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Medical laboratories — Requirements for collection, transport, receipt, and handling of samples

Laboratoires de biologie médicale — Exigences pour le prélèvement, le transport, la réception et la manipulation des échantillons

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical Laboratory testing and in vitro diagnostic test systems*.

Introduction

Medical laboratory services are essential to patient care and public health and therefore, have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services are required to be performed according to documented policies and procedures for examination requests, patient preparation, patient identification, collection of samples, transportation of samples, sample storage, processing, examination of samples and reporting results, in addition to the considerations of safety and ethics in medical laboratory work.

This document provides guidance from a number of sources that are incorporated into a set of good laboratory practices encompassing the pre-examination processes, in a way that meets published requirements for sample collection and handling. This document is intended to be used by individuals and organizations engaged in the collection of samples for submission to medical laboratories for examination, for the purpose of ensuring the quality of laboratory services and to achieve better health outcomes for the public.

It is acknowledged that a country could have its own specific guidance or requirements applicable to professional personnel, their activities and their responsibilities in this domain.

Each laboratory or sample collection organization should determine its level of adherence to the good laboratory practices described in this document. Management should take the first step by setting appropriate priorities based on patient and customer needs, the resources available, as well as local, regional and national mandates.

This document was developed based on the Canadian Standard CSA Z316.7–12.

Medical laboratories — Requirements for collection, transport, receipt, and handling of samples

1 Scope

This document specifies requirements and good practice recommendations for the collection, transport, receipt and handling of samples intended for medical laboratory examinations.

This document is applicable to medical laboratories and other medical services involved in laboratory pre-examination processes that include the examination request, patient preparation and identification, sample collection, transport, receipt and storage. It may also be applicable to some biobanks.

This document does not apply to blood and blood products intended for transfusion.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

3.1
arterial puncture
procedure (3.13) that involves the collection of blood from arteries by puncturing the skin

3.2
biobank
entity that performs *biobanking* (3.3)

Note 1 to entry: A biobank encompasses staff, facilities and procedures (e.g. management systems) and includes service providers, as well as repositories of biological materials.

3.3
biobanking
process (3.14) of receiving, collecting, storing and distributing biological materials from human, animal, plant and microorganisms, as well as related information and data, for the purpose of research and development

Note 1 to entry: Some or all of the following activities may also be included: processing, testing and analysing.

Note 2 to entry: For the purpose of this document, this definition only includes human materials procured solely for diagnostic and treatment purposes, e.g. surgical pathology archives.

3.4
capillary puncture
procedure (3.13) that involves the collection of blood from capillaries by puncturing the skin

3.5
cleaning
process (3.14) to remove any type of contamination, visible or not

[SOURCE: ISO 15190:2003, 3.5]

3.6
decontamination
procedure (3.13) that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects

[SOURCE: ISO 15190:2003, 3.7]

3.7
disinfection
process (3.14) of reducing the number of microorganisms, but not usually bacterial spores, without necessarily killing or removing all organisms

[SOURCE: ISO 15190:2003, 3.9]

3.8
examination processes
analytical phase
set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: Laboratory examinations are also often called assays or tests.

[SOURCE: ISO 15189:2012, 3.7, modified — Notes to entry 2 and 3 have been omitted.]

3.9
hand hygiene
general term referring to any action of hand cleansing

[SOURCE: WHO Guidelines on Hand Hygiene in Health Care, 2009]

3.10
medical laboratory
clinical laboratory
laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

Note 1 to entry: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

[SOURCE: ISO 15189:2012, 3.11]

3.11
post-examination processes
post-analytical phase
processes (3.14) following the examination, including review of results, retention and storage of clinical material, sample and waste disposal, as well as formatting, releasing, reporting and retention of examination results

[SOURCE: ISO 15189:2012, 3.14]

3.12
pre-examination processes
pre-analytical phase
processes (3.14) that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s) and transportation to and within the laboratory and end when the analytical examination begins

[SOURCE: ISO 15189:2012, 3.15]

3.13
procedure
specified way to carry out an activity or a *process* (3.14)

[SOURCE: ISO 9000:2015, 3.4.5]

3.14
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Inputs to a process are generally outputs of other processes and outputs of a process are generally the inputs to other processes.

[SOURCE: ISO 9000:2015, 3.4.1]

3.15
personal protective equipment
materials used to form a barrier to prevent contamination of a person by chemical or biological substances

Note 1 to entry: This includes, but is not limited to, lab coats, gowns, gloves, face shields and goggles.

3.16
sample
primary sample
discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

Note 1 to entry: Global Harmonization Task Force (GHTF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

Note 2 to entry: In some ISO and CEN documents, a specimen is defined as "a biological sample derived from the human body."

Note 3 to entry: In some countries, the term "specimen" is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

Note 4 to entry: The term "sample" is used in this document to include both the primary sample (specimen) and sample (aliquot).

[SOURCE: ISO 15189:2012, 3.16, modified — Note 4 to entry has been added.]

3.17
sample collection
process of obtaining a *primary sample* (3.16)

3.18
venipuncture
procedure (3.13) that involves the collection of venous blood by penetrating a vein with a needle or other collection apparatus

4 Quality management

An organization engaged in collecting, handling and submitting samples for examinations by medical laboratories, should establish, document, implement and maintain a system, to enhance customer satisfaction through assurance of conformity to customer needs, fulfil applicable statutory and regulatory requirements and include processes to improve the system. Having a quality management system in place will facilitate the implementation of these requirements.

5 Pre-examination processes relating to patient samples

5.1 General

This document presents requirements and good practice recommendations in the order of the process flow for sample collection, handling, transport and receiving. Only a brief description of each activity follows Figure 1, details are provided in the subsequent sections.

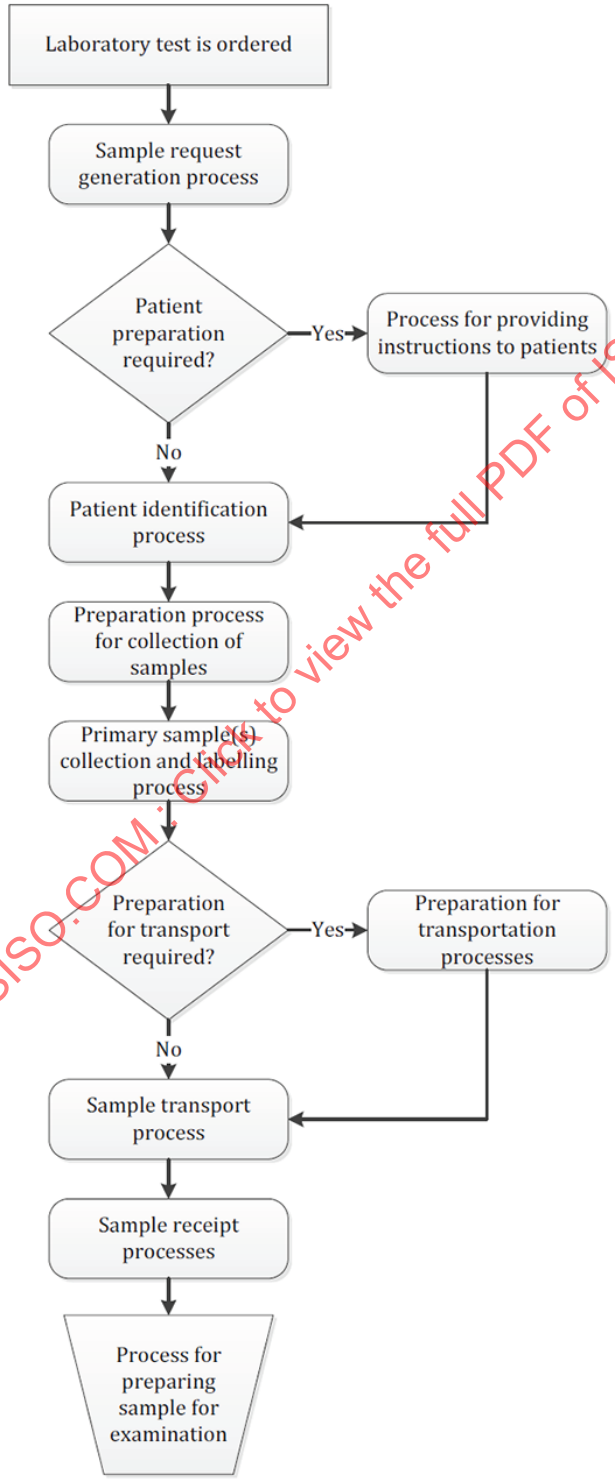

Figure 1 — Pre-examination processes relating to patient samples

5.2 Laboratory test is ordered

The organization shall provide information on how to order tests to all users of the services. There shall be instructions provided for the completion of a test request form (see 10.1 and Clause 11).

5.3 Sample request generation process

The organization shall have procedures for the handling of requests for sample collection. This will include both written and verbal requests, in routine and emergency situations, in both paper and electronic formats. (See 11.2)

5.4 Process for providing instructions to patients

The organization shall have procedures describing information that is given to and obtained from patients. The type of test requested will determine the need for fulfilment of specific requirements before sample collection (see 10.2).

5.5 Patient identification process

The organization shall have policies and procedures for patient identification for both routine sample collection and sample collection in medical emergency situations (see 12.2 and 12.3).

5.6 Preparation for sample collection process

The organization shall have policies and procedures for infection prevention and control (see Clause 8), informed consent (see 14.2), patient preparation and for recording any deviations.

5.7 Primary sample collection and labelling process

The organization shall have procedures for the proper collection, labelling and handling of samples (see Clause 13, 14.3, 14.5, 14.6).

5.8 Preparation for transportation process

The organization shall have procedures for samples that require special handling to maintain the integrity of the sample prior to and during transportation to the laboratory (see Clause 15).

5.9 Sample transport process

The organization shall have procedures for packaging and transporting of samples (see Clause 16). Transportation of samples is subject to statutory and regulatory requirements.

5.10 Sample receipt process

The organization shall have procedures for the receipt, assessment, processing and storage of samples. Sample reception procedures shall cover all sample types received by the facility (see Clause 17).

5.11 Process for preparing sample for examination

The organization shall have procedures for preparing samples for examination. This process may occur at the collection facility or following transportation to the testing laboratory (see Clause 18).

6 Infrastructure and environmental conditions

6.1 General

Sufficient space shall be allocated for pre-examination activities to ensure the quality of work, safety of personnel and patient care services are not compromised. The materials and equipment need to be adequate for supporting the activities of the facility and be maintained in functional and reliable condition.

6.2 Design

6.2.1 General

The design of the sample collection facilities shall support efficient operations and minimize the risk of injury and occupational illness. Patients, personnel and visitors shall be protected from recognized hazards.

When designing locations for sample collection, consideration shall be given to accessibility, comfort, safety, privacy and confidentiality for patients and personnel.

Statutory and regulatory requirements may apply.

6.2.2 Safety and accessibility

The following shall be considered in the design process:

a) accessibility for mobility devices;

b) ease of evacuation in case of emergency;

c) non-skid floor surface;

d) access to a sink for hand washing, or the provision of alcohol-based or other hand sanitizer;

e) specific safety aspects for children in collection rooms (e.g. child proof locks on cupboards, safe height for needles/sharps containers and any features in a waiting room) as well as for paediatric sample collection;

f) availability and proximity of toilets;

g) ergonomically designed furniture for ease of collection for both personnel and patients, including a bed, a chair able to be easily reclined, with two side armrests, or a stretcher for the patient to lie down in the case of a medical emergency;

h) space between seats in the patient waiting area to minimize risk of droplet infection from symptomatic patients of respiratory tract infection to other patients;

i) some facilities may need to have equipment for resuscitation; statutory and regulatory requirements may apply;

j) access to first aid;

k) posted instructions for how to obtain rapid medical attention when required;

l) access to a biohazardous spill kit for safe disposal of broken or leaking samples;

m) separation of areas in which there are incompatible activities.

6.2.3 Privacy and confidentiality

To protect patient privacy and confidentiality, sample collection shall be performed in an area that

a) provides sufficient privacy to ensure patient confidentiality is maintained,

b) provides personal privacy for the patient during sample collection (e.g. during a blood draw or collection of a urine sample and when removal of clothing is necessary),

c) has a secure place for storage of a patient's personal property if needed, and

d) protects confidentiality of information on documents and in electronic systems.

6.2.4 Equipment, supplies and storage

When relevant, the facility design shall be able to accommodate

a) space for storage of all the required materials and supplies used in sample collection, and

b) space for materials and equipment needed for the collection and stabilization of samples, transport and storage.

6.3 Facility maintenance and environmental conditions

Work areas shall be clean and well maintained. The facility shall design and verify a cleaning and disinfection process, with emphasis on infection control.

The spaces dedicated to pre-examination processes need to be designated smoke-free.

Measures need to be taken to ensure good housekeeping in the facility. This includes special procedures for decontamination, as well as training for personnel involved in housekeeping tasks.

6.4 Personnel facilities

There shall be adequate access to washrooms, to a supply of drinking water and facilities for storage of personal protective equipment and clothing.

Safety of personnel working alone should be considered.

7 Equipment and supplies

7.1 General

Procedures shall be developed and implemented for the selection and use of purchased external services, equipment and consumable supplies. Purchased items need to consistently meet the organization's quality requirements.

Equipment, including hardware, software, consumables and reagents shall be safeguarded from adjustments or tampering that might invalidate pre-examination activities or subsequent examination results.

NOTE Refrigerators, centrifuges and transport boxes are some of the most widely used equipment in sample collection facilities.

7.2 Equipment acceptance testing

Equipment shall be verified upon receipt and before use to ensure that it is capable of achieving the necessary performance and that it complies with requirements specified at the time of procurement.

Each item of equipment shall be uniquely labelled, marked or otherwise identified.

7.3 Inspection and storage

Consumable materials shall be inspected on receipt and accepted or rejected in accordance with the organization's specified requirements; then stored according to manufacturer's specifications. Records of the acceptance or rejection of consumable materials shall be kept for a defined period, in accordance with the facility's document and record control system. Statutory and regulatory requirements may apply.

Equipment and supplies shall be available in sufficient quantities and suitable for their intended use in sample collection, stabilization, transport and storage processes. When selecting equipment, use of energy and future disposal (i.e. protection of the environment) should be taken into account.

Equipment and supplies shall be clean and well maintained. Supplies shall be kept under controlled conditions during transport and storage.

Selection of sample collection devices shall take into account local and regional safety regulations.

Procedures shall be developed and implemented for the safe handling, maintenance, transport, storage and use of equipment, to prevent its contamination or deterioration.

7.4 Inventory management

An inventory control system for supplies shall be established to ensure that

a) supplies shall not be used after their expiry date,

b) sufficient supplies are available to meet the needs of the operation, and

c) safety data sheets are available.

7.5 Equipment maintenance and repair

Current instructions on the use, safety and maintenance of equipment, including any documentation provided by the manufacturer of the equipment shall be available. Procedures for proper calibration of equipment used in pre-examination activities shall be provided. Documented and recorded processes and procedures for preventive maintenance that, at a minimum, follows the manufacturer's recommendations are also required.

Equipment used in sample collection, processing and transport should be designed and constructed of materials facilitating thorough internal and external cleaning and disinfection. Beds, chairs and countertops shall be made of materials that can be easily cleaned and disinfected when soiled.

When equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired. The effect of the defect should be evaluated and any follow up action taken when indicated. Records shall be available that confirm the equipment's acceptability for return to service after damage, malfunction and repair. .

Reasonable measures shall be taken to decontaminate equipment before service, repair or decommissioning. Repair shall take place in safe working conditions and appropriate personal protective equipment shall be provided. Decontamination and disposal of used equipment shall be performed in accordance with any statutory and regulatory requirements.

7.6 Equipment operation

Only trained and competent personnel shall operate equipment. Instructions on the use and maintenance of equipment, (including any relevant manuals and directions for use provided by the manufacturer), shall be available to facility personnel. This includes instructions for decontaminating centrifuges after tube breakages.

Refrigerator and freezer temperatures shall be monitored and recorded to eliminate risk for unreliable results. Temperature ranges established shall meet the requirements of items stored within.

Centrifuges shall have the timing mechanism, rotation speed and internal temperature checked periodically; as appropriate for refrigerated centrifuges.

Equipment shall be cleaned and maintained in a safe working condition. This includes examination of electrical safety and emergency stop devices, safety features on sample collection devices and the safe handling and disposal of biological materials by authorized persons. The manufacturer's intended use of a device shall be observed.

7.7 Computer equipment

When computers or automated pre-examination equipment are used for the collection, processing and recording of data, the organization shall ensure that

a) computer software is documented and validated as being adequate for use in the facility,

b) procedures are established and implemented for protecting the integrity of data at all times,

c) the computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data,

d) computer programs are adequately protected to prevent access, alteration or destruction by unauthorized persons or inadvertently, and

e) any software upgrades are adequately documented and validated for its functional specifications and intended use.

7.8 Equipment records

Records are to be maintained for each item of equipment contributing to the performance of pre-examination activities. These records shall include, at a minimum, the following:

a) identity of the equipment, manufacturer's name, model and serial number or other unique identification;

b) contact information for the supplier or the manufacturer;

c) date of receipt and the date of placing the equipment into service;

d) current location;

e) condition when received (e.g. new, used or reconditioned);

f) manufacturer's instructions;

g) records that confirmed the equipment's initial acceptability for use;

h) records of maintenance and service carried out and planned;

i) records of equipment damage, malfunctions, modifications and repairs;

j) predicted replacement date, if possible;

k) manufacturer's recall notice on equipment and action taken as appropriate.

These records shall be maintained and available throughout the life of the equipment or for any other time period required by statutory and regulatory requirements.

8 Infection prevention and control (biosafety)

8.1 Personal protective equipment

Personal protective equipment (PPE) shall be available for persons collecting and handling samples. The PPE shall be appropriate to the level of risk. Basic PPE includes lab coats or gowns and gloves. Hypoallergenic PPE, e.g. non-latex gloves, shall be available when necessary.

Protective clothing shall be changed at appropriate intervals to ensure cleanliness and changed immediately if it is contaminated with hazardous materials.

Approved safety glasses, facial shields or other eye and face protection shall be available and worn, if there is the potential for splashing of samples to occur, as well as when handling hazardous materials. Additional eye protection shall be worn with contact lenses, as these lenses offer no protection from splashes.

8.2 Hand hygiene

Hand hygiene is, at a minimum, to be performed before and after patient contact, between patients, as well as after glove removal (see Annex A). In circumstances where hands look or feel dirty, they need to be washed with soap and water. At all other times it should be acceptable to use alcohol-based hand sanitizer.

Hand hygiene stations (including alcohol-based hand sanitizers) are to be easily accessed.

NOTE Alcohol-based sanitizers are not effective against some gastro enteritis viruses such as Norovirus and one of the major causes of healthcare acquired infections *Clostridium difficile*. Other appropriate means of disinfection, such as soap and water is needed for patients suspected of having these diseases.

When either a patient is, or personnel are allergic to alcohol-based sanitizers, an alternative such as chlorhexidine-based products should be considered.

Handwashing sinks are not to be used for disposal of samples.

8.3 Personnel practices

Personnel should avoid wearing artificial nails, rings and loose jewellery. Natural nails should be kept short to prevent tearing of gloves. Long hair shall be secured back.

Personal protective equipment (PPE) that is appropriate to the task shall be worn and equipment such as gloves, gowns and masks shall be properly fitted.

Gloves shall be changed between each patient sample collection when used.

8.4 Safe disposal

Single-use equipment shall be disposed of after each collection. Statutory and regulatory requirements may apply.

Safe disposable equipment such as needles with built-in safety devices should be used.

Sharps shall be disposed of immediately after use in puncture-resistant containers and in accordance with applicable statutory and regulatory requirements.

The minimum standard for segregating healthcare wastes is the “three-bin system”, where separate containers are provided for infectious waste, used sharps and general waste.

Biohazardous waste shall be disposed of in designated containers, with appropriate biohazard symbols and in accordance with applicable statutory and regulatory requirements.

8.5 Patient protection

Sterile single-use supplies shall be used in sample collection.

Tourniquets should be latex-free, or be applied on top of clothing.

Tourniquets shall be cleaned between uses when single use is not possible.

Disposable surgical masks can be made available to patients when respiratory organisms are circulating in the community to reduce the potential respiratory spread of infection, including seasonal influenza outbreaks, or increased incidence of other infections spread by droplets.

8.6 Cleaning and disinfection

Trays or carts used to hold supplies shall be made of materials that can be cleaned and disinfected.

To minimize contamination risk, the environment where samples are collected shall be cleaned as follows:

a) phlebotomist chairs, beds and horizontal surfaces in sample collection areas (tables, desks, counters, floors, etc.) shall be cleaned at least daily and when soiled;

b) patient waiting areas shall be cleaned at least daily and more frequently depending on use;

c) surfaces that come into contact with patients (bed rails or surfaces, arm rests) shall be cleaned at least daily and between patients when soiled;

d) toilets and doorknobs shall be cleaned daily or more frequently, depending on use and immediately following use by a patient suspected of having infectious enteritis;

e) toys and any other items provided for children shall be cleaned at least daily.

The most commonly used disinfectants are ethyl or isopropyl alcohol (70 % to 85 %), chlorine compounds (0,01 % to 5 %), or quaternary ammonium compounds (0,1 % to 2 %). In all cases the manufacturer's instructions shall be followed (see Annex B).

8.7 Special precautions

Procedures shall be followed when samples are collected from patients in need of special precautions, such as immune compromised patients or patients otherwise requiring isolation.

9 Personnel

9.1 General

Job descriptions shall be available that define the qualifications and duties of all personnel. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed and be appropriate to the tasks performed.

Personnel resources shall be adequate for undertaking the work of collecting, handling and transporting samples, as well as fulfilling the organization's quality management system functions.

9.2 Training and competence

9.2.1 Personnel training

A process for introduction of new personnel shall be documented and implemented. This shall include an introduction to the organization, the terms and conditions of employment, personnel policies, health and safety requirements (including fire and emergency) and any occupational health services.

Personnel training shall specifically include:

a) procedures for
   - accurate patient and sample identification,
   - proper collection techniques for the sample types likely to be encountered,
   - sample storage and handling requirements,
   - reporting and documentation of adverse events and other nonconformities,
   - prevention or containment of the effects of adverse events (e.g. first aid training),
   - emergency situations, and
   - use of computers and other relevant information technology.

b) safety and infection control procedures for protection of the personnel and patients;

c) patient privacy expectations and confidentiality of patient information, statutory and regulatory requirements may apply;

d) assigned work processes and procedures.

Personnel undergoing training shall be supervised at all times.

The effectiveness of the training programme shall be periodically reviewed.

9.2.2 Competence and continuing education

The competence of each person to perform assigned tasks shall be assessed following initial training and periodically thereafter. Retraining and reassessment shall occur when necessary.

A continuing education programme shall be available to all personnel to support professional development and competence. All personnel shall take part in continuing education.

Records of competence assessments and continuing education are required.

9.3 Confidentiality and access to information

Confidentiality of patient information shall be respected and maintained by all personnel. Statutory and regulatory requirements may apply.

Documented procedures shall identify which personnel are authorized to

a) use the electronic laboratory information system,

b) access patient data on a need to know basis,

c) enter and revise patient data,

d) correct billings, and

e) modify computer programs.

9.4 Personnel records

Personnel records shall be maintained and available to authorized personnel and include:

a) educational and professional qualifications;

b) copy of any certification or license, when applicable;

c) previous work experience;

d) job descriptions;

e) evidence of completion of initial training and orientation of new personnel;

f) evidence of training in current job tasks;

g) competency assessments;

h) records of continuing education and achievements;

i) reviews of staff performance;

j) reports of accidents and exposure to occupational hazards;

k) immunization status, when relevant to assigned duties.

10 Information for patients and users of services

10.1 Information to be provided by laboratories that will receive the samples

Each laboratory is expected to provide the following information to sample collection facilities:

a) information necessary for selection and requesting of examination procedures:

   1) the examinations offered by the laboratory including, as appropriate, information concerning type of samples required, primary sample volumes, special precautions, turnaround times, biological reference intervals and clinical decision values;

   2) factors known to significantly affect the performance of the examination or the interpretation of results;

   3) for each molecular genetic test, the following information:

      — intended use, to include the nucleic acid target the test intends to analyse (for example, genes, sequence variation), the purpose of testing and appropriate use of the test and the recommended patient population(s);

      — specifications of applicable performance characteristics, to include information on both analytic validity and clinical validity of the test;

      — limitations of the test;

b) information regarding patient preparation:

   1) instructions for preparation of the patient;

   2) instructions for patient-collected samples;

   3) any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals) in compliance with applicable statutory and regulatory requirements;

c) information relating to collection, handling and transportation of samples:

   1) sample type, amount or volume and collection container, device and system;

   2) minimal sample requirements;

   3) sample preparation;

   4) sample preservation, stability and transport conditions;

5) instructions for transportation of samples, including any special handling needs;

6) the laboratory's criteria for accepting and rejecting samples;

d) information needed by the laboratory to initiate and perform examination procedures in a timely manner:

1) patient information required to perform the testing and interpret test results, including relevant clinical information, and when applicable, the patient's race/ethnicity information, family history and/or pedigree and patient consent information;

2) date and time of sample collection, storage conditions and transport conditions;

3) time specimen placed into 10 % neutral buffered formalin (NBF);

e) availability of consultation and advice from the laboratory regarding test selection and requesting, sample submission, result interpretation and understanding of the implications of test results;

f) the laboratory's policy on protection of personal information.

NOTE Laboratories are responsible for providing information regarding the examinations they perform to users of their services, to facilitate appropriate test selection, test requests, sample collection and handling, as well as patient care management. This is usually provided in the form of a sample collection manual or laboratory handbook, in either hard copy or electronic format.

10.2 Information for patients

Patients shall be given information to enable them to understand the risks, benefits and possible outcomes of collection procedures. Information shall be available that includes an explanation of the procedure to be performed to enable informed consent. Importance of provision of patient and family information shall be explained to the patient where necessary (e.g. for interpreting genetic examination results).

NOTE Genetic counselling may be a requirement prior to the examination.

Clear and precise instructions shall be given to patients with regard to collection requirements, for example:

a) time period for fasting before collection;

b) time period and contents of any special diet before collection;

c) medications and supplements that should not be taken prior to collection;

d) requirement for specific time of last dose of medication;

e) the need to refrain from specific activities prior to sample collection;

f) requirement for collecting the sample at a precise time.

Instructions for patient-collected samples shall be provided. e.g. midstream urine sample collection, faecal sample collection.

Plain language shall be used to convey information at a level the patient can understand. When possible, language barriers should be resolved to ensure the information is clearly understood by the patient. Written instructions (as well as graphic educational materials designed for patients) can be used to complement verbal communication. Consideration shall also be given to translation into other languages, depending on local population needs.

11 Request form

11.1 Request form information

Procedures shall be developed and implemented for the management of requests for sample collection.

Information sufficient to identify the patient and the authorized requester, as well as relevant clinical data are required. Statutory and regulatory requirements may apply.

NOTE 1 In jurisdictions allowing self-ordering, the patient is considered to be the authorized requester.

The request form or electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:

a) patient identification including:

   — first and last name of the patient or equivalent information if these are not available,

   — date of birth and gender of the patient,

   — location/contact details of the patient, and

   — a unique patient identifier.

   NOTE 2 Unique identification includes an alpha and/or numerical identifier such as a hospital number, medical record number, or personal health number.

b) name or other unique identifier of the physician or other person legally authorized to request examinations or use medical information;

c) an address and contact details where results can be delivered and emergency contact information for reporting critical results;

d) type of primary sample and, where relevant, the anatomic site of origin;

e) examinations requested; and

f) clinically relevant information about the patient and the request.

NOTE 3 Information needed for examination performance and results interpretation can include the patient's ancestry, family history and travel and exposure history, communicable diseases and other clinically relevant information.

Space may be included for additional information such as

a) date the request form was completed,

b) date and time of primary sample collection,

c) identity of the person who collected the sample, and

d) date and time of receipt of the sample by the laboratory.

The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory shall be determined in consultation with users of the laboratory's services.

Request forms received by the collection facility shall be reviewed for completeness of information. Any omissions of required information shall be corrected before proceeding with sample collection.

11.2 Verbal requests

A procedure is required for verbal requests for examinations. The procedure shall specify that the verbal request be subsequently confirmed by a request form (either electronic or paper) within a specified time.

The procedure shall also include actions required for additional tests requested after samples have been received in the laboratory.

11.3 Transcription

If the information provided on the request form is transcribed into a record system or an information system, the organization shall have procedures to ensure that the information is transcribed or entered accurately.

Scheduled data registration checks shall be performed to identify and reduce transcription errors.

12 Patient identification

12.1 General

Procedures for the determination of patient identification prior to sample collection shall include a requirement for at least two unique identifiers attributable to the patient and specified by the organization.

NOTE More than two identifiers may sometimes be required in order to establish a unique identity.

Procedures for patient identification are required for both routine sample collection and in medical emergency situations.

Patient privacy shall be protected at all times and in accordance with any statutory and regulatory requirements.

12.2 Routine patient identification

Before initiating routine sample collection, patient identity shall be verified by the person collecting the sample, using at minimum two unique identifiers as specified by the organization:

a) patient is asked to state his or her full name and the information provided in the response shall be compared to the information on the request form and the unique identifiers specified by the organization;

NOTE 1 An exception to this may occur if a sample is to be collected and identified anonymously, in which case other identifiers will be used

b) any discrepancy, however minor, shall be reported to the appropriate personnel and resolved before any sample is collected.

When a patient is unable to state or provide the required identifiers:

— identity can be verified by a responsible adult who knows the patient (e.g. a relative or caregiver);

— the name of the person who confirmed the patient's identity shall be recorded.

NOTE 2 Reasons for lack of verbal communication include patient not speaking the language of the health care provider, cognitive impairment, unconsciousness and speech disabilities.

12.3 Patient identification in medical emergency situations

In a medical emergency situation, an unidentified patient shall have a temporary identity assigned, until positive identification can be made. For a person who cannot be identified immediately, it is necessary to

a) assign a master identification number (temporary) to the patient in accordance with organizational policy,

b) select the appropriate request forms and record with the master ID number, and

c) complete the necessary labels either by hand or by computer and apply the labels first to the request forms and then the samples after collection is complete;

The temporary master identification number shall be traceable to the permanent identification to ensure correct identification and correlation of patient and examination result information.

In all cases, the name and permanent or temporary identification designation need to be attached to the patient's body, either by way of an identification band or some similar device, except in the case of isolation patients, or patients with skin damage such as burns, when bed labels may be used in place of bands.

12.4 Patient identification of babies and young children

A family member, guardian, or authorized healthcare professional shall state the child's name and date of birth. The name of the family member or guardian who has identified the child and the relationship to the child shall be recorded. If the patient was identified by a healthcare professional, the person's name and title shall be recorded on the request form.

Any identification band (if present) shall be compared with the verbal information and the request form to confirm

a) the child's name,

b) the child's date of birth,

c) the child's gender,

d) the child's hospital number, medical record number, personal health number or other unique identifier, and

e) the mother's last name, or last name of other party provided at the time of registration.

Each institution shall have procedures in place to manage maintaining identities in the case of multiple births.

Sample collection shall proceed only when all of the criteria match. When discrepancies are noted, corrections need to be made and documented.

13 Identification of samples

Unique labelling to ensure traceability to the patient from whom they were collected, shall be used to identify samples. This requires the use of two identifiers on all labels.

Samples need to be traceable, normally by a request form, either paper or electronic, to an identified individual.

The risks associated with labelling collection containers prior to sample collection shall be understood and controls included in the process to preclude errors. The preferred practice for labelling sample containers after collection also requires controls.

The patient identifiers shall include patient name and identifying number and always be clearly readable.

Additional information, which shall be recorded on the request form includes:

a) identity of the person who collected the sample;

b) collection date, and when relevant, collection time.

NOTE Bar codes are often used to label samples, with some of the required information embedded in the bar code.

There may be special circumstances where the identity of the patient will not be revealed to the laboratory. In such cases, adequate precautions need to be taken to maintain unique identification of the sample by other means at all stages.

14 Sample collection

14.1 General

Procedures for the proper collection and handling of samples shall be available to all those responsible for sample collection.

When deviations or exclusions from, or additions to the documented procedures occur for any reason, this information shall be recorded and may need to be included in reports containing examination results. This information shall also be communicated to the appropriate personnel.

14.2 Informed consent

All procedures carried out on a patient shall have the appropriate informed consent of the patient. For most routine collection procedures consent can be inferred when the patient presents with a request form and willingly submits to the usual collecting procedure, for example extending an arm for venipuncture. Patients in a hospital bed should be given the opportunity to refuse.

In emergency situations, consent may not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest and authorized by a qualified healthcare professional. Statutory and regulatory requirements may apply.

Recommended practice includes:

a) the person collecting the sample explains the procedure to the patient using terminology appropriate to the patient's comprehension level;

b) patient consent is confirmed before proceeding with sample collection;

c) any doubt about consent to the purpose of the collection is referred to the person who requested the sample collection;

d) if the patient is not of legal age or competent to give consent, consent is obtained from an accompanying parent or legal guardian;

e) if the patient refuses the procedure, the person collecting the samples records the refusal and ensures the person who requested the test is notified promptly;

f) the patient is allowed to withdraw consent at any time during the procedure;

g) when applicable, a patient shall receive an explanation and confirm that consent is extended to a secondary use of the collected sample, such as for research purposes.

14.3 Instructions for collection activities

Procedures for sample collection shall include instructions for the following:

a) appropriate type of sample(s) to be collected;

b) volume or amount of sample required, (for example, volume of sample required to ensure the optimal blood to anticoagulant ratio; volume of sample required for examination procedures);

c) collection container or device to be used (for example, evacuated sample collection tubes, tubes with specific anticoagulant, specific cups or tubes containing sterile tissue culture media, buccal swabs);

d) any special timing of sample collection, when needed;

e) proper mixing of tubes following sample collection;

f) recording time of collection (for example, time placed in 10 % neutral buffered formalin)

g) when applicable, recording patient demography, disease stage and, whether samples are being collected before, during or after treatment, time from diagnosis;

h) safe disposal of materials used in the sample collection process.

14.4 Handling urgent requests

There shall be instructions for labelling, processing and handling samples deemed to be urgent.

The instructions shall include details of any special labelling of the request form and sample, the mechanism of transport and any special reporting requirements.

14.5 Blood sample collection

14.5.1 General

a) Single-use needles shall be used, preferably with safety devices on the needles. For other blood sample collection devices, such as tube holders and tourniquets, single-use devices should be used when available.

NOTE 1 The selection of the appropriate device and needle gauge is based on the physical characteristics of the vein and the volume of blood to be collected. Consideration of needle gauge size includes both outer and inner diameter of the needle, as inner diameter may vary across devices with the same exterior diameter. The inner needle diameter affects the rate at which blood flows through the device and can affect the quality of the sample obtained.

b) Tubes shall be selected according to the test requested and the laboratory's requirements.

NOTE 2 The use of plastic tubes is preferred.

c) All additive tubes shall be filled to within 10 % of the stated volumes.

d) Immediately following collection, blood samples in tubes containing additives shall be mixed gently and thoroughly by inverting the tube slowly for the required number of inversions in accordance with the manufacturer's instructions.

e) Closures shall preferably not be removed to fill a tube or to transfer blood from one tube to another.

f) There shall be procedures for the care of patients who experience adverse reactions during the sample collection process.

14.5.2 Order of draw

The order of draw specified by the facility shall be followed when collecting multiple blood samples during a single venipuncture or capillary blood collection.

NOTE The order of draw is usually based on information from the manufacturer of the tubes used for collection. The objective is to avoid contamination of blood culture samples and cross contamination of additives between tubes.

14.5.3 Special considerations when performing venipuncture

The following circumstances should be considered when performing venipuncture:

a) rest periods prior to collection should be defined when critical for medical interpretation of test results; to minimize influences of posture and physical activity on test results, it is recommended that the patient be seated or otherwise at rest for 15 min prior to blood collection;

b) compliance with any dietary restrictions, such as fasting, or other patient preparatory requirements shall be verified;

c) tourniquet application time should not exceed 1 min;

d) fist pumping or repetitive closing and opening of hand should be avoided to prevent falsely elevated potassium levels;

e) the site chosen for venipuncture should minimize the risk of nerve injury;

f) the number of attempts at venipuncture should be limited;

g) when collecting blood culture samples, strict aseptic technique shall be used and manufacturer's instructions for use of paired aerobic/anaerobic blood culture bottles followed;

h) areas with evidence of fistulas shall be avoided;

i) areas with evidence of oedema, haematoma, extensive scarring, fresh tattoos, burns, damaged or occluded veins should be avoided;

j) an arm on the same side as a mastectomy or one with paralysis, should also be avoided;

k) blood shall not be collected from an arm that is being infused with any fluid, unless appropriate precautions are taken and recorded.

14.5.4 Adult capillary puncture

Procedures for adult capillary puncture shall include instructions for the following:

a) selection of an appropriate puncture site;

NOTE When a finger is used as the puncture site, the middle or ring finger is the finger of choice.

b) areas that should be avoided, such as oedematous, bruised and previously punctured areas;

c) warming the puncture site to increase blood flow;

d) cleansing and disinfecting the puncture site;

e) wiping away the first drop of blood before proceeding with blood collection, unless specifically contraindicated for the test;

f) avoiding squeezing, scooping or scraping of the puncture site;

g) labelling the sample and recording time of collection;

h) confirming that bleeding has stopped before releasing the patient;

i) proper disposal of the lancet/incision device and other contaminated materials, such as gauze and gloves.

14.5.5 Paediatric venipuncture

14.5.5.1 General

Collection of samples from children less than two years of age shall be performed by experienced personnel who understand and can manage the potential hazards and risks associated with the procedure.

14.5.5.2 Patient preparation

For the paediatric patient extra special care and consideration is essential.

Depending on the age of the child, this could include aversion techniques, as well as dermal anaesthesia.

NOTE Certain groups of paediatric patients can be at risk for being combative (for example, developmentally disabled and autistic) and therefore require not only special preparation but additional personnel to achieve a successful and safe specimen acquisition.

14.5.5.3 Collection technique

An appropriate blood sample collection technique (i.e. venipuncture or capillary) shall be selected based on procedures that take into account:

a) age;

b) general health;

c) weight and height, or other physical determinants;

d) examinations requested.

Low-volume tubes shall be used when collecting blood samples from paediatric patients.

Collection procedures shall minimize discomfort for the child as much as practically possible. Excessive crying shall be recorded, as it may affect test results.

The maximum blood volume to be collected from a paediatric patient shall be based on weight. The medical or nursing personnel shall record in the patient's chart the total amount of blood collected on each draw from paediatric patients susceptible to iatrogenic anaemia.

NOTE Guidelines for blood samples volume limits (ranging from 1 % to 5 % of total blood volume within 24 h and up to 10 % of total blood volume over 8 weeks) are consistent with the limited evidence available on "minimal risk" to children.

Lower limits for sick children are advisable and a maximum of 3 ml/kg for neonates within 24 h (3.8 % of total blood volume), is a reasonable guideline, although each case should be judged on its own merits and greater caution may be needed in children with illnesses that impair the replenishment of blood volume or haemoglobin.

14.5.6 Paediatric capillary puncture

Experienced personnel shall perform paediatric capillary puncture.

Select an appropriate puncture site; fingers shall not be used on infants less than 6 months old.

NOTE the lateral or medial plantar surface of the heel is commonly the site of choice for children under one year old, or who have not begun to walk.

Lancets or blades longer than 2,0 mm might puncture the heel bone of a new-born and therefore, should not be used.

Procedures for collection shall be the same as for adults and are listed in 14.5.4 a) to i).

14.6 Other samples

Procedures are required for collection and handling of all other types of samples submitted to laboratories for examination, such as:

a) swabs;

b) sputum;

c) faecal samples;

d) urine;

e) samples for fertility testing (semen);

f) cerebrospinal fluid;

g) other body fluids;

h) biopsies and other tissue samples;

i) samples for cytology (Pap smears, fine needle aspirations, aspirated fluids).

Instructions for patient preparation shall be provided where applicable. Suitable collection containers shall be made available.

15 Sample integrity and stability

15.1 Sample integrity

In order to avoid compromising sample integrity, which in turn can affect examination results, the following should be ensured:

a) collection tubes and containers shall be stored according to manufacturer's instructions;

b) use of small bore needles may cause haemolysis and should be avoided;

c) traumatic or repeated attempts at venipuncture should be avoided;

d) sample tubes should be adequately mixed immediately following collection;

e) excessive mixing of sample should be avoided;

f) correct sample volume should be specified and collected;

g) correct volume for acceptable sample to additive ratio should be collected;

h) correct container or additives shall be used.

Samples shall be kept under temperature and storage conditions that will maintain their integrity until examinations can be performed, as well as for a specified period of time afterwards in case additional examinations are requested.

The laboratory receiving the blood samples for examination shall provide instructions on the type of tube in which the sample is to be stored and provide test specific information for storage temperature, including freeze–thaw cycles and length of time for all samples.

For body fluids, information regarding sample type, primary container type, pre-centrifugation delay, centrifugation, post-centrifugation and long-term storage should be recorded.

For solid tissue, at least sample type, type of collection, warm ischemia time, cold ischemia time, fixation type and time, storage type and time should be recorded.

Procedures to maintain sample integrity throughout the pre-examination process shall be validated and periodically audited.

15.2 Stability

The laboratory receiving the sample for examination shall provide test specific information for storage temperature and storage duration for all samples.

NOTE 1 Stability of a stored patient sample means that the sample will maintain a specified property value within specified limits for a specified period of time.

NOTE 2 Conditions that can affect the stability of samples for examination include metabolism of blood cells, evaporation, chemical reactions, microbiological decomposition or overgrowth, the effects of light, gas diffusion, contamination, time, temperature and leakage.

Sample stability information may include the timeframe beyond which the stability of a sample or the measurable entity to be detected in a sample may be compromised.

15.3 Stabilization

Some samples may need to undergo stabilization processes before being transported to the testing laboratory.

Examples of stabilization include centrifugation to separate serum from the cellular component of a blood sample, preparing blood smears in the case of haematology samples and storage of samples at a specific temperature.

The laboratory receiving the samples for examination shall specify which samples need stabilization and how long these samples can be stored before stabilization is performed. This information shall be made available to personnel performing stabilization activities.

16 Transport of samples

16.1 General

Procedures for packaging and transport of samples shall be available. Transportation of samples is subject to statutory and regulatory requirements.

Patients or any other persons carrying samples shall be made aware of the hazards associated with breaks and spills and informed about safe and appropriate handling and packaging for transport.

NOTE For the purposes of transport, infectious substances are defined as substances, which are known or are reasonably expected to contain pathogens.

16.2 Sample transport

The transport of samples to the testing laboratory shall be carried out in accordance with instructions provided by the testing laboratory.

a) Transport containers shall be validated to ensure that the required specifications are met. This shall include ensuring appropriate temperature conditions and testing for freeze–thaw cycling during transport.

b) When samples are transported outside of the facility, contact information of a designated person and biohazard signage shall be provided on the outside of a leak-proof container for sample transport. In an emergency situation, authorities should know whom to contact. Statutory and regulatory requirements may apply.

c) Sample transport should ensure sample integrity, prevent leakage and minimize agitation of tube contents to reduce the potential for haemolysis. Special transport requirements shall be defined when critical for testing.

d) To avoid contamination in case of leakage, sample request forms and any other documentation shall not be in direct contact with samples.

e) Patient confidentiality shall be protected in the transportation process.

f) Any deviations from the established environmental conditions or delays shall be recorded and included in the examination report.

16.3 Quality monitoring

Transportation of samples shall be monitored to ensure they are transported

a) within a time frame appropriate to the requested examinations,

b) within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity and stability of samples, and

c) in a manner that ensures the integrity of the sample and the safety of the carrier, the general public and the receiving laboratory, in compliance with established requirements.

17 Sample receipt and assessment

17.1 General

Procedures for the receipt, assessment, processing and storage of samples shall contain all information necessary for performing each of these processes. Sample reception procedures shall cover all sample types received by the laboratory.

All samples received by a laboratory shall be systematically reviewed and assessed against the laboratory's documented criteria for acceptance/or rejection (see 17.2).

Samples are required to be unequivocally traceable, by request form and labelling, to an identified patient.

17.2 Criteria for sample acceptance or rejection

The procedures for sample reception shall include defined criteria for acceptance and rejection of samples. When a sample fails to meet acceptance criteria, the authorized person named on the request form should be notified promptly.

Samples may be rejected due to:

a) improper handling or transport of the sample;

b) unlabelled or mislabelled containers;

c) discrepancy between label and request form;

d) absence of unique identifiers on the sample or the request form;

e) use of inappropriate anticoagulants, incorrect blood to additive ratio (under filled or over filled tubes), incorrect media, or inappropriate sample type;

f) commingled or possibly contaminated samples that may affect examination results;

g) lack of information necessary to determine whether the sample or test requested is appropriate for answering the clinical question;

h) sample exposure to temperature extremes that affect sample stability or integrity;

i) insufficient sample volume or quantity;

j) inappropriate container;

k) damage to the container and/or sample haemolysis;

l) time between obtaining sample and receipt in the laboratory exceeding specified time period, e.g. urine.

Each sample rejection shall be documented. This information can be used for quality monitoring.

17.3 Sample label confirmation

17.3.1 General

The patient identification information on sample labels shall match the patient identification information provided in the request form. Samples lacking proper identification shall not be accepted or processed by the laboratory.

All portions or aliquots of samples shall be unequivocally traceable to the original primary sample.

17.3.2 Managing nonconformities

Samples received unlabelled, mislabelled or insufficiently labelled shall not be relabelled by laboratory personnel after receipt in the laboratory.

Any changes made by a person authorized in accordance with organizational policies, shall be documented. Documentation shall include both the name of the person making the changes and the person who authorized the change.

When the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, despite problems with labelling, the final report shall indicate the nature of the problem, and where applicable, that caution is required when interpreting the result. Samples to be set aside or stored for future examination (e.g. viral antibodies, metabolites relevant to the clinical syndrome) shall also be properly identified.

17.4 Records of sample receipt

All samples received by a laboratory shall be recorded in an accession book, worksheet, laboratory information system or other comparable system. The record shall include:

a) identity of the patient [first and last name and unique patient identifier(s)];

b) if applicable, a sample identification number (e.g. an accession number);

c) the date and time of collection and identity of the person who collected the sample;

d) the date and time that the sample was received by the laboratory;

e) the identity of the person receiving the sample;

f) type of sample received;

g) for body fluid, at least information regarding sample type, primary container type;

h) for solid tissue, at least sample type, type of collection, warm ischemia time, cold ischemia time, fixation type and time;

i) if necessary, comments pertaining to the quality of the sample (e.g. haemolysis, insufficient quantity, or sample drawn from above an IV line);

j) if applicable, information on samples that have been rejected and the reason for their rejection.

17.5 Sample tracking

Samples and associated records (worksheets, slides, etc.) shall be uniquely identified during all stages of handling and testing.

This may be achieved by the use of a unique laboratory number. The uniqueness of a numbering system shall take into consideration the sample storage time and ensure that two samples with the same number cannot be in the laboratory at the same time.

Request forms received in the laboratory shall be retained for a specified period. Statutory or regulatory requirements may apply.

17.6 Urgent samples

Procedures are required for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions shall include details of any special labelling of the request form and sample, any rapid processing mode to be used, the mechanism for transfer of the sample to the examination area of the laboratory and any special reporting criteria to be followed.

17.7 Chain of Custody

The location of any sample shall be determinable at any time. A procedure and associated forms are required to ensure proper identification and handling of samples when chain-of-custody records are required. There shall be a complete audit trail record of all samples collected, including the identity of all persons handling or transferring the samples, together with details of all relevant dates and times. These records shall be stored securely as they may be required to be used as evidence.

18 Sample storage prior to examination

Procedures and appropriate facilities are required to prevent sample deterioration, loss or damage during pre-examination activities, including storage and preparation for transportation to the laboratory.

Laboratories shall specify how long and under what conditions samples can be stored before proceeding with the examination processes. This may enable repeat testing if required, or for additional examinations to be requested, after reporting of the initial result.

Samples shall be retained, stored and disposed of in accordance with procedures for handling biohazardous waste. Statutory and regulatory requirements may apply.

19 Customer satisfaction

Data relating to customer perceptions of the degree to which expectations and requirements have been met shall be collected and analysed. This can be achieved by obtaining customer feedback about the organization's processes and services. Customers may be the patient whose samples have been collected, the health care professional requesting sample collection and/or the laboratory receiving the samples for analysis.

Customer satisfaction shall be monitored periodically.

Opportunities to improve and to enhance customer satisfaction shall be identified and appropriate action implemented.

20 Identification and control of nonconformities

20.1 Identification of nonconformities

The organization shall have a procedure to identify and manage nonconformities.

NOTE Nonconformities can occur throughout the pre-examination processes and can be identified in many different ways, including complaints from patients or users of the services, checking of consumable materials and personnel comments.

The procedure shall ensure:

a) each nonconformity occurrence is recorded, with these records being reviewed at regular specified intervals by the organization's management to detect trends and initiate corrective action;

b) personnel responsible for problem resolution are designated;

c) the actions to be taken are defined;

d) the medical significance of the nonconforming pre-examination activities is considered and, where appropriate, the requesting healthcare professional informed;

e) immediate action is taken, when relevant;

f) root cause analysis is done where relevant, followed by corrective action;

g) review of effectiveness of any corrective action.

20.2 Records of nonconformities

The information that shall be recorded includes:

a) the date, time and location of the nonconformity;

b) the name of the patient whose sample was or may have been affected;

c) the name of the person who ordered the test request;

d) a brief description of the event (including a classification of the type of nonconformity);

e) a description of the remedial steps taken to reduce any negative consequences of an error;