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|  | Arth Diagnostics | Doc No: ADPL-OUTS&T |
| | | Ref Std NABH, NABL, ISO15189:2012 |
| | Outsourced Sample Transportation Packing | Issue Date: 01.10.2021 |
| | | Rev. No.: 02 Rev. Date: 15.10.2021 Page 1 of 10 |

Outsourced Sample Transportation Packing

of

Arth Diagnostics Private Limited

ADPL – QM

COPY No. 01(Master copy)

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ISSUE No. II

ISSUE DATE 01.10.2021

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The holder of the copy of this Manual shall ensure to maintain it in current status by inserting latest amendments as and when the amended versions are received.

Quality Manager is responsible for issuing the amended copies to the copyholders, the copyholder should acknowledge the same and he /she should return the obsolete copies to the Quality Manager.

The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.

The manual is reviewed once a year and is updated as relevant to the laboratory's policies and procedures. Review and amendment can happen also as corrective actions to the non-conformities raised during the audits and evaluations.

The authority over control of this manual is as follows:

| Preparation | Approval | Issue |
|-----------------|---------------------|-----------------|
| Quality Manager | Laboratory Director | Quality Manager |


The manual with original signatures of the above on the title page is considered as 'Master Copy', and the photocopies of the master copy for the distribution are considered as 'Controlled Copy'.

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AMENDMENT SHEET

| S N o | Document Details | Amendment Date | Details of Amendments | Reason | Issue No. | Appr By |
|-------------|------------------|----------------|-------------------------|--------|-----------|----------|
| 01 | ADPL-RSM | 01/01/2021 | Reviewed no change done | - | I | Lab Dir. |
| 02 | ADPL-RSM | 10/01/2021 | Reviewed no change done | - | II | Lab Dir. |
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1. Purpose: This document describes the processes for collection, packaging and transport of clinical specimens.

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. Routing of samples

All samples intended for laboratory testing for high risk viral pathogens should be forwarded through the outsourcing department.

5. 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 and mask.
- Screw-capped, sturdy, leak-proof, polypropylene tubes of reliable quality.
- The sample vials should carry clear labels specifying the barcode and time of sample collection.

6. Types of samples to be collected

- Blood, throat swab, urine and cerebrospinal fluid (CSF) samples should be collected from the affected individuals.
- Atleast 5mL 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 10-20ml of urine samples should be collected into 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.
- Tissue biopsy specimens, if available, should be transported in a screw-capped,

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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.

7. 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 by barcode and request form for 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, 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 10x 10 x 10 cm.]
- e. Before dispatching the outer container is clean by disinfectant spray.
- 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
- With telephone number

7. 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.

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 hand washing.

8. Shipment of samples

- The samples should be shipped only after prior intimation to the referral laboratory online.

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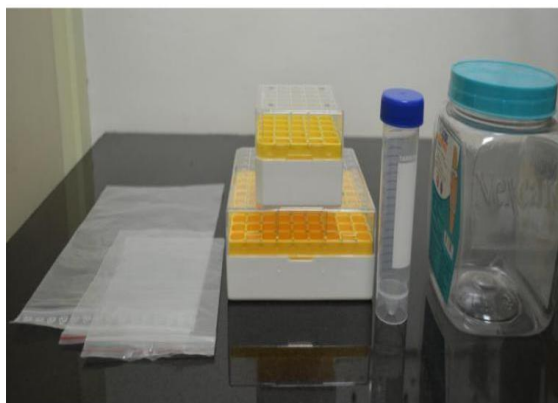
1.Appropriate sample vials



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.,thermocool box,ice-box,hard-boardbox)
(minimum dimensions: 10 x 10 x 10 cm)**






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INSTRUCTIONSON SAMPLE PACKAGING AND TRANSPORT

STEP1:ARRANGING THE SAMPLE VIALS

| A | B | C |
|---|---|---|
|  |  |  |
| <p>Wear full set of Personal Protective Equipment and identify the labeled Sample tubes.</p> | <p>Seal the neck of the sample vials using TAPE to prevent leakage during transit.</p> | <p>Cover the sample vials using Absorbent material to contain leakage, In the event of a breakage.</p> |


STEP2: ARRANGING THE PRIMARY VIALS WITH IN ASTURDY,LEAK-PROOF SECONDARY CONTAINER

| A | B |
|---|---|
|  |  |
| <p>Option1: Using a cryo-box as a secondary container. (Seal the lid of the box after arranging the samples, using cello.)</p> | <p>Option2: Using a 50-mL centrifuge tube as a secondary container. (Seal the neck of the tube using cello.)</p> |
| C | D |
|  |  |
| <p>Placing the centrifuge tube inside a zip-lock pouch</p> | <p>Placing the zip-lock pouch inside a sturdy plastic container. (Seal the neck of the container using cello.)</p> |


[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.]

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STEP3:ARRANGING THE OUTER CONTAINER

| | | |
|---|--|--|
| <p style="text-align: center;">A</p>  <p style="text-align: center;">Option 1:</p> <p>Using a thermocol box as an outer container and placing the secondary container within it, surrounded by hard-frozen gel packs</p> | <p style="text-align: center;">B</p>  <p style="text-align: center;">Option 2:</p> <p>Using a hard-board box as an outer container and placing the secondary container and the gel packs</p> | <p style="text-align: center;">C</p>  <p style="text-align: center;">Placing the completed Case Report Form/Request Form inside a leak-proof, zip-lock pouch</p> |
| <p style="text-align: center;">D</p>  <p style="text-align: center;">Securing the zip-lock pouch with the Case Report For the outer container</p> | <p style="text-align: center;">E</p>  <p style="text-align: center;">Attaching the labels:</p> <ul style="list-style-type: none"> • Sender's Address and contact number; • Consignee's Address and contact number; • Emergency Contact's name and number; • 'Biological Substance-CategoryB'; | <p style="text-align: center;">Documents to accompany:</p> <p style="text-align: center;">1) Perform a Invoice</p> |

Note:

1. A vaccine-carrier/ice-box can also be used as an outer container
2. The minimum dimension of the outer containers should be 10x10x10cm (length x width x height)

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