
SPECIMEN MANAGEMENT: Collection, Packaging and Transport of EVD Specimens

OUTLINE

- Introduction
- Specimen collection
 - Guidelines
 - Timing of Collection and Appropriate specimen
 - Best practices
- Specimen packaging
 - Guidelines
 - Best practices
- Specimen transport
 - Guidelines
 - Procedure
- Transmittal of results

Ebola virus disease (EVD)

- viral hemorrhagic fever and one of the most virulent viral diseases known to humankind
- Case fatality rate – 50%-60%
- Incubation Period: 2-21 days
- Transmission: direct contact
- Virus is detected in BLOOD after 3 days from onset of symptoms

To minimize the risks...

- Facility/Physical layout of the lab
- Proper PPE

PROPER SPECIMEN HANDLING

Specimen management

Hospital Ward	Sending Laboratory	Reference Lab (RITM)
<ul style="list-style-type: none">• Specimen collection• Specimen testing (POC)	<ul style="list-style-type: none">• Specimen processing• Specimen Packaging	<ul style="list-style-type: none">• Transport• Specimen testing• Storage• Transmittal of results

Interim Guidelines



Department of Health
Research Institute for Tropical Medicine
National Reference Laboratories for Emerging Infectious Diseases
Filinvest Corporate City, Alabang, Muntinlupa City 1781



INTERIM GUIDELINES FOR SPECIMEN COLLECTION, PACKAGING AND TRANSPORT FOR CONFIRMATORY TESTING OF EBOLA VIRUS DISEASE (EVD)

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BACKGROUND

Ebola virus disease (EVD) is a viral hemorrhagic fever and one of the most virulent viral diseases known to humankind. The current EVD outbreaks in affected countries in West Africa have a case fatality rate of 50%-60%. The virus is transmitted to people from wild animals and spreads in the human population through person-to-person transmission. Person-to-person transmission by means of direct contact with infected persons or their body fluids/secretions is considered the principal mode of transmission. The patient becomes contagious once they begin to show symptoms. The incubation period ranges from 2 days-21 days.

Laboratory confirmation is needed to classify a patient as a confirmed case of Ebola Virus Disease (EVD) to initiate appropriate clinical management and epidemiological investigations. The Research Institute for Tropical Medicine (RITM), the National Reference Laboratory for Emerging and Re-emerging Infections, performs WHO-recommended methods of molecular detection by polymerase chain reaction (PCR) and Enzyme-linked

GENERAL GUIDELINES

- All hospital staff responsible for collecting, processing and routine testing of specimens should be aware of and trained in appropriate biosafety and infection control guidelines in order to minimize the risk of infection with EVD.
- **Any facility that is not capable of handling these cases must refer to the nearest capable regional referral hospital and medical center.**

GENERAL GUIDELINES

Must identify these areas:

- **PPE Storage and Donning Area** - an area outside the Ebola patient room (e.g. nearby vacant room; where healthcare workers can don PPE. This is a CLEAN AREA.
- **Hot zone or Patient Room** - Any item or healthcare worker exiting this room is considered contaminated.
- **PPE Removal Area** - an area near the patient's room (e.g., anteroom that is separate from the clean area) where healthcare workers can doff PPE assisted by the safety officer.

GENERAL GUIDELINES

Must have a “buddy system” and safety officer:

Medical technologist

- phlebotomist, ensures proper packaging and transport of specimens

“Buddy”/Partner –

- assist the staff in case of breach in infection control procedures
- make sure that infection control practices are observed at every step
- remind the person of the next step
- make sure no breach in protocol arises
- reports any breach in protocol.

Safety Officer – trained observer

- ensures that procedures are followed accordingly
- helps prepare the sample for transport
- assists with putting on the personal protective equipment
- informs the nurse-on-duty when the phlebotomist and his/her buddy are ready for blood extraction

GENERAL GUIDELINES

- DO NOT ENTER THE PATIENT AREA IF YOU DO NOT HAVE ALL PROTECTIVE GEAR ON.
- Proper grooming should be strictly observed.
 - Wear hairband/hair pin to prevent hair fall.
 - Remove earrings, watches, rings, necklace, bracelets ID badges.
 - Secure eyeglasses by taping it to the bridge of the nose.
- All staff who will use the N95 respirator should have had a documented fit test.
- Alert the Infection Control Committee for any untoward incidence or breach in the procedures (NEEDLEPRICK)
- Ensure the availability and sufficiency of all materials.

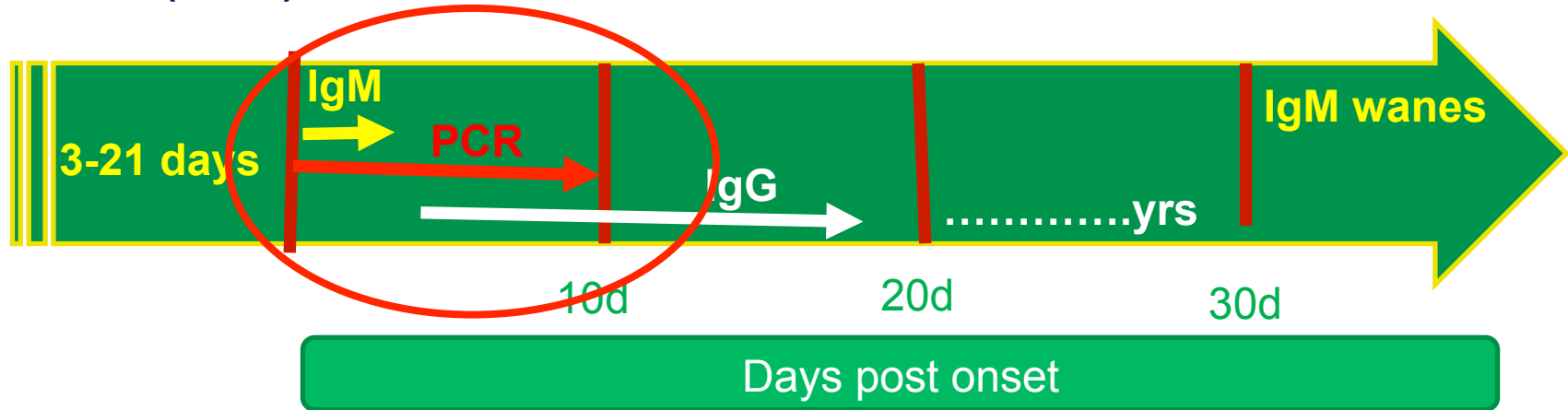
GENERAL GUIDELINES

- **Check all PPE for completeness and defects.**
- Rubber boots – leak-proof, knee-high, correct size
- Cover-all – disposable, impermeable
- N95 respirator
- Gloves - (inner gloves – nitrile
(outer gloves - high-cuff, surgical)
- Goggles – anti-fog
- Apron – single used, impermeable
- Shoe/Foot cover - disposable
- Hair net/Hair pin/Head band
- Anti-fog spray
- **No skin should be exposed!**

SPECIMEN COLLECTION

TIMING OF COLLECTION

Onset (fever)



- Should be taken when a symptomatic patient reports to a healthcare facility and is suspected of having an EVD exposure

Guidelines

- Specimen collection and processing should be planned ahead of time and should be timed during non-peak hours in the laboratory.
- Hospital infection control officers must be informed **BEFORE** the collection of specimens from EVD suspects for routine diagnostic testing in the point-of-care laboratory.
- Ensure that all laboratory staff are trained in routine good laboratory practices, including biosafety.
- Specimens should only be obtained by trained staff.

Best practices

- Do not use glass specimen collection devices/containers.
- Assemble all equipment for blood collection and preventing infections BEFORE entering the patient's room.
- Pre-label tubes prior to the collection of patient specimens – use permanent marker, should be clear and legible
(name, sex, age, date of collection)
- All used needles should be discarded into leak-proof and puncture resistant sharps containers.

Blood extraction

- Collect at least 2ml of blood/tube
 - 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)
- Timing:
 - OPTIMALLY, w/in 10 days from onset of symptoms, collect as soon as possible
- Storage: keep refrigerated until transport to RITM
- Container: plastic, conical tube, puncture-resistant, screw-capped, water-tight

Best Practices

- DISPOSE EVERYTHING IN PUNCTURE-PROOF CONTAINERS
 - Phlebotomy materials (tourniquet, syringes, cotton swabs, vacutainer adapter)
- Do not recap needles.

SPECIMEN PACKAGING

Guidelines

- Responsibility of the sending laboratory
 - proper disinfection of specimen containers
 - packaging of specimens
 - assuring that specimens reaches RITM in good condition
- Observance to the **basic triple packaging system**
 - Primary sample container
 - (e.g., violet top and red top/yellow top tube) wrapped with absorbent material (e.g., cotton) and placed in separate resealable plastic bags
 - Secondary receptacle (watertight, leak-proof container);
 - An outer shipment box

Packaging

- Important:
 - a. Keep infectivity and viability of specimens
 - b. Prevent other persons, community and environment from being infected
- Secure conical tubes with adhesive tape or parafilm to prevent from unscrewing
- Wrap in absorbent material (cotton or tissue paper) to absorb any leakage or spillage
- Place specimens in main receptacle.

Specimen manipulation

- All packaging of specimens to be shipped to RITM for confirmatory testing of EVD should be done inside a **Biosafety Cabinet Type II** with the staff wearing the appropriate PPE.

Packaging material

If the ideal packaging material is not available, use an alternative method provided that the specimen is triple packaged and the outermost container bears the appropriate signages:

Infectious Substance Label

(Category A:EVD)

Shipper Identification

NAME OF RESPONSIBLE PERSON

Position

Hospital

Hospital Address:

Contact numbers:

Orientation

Receiver or consignee identification

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Filinvest Corporate City Compound,

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--“3 packaging system inside.”

FROM THE HOSP. CLINICAL LAB TO THE RITM SPECIAL
PATHOGENS LABORATORY

SPECIMEN TRANSPORT

Guidelines/Conditions

- Routine arrangements
 - Coordination with the courier, RITM SU, and the RESU
- **Accompanying Forms**

The filled up EVD CIF and RITM Official Laboratory Request Form for Special Diagnostic Tests shall be placed in a separate zip-locked plastic bag which is sealed and secured on top of the outer shipment box with tape.
- Must arrive at RITM not later than 48 hours after collection

Transport

- Transport in reverse cold chain (5-8 °C)
- At least six (6) frozen ice packs inside the shipment box.
- Put the frozen ice packs in first, at the bottom and at the sides of the carrier box; then place the secondary container (containing the primary sample tubes) at the middle so that they are surrounded by the ice packs.
- Use insulated, water-tight specimen carriers

For EVD testing, address to...

DR. FE ESPERANZA J. ESPINO
Chief, Laboratory Research Division
Research Institute for Tropical Medicine
Filinvest Corporate City, Alabang,
Muntinlupa City

NOTE: For safety considerations of the RITM staff handling the shipments, PLEASE DO NOT mix specimens for Ebola testing with other specimens to be received by other laboratories.

Transmittal of Results

- The Director's Office of RITM
 - FAXING the results to the requesting RESU/physician
- RITM Surveillance Unit
 - sends the results to the requesting RESU/physician, to NEC and HEMS-OPCEN by E-MAIL.

As an institutional policy, RITM does not release Official Results by phone.

Practice FEEDFORWARD-FEEDBACK mechanism

- **Storage of Clinical Samples**

- Clinical samples for EVD testing shall be stored at RITM. All boxes/containers used for specimen transport will be decontaminated and disposed of by RITM as infectious waste.

- **Contact Information**



- The RITM-SU can be reached at telephone number [\(02\)994-1887](tel:(02)994-1887) and ritmsu@gmail.com