GUIDELINES FOR COLLECTION, PACKAGING AND TRANSPORT OF SPECIMENS FOR TESTING FOR HIGH RISK VIRAL PATHOGENS
ICMR-NATIONAL INSTITUTE OF VIROLOGY
PUNE 411021, MAHARASHTRA

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1. **Purpose:** This document describes the processes for collection, packaging and transport of clinical specimens to Maximum Containment (Biosafety Level 4) laboratory of the ICMR-National Institute of Virology (NIV), Pune for diagnosis of high risk viral pathogens affecting humans.

2. **Scope:** This document is intended for use by clinicians/laboratories planning to collect, pack and transport clinical specimens from patients suspected to have high risk viral pathogens.

3. **Responsibilities:**
   - The clinician, based on the clinical presentation of the patient and associated epidemiological factors, shall decide the necessity for laboratory testing and the type(s) of specimen to be collected for high risk pathogen infection.
   - A physician, trained nurse or medical laboratory technologist would be responsible for collecting the right type of specimen as per standard protocols and test requirements.
   - A trained medical laboratory technical staff or another staff member supervised by a clinical microbiologist/scientist/laboratory supervisor shall perform the standard triple packaging of the specimens and make arrangements for their safe and prompt shipment to the testing laboratory.
   - All documentation related to the sample collection, packing and transportation should be checked and signed by the laboratory supervisor and the head of the laboratory.

4. **Laboratories authorized for testing for high risk viral pathogens in India:** The Ministry of Health & Family Welfare, Govt. of India has designated the following entity as the apex laboratory for testing for high risk viral pathogens affecting humans, in India:

Primary contact person:

a. **Dr. Pragya D. Yadav**, Scientist-'F' & Group Leader,
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ICMR-NIV, Microbial Containment Complex,
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Tel: Office: 020-26006111;
Email id: hellopragya22@gmail.com

Secondary contact person:

a. **Dr. Rima R. Sahay,** Scientist 'C',
Maximum Containment Facility,
ICMR-NIV, Microbial Containment Complex,
130/1, Sus Road, Pashan, Pune-411021.
Tel: Office: 020-26006160;
Email id: dr.rima.sahay@gmail.com

5. Routing of samples

All samples intended for laboratory testing for high risk viral pathogens should be forwarded through the head of the department/institute and the State Surveillance Officer.

6. Preparations for sample collection

- Prior to collecting the clinical specimen, the technologist should verify the identity of the patient and the type and volume of sample to be collected.
- The individual collecting the clinical specimen must wear a full set of recommended personal protective equipment (PPE) including a laboratory gown, two pairs of gloves, goggles, N95 mask, and booties.
- All necessary instruments and supplies required for sample collection should be assembled prior to starting the work. These include spirit swabs, tourniquet, and syringes with needles/vacutainers/butterfly needles, serum collection tubes/gel separator tubes, tube racks, labels, sample storage boxes, sterile swabs with viral transport medium, screw-capped vials/urine collection cups, etc.
- Screw-capped, sturdy, leak-proof, polypropylene tubes of reliable quality and preferably with an O-ring cap, should be used to collect the samples.
- The used syringes and needles should be discarded into a sharps container, and precautions must be taken against needle-stick injuries.
- The sample vials should carry clear labels specifying the patient's name, age, gender, hospital ID and date and time of sample collection.

7. Types of samples to be collected

- Blood, throat swab, urine and cerebrospinal fluid (CSF) samples should be collected from the affected individuals. Where available, autopsy tissue specimens should also be forwarded.
- At least 5 mL of whole blood should be collected in a plain tube.
- Throat swabs should be collected and transported in Viral Transport Medium (VTM) in a sterile, screw-capped polypropylene tube.
- About 10-20 ml of urine samples should be collected in to a sterile, screw-capped, leak-proof and sturdy container.
- About 2-3 ml of CSF specimens should be collected by lumbar puncture into a sterile tube, and The CSF specimen should not be frozen.
- Samples for PCR testing should preferably be sent in dry ice, or at -20°C, using hard-frozen gel packs.
- Tissue biopsy specimens, if available, should be transported in a screw-capped, leak-proof container with a small volume of Viral Transport Medium, preferably in dry ice or at -20°C.
- Where feasible, the blood, throat swab and urine samples of the patient contacts/caregivers should also be forwarded for testing.

8. Packing of specimens

a. Sample has to be packed following the principles of the standard triple packaging system.

b. **Primary container**: Screw-capped vials to be used for sending serum/CSF. Vials should be labeled with the sample number and test required. Keep the vials in upright position.

c. **Secondary Container**: A leak-proof plastic container (e.g., zip-lock bag, 50 mL centrifuge tube or other similar containers) can be used to place the primary vials. Plastic pouches, if used, should be heat-sealed or tightly closed by applying rubber bands. There should be enough absorbent material (paper napkins/old newspaper) packed around the vials to absorb all fluid in case of breakage or leakage. More than one vial can be placed in secondary container.

d. **Outer Container**: If a plastic pouch was used as a secondary container, it can now be placed inside a separate plastic container and adhesive tape should be applied around the lid of the container. This container can be placed in another plastic pouch and sealed with rubber bands before placing it in the outer container. A Thermocol box or vaccine carrier containing ice/gel packs could be used as the outer container. [The smallest overall external dimension of the outer container shall be 10 x 10 x 10 cm.]

e. Before despatching the outer container, Bleach can be used for surface disinfection. A 1:100 dilution of bleach or 5% Lysol solution should be used to clean the outer surfaces of the container.

f. The complete Case Report Form carrying all requisite information should be placed inside a sealed plastic cover on the outer container.

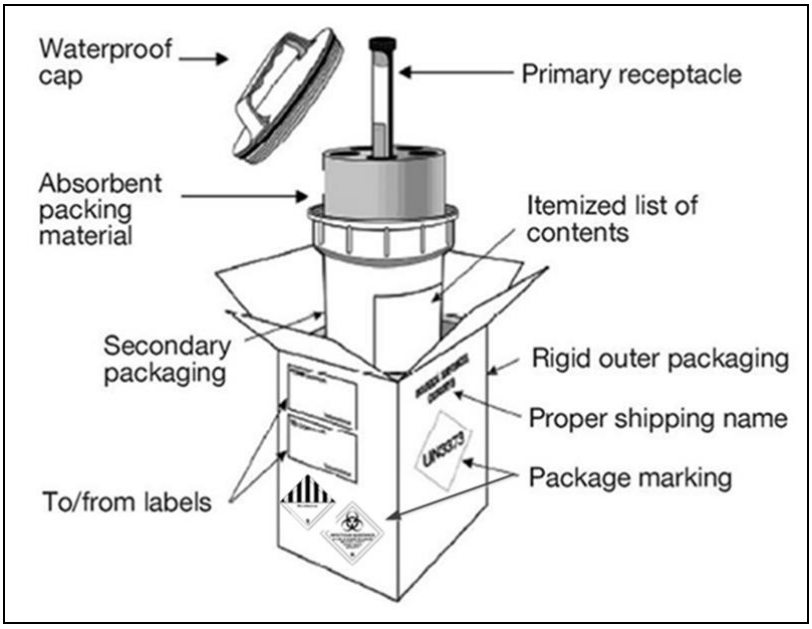
g. Label the outer container as follows:
    - The sender's name, address and telephone number
    - The receiver's name, address and telephone number
    - "BIOLOGICAL SUBSTANCE, CATEGORY B"
    - Whom to contact in an emergency, with telephone number

9. Documents required:

- Patients history sheet to be part of document
- To be prepared and signed by the sender: A packing list/proforma invoice that includes the sender's and the receiver's address, the number of packages, details of contents, weight, value
- To be prepared by the sender or the shipper's agent: An air waybill for air transport or weight, value equivalent documents for road, rail and sea journeys.

Sample packing and transport is to be done as per **WHO Guidance on regulations for the Transport of Infectious Substances 2013–2014.**

A diagrammatic representation of the Standard Triple Packaging is given below:



Before dispatching the samples, the outer container may be wiped using 1:100 diluted bleach or 5% Lysol solution.

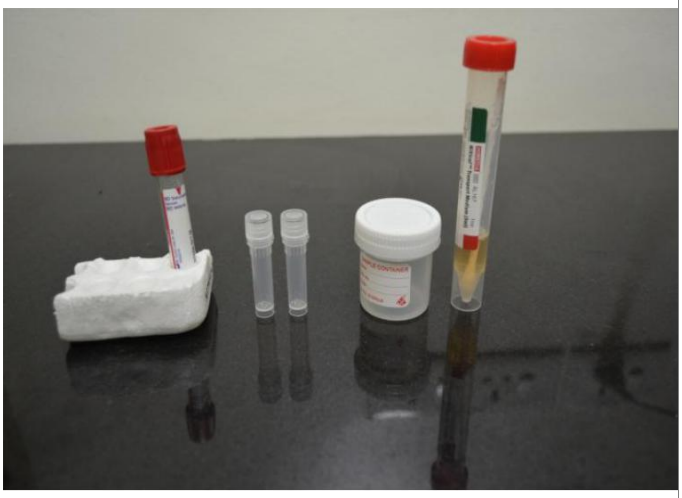
Upon completion of sample packing, the personnel should perform thorough handwashing.

10. Shipment of samples

- The samples should be shipped only after prior intimation to the referral laboratory.
- The ICMR-NIV can assist in sample shipment from difficult locations, and the laboratories can contact the above persons.

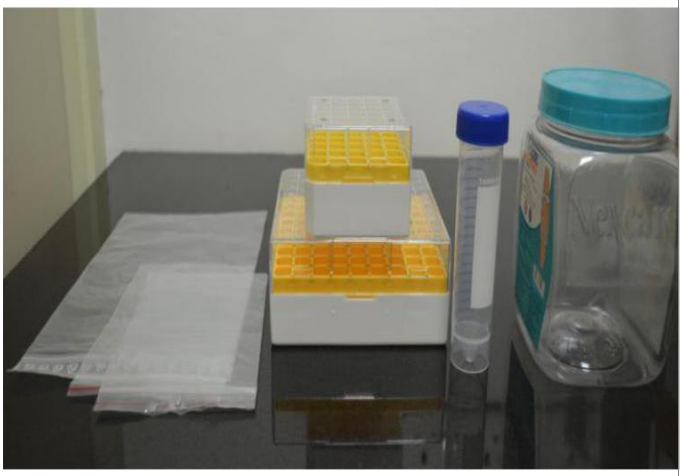
ASSEMBLING THE ITEMS REQUIRED FOR CLINICAL SAMPLE PACKAGING AND TRANSPORT

1. Appropriate sample vials



2. Absorbent material and other accessories

A leak-proof, sturdy, secondary container (e.g., ziplock pouch, cryobox, 50 mL centrifuge tube, plastic container)

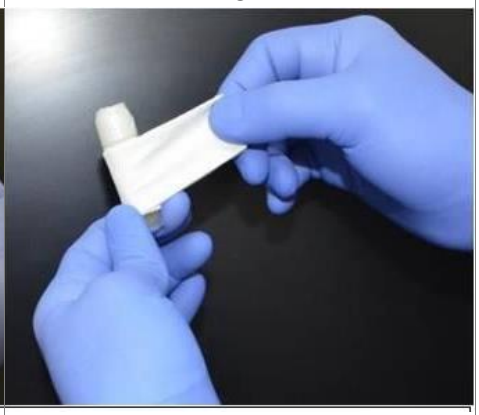


4. Hard-frozen Gel Packs

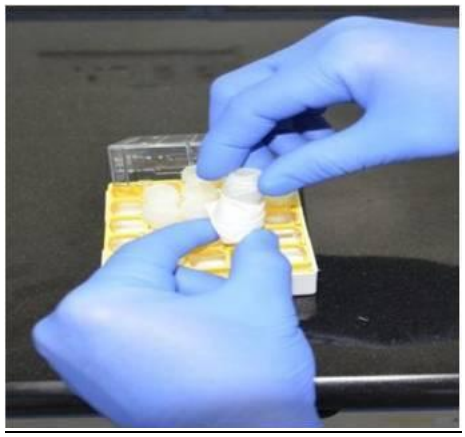
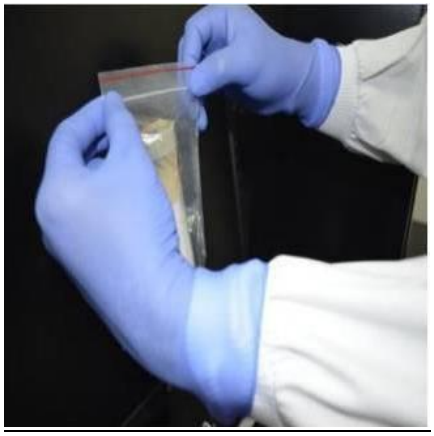
5. A suitable outer container (e.g., thermocol box, ice-box, hard-board box) (minimum dimensions: 10 x 10 x 10 cm)

INSTRUCTIONS ON SAMPLE PACKAGING AND TRANSPORT

STEP 1: ARRANGING THE SAMPLE VIALS

A	*B*	*C*
		
Wear full set of Personal Protective Equipment and identify the labelled sample tubes.	**Seal the neck of the sample vials using parafilm to prevent leakage during transit.**	**Cover the sample vials using absorbent material to contain leakage, in the event of a breakage.**

STEP 2: ARRANGING THE PRIMARY VIALS WITHIN A STURDY, LEAK-PROOF SECONDARY CONTAINER

A	*B*
	
<u>Option 1</u>: Using a cryo-box as a secondary container. (Seal the lid of the box after arranging the samples, using cello.)	**<u>Option 2</u>: Using a 50-mL centrifuge tube as a secondary container. (Seal the neck of the tube using cello.)**
C	***D***
	
Placing the centrifuge tube inside a zip-lock pouch	**Placing the zip-lock pouch inside a sturdy plastic container. (Seal the neck of the container using cello.)**

[Note: Sample vials can also be placed inside a zip-lock pouch, covered in absorbent material and secured by heat-sealing or rubber bands. Then, the zip-lock pouch should be placed inside another plastic pouch and secured.]

STEP 3: ARRANGING THE OUTER CONTAINER

<table>
<tr>
<td>A
 
Option 1:
Using a thermocol box as an outer container and placing the secondary container within it, surrounded by hard-frozen gel packs</td>
<td>B
 
Option 2:
Using a hard-board box as an outer container and placing the secondary container and the gel packs</td>
<td>C
 
Placing the completed Case Report Form/Request Form inside a leak-proof, zip-lock pouch</td>
</tr>
<tr>
<td>D
 
Securing the zip-lock pouch with the Case Report Form on the outer container</td>
<td>E
 
Attaching the labels:
• Sender’s Address and contact number;
• Consignee’s Address and contact number;
• Emergency Contact’s name and number;
• ‘Biological Substance-Category B’;
• ‘UN 3373’; Orientation Label;</td>
<td><u>Documents to accompany:</u>
1) Packing list/Proforma Invoice
2) Air way bill (for air transport) (to be prepared by sender or shipper)
3) Value equivalence document (for road/rail/sea transport)</td>
</tr>
</table>

Note:

1. **A vaccine-carrier/ice-box can also be used as an outer container**
2. **The minimum dimensions of the outer container should be 10 x 10 x 10 cm (length x width x height)**