

PPHRL-R&D /PPE/L2-013		<b>Procedure for Pre-Examination (PPE)</b>	 Primary & Secondary Healthcare Department
Issue on	DD-MM-YYYY		
Revision	00		
Curator	PPHRL, P&SHD		
Approved By	IRB, P&SHD		

## Purpose

This procedure describes the mechanism for pre-examination activities includes sample collection, sample type, sample volume, storage conditions, and criteria for sample rejection, transportation of samples, retention and discard of sample. This information is available for everyone who intends for laboratory services.

## Application

This procedure applies to all labs / sections of PPHRL. A controlled hardcopy of this procedure has been issued to relative section.

## Responsibilities

- Quality Manager is responsible for implementation of this procedure at Reception Section and also to manage the record related to pre-examination.
- Front Desk officer / Reception staff is responsible to record necessary information related to patient and sample.

## Procedure

### Information for Laboratory Users:

The lab has defined scope of services and the information related to the services are available at the Reception. These information are available in printed form.

- Address/location of the laboratory
- Organizational structure of laboratory
- Detailed scope of PPHRL bears the information related to sample required for examination, type and volume of sample, special precautions, turnaround time, biological reference intervals, and clinical decision values
- Guidelines how to complete the request form
- instruction for preparation of the patient
- instructions for patient-collected samples
- instructions for transportation of samples, including any special handling needs
- the laboratory's criteria for accepting and rejecting samples
- List of factors known to significantly affect the performance of the examination or the interpretation of the results

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- Laboratory's policy on protection of personal information
- Complaint and feedback procedure

#### Completion of Request Form:

Front desk officer will have to record the necessary information related to patient and desired examinations details of patient who requested for the laboratory services. These information include:

- Case No. (unique identification of sample)
- Patient No. (Unique identification of patient)
- Registration date & time (sample receiving date/with drawl for examination)
- Patient Name
- Age / Sex
- NIC (it is optional)
- Phone No. (Mandatory)
- Address
- Consultant Name
- Registration Location
- Reporting Location (Optional)
- Tests Requested
- Sample condition
- Standard test method
- clinician, healthcare provider, or other person legally authorized to request
  - examinations or use medical information
- type of primary sample and, where relevant, the anatomic site of origin
- patient's ancestry, family history, travel and exposure history, communicable
  - diseases and other clinically relevant information.

#### Primary sample collection and handling

PPHRL personnel who will collect the sample must prepare the patient for this activity, he performs followings:

- Informs about the method how he will collect the sample, etc.

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- The phlebotomist / customer support leads the patient towards the sample collection room. This room must have Bed, easy chair, vacationer, tourniquet, syringes, cotton, alcohol swabs, labelling marker / bar code printer, bandages, surgical tape, vacationer vials, needle sharp containers / cutter, etc.
- Phlebotomist prepares himself to collect the sample, (wearing lab coats, gloves, face mask etc.)

### **Blood Collection (Venipuncture):**

- After putting on gloves, inspect the patient's arms to determine where a sample can be collected. Apply the tourniquet and clean the site with the alcohol swab in round shape
- After the site has dried, insert the needle into the vein and fill each tube
- Remove the tourniquet before removing the needle. The vacationer tube should be removed from the needle before removing the needle from the vein. The tubes that contain additive must be inverted 8 – 10 times immediately after drawing. After the needle has been removed, apply direct pressure with a cotton ball or gauze on the insertion site. The bleeding should have stopped before 5 minutes and can now be bandaged.

### **Protocol for Sample Collection for Ammonia Level**

- Patient should be fasting at least 8 hours prior to collection
- Patient should not smoke at least 8 – 10 hours prior to sample collection
- Excessive protein intake and strenuous exercise can increase ammonia levels, so instruct the patient to avoid these
- Avoid hemolysis and prolonged tourniquet application because it can cause elevated ammonia levels

### **Transportation of Sample**

- Ammonia level is constant at – 4°C for one hour
- Freeze the sample at – 20 °C if there is delay in processing for more than one hour
- Sample must be transported to the lab within ½ an hour with ice pack. Not allowed to be received from outstation

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### Protocol for Sample Collection for Semen Analysis

- There should be minimum 03 days abstinence period prior to passing the semen sample
- Patient should never use the saliva, oil or condom, etc during passing the semen
- Due to most urgency, sample must be passed at running lab. Not allowed to be received from outstation / collection centres

### Protocol for Sample Collection for ABG's

- Sample should be drawn at 90° angle from artery vein and there should be no space or air in blood
- Due to most urgency, sample must be passed at running lab. Not allowed to be received from outstation

### Protocol for Sample Collection for Lactate Level

- Sample must be transported to the lab within ½ an hour. Not allowed to be received from outstation

### Protocol for Sample Collection for Electrolyte and Calcium

- Sample should be drawn without tourniquet, avoiding the vein or arm where any medicine or like glucose or saline is transfused
- Sample is sealed and labelled (case no. with name, date, time, fasting, 2 hours, etc)

### Rejection of Samples

If the "Patient Request Form" is not complete or if the specimen(s) are not with the request form, the sample management representative will mark the form to indicate the missing information and/or specimen(s). Then the form will be signed and dated and sent back to the submitter. As an alternative the submitter may be contacted by telephone or email. Once the submitter completes the form and/or finds the specimens, they should submit the form with the specimen(s) to the Laboratory.

Other causes for specimen rejection;

- The "Patient Request Form" is not complete.
- The specimen is collected in the incorrect manner (i.e. incorrect collection tube or incorrect collection kit)
- All the specimen(s) are not with the request form

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- Specimens lacking proper identification or not labelled
- Specimens labelled with information that does not match information on the request form
- Specimen containers that are broken, leaking, or have evidence of contamination of outer surfaces or of the request form
- Specimens delayed in transit making results invalid
- Urine specimens for culture that have been held at room temperature for more than two hours from time of collection and pooled 24-hour urine
- Sputum specimens for mycobacterial cultures that have been held at room temperature for more than two hours from time of collection, or pooled 24-hour sputum.
- Cultures should not be submitted in petri dishes
- Incorrect Specimens- Specimen(s) that are not correct, i.e. a sputum specimen which is not sputum but saliva
- Specimen is less than the minimal volume needed for testing, commonly referred to as QNS- Quantity Not Sufficient for testing

Enteric specimens (fresh) for Campylobacter cultures that have been held at room temperature for more than two hours from time of collection, or specimens not refrigerated at 2-8 degrees Centigrade

### **Record Of Rejected Samples**

When rejecting a sample, it is important to:

- promptly inform authorized person (FDO / supervisor / phlebotomist) that the sample is unsuitable for testing
- request another sample be collected following procedure outlined in the Laboratory Primary Sample Collection Manual (PSCM) section 1.0
- Retain rejected sample pending a final decision regarding disposition
- In some circumstances and after consultation with the requester, it may be necessary to proceed with the testing of a sample that is not optimal. Sample condition must be mention on result report issued to requester

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PPHRL Management regularly reviews the number of rejected samples and reasons for rejections, conduct training on sample collection (if necessary). The lab maintained a “Sample Log Register” at Sample Management containing the information about rejected samples

The register includes:

- date and time of collection
- date and time the sample was received in laboratory
- sample type
- patient name and demographics, as required
- laboratory assigned identification (sample code)
- reason for rejection of sample
- examination performed or re sampling / fresh sample performed

### **Sample Handling & Transportation**

Laboratories that mail or transport samples by air, sea, rail, and road between local, regional, and reference laboratories or between laboratories in other countries must adhere to a number of regulations. These regulations are designed to deal with transportation accidents and spills, reduce biohazards, and keep samples intact for testing. PPHRL follows all the regulations defined by Ministry of Health, Govt. of Pakistan, while transporting the samples from collection centers to main lab. Specimen is classified as Non Infectious and Infectious:

#### **Non Infectious Specimen:**

Specimens or samples suspected or known to contain risk group 1 or 2 Pathogens are classified as non infectious.

#### **Infectious Specimen:**

Specimens or samples suspected or known to contain risk group 3 or 4 Pathogens are classified as infectious. Infectious substances capable of causing permanent disability or life-threatening or fatal disease to humans or animals and required serious attention for their handling and processing

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Inside the lab the sample are transported by the Sample Management by following safety measures as follows:

- Samples containers are sealed
- outer surface of container is dry
- samples are placed in plastic basket having on the bottom surface cotton wool which will act as absorbent material in event of any spillages

Samples are also transported to main lab from different collection centres of PPHRL, so samples are properly packed for the safety of personnel and for producing true results

### Requirements of Packing

All categories of samples have specific packaging instructions and labelling requirements described in above depending on their classification. All potentially hazardous material requires triple packaging

- The **primary container** is a tube or vial containing the sample; it is made with either glass, or metal, or plastic. It must have a leak-proof seal; if necessary it can be wrapped with waterproof tape. The tube or vial must be labelled with a permanent marker / bar code.
- The **secondary container** is a watertight polyethylene box / plastic bag intended to protect the primary container. Absorbent material (gauze, absorbent paper, cotton etc) must be added in a sufficient quantity to absorb the fluid completely in case of breakage
- The **outer container** is a strengthened cardboard box / Box Specs. used to protect the secondary container. Both the secondary and outer containers are reusable as long as they are intact, but old container must be removed
- dry-ice / ice plates to maintain the temperature requirements

### Packing of Samples

#### Non Infectious

- Specimen to be sent should be stored in a secure (preferably plastic) primary container

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- Wrap the container in tissue or cotton wool which will act as absorbent material in event of any spillages
- This will be placed in a biohazard bag
- Place the biohazard bag with the sample in a padding envelope
- Label the envelope with a hazard warning label, “**Diagnostic Specimen**”
- Place the name, address and contact number of the destination collection centre on the outside of the envelope
- Place the name, address and contact number of the originator on the outside of the envelope
- The specimen can be transported or posted as appropriate
- Storage conditions are required to be maintained for sample as explained in table 1.0

### **Infectious Specimens**

- Specimens or samples to be sent should be stored in a secure (preferably plastic) primary container
- Wrap the container in tissue or cotton wool which will act as absorbent material in event of any spillages
- Place the wrapped primary specimen or sample container inside of the plastic container of the sealed plastic bag
- Place the container inside the cardboard box
- The box should contain a label “ **Infectious Substance**”
- Write the name of the suspected microbe being transported in brackets
- Place the name, address and contact number of the destination laboratory on the outside of the box
- Storage conditions are required to be maintained for sample as explained in table 1.0
- Place the name, address and contact number of the originator on the outside of the box.

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- After packing of infectious and non infectious specimen / samples, complete document (lab copy of sample receiving invoice, any other if required), provide packed specimen with document to courier for transportation

### Referring Sample to other Labs

When referring samples to other laboratories for testing ensure that:

- Samples is packed in correct container as described in section 7.0 of this manual
- Sample is labelled correctly
- Accompanied by a requisition form that specifies the required test(s), and includes the sending laboratory's contact information;
- PPHRL keep record of all samples referred in referral sample record file. This record at contains following information:
  - Date of referral
  - Name and address of referral lab
  - Sample code, type and volume
  - Test requested
  - Name of person referring the test
  - Report / results received for each referred sample

### Sample Retention

PPHRL will retain all samples for the period of minimum 24 hours to 7 days depending upon nature of specimen after the issuance of report. Sample will be retained for one or more of following reasons:

- Quality assurance activities (Replicate testing, Retesting) retention frequency will be according to PPHRL "Procedure for Quality Assurance"
- Re verification of results on request of patient
- Second opinion from any other lab

Some samples can be quickly discarded, and others may need to be retained as per frequency defined in QSPs of PPHRL. Monitor stored samples (Storage conditions are

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required to be explained in table 1.0), and do not keep for longer than necessary, as refrigerator and freezer space may be limited

### Sample Disposal

The laboratory is responsible for ensuring that disposal of all laboratory waste is handled in a safe manner. To ensure proper disposal of patient samples, regulations of Ministry of Health, Government of Punjab are followed.

Sr. No.	Nature of Material	Requirements to deactivate the sample
1	Any Specimen	<b>INCINERATION</b>
2	Clotted Blood (Uncentrifuged)	
3	CSF	
4	EDTA Plasma	
5	Heprinized Plasma	
6	EDTA Whole Blood	
7	Fluid	
8	Fluorided Plasma	
9	Na Cit. Plasma	
10	Semen	
11	Serum	
12	Slides or Blocks or Both	
13	Stone	
14	Stool	
15	Tissue	

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16	Urine	
17	Whole Blood	

### Related Documents

- Test Report Approved Format