

	NATIONAL CENTRE FOR ANIMAL HEALTH LABORATORY SERVICES UNIT	Second edition
	STANDARD OPERATING PROCEDURE	Version 2018.1
	SAMPLE REFERRAL	

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**STANDARD OPERATING PROCEDURE
NATIONAL VETERINARY LABORATORY
NATIONAL CENTRE FOR ANIMAL HEALTH, SERBITHANG**

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Number: REF 01

Version: 2018.1

Print Date: 11 Mar. 19

TITLE: Sample Referral to National veterinary Laboratory

PREPARED BY: Laboratory Services Unit

REVISED BY: Laboratory Services Unit

APPROVED BY: Head, LSU

DATE: 11.06.2018

1. INTRODUCTION

In the field, diagnosis of diseases depends mainly on history and symptoms, but in many cases, symptoms exhibited by the ailing animals are confusing leading to inaccurate diagnosis. It is in such instances, field staff has to seek the help of the laboratory for the confirmation of the diagnosis or for the diagnosis itself. To a large extent, the success of the laboratory examination depends on the skill and the care, with which the clinician selects, collect, preserves and transports the specimens to the laboratory.

The general considerations for collecting laboratory materials for examination include:

- 1.1 The specimen from an animal in acute stage of disease is most desirable. If the disease poses a flock/herd problem, specimens should be collected from more than one affected animal.
- 1.2 Obtain the materials free from contamination as far as possible.
- 1.3 Collect the specimens before the treatment starts.
- 1.4 The specimen collected should be characteristic of the disease seen in the field.
- 1.5 Specify the source of the materials.
- 1.6 Include the details of post mortem findings, history, treatment and the tests requested along with the samples.

2. OBJECTIVES OF LABORATORY SAMPLE COLLECTION

Samples are to be collected and handled in a manner that will permit high recovery rate of the causative factors /agents. The main objectives of sample collection are as follows:

- 2.1 Sample collection is done for confirmatory diagnosis and it is highly essential to provide efficient treatment and effective control & preventive measures.
- 2.2 The sample collection from the field is done to carry out the surveillance or prevalence of economically important diseases like Rinderpest, Brucellosis, New Castle disease etc.
- 2.3 The sample collection is sometimes carried out to monitor the immune response of the vaccine following vaccination.
- 2.4 It is also done to monitor the health of reproductive animals.
- 2.5 It is also carried out during outbreaks for sero-typing of diseases like FMD.
- 2.6 Sample collection is also done regularly for endo-parasitic survey for different livestock and to subsequently reduce the expenditure on medication.

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3. GENERAL GUIDELINES FOR COLLECTION OF LABORATORY SAMPLES

- 3.1 All material collected should be accompanied with the full history of disease outbreak, number of animals affected, number of animal died, clinical signs, duration of the disease, species affected, age of the animal, disease suspected etc.
- 3.2 The materials from more than 10 ailing animals should be collected at the height of body temperature/clinical signs.
- 3.3 Collect the specimen before therapy.
- 3.4 When serological diagnosis is required, always send the paired serum samples of about 2ml each collected first at the time of the start of the disease and the other sample at the height of the disease (usually 2-3 weeks).
- 3.5 All biological specimens should be transported on ice to the laboratory. The preservatives need to be added if it takes long to reach the laboratory. Materials collected for bacteriological examination should not be kept at subzero temperature but for virus isolation these can be stored at -20°C to -80°C . For most of the diseases sample are stored at 4°C .
- 3.6 When death is recorded in the ailing animals, the post mortem examination should be conducted at the earliest before putrefaction sets in. Putrefied materials are unfit for laboratory examination.
- 3.7 Details post-mortem report should be dispatched with the specimen preserved in 10 % formalin. It is always desirable to collect tissue in sterile container, sealed and transported to the nearest laboratory. Small tissue pieces of 2 x 2 cm thick from organs showing the lesions are considered appropriate and fixation is done in 10% formalin for histopathological studies. The specimen bottles with wide mouth are always considered better for formalin fixed tissues. All specimen collected in bottle should be sealed and labelled clearly.
- 3.8 Take a wide selection of samples if you are not sure what specific disease you are dealing with. The specific guidelines for collection of relevant samples for specific diseases are given separately.
- 3.9 All samples must be labelled properly, including the animal identification number, type of sample, from where it was collected and the date of collection.

4. LABELLING OF SAMPLES

- 4.1 Each sample should be individually labelled, to include at least the following information:
- 4.2 Date of sample collection
- 4.3 Sample number, that can be linked to more detail that is included on the submission form, such as animal ID etc)
- 4.4 Type of tissue (eg epithelium, vesicular fluid, blood)
- 4.5 All labelling of the sample should be made in indelible ink

5. LABORATORY SUBMISSION FORM

The laboratory submission form should be completed accurately, and should include at least the following information:

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- 5.1 Date of sample collection and submission
 - 5.2 Location of the premises
 - 5.3 Diseases suspected and tests requested
 - 5.4 The species, breed, sex, age and identity (if available) of the animals sampled
 - 5.5 The vaccination status of the animals (if known)
 - 5.6 List of samples submitted with transport media used (if relevant)
 - 5.7 A complete history of the disease investigation
 - 5.8 All paper records should be placed in a sealed plastic sleeve to prevent wetting of paper documents

6. PACKAGING OF SAMPLES

Samples must be packed in a primary and secondary container so that the samples arrive in good condition and do not present any hazard to persons or animals during shipment. It is essential that the contents of containers, which break or leak during transit do not contaminate the outside layer of the package.

The recommended procedure for packing samples is as follows:

- 6.1 Samples must be put a primary container (glass or plastic tubes or bottles) with screw caps and wrapped with paraffin film or adhesive tape individually in order to prevent leakage of fluid. The wrapping of bottles or primary containers should be carried out in clean surroundings.
- 6.2 The primary container must be packed in watertight secondary packaging, which should be a strong crushproof and leak-proof metal container. The container should contain absorbent cotton wool sufficient to absorb the entire contents of the primary container.
- 6.3 The secondary packaging must be placed in an outer container. This should be a polystyrene foam box covered with a hard box or other appropriate container .
- 6.4 Sufficient information and a list of samples or materials should be enclosed in an envelope, enclosed in a plastic bag and placed between the secondary packaging and outer box.
- 6.5 It is recommended that a freezer box is put outside the secondary packaging to ensure that all materials are kept cool during shipment. These packs should be pre-frozen at -20 degrees centigrade before packaging.

7. TRANSPORT OF SAMPLES

The specimens should be forwarded to the laboratory by the fastest method available. If they can reach the

laboratory within 48 hours, samples should be sent refrigerated. If dry ice is used, the additional packaging

requirements must be met. Infectious substances, which can include diagnostic specimens, are not permitted to

be shipped as checked luggage or as carry on luggage and must be shipped as cargo.

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8. REFERENCES

OIE terrestrial manual 2008, Chapter 1.1.1 collection and shipment of diagnostic samples.

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Number: REF 02

Version:

Print Date: 11 Mar. 19

TITLE: Sample referral abroad (air transport)

PREPARED BY: LSU, Serbithang

REVISED BY: LSU, Serbithang

APPROVED BY: Dr RB Gurung, Head, LSU

DATE: June 12, 2018

1. INTRODUCTION

Laboratory diagnosis of disease is critical for quick response to management of disease outbreak and containment. The National Veterinary Laboratory, National Centre for Animal Health, Serbithang has wide range of diagnostic capacity for the diagnosis of livestock, poultry and wildlife diseases. However, there are certain tests that require high containment facility for the conduct of such test. Therefore, the NCAH on regular basis refer biological samples for advanced test such as molecular, isolation, sequencing and phylogenesis. Sample referral involves considerable amount of documentation, logistic arrangement and exploring receiving laboratories. Such arrangements are made to ensure smooth transition of consignment to destination, storage conditions, biosafety requirement and integrity of sample quality.

2. OBJECTIVE

This document is used to support the process of sample referral to destination or receiving laboratory.

3. APPARATUS

- 3.1 Sample shipment container
 - 3.1.1 Primary container
 - 3.1.2 Secondary container
 - 3.1.3 Outer packing
- 3.2 Ice pack
- 3.3 Thermal box
- 3.4 Dry ice (below 2 kg)
- 3.5 Packaging instruction
- 3.6 Cello-tape (transparent)
- 3.7 Document holder

4. REAGENTS, SOLUTION AND BUFFE

- 4.1 Samples
- 4.2 Buffer

5. PROCEDURE

- 5.1 Import letter from Institute

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- 5.2 Import permit or certificate from the receiving laboratory duly signed by competent authority of that country has to be obtained well in advance. The certificate has to clearly mention the willingness to receive consignment and test at their facility
- 5.3 Export letter from BAFRA
The shipping laboratory has to obtain export permit from competent authority of that country well in advance. While applying for export permit, the shipping laboratory has to mention in the letter all details of samples, number of samples, destination laboratory details, purpose of shipment and commercial value if any
- 5.4 Special permit
In addition to the above two documents the shipping laboratory has to obtain special permit for the referral of samples originating from Schedule I species of fauna and flora mentioned in the Forest and Nature Conservation Act of the Kingdom of Bhutan
- 5.5 Sample details
Once the above documents are obtained, the shipping laboratory has to pack samples in strict compliance to AITA regulation by observing all air transport safety rules. The sample packing has to comply triple packing system with all necessary signage on the outer packing.
- 5.6 Invoice of samples
The shipping laboratory has to prepare proforma invoice (PI) with details of samples (type, volume/quantity, commercial value). These information are required for custom clearance at the entry point of another country
- 5.7 Forward letter of sender
The shipping laboratory will prepare a forwarding letter addressed to the concerned officer at receiving laboratory stating that a consignment is being sent for laboratory diagnosis. The forwarding letter should accompany all other above documents. Three separate sets of these documents are required (shipping laboratory, receiving laboratory and accompanying consignment).
- 5.8 Sample referral control documents.
Refer sample referral document of the shipping laboratory for authorization of release of consignment (ANNEXURE)

6. RISK ASSESSMENT

- 6.1 Ensure proper packing to avoid leakage of samples
- 6.2 Ensure not to exceed dry ice weight 2 kg if the consignment is transported in passenger flight

7. TROUBLESHOOTING

- 7.1 Mismatch of sample details
- 7.2 Inappropriate of address

8. REFERENCES

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9. ANNEXURE

SAMPLE REFERRAL CONTROL DOCUMENT

**LABORATORY SERVICE UNIT
NATIONAL CENTRE FOR ANIMAL HEALTH, SERBITHANG
THIMPHU: BHUTAN**

SAMPLE REFERRAL NO: DATE:

A: REFERRING AND REFERRED AGENCIES

DETAILS OF REFERRING AGENCY

Name:

Address:

Telephone:

Fax No:

Email:

DETAILS OF AGENCY REFERRED TO

Name:

Address:

Telephone:

Fax No:

Email:

B: SAMPLE DETAILS

SI no	Sample type	Quantity	Test requested

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Attach separate sheet for additional details of sample

D: TO BE COMPLETED BY BIO-SAFETY OFFICER AND OFFICER PACKING THE SAMPLE (put tick mark)

1. Confirmed that the consignee address is correct
2. Confirmed that the samples packed are the intended samples
3. Confirmed that the samples are packed in compliance with shipment regulations

Name: Technician.....

Sign..... **Date**.....

Name: Bio-safety Officer (IATA certified staff)

Sign..... **Date**.....

E: TO BE VERIFIED BY SECTION HEAD (put tick mark)

1. Verified that consignee address is correct
2. Verified that samples packed are correct
3. Verified that the samples are packed in compliance with shipment regulation
4. Confirmed that EXPORT and IMPORT certificates are attested

Name: **Sign**..... **Date**.....

F; APPROVAL FOR SAMPLES TO LEAVE NCAH

Verified that information in section D and E are correct

Name:

Head LSU:**Sign** **Date:**

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Number: REF 03

Version: 2018.1

Print Date: 11 Mar. 19

TITLE: Sample Receipt and Handling of Samples

PREPARED BY: Laboratory Services Unit

REVISED BY: Laboratory Services Unit

APPROVED BY: Dr RB Gurung, Head, LSU

DATE: 11.06.2018

1. INTRODUCTION

All data must be recorded on laboratory request forms and samples assessed for quality and adequate volume for testing. If critical data is missing or a test cannot be performed because of insufficient quantity or unacceptable quality, additional information or samples must be obtained to assure all tests are performed. Samples must be stored according to guidelines prior to analysis to preserve sample integrity and afterwards should additional or repeat testing be required. Non-archived samples must be treated as infectious waste and autoclaved prior to discarding.

2. OBJECTIVES OF LABORATORY SAMPLE COLLECTION

This standard operating procedure (SOP) describes the steps for the receipt of laboratory samples for processing, assessing acceptability, rejection criteria, pre and post analysis storage and distribution of samples to other laboratories for testing or archiving (freezing).

3. SCOPE

This SOP applies to the receipt and handling of specimens for all laboratory personnel who have been trained and are competent in the receipt, handling and distribution of specimens for laboratory tests.

4. RESPONSIBILITY

All laboratory personnel who have been trained and are competent in the receipt, handling and distribution of specimens for laboratory tests.

5. STANDARD PRECAUTIONS

Wear gloves when handling participant specimens to protect from exposure to blood borne pathogens.

6. SPECIMEN RECEIPT PROCEDURES

All laboratory personnel who have been trained and are competent in receiving, storing and redirecting specimens when appropriate.

Laboratory sample receipt occurs when a package containing samples is accepted, the package and sample containers are surveyed for external surface contamination and level, and the physical integrity of the package and samples is checked.

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- 6.1 Check laboratory submission form for the following information:
- 6.1.1 Reference details
 - 6.1.1.1 Collection Date
 - 6.1.1.2 Date of receipt
 - 6.1.1.3 Senders Ref.no.
 - 6.1.1.4 Lab. Ref. no.
 - 6.1.2 Details of the animal owner
 - 6.1.2.1 Owner
 - 6.1.2.2 Sender
 - 6.1.2.3 Village
 - 6.1.2.4 Geog
 - 6.1.2.5 Dzongkhag
 - 6.1.2.6 Contact
 - 6.1.3 Details of animals
 - 6.1.3.1 Species
 - 6.1.3.2 Breed
 - 6.1.3.3 Age
 - 6.1.3.4 Sex
 - 6.1.3.5 Animal Id.
 - 6.1.4 Specimen details
 - 6.1.4.1 Carcass
 - 6.1.4.2 Feces
 - 6.1.4.3 Skin scraping
 - 6.1.4.4 Milk
 - 6.1.4.5 Whole blood
 - 6.1.4.6 Blood smear
 - 6.1.4.7 Serum
 - 6.1.4.8 Swab
 - 6.1.4.9 Organs (fresh/formalin)
 - 6.1.4.10 Others
 - 6.1.5 Case History
 - 6.1.5.1 Nos. affected
 - 6.1.5.2 Nos. at risk
 - 6.1.5.3 Nos. dead
 - 6.1.5.4 Length of illness
 - 6.1.5.5 Symptoms
 - 6.1.5.6 Summary of PM findings
 - 6.1.5.7 Treatment
 - 6.1.5.8 Vaccination
 - 6.1.5.9 Disease suspected
 - 6.1.5.10 Examination requested
 - 6.1.6 Laboratory section referred to
- 6.2 If any data is missing, enquire and complete the information. Cross check the specimen numbers so as not to compromise specimen integrity.

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- 6.3 Inspect all sample tubes/bottles for proper labelling and Collection date. Unlabelled specimens are not acceptable for testing.
 - 6.4 Check off all specimens received and record dak receipt numbers and enter initials in the space provided.
 - 6.5 Determine if sufficient specimen of acceptable quality is available for all tests.
 - 6.6 Keep all laboratory test request forms for 10 years in a secure, fire-protected space.

7. DISTRIBUTION OF SAMPLES TO OTHER LABORATORIES/SECTIONS FOR TESTING

- 7.1 Refer the sample referral section for sample destinations.
- 7.2 Make a copy of the request form to be sent with specimen.
- 7.3 Check that there is adequate sample for testing.
- 7.4 Place sample in Biohazard specimen bag and seal.
- 7.5 Take samples to the appropriate laboratory/section.
- 7.6 Obtain signature of person receiving the specimen on the original specimen request form.

8. SPECIMEN STORAGE/ARCHIVING

- 8.1 Specimens held for testing in the laboratory or awaiting aliquoting/archiving should be placed in labelled racks at the appropriate temperatures.
- 8.2 Each site should use their Laboratory Data Management System for organizing freezer placement and labelling samples. This is to ensure that sites storage style are not disorganised.
- 8.3 Records of sample locations will be retained in log book format.

9. SPECIMEN DISPOSAL

- 9.1 Specimens should be retained for the appropriate length of time post analysis.
- 9.2 Discard specimens regularly into an biohazard waste bag.
- 9.3 Autoclave bag for 15 minutes at 121° C.
- 9.4 Place bag in waste disposal area for incineration.
- 9.5 Record Specimen Collection dates.
- 9.6 Enter the initials of the staff that made the request and date.

8. REFERENCES

OIE terrestrial manual 2008, Chapter 1.1.1 collection and shipment of diagnostic samples.

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Number: REF 04

Version:

Print Date: 11 Mar. 19

TITLE: Sample referral abroad (air transport)

PREPARED BY: Laboratory Services Unit

REVISED BY: Laboratory Services Unit

APPROVED BY: Dr RB Gurung, Head, LSU

DATE: June 12, 2018

1. INTRODUCTION

Laboratory diagnosis of disease is critical for quick response to management of disease outbreak and containment. The National Veterinary Laboratory, National Centre for Animal Health, Serbithang has wide range of diagnostic capacity for the diagnosis of livestock, poultry and wildlife diseases. However, there are certain tests that require high containment facility for the conduct of such test. Therefore, the NCAH on regular basis refer biological samples for advanced test such as molecular, isolation, sequencing and phylogenesis. Sample referral involves considerable amount of documentation, logistic arrangement and exploring receiving laboratories. Such arrangements are made to ensure smooth transition of consignment to destination, storage conditions, biosafety requirement and integrity of sample quality.

2. OBJECTIVE

This document is used to support the process of sample referral to destination or receiving laboratory.

3. APPARATUS

- 3.1 Sample shipment container
 - 3.1.1 Primary container
 - 3.1.2 Secondary container
 - 3.1.3 Outer packing
- 3.2 Ice pack
- 3.3 Thermal box
- 3.4 Dry ice (below 2 kg)
- 3.5 Packaging instruction
- 3.6 Cello-tape (transparent)
- 3.7 Document holder

4. REAGENTS, SOLUTION AND BUFFER

- 4.1 Samples
- 4.2 Buffer

5. PROCEDURE

- 5.1 Import letter from Institute
 - Import permit or certificate from the receiving laboratory duly signed by competent authority of that country has to be obtained well in advance. The

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certificate has to clearly mention the willingness to receive consignment and test at their facility

5.2 Export letter from BAFRA

The shipping laboratory has to obtain export permit from competent authority of that country well in advance. While applying for export permit, the shipping laboratory has to mention in the letter all details of samples, number of samples, destination laboratory details, purpose of shipment and commercial value if any

5.3 Special permit

5.4 In addition to the above two documents the shipping laboratory has to obtain special permit for the referral of samples originating from Schedule I species of fauna and flora mentioned in the Forest and Nature Conservation Act of the Kingdom of Bhutan

5.5 Sample details

Once the above documents are obtained, the shipping laboratory has to pack samples in strict compliance to AITA regulation by observing all air transport safety rules. The sample packing has to comply triple packing system with all necessary signage on the outer packing.

5.6 Invoice of samples

The shipping laboratory has to prepare proforma invoice (PI) with details of samples (type, volume/quantity, commercial value). These information are required for custom clearance at the entry point of another country

5.7 Forward letter of sender

The shipping laboratory will prepare a forwarding letter addressed to the concerned officer at receiving laboratory stating that a consignment is being sent for laboratory diagnosis. The forwarding letter should accompany all other above documents. Three separate sets of these documents are required (shipping laboratory, receiving laboratory and accompanying consignment).

5.8 Sample referral control documents.

Refer sample referral document of the shipping laboratory for authorization of release of consignment (ANNEXURE)

6. RISK ASSESSMENT

6.1 Ensure proper packing to avoid leakage of samples

6.2 Ensure not to exceed dry ice weight 2 kg if the consignment is transported in passenger flight

7. TROUBLESHOOTING

7.1 Mismatch of sample details

7.2 Inappropriate of address

8. REFERENCES

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**ANNEXURE
SAMPLE REFERRAL CONTROL DOCUMENT**

**LABORATORY SERVICE UNIT
NATIONAL CENTRE FOR ANIMAL HEALTH, SERBITHANG
THIMPHU: BHUTAN**

SAMPLE REFERRAL NO: DATE:

**A: REFERRING AND REFERRED AGENCIES
DETAILS OF REFERRING AGENCY**

Name:

Address:

Telephone:

Fax No:

Email:

DETAILS OF AGENCY REFERRED TO

Name:

Address:

Telephone:

Fax No:

Email:

B: SAMPLE DETAILS

SI no	Sample type	Quantity	Test requested

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Attach separate sheet for additional details of sample

D: TO BE COMPLETED BY BIO-SAFETY OFFICER AND OFFICER PACKING THE SAMPLE (put tick mark)

1. Confirmed that the consignee address is correct
2. Confirmed that the samples packed are the intended samples
3. Confirmed that the samples are packed in compliance with shipment regulations

Name: Technician.....

Sign..... Date.....

Name: Bio-safety Officer (IATA certified staff)

Sign..... Date.....

E: TO BE VERIFIED BY SECTION HEAD (put tick mark)

1. Verified that consignee address is correct
2. Verified that samples packed are correct
3. Verified that the samples are packed in compliance with shipment regulation
4. Confirmed that EXPORT and IMPORT certificates are attested

Name: Sign..... Date.....

F; APPROVAL FOR SAMPLES TO LEAVE NCAH

Verified that information in section D and E are correct

Name:

Head LSU:Sign

Date: