tipped, aerosol resistant tips, 100 ul or 200 ul
Sterilium or 0.05% sodium hypochlorite solution or 70% alcohol
0.5% Sodium hypochlorite
Specimens in transport container
Autoclave
Lab mat
Tube racks
Paper towel
Ice packs/Cold dogs
PPE
Rubber boots -
Cover-all – Kleen-GARD
N95 respirator
Gloves (preferably nitrile and surgical gloves)
Goggles
Apron
Hair net/Hair pin
Anti-fog spray
Shoe cover

5. DEFINITION OF TERMS AND ACRONYMS:

5.1. TECHNICAL TERMS:

- 5.1.1. Yellow top tube – tube without preservative but with serum separator
- 5.1.2. Violet top tube – tube with EDTA preservative
- 5.1.3. Green top tube – tube with sodium heparin preservative
- 5.1.4. Red top tube – plain tube
- 5.1.5. PPE Storage and Donning Area - this is an area outside the Ebola patient room (e.g., a nearby vacant patient room, a marked area in the hallway outside the patient room) where clean PPE is stored and where medical

technologist/nurse/safety officer can don PPE before entering the patient's room. This is a CLEAN AREA.

- 5.1.6. PPE Removal Area - this is an area in proximity to the patient's room (e.g., anteroom or adjacent vacant patient room that is separate from the clean area) where healthcare workers leaving the patient's room can doff and discard their PPE assisted and supervised by the safety officer (trained observer).

5.2. ACRONYMS:

- 5.2.1. PPE: Personal Protective Equipment
- 5.2.2. BSC : Biological Safety Cabinet
- 5.2.3. I-STAT:

6. RESPONSIBILITY:

- 6.1. The Head of the lab is aware of the process and provides the necessary resources to fully implement and maintain test quality.
- 6.2. The Laboratory Heads ensure that laboratory personnel performing this procedure are qualified, trained and proficient as evidenced in her certificate of attendance to the Ebola Training conducted by RITM.
- 6.3. The Laboratory heads are responsible for reviewing checklist of materials and case investigation forms, identifying possible errors, and taking corrective actions.
- 6.4. The medical technologist and his/her "buddy" (preferably a fellow medical technologist) ensure that procedures are followed accordingly and are responsible for the proper collection of blood specimens from suspected cases of EVD.
- 6.5. It is the role of the "buddy" to:
 - 6.5.1. Observe for and assist the staff in case of breach in infection control procedures.
 - 6.5.2. Make sure that infection control practices are observed at every step.
 - 6.5.3. Remind the person of the next step.
 - 6.5.4. Make sure no breach in protocol arises.
 - 6.5.5. Reports any breach in protocol.
- 6.6. The safety officer ensures that procedures are followed accordingly and is responsible for the proper donning and doffing of PPE of the medical technologist and the buddy. . Specifically, the tasks of the safety officer are the following:
 - help prepare the sample for transport
 - assist with putting on the personal protective equipment
 - informs the nurse-on-duty when the phlebotomist and his/her buddy are ready for blood extraction

7. REFERENCES:

- 7.1. **PRODUCT INSERT:** I-STAT System Manual Art, 714362-01P Revised Latest Ed. 24-Apr-2014.

8. PROCEDURE:

It is highly advisable that identified lab personnel in tandem shall do the testing.

Pre-analytic Phase (DONNING OF PPE Area)

1. Don PPE as described in the SOP for blood extraction.
2. Get the specimen in a transport container (in a Coleman with ice packs) from the ward.
3. Ensure the availability of materials.
4. Enter the laboratory testing area.

Analytic Phase (i-STAT analysis for blood chemistry)

5. Turn on the BSC Class II. Wait for at least 15 minutes before putting any materials in the BSC II.
6. Disinfect the materials before placing inside the BSC II with 0.5% sodium hypochlorite.
7. Operate the i-STAT machine.
 - 7.1. Press ON/OFF key.
 - 7.2. On the MENU page, Press 2 to select i-STAT cartridge.
 - 7.3. Press SCAN or manually enter the Operator ID then press ENTER key.
 - 7.4. Press SCAN or manually enter the Patient ID then press ENTER key.
 - 7.5. Press SCAN to enter cartridge lot number.
 - 7.6. Fill the sample well up to the blue marker with this blood tube sequence: Red tube for PT/INR, Green for Chem8
 - 7.6.1. Get the tube. Disinfect the tube with Sterilium.
 - 7.6.2. Gently mix the tube. Place in a tube rack.
 - 7.6.3. Open the cartridge.
 - 7.6.4. Open the tube.
 - 7.6.5. Aspirate about 100 uL of blood using a pipettor with long, aerosol-resistant tip.
 - 7.6.6. Fill the cartridge with 100 ul sample. Discard the tip.
 - 7.6.7. Close the snap closure.
 - 7.7. Insert filled cartridge into the cartridge port.
 - 7.8. Wait for a few minutes until results are displayed on the screen.
 - 7.9. Align the analyzer's infrared window to the Martel Printer then press the PRINT key.
 - 7.10. Press 1 to remove cartridge. Analyzer is ready for the next patient's sample.
 - 7.11. Discard the cartridge into the biohazard bag.
8. Disinfect the surface of the BSC II as well as all the materials and equipment inside with 0.5% sodium hypochlorite then 70% alcohol to prevent corrosion of BSC II.
9. Place the blood tubes inside the transport container and wait for the person in charge of packaging and transport of specimen to the Research Institute for Tropical Medicine, Special Pathogens Laboratory for further testing.
10. Place the discard bag in the autoclave.
11. Perform hand hygiene.
12. Exit the laboratory.

Post-analytic (Doffing of PPE Area)

13. Doff the PPE as described in ICC Guideline and Procedures of Doffing PPE.
14. Alert the laboratory staff in charge for the packaging and transport of specimens.

SOP: Packaging and transport of Ebola virus disease samples

1. OBJECTIVE:

This documents the proper packaging and transport as well as the shipping instructions for Ebola virus disease specimens.

2. SCOPE:

This work instruction describes the principles and procedures in transporting specimens from ward to hospital laboratory and from hospital laboratory to RITM. This also include detailed steps, biosafety considerations and responsibilities of staff concerned.

3. POLICY/PRINCIPLE:

3.1. POLICIES:

- 3.1.1.** The hospital laboratory is committed to provide quality and timely clinical laboratory services that satisfy the customers' requirements.
- 3.1.2.** The procedures will be performed in accordance with the patient's rights and institute policy on patient confidentiality and autonomy.
- 3.1.3.** Only qualified or trained personnel shall perform procedures in this process.
- 3.1.4.** Proper coordination with hospital authorities regarding the schedule of blood extraction and testing should be in place.

3.1.5. SAFETY PRECAUTIONS:

- 3.1.5.1.** All procedures will comply with RITM Laboratory Biosafety Manual guidelines and the Interim Guidelines on Specimen Collection, Packaging, and Transport for Ebola virus disease version 4.
- 3.1.5.2.** DO NOT ENTER THE PATIENT AREA IF YOU DO NOT HAVE ALL PROTECTIVE GEAR ON.
- 3.1.5.3.** Always have a buddy system (or in pairs) and a safety officer when performing the procedures.
- 3.1.5.4.** The responsibilities must be clear to all staff involved in the performance of the procedures.
- 3.1.5.5.** Proper grooming should be strictly observed.
 - 3.1.5.5.1.** Wear hairband/hair pin to prevent hair fall.
 - 3.1.5.5.2.** Remove earrings, watches, rings, necklace, bracelets ID badges.
 - 3.1.5.5.3.** Secure eyeglasses by taping it to the bridge of the nose.
- 3.1.5.6.** Check all PPE for defects.
- 3.1.5.7.** Make sure that all staff who will use the N95 respirator had a documented fit test.
- 3.1.5.8.** Alert the Infection Control Committee for any untoward incidence or breach in the procedures.
- 3.1.5.9.** Always make sure the availability and sufficiency of all materials.
- 3.1.5.10.** Specimen collection and processing should be planned ahead of time and should be timed during non-peak hours in the laboratory.
- 3.1.5.11.** BSC must be located a specified distance from lab doors, operable windows, supply diffusers, and other sources of air movement.

- 3.1.5.12.** Any laboratory staff involved in manipulating, processing or testing of non-inactivated specimens should do so in a certified Biological Safety Cabinet Class II with enhanced precautions.

3.2. PRINCIPLE:

Specimens collected for EVD testing should be packaged and shipped without attempting to open collection tubes or aliquot specimens. Specimens for shipment should be packaged following the basic triple packaging system:

Primary container (e.g. tubes – violet/green, blue and yellow top) wrapped with absorbent material;

Secondary receptacle (water tight, leak-proof, screw-capped container) and;

An outer shipment box (or Coleman, styrobox, improvised IATA-approved box).

4. SUPPLIES/MATERIALS/EQUIPMENT:

Biological Safety Cabinet (BSC) Class II

Centrifuge – swing bucket, with cover

Discard bag with stand

Sterilium or 0.5% sodium hypochlorite solution or 70% alcohol

0.5% Sodium hypochlorite

Specimens (violet, green, blue and yellow top tubes)

Cotton / any absorbent material e.g. paper towels

Autoclave

Lab mat

Tube racks

Paper towel

Parafilm

Ziplock bag – primary container together with the tube

Conical, plastic tube – secondary container

Transport box/container (Coleman, IATA-approved box, styrobox) – main/tertiary/outer container

Marker/pen -permanent

Scissors

Stickers (Infectious substance label,, This Side Up mark, Addressee, Shipper)

Ice packs/cold dogs

PPE

Rubber boots -

Cover-all – Kleen-GARD

N95 respirator

Gloves (preferably nitrile and surgical gloves)

Goggles

Apron

Hair net/Hair pin

Anti-fog spray

Shoe cover

5. DEFINITION OF TERMS AND ACRONYMS:

5.1. TECHNICAL TERMS:

5.1.1. Triple packaging system -

5.2. ACRONYMS:

5.2.1. PPE: Personal Protective Equipment

5.2.2. EVD: Ebola virus disease

5.2.3. BSC : Biological Safety Cabinet

5.2.4. IATA:

6. RESPONSIBILITY:

6.1. The Head of the lab is aware of the process and provides the necessary resources to fully implement and maintain test quality.

6.2. The Laboratory Heads ensure that laboratory personnel performing this procedure are qualified, trained and proficient as evidenced in her certificate of attendance to the Ebola Training conducted by RITM.

6.3. The Laboratory heads are responsible for reviewing checklist of materials and case investigation forms, identifying possible errors, and taking corrective actions.

6.4. The medical technologist and his/her "buddy" (preferably a fellow medical technologist) ensure that procedures are followed accordingly and are responsible for the proper collection of blood specimens from suspected cases of EVD.

6.5. It is the role of the "buddy" to:

6.5.1. Observe for and assist the staff in case of breach in infection control procedures.

6.5.2. Make sure that infection control practices are observed at every step.

6.5.3. Remind the person of the next step.

6.5.4. Make sure no breach in protocol arises.

6.5.5. Reports any breach in protocol.

6.6. The safety officer ensures that procedures are followed accordingly and is responsible for the proper donning and doffing of PPE of the medical technologist and the buddy. . Specifically, the tasks of the safety officer are the following:

- help prepare the sample for transport
- assist with putting on the personal protective equipment
- informs the nurse-on-duty when the phlebotomist and his/her buddy are ready for blood extraction

7. PROCEDURE:

It is highly advisable that trained med tech in tandem (buddy) shall do the packaging and transport of blood specimens from the ward to the laboratory and from laboratory to RITM Special Pathogens Laboratory.

Specimens should be stored in a refrigerator until being shipped for testing. Preferably, shipping must be done within 24 hours from time of collection.

FROM ANTEROOM IN THE WARD TO I-STAT ANALYSIS IN THE HOSPITAL CLINICAL LABORATORY

1. Don PPE as described in the SOP for Blood extraction(Donning of PPE).
2. Get the specimen in the sturdy, biohazard and properly labeled transport container from the ward.
3. Enter the laboratory testing area.
4. Test for i-STAT analysis (Refer to SOP on the Use of i-STAT for blood chemistry analysis).

FROM THE HOSPITAL CLINICAL LABORATORY TO THE RITM SPECIAL PATHOGENS LABORATORY
Pre-analytic Phase

1. Contact the DOH-commissioned transporting company/courier to either pick-up shipment or inform them that you will bring the shipment to them. Inform the transporting company if short delivery times are required due to refrigeration.
2. Get the Case Investigation/Request Form from the ward. Place in a ziplock bag or plastic bag which is sealed with tape. Place and secure on top of the shipment/transport box with tape.
3. If several patients have to be sampled in the same place or during the same investigation, create a line list. One patient per line. The list should include: patient name, sex, age (birthdate), clinical information: date of onset, date specimen was collected.
4. Print all the necessary labels and paste on the transport box/container.

IF using a Coleman/Styrobox

4.1. Shipment Addressee:

DR. FE EZPERANZA J.ESPINO
 Chief, Laboratory Research Division
 Research Institute for Tropical Medicine
 Fillinvest Corporate City Compound,
 Alabang, Muntinlupa City Tel# (02) 992-1887

4.2. Name of sending hospital/Shipper's name:

NAME OF RESPONSIBLE PERSON
 Position
 Hospital
 Hospital Address:
 Contact numbers:

IF using an improvised box:

4.3. Shipment Addressee:

DR. FE EZPERANZA J.ESPINO
 Officer-in-Charge, Laboratory Research Division
 Research Institute for Tropical Medicine
 Fillinvest Corporate City Compound,
 Alabang, Muntinlupa City Tel# (02) 992-1887

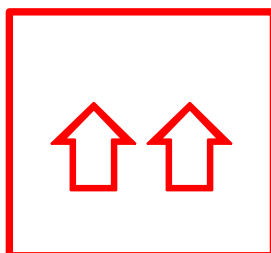
4.4. Name of sending hospital:

NAME OF RESPONSIBLE PERSON
 Position
 Hospital
 Hospital Address:
 Contact numbers:

4.5. Infectious Substance label:



4.6. This Side Up mark:



5. Pre-label the ziplock bag, conical tube and the box to be use for shipment. Use a permanent marker that can withstand cleaning with disinfectant like 0.5% sodium hypochlorite, Sterilium or 70% alcohol.
6. Don PPE as described in the ICC Guideline and Procedure of donning PPE.
7. Enter the laboratory together with the pre-labeled materials.

Analytic Phase

8. Ensure the availability of materials.
9. Turn on the BSC Class II. Wait for at least 15 minutes before putting any materials in the BSC II.
10. Disinfect the materials before placing inside the BSC II with 0.5% sodium hypochlorite.
11. Assemble materials in the BSC II.
12. Get the blood tubes placed in a conical tube and disinfect the exterior of the conical tubes with 0.5% sodium hypochlorite.
13. Wrap the conical tubes with parafilm.
14. Place in a tube rack.
15. Centrifuge the yellow tube at 3000 rpm for 10 minutes to separate the serum.
NOTE: Secure the tube cover with parafilm during the centrifugation process to prevent accidental spillage. Do not uncover the tube once the centrifugation is done.
16. Prepare blood sample tubes for transport.
 - 16.1. Pack each blood tube in the following sequence:
 - 16.1.1. Plain or yellow top tube – already centrifuged;
 - 16.1.2. Sodium heparin or green top tube
 - 16.1.3. EDTA or violet top tube
 - 16.2. Seal each conical tube with parafilm/sealing tape.
 - 16.3. Wrap each conical tube with cotton or any absorbent material.
 - 16.4. Place in a pre-labelled ziplock bag. Close the ziplock bag ensuring that no air is inside so that it can be folded.
 - 16.5. Once completed, disinfect the conical tube with 0.5% sodium hypochlorite.
17. Place all specimens in a transport container..
 - 17.1. Place at least 6-8 frozen ice packs inside the shipment box to maintain the reverse cold chain.
 - 17.2. Put the frozen ice packs in first, at the bottom and sides of the box.
 - 17.3. Place the conical tubes in the main receptacle. Close the receptacle.
 - 17.4. Place the receptacle in the middle of the transport box/container so that it is surrounded by the ice packs.
 - 17.5. Ensure that the receptacle is placed stationary by putting paper towels in the hollow space.
 - 17.6. Place the last ice pack on top of the receptacle.
 - 17.7. Cover the transport box/container.

NOTE: It is advisable that specimens should be transported within the day of collection or within 24 hours for laboratory investigation and prompt public health response.

18. Call the courier again.
19. Obtain shipping and tracking receipt from the courier.
20. Inform RITM Surveillance Unit of the shipment. Call (02) 994—1887. If possible, scan and email the tracking receipt and email to ritmsu@gmail.com .

Post-analytic

Doff PPE as described in the ICC Guideline and Procedure of doffing PPE.

Exit the laboratory

ANNEX

PREPARATION OF 5% SODIUM HYPOCHLORITE

Weight 5 g dry NaClO and add it to about 90 mL water, dissolve completely and fill up till 100 mL exactly: then you've got a 5 g/100 mL solution.

PREPARATION OF 0.5% SODIUM HYPOCHLORITE

Add 10 ml of 5% Sodium hypochlorite solution (Step 1) to 90 ml water. Mix gently by swirling.

PREPARATION OF 0.05% SODIUM HYPOCHLORITE

Add 10 ml of 0.5% Sodium hypochlorite solution (Step 2) to 90 ml water. Mix gently by swirling.