

## Content Sheet 5-1: Overview of Sample Management

### Role in quality management system

Sample management is a part of process control, one of the essentials of a quality management system.

The quality of the work a laboratory produces is only as good as the quality of the samples it uses for testing. The laboratory must be proactive in ensuring that the samples it receives meet all of the requirements needed to produce accurate test results.



### Sample vs. specimen

ISO and CLSI define a sample as “one or more parts taken from a system and intended to provide information on the system” (ISO 15189:2007). The term “specimen” is very commonly used in the laboratory to indicate a sample taken from the human body, but the terminology used throughout ISO documents is “primary sample”, or just “sample”. In this workshop, the terms “sample” and “specimen” should be considered interchangeable.

It is useful to note that in some of the existing transport regulations, the term “specimen” continues to be used.

### Importance of good management

Proper management of samples is critical to the accuracy and reliability of testing, and, therefore, to the confidence in laboratory diagnosis. Laboratory results influence therapeutic decisions and can have significant impact on patient care and outcomes. It is important to provide accurate laboratory results in order to assure good treatment.

Inaccuracies in testing can impact length of hospital stays, as well as hospital and laboratory costs. Inaccuracies can also affect laboratory efficiency, leading to repeat testing with resultant waste of personnel time, supplies, and reagents.

### Sample management components

Written policies for sample management must be established and reflected in the Laboratory Handbook. Components to be addressed include:

- information needed on requisitions or forms
- handling urgent requests
- collection, labeling, preservation and transport
- safety practices (leaking or broken containers, contaminated forms, other biohazards)
- evaluating, processing, and tracking samples
- storage, retention, and disposal.

## Content Sheet 5-2: The Laboratory Handbook

### **Purpose and distribution**

To ensure that all samples are managed properly and that persons collecting samples have the needed information, the laboratory should develop a laboratory handbook. This handbook should be made available at all sample collection areas, including those that are distant from the laboratory.

All laboratory staff should also be familiar with the information in the handbook, and should be able to answer questions about the information included.

The laboratory handbook is an important laboratory document. It must be kept up-to-date and be referenced in the laboratory's quality manual.

### **Content**

Important information that should be included in the laboratory handbook:

- contact names and telephone numbers of key personnel;
- name and address of the laboratory;
- hours of operation of the laboratory;
- list of tests that can be ordered;
- detailed information on sample collection requirements;
- sample transport requirements, if any;
- expected turnaround times (TAT);
- description of how urgent requests are handled; this should include a list of what kinds of tests are done on an urgent basis, what are the expected turnaround times, and how to order them.

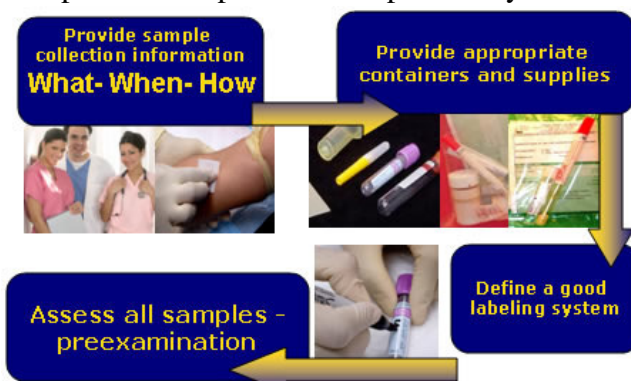


The laboratory should periodically provide training sessions to health care and laboratory personnel who are responsible for the collection of samples.

## Content Sheet 5-3: Collection and Preservation

### The laboratory's responsibilities

The collection of appropriate and optimum samples is the responsibility of the laboratory, even though the actual collection process is often carried out by persons who are not part of the laboratory staff. The sample may be collected at the bedside by a nurse if the patient is being managed in a hospital. The health care provider may collect a sample in a clinic setting.



The laboratory can help to assure good samples by providing collection information to health care personnel at the collection site, making sure that appropriate containers and collection supplies are available, defining a good labeling system, and checking all samples carefully when they arrive in the laboratory.

### Test requisition

The first step in the process of obtaining the sample is the request for testing. The laboratory must make available a test request form that specifies all the information that will be needed for proper handling and reporting.

Essential information for the test request form includes:

- patient identification;
- tests requested;
- time and date of the sample collection;
- source of the sample, when appropriate;
- clinical data, when indicated;
- contact information for the health care provider requesting the test.

| Field Data Collection Form  |      |                    |   |  |         |
|---|------|--------------------|---|--|---------|
| <b>General patient information</b><br>Name: _____<br>Address: _____<br>Country: _____<br>County: _____<br>City/town/village: _____      |      |                    | <b>Tracking record number</b><br>Date of Birth (dd/mm/yyyy): _____<br>Sex: M [ ] F [ ]<br>Nationality: _____<br>Occupation: _____ |  |         |
| Date of onset of illness (dd/mm/yyyy): _____  |      |                    |   |  |         |
| Clinical specimens  |      |                    |   |  |         |
| Unique ID No.   | Type | Date of collection | Clinical diagnosis  | Health status when specimens collected | Remarks |
|   |      |                    |   |  |         |
|   |      |                    |   |  |         |
|   |      |                    |   |  |         |
|   |      |                    |   |  |         |
| Post-mortem specimens   |      |                    |   |  |         |
| Date of death(dd/mm/yyyy): ____/____/____   |      |                    |   |  |         |
|   |      |                    |   |  |         |
|   |      |                    |   |  |         |
|   |      |                    |   |  |         |
|   |      |                    |   |  |         |
| Name of person completing form: _____<br>Institutional affiliation: _____<br>Contact details: _____<br>Date(dd/mm/yyyy): ____/____/____ |      |                    |   |  |         |

Collection of samples in the field for epidemiological studies should be accompanied by a form that includes the patient's name, a unique identification number, demographic information, and the patient's health status. The additional information is necessary to assist in identifying the source of an infection, and finding potential contacts.

## Sample collection requirements

Sample collection and preservation will vary, depending on the test and the type of sample to be collected. The laboratory must carefully define a sample collection process for all tests it performs. The following should be considered when preparing instructions:

- **Patient preparation**—Some tests require that the patient be fasting. There may also be special timing issues for tests such as blood glucose, drug levels, and hormone tests.
- **Patient identification**—The person collecting the sample must accurately identify the patient. This might be done by questioning the patient, by questioning an accompanying family member, or by the use of an identifying wrist band or other device.
- **Type of sample required**—Blood tests might require serum, plasma, or whole blood. Other tests might require urine or saliva. Microbiology testing deals with a variety of sample types, so specific information as to what is required for the test is needed.
- **Type of container**—The container for the sample is often very important, as it will affect volume and any needed additives such as anti-coagulants and preservatives. If the container does not control volume, for example as with Vacutainer® tubes, this will need to be clearly specified. Some microbiology samples will require specific transport media to preserve microorganisms.
- **Sample labeling**—All requirements for labeling of the sample at the time of collection will need to be explained in detail in the instructions for collection.
- **Special handling**—Some samples may require special handling, such as immediate refrigeration, protection from light, or prompt delivery to the laboratory. Any important **safety precautions** should be explained.

Patient samples are sometimes collected by the patient themselves, for example, faecal parasitology samples. It is important that the laboratories have set protocols to ensure that appropriate collection kits with instructions for collection, safety precautions, and labeling are available for their patients. It is suggested that instructions for the patients be in the languages for the community the laboratory is serving or presented as simple easy-to-understand graphics.

## Sample labeling

Each sample should be clearly labeled with:

- the patient's first and last name;
- a unique identification number – this might be a hospital number or a number assigned by the laboratory;

- the test that has been requested;
- the time and date of collection;
- the initials of the person collecting the sample.

**Potential  
outcomes of  
collection  
errors**

Proper sample collection is an important element for good laboratory practice. Improper collection of samples can lead to poor outcomes, such as:

- delays in reporting test results
- unnecessary re-draws/re-tests
- decreased customer satisfaction
- increased costs
- incorrect diagnosis / treatment
- injury
- death.

## Content Sheet 5-4: Sample Processing

### Verification of quality

Once a sample enters the laboratory, there are a number of steps needed prior to testing. These pre-examination steps include:

- verifying the sample is properly labelled, adequate in quantity, in good condition, and appropriate for the test requested. The test request must be complete and include all necessary information;
- recording sample information into a register or log;
- enforcing procedures for handling sub-optimum samples, including sample rejection, when necessary.

### Rejection of samples

The laboratory should establish rejection criteria and follow them closely. It is sometimes difficult to reject a sample, but remember that a poor sample will not allow for accurate results. It is the responsibility of the laboratory to enforce its policies on sample rejection so that patient care is not compromised.

Management should regularly review the number of rejected samples and reasons for rejections, conduct training on sample collection, and revise written procedures for sample management as needed.

The following are examples of samples that should be rejected:

- unlabeled sample;
- broken or leaking tube/container;
- insufficient patient information;
- sample label and patient name on the test request form do not match;
- hemolyzed sample (depending on test requested);
- non-fasting samples, for tests that require fasting;
- sample collected in wrong tube/container; for example, using the wrong preservative or non-sterile container;
- inadequate volume for the quantity of preservative;
- insufficient quantity for the test requested;
- prolonged transport time, or other poor handling during transport.



**Record the reason for rejection in the log book and include all pertinent information.**

When rejecting a sample, it is important to:

- promptly inform authorized person that the sample is unsuitable for testing;
- request another sample be collected following procedures outlined in the laboratory handbook;
- 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.

### **Register or log**

The laboratory should keep a register (log) of all incoming samples. A master register may be kept, or each specialty laboratory may keep its own sample register.

Assign the sample a laboratory identification number – write the number on the sample and the requisition form. If computers are used for reports, enter the information into the computer.

The register should include:

- 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 (e.g., number 276\_01\_06\_2009);
- tests to be performed.



### **Tracking system**

The laboratory needs a system to allow for tracking a sample throughout the laboratory from the time it is received until results are reported.

This can be done manually by careful keeping of records.

- confirm receipt of samples, include date and time;
- label samples appropriately; keep with the test requisition until laboratory ID is assigned;
- track aliquots–traceable to the original sample.

If computers are available, maintain a database for tracking. The following information about each sample should be entered into the database:

- identification number;
- patient information;
- collection date and time;
- type of sample: for example, urine, throat, cerebrospinal fluid for culture;
- tests to be performed;
- name of ordering physician (or other health care provider);
- location of patient, such as ward, clinic, outpatient;
- diagnostic test results;
- time and date results are reported.

Sample  
handling

**Handle all samples as if infectious**





## Content Sheet 5-5: Sample Storage, Retention, and Disposal

### Sample storage

Written policies should be developed that include:

- description of what samples should be stored;
- retention time;
- location—consider ease of access;
- conditions for storage, such as atmospheric and temperature requirements;
- system for storage organization, one method being to store samples by day of receipt or accession number.

### Sample retention

Set a laboratory policy for retention of each type of sample. Some samples can be quickly discarded, and others may need to be retained for longer periods. Monitor stored samples, and do not keep for longer than necessary, as refrigerator and freezer space may be limited. Sample freeze/thaw cycles must be monitored, as samples may deteriorate with these conditions.

Planning is required for samples that may need long-term storage. An organized, accessible system using computer tracking would be useful for these samples. The inventory of stored samples should be reviewed at specified intervals to determine when they should be discarded.

### Sample referral

When referring samples to other laboratories for testing:

- obtain a laboratory handbook with detailed procedures from each laboratory;
- ensure the sample is labelled correctly, in the correct container, accompanied by a requisition form that specifies the required test(s), and includes the sending laboratory's contact information;
- carefully monitor samples that are referred:
  - keep a record of all tests / samples referred, date of referral, name of person referring the test;
  - record and report results received for each referred sample;
  - monitor turn around times and record any problems encountered.

### 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:

- develop a policy for sample disposal; apply local, as well as country regulations for disposal of medical waste;
- establish and follow procedures to disinfect samples prior to disposal.

## Content Sheet 5-6: Sample Transport

### Need for transport

Frequently, samples are collected outside the laboratory, and must be transported for subsequent processing and testing. Transport may be for a short distance, but sometimes a distant clinic or collection site requires the use of vehicles or airplanes. In addition, it may be necessary for the laboratory to ship samples to referral laboratories. In all cases, transport must be managed carefully in order to maintain integrity of the sample, giving attention to temperature, preservation needs, special transport containers, and time limitations. It is also important to ensure the safety of those handling the material before, during, and after transport.

### Safety requirements

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.

### Regulations

Regulations for transporting samples come from several sources, including:

- national transport regulations;
- International Civil Aviation Organization (ICAO), as conveyed by the International Air Transport Association (IATA);
- rail and road traffic agencies;
- postal services.

Private courier companies may have their own requirements.

Compliance with industry standards and regulations is mandatory. Heavy fines may be imposed on personnel who violate these regulations. At risk are: the safety of courier, carrier, and laboratory personnel, as well as passengers.

The United Nations committee of experts, consisting of voting representatives from over 30 countries and non-voting advisors from various organizations, makes recommendations for the transport of dangerous goods. Many countries adopt the United Nations regulations in their entirety to stand as their national dangerous goods regulations. Some countries apply variations. National authorities should provide details of their own national requirements.

### Classification

Sample transport requirements are based on the category of samples being transported. Infectious substances are classified as Category A or Category B. There is no direct relationship between Risk Groups and Category A and B.



**Category A:** Infectious substances capable of causing permanent disability or life-threatening or fatal disease to humans or to humans and animals. These are assigned the following proper shipping name and UN number:

- Infectious substance, affecting humans, UN 2814
- Infectious substance affecting animals *only*, UN 2900

**Category B:** Infectious substances that do not meet the criteria for inclusion in Category A. They are assigned the following proper shipping name Biological substance, Category B, and UN number UN 3373

Medical or clinical wastes that contain infectious substances also need to be classified as Category A or B depending on the infectious material and whether it is present in the culture.

**Exemptions:** The UN Model *Regulations for the Transport of Infectious Substances* includes a list of exemptions, which are samples that have a minimal likelihood that pathogens are present. They do not have the same requirements for packaging and shipping as Categories A and B. See Annex 5-G for more information.

### **Packaging requirements**

All three categories of samples have specific packaging instructions and labelling requirements 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.
- The **secondary container** is a watertight polyethylene box intended to protect the primary container. It is supplied with cardboard or bubble-wrap or a vial holder in which several primary containers can be placed in order to protect them. Absorbent material (gauze, absorbent paper) must be added in a sufficient quantity to absorb the fluid completely in case of breakage.
- The **outer container** is a strengthened cardboard box used to protect the secondary container. Both the secondary and outer containers are reusable as long as they are intact, but old labels must be removed.

There is specific packaging for samples requiring shipment on dry-ice.

### **Managing sample transport**

Assure that all regulations and requirements are met when transporting samples; be aware of any national requirements that apply to samples transported by hospital or laboratory vehicles.

All personnel who package or who drive transport vehicles should be trained in the proper procedures, both for safety and for good maintenance of samples. If ICAO regulations must be met, staff must have specific training in packaging of dangerous goods.

When transporting locally, whether by ambulance, or by clinic or laboratory staff, it is important to maintain sample integrity. Assure that temperatures are controlled, using ice boxes or air conditioning, set an acceptable transport time, and monitor compliance.

## Content Sheet 5-7 : Summary

### Summary

A laboratory handbook describing sample collection and providing testing information must be available to everyone who needs this information.

It is important to have a system for tracking samples as they move through the laboratory.

Establish and implement a policy for sample storage and sample disposal.

Maintain sample integrity and assure that all regulations and requirements are met.

It may be useful to appoint someone with oversight responsibilities for sample management.

### Key messages

- The laboratory must have good samples in order to ensure accuracy and reliability of testing and confidence in results.
- Sample management directly affects patient care and outcome.