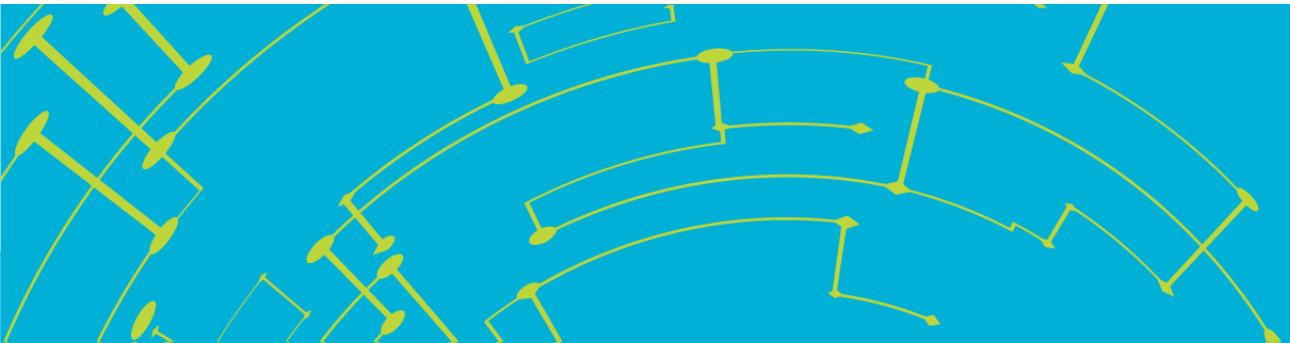
Sample Management



The science you expect.
The people you know.

Learning Objectives

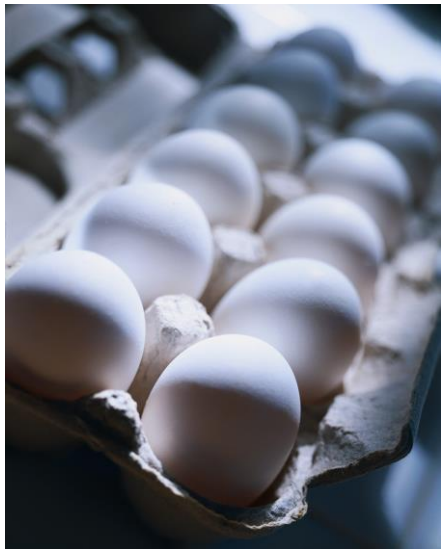
- At the end of this training, participants will be able to:
    - List contents that should be included in a laboratory handbook
    - Describe a system for sample collection, handling, transport, storage, and disposal
    - Understand the rationale for defining sample acceptance and rejection criteria
    - Understand the criticality of sample quality for the accuracy of diagnostic test result
    - Explain the importance of maintaining sample integrity and compliance with all regulations when transporting samples

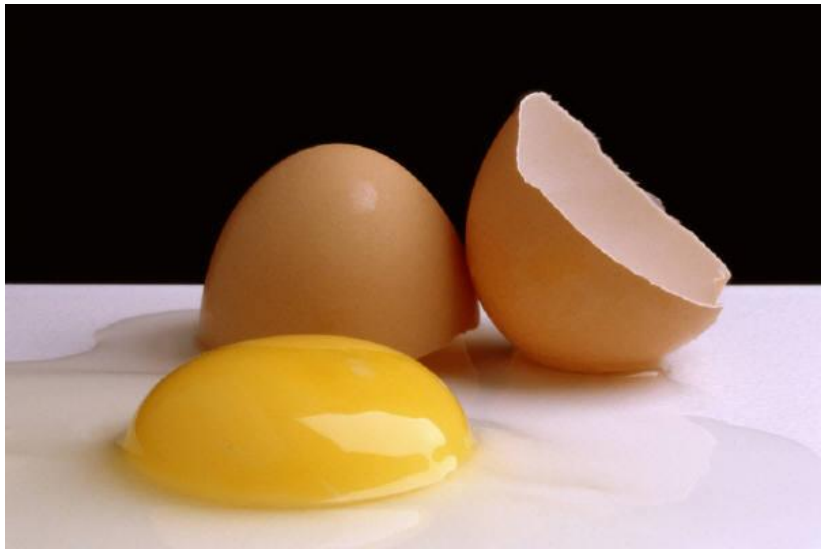
Overview of Sample Management

1. Sample management is part of Process Control, one of the essentials of a quality management system (QMS)
2. The quality of the work of a laboratory is reflective of the quality of the samples used for testing
3. Sample acceptance/rejection criteria should be clearly defined

Importance of Good Sample Management

- The result of any laboratory examination is only as good as the sample received in the laboratory





Sample Management Components

- Define the information needed on requisitions or forms
- Collection, labeling, preservation and transport instructions
- Evaluating, processing, and tracking samples
- Storage, retention, and disposal policies and procedures

Laboratory Handbook

- Each laboratory should develop a laboratory handbook:
  - Contains information needed by those who collect samples
  - Should be available at all sample collection areas/sites
  - Information included should be understood by sample collection area/site and laboratory staff
  - Should be kept up-to-date and referenced in the laboratory quality manual

Laboratory Handbook Contents

- Name and address of the laboratory
- Contact names and phone numbers of key personnel
- Hours of operation
- Types of research samples to be collected
- Detailed information on sample collection requirements
- Sample transport requirements

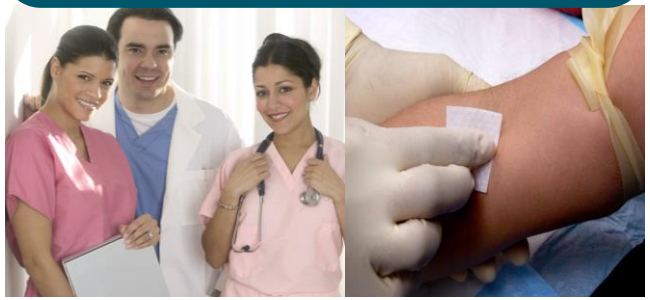
Sample Collection and Preservation

Biosafety Considerations

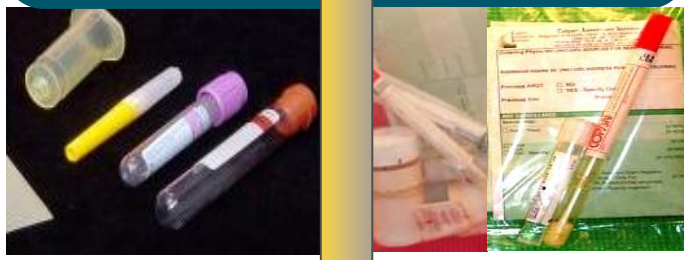
- Recommended personal protective equipment (PPE) for workers collecting specimens for COVID-19 testing:
  - N95 or higher-level respirator mask
  - Eye protection
  - Gloves
  - Gown
- Process clinical specimens in a Biological Safety Cabinet (BSC) certified within the last year

Laboratory Responsibilities

Provide sample collection information
What- When- How



Provide appropriate containers and supplies

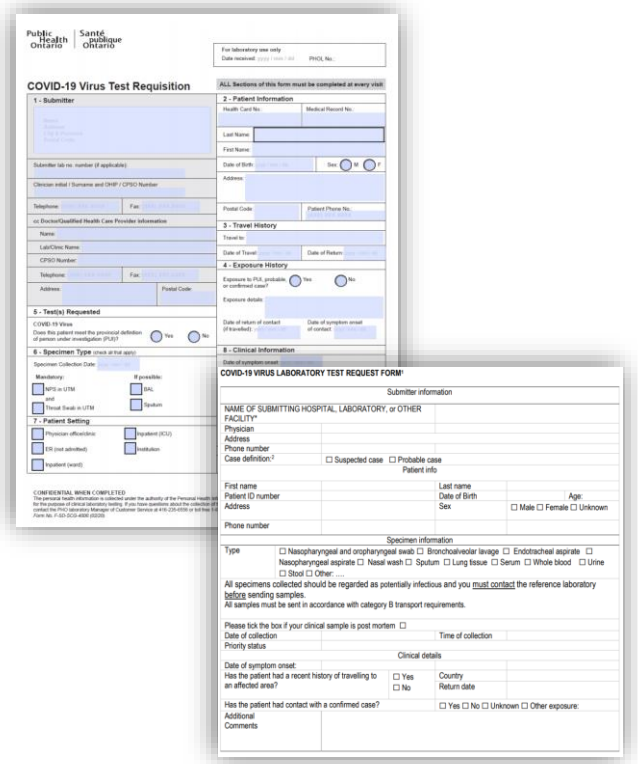


Define a good labeling system

Assess all samples - pre-examination

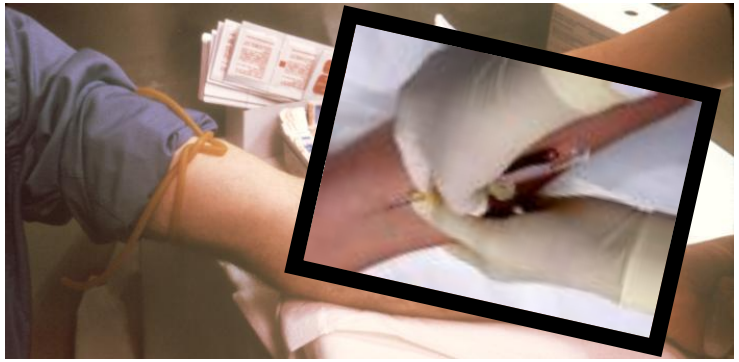
Sample Submission From

- Form should include the following information:
  - Patient identification
  - Patient demographics (age, sex, race)
  - Time and date of the sample collection
  - Source of the sample
  - Clinical data
  - Contact information of the physician submitting the sample



Sample Collection Requirements

- Vary depending on the test and type of sample:
  - Patient identification: accurate identification of patient is important
  - Type of sample required (nasopharyngeal, oropharyngeal, nasal, etc.…)
  - Type of container needed (specific transport media, etc.…)
  - Sample labeling: requirement for labeling at time of collection should be indicated
  - Special handling instructions (immediate refrigeration, protection from light, safety precautions, etc.…)



Sample Labeling

- Sample should be clearly labeled with:
  - Patient identification
  - A unique identification number (hospital- or collection site-generated number or number provided by the laboratory)
  - Requested test
  - Time and date of collection
  - Initials of person collecting the sample

➢ **A computer-generated bar code should be used when possible**

Sample Processing

Sample Quality Verification

- Pre-examination verification
  - Proper labeling
  - Adequate volume
  - Good condition
- Enforce sample rejection criteria
- Record sample information in register or log

Define Sample Rejection Criteria

- Is the sample correctly labeled?
- Is the sample container compromised?
- Is the correct tube or container used?
- Does sample label and patient name match?
- Is the volume enough for the requested test?
- Was the transport time too long?
- Was the sample handled correctly during transport?

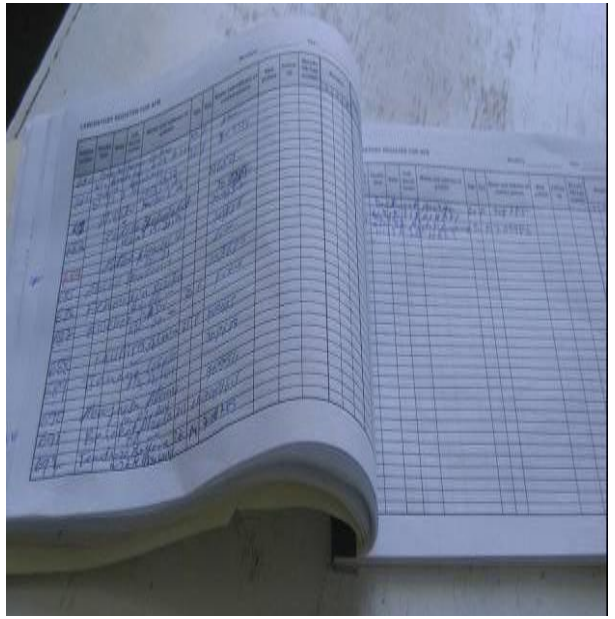
Nasal swab in viral transport media with incomplete label.

➢ Poor sample quality will not allow for high quality sequencing results

Sample Registration

- All incoming samples should be registered

- Registration should include:
  - Date and time of collection
  - Date and time sample was received at the laboratory
  - Sample type
  - Patient identification and demographics
  - Laboratory-assigned identification
  - Test to be performed (if also submitted for clinical testing)
  - Other metadata as available



A database/spreadsheet can be created from the register log

➢ Poor sample registration will lead to errors

Manual Sample Tracking System

- A tracking system from sample reception until results reporting should be available
- Confirm receipt of sample; include date and time
- Label sample appropriately; keep with the test requisition until laboratory ID is assigned
- Track aliquots: traceable to the original sample

Electronic Sample Tracking System

- A tracking system from sample reception until results reporting should be available
- An electronic database can be used to track key information:
  - Identification number
  - Patient information
  - Collection date and time
  - Type of sample
  - Tests to be performed
  - Name of ordering physician
  - Location of patient
  - Diagnostic test results
  - Time and date results are reported

Sample Storage, Retention, and Disposal

Sample Storage

- Written policies should be developed that include:
  - Retention time
  - Location
  - Condition of storage (temperature requirements)
  - System for storage organization: by date of receipt or accession number

Sample Retention

- An organized, accessible system using computer tracking system should be available
  - Review inventory of stored samples at defined intervals
  - Monitor freeze/thaw cycles
  - Define policy for retention of each type of sample

Sample Disposal

- Set policy for sample disposal
- Comply with local and country regulations
- Establish and follow procedures for sample disinfection prior to disposal
- Define sample disposal documentation requirements

Sample Transport

Sample Transport

- Maintain integrity of sample during transport
  - Temperature
  - Special transport containers
  - Sample preservation
  - Time limitation

- Compliance with safety regulations
  - National transport regulations
  - ICAO/IATA transport regulations (air)
  - Rail, road, and sea traffic agencies
  - Postal services

Infectious Substances Classification

- **Category A**: infectious substances capable of causing:
  - Permanent disability
  - life-threatening or fatal disease to humans or humans and animals

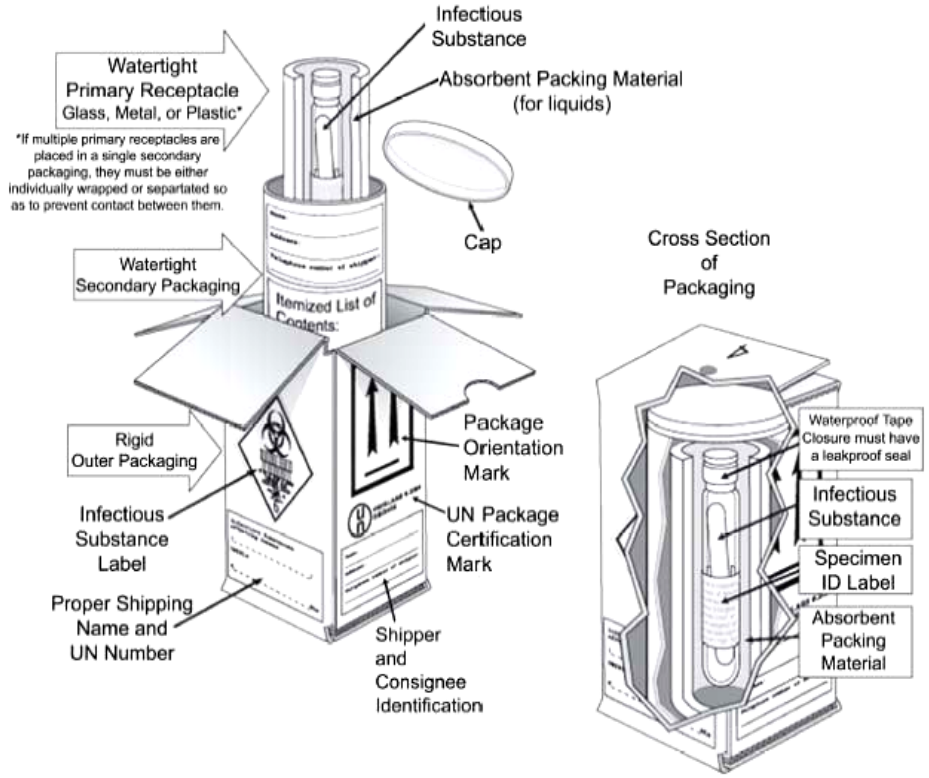
  - Packaging: most durable triple packaging with full **dangerous goods documentation**

  - Training of transport staff required

- **Category B**: Infectious substances not include in Category A

  - Less stringent triple packaging

  - No dangerous goods documentation required



Summary

- Laboratory handbook describing sample collection and providing testing information must be available to everyone who needs the information
- System for samples tracking must be available
- A policy for sample storage and disposal should be available
- Maintain sample integrity during transport and comply with all regulations
- Every sample should be checked against acceptance and rejection criteria
- Quality of results is directly related to the quality of sample received

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