
Requirements for the collection and transport of samples for medical laboratory examinations

*Exigences pour le prélèvement et le transport d'échantillons à des fins
d'examens en laboratoire médical*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 of 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 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*.

This first edition cancels and replaces ISO/TS 20658:2017, which has been technically revised.

The main changes are as follows:

- The Scope is now limited to activities occurring before samples are received by a laboratory for examination.
- The title has been changed to reflect a potentially wider audience than medical laboratories.
- This document is published as an International Standard rather than a Technical Specification.
- This document recognises that collection of samples can be provided by facilities independent of the medical laboratory.
- This document is closely aligned with ISO 15189 which is now included as a normative reference to this document.
- This document has been aligned with the mandatory ISO structure, which reflects its normative reference to ISO 15189.
- This document includes processes for emergency situations such as the COVID pandemic and indicates the possibility that samples may be collected in temporary or pop-up collection sites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Medical laboratory services are essential to patient care and public health. A critical element of a medical laboratory service is the collection and transport of samples to a medical laboratory for testing.

These activities are collectively known as pre-examination processes, which also include receipt and handling of samples. [Annex C](#) provides an informative schematic of the pre-examination process.

This document provides the requirements for all activities related to collection and transport of samples to ensure the quality of medical laboratory examination results and to achieve better health outcomes for patients.

Receipt and handling of samples are deemed laboratory functions and covered in ISO 15189.

Collection and transport of medical laboratory samples can be undertaken in many different scenarios, some examples are described below:

- hospital in-patient collection;
- out-patient collection;
- home collection at the site of the patient;
- patient self-collection;
- physician office/clinic collection;
- pop-up/temporary and mobile collection sites.

Whatever the scenario, this document identifies the requirements to be followed to minimise poor patient outcomes.

In emergency situations, such as the response to the COVID-19 pandemic, temporary collection facilities were established in various jurisdictions with the aim of providing more access to collection services. This enabled more testing for COVID to occur. Temporary collection facilities may not be able to meet all of the requirements in this document, however, as far as possible they should conform to this document in order to reduce potential risks to patients. Local jurisdictions can provide further guidance on minimum best practice for sample collection and transport in these sorts of temporary facilities.

It has been well documented that unless the pre-examination processes of a medical laboratory are performed accurately, a significant risk to patient safety and poor patient outcomes can result.

The primary consideration is always the welfare of patients. This document has been developed with the objective of promoting the welfare of patients through confidence in the quality and competence of those collecting and transporting samples to medical laboratories.

The responsibility for the sample collection and transport of samples lies with the facility/person directly performing those activities. However, the medical laboratory performing the examination should clearly define its responsibility in the process including where collection and transport is outside of either its direct control or responsibility, or both.

Requirements for the collection and transport of samples for medical laboratory examinations

1 Scope

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

This document is applicable to medical laboratories and service providers, which can be independent from the medical laboratory, involved in laboratory pre-examination processes that include the examination request, patient preparation and identification, sample collection and transport. It can also be applicable to some biobanks.

This document does not apply to blood and blood products intended for transfusion, e.g. red blood cells, platelets, fresh frozen plasma, but can cover the collection and transport of donor samples for testing.

NOTE International, national or regional regulations or requirements can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2022, *Medical laboratories — Requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189 the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

arterial puncture

procedure (3.15) that involves the collection of blood from arteries by puncturing the skin

3.2

biobank

legal entity or part of a legal entity that performs *biobanking* (3.3)

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

[SOURCE: ISO 20387:2018, 3.5, modified — Note 1 to entry added.]

3.3

biobanking

process (3.16) of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data

Note 1 to entry: Some or all of the following activities can 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.

[SOURCE: ISO 20387:2018, 3.6, modified — Notes 1 and 2 to entry added.]

3.4

capillary puncture

procedure (3.15) that involves the collection of blood from capillaries by puncturing the skin

3.5

cleaning

process (3.16) to remove any type of contamination, visible or not

[SOURCE: ISO 15190:2020, 3.6]

3.6

decontamination

procedure (3.15) 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 15190:2020, 3.7]

3.7

disinfection

process (3.16) to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms

[SOURCE: ISO 15190:2020, 3.9]

3.8

examination

set of operations having the objective of determining the numerical value, text value or characteristics of a property

Note 1 to entry: An examination may be the total of a number of activities, observations or measurements required to determine a value or characteristic.

Note 2 to entry: Laboratory examinations that determine a numerical value of a property are called "quantitative examinations"; those that determine the characteristics of a property are called "qualitative examinations".

Note 3 to entry: Laboratory examinations are also called "assays" or "tests".

[SOURCE: ISO 15189:2022, 3.8]

3.9

facility

entity involved in the collection and transport of samples to a medical laboratory

Note 1 to entry: Includes all circumstances of collection and transport of samples, including where these are performed by medical laboratories, by healthcare workers such as clinicians, general practitioners and nursing personnel or by independent collection companies not directly associated with a medical laboratory.

Note 2 to entry: Includes all types of accommodation whether purpose built, pop-up, mobile, permanent and/or temporary facilities.

3.10 facility management

person(s) with responsibility for, and authority over a *facility* (3.9)

Note 1 to entry: Facility management has the power to delegate authority and provide resources within the laboratory.

Note 2 to entry: The facility management includes the facility manager and delegates, together with individuals specifically assigned to ensure the quality of the activities of the laboratory.

3.11 hand hygiene

any action of hand cleansing

[SOURCE: WHO Guidelines on Hand Hygiene in Health Care, 2009^[47]]

3.12 medical laboratory laboratory

entity for the *examination* (3.8) of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health

Note 1 to entry: The laboratory can also provide advice covering all aspects of *examinations* (3.8) appropriate selection, the interpretation of results and advice on further examinations.

[SOURCE: ISO 15189:2022, 3.20, modified — Notes 2 and 3 to entry were deleted.]

3.13 patient

person undergoing *sample collection* (3.20) who is the source of material for *examination* (3.8)

Note 1 to entry: In this document the term patient has been used for consistency.

Note 2 to entry: A person who undergoes *sample collection* (3.19) can be a client or employee being tested for reasons other than to receive medical care, such as health or community screening.

3.14 pre-examination processes

processes (3.16) that start, in chronological order, from the user's request and include the examination request, preparation and identification of the *patient* (3.13), collection of the primary sample(s) and transportation to and within the laboratory, ending when the *examination* (3.8) begins

[SOURCE: ISO 15189:2022, 3.24]

3.15 procedure

specified way to carry out an activity or a *process* (3.16)

[SOURCE: ISO 9000:2015, 3.4.5]

3.16 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, modified — Notes 1, 3, 4, 5, and 6 to entry have been deleted and Note 2 to entry is Note 1 to entry.]

3.17

personal protective equipment

PPE

variety of barriers including clothing and respirators used alone or in combination to protect mucous membranes, airways, skin, and clothing from contacts with infectious or hazardous agents

[SOURCE: ISO 15190:2020, 3.17]

3.18

primary sample

specimen

discrete portion of a body fluid or tissue or other sample associated with the human body taken for *examination* (3.8), study or analysis of one or more quantities or characteristics to determine the character of the whole

Note 1 to entry: The International Medical Device Regulators Forum (IMDRF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a *medical laboratory* (3.12).

[SOURCE: ISO 15189:2022, 3.25]

3.19

sample

one or more parts taken from a *primary sample* (3.18)

Note 1 to entry: For the purpose of this document sample has been used generically as the material collection from a *patient* (3.13) and transported to a laboratory. In most cases the sample collected and transported will be a primary sample. In some cases, it will be a sample. This document is pertinent to all scenarios.

[SOURCE: ISO 15189:2022, 3.28, modified — Note 1 to entry added.]

3.20

sample collection

process of obtaining a *primary sample* (3.18)

3.21

user(s)

individual or entity requesting services of the collection facility

Note 1 to entry: Users can include *patients* (3.13), clinicians and other institutions who request samples to be collected.

3.22

venepuncture

procedure (3.15) that involves the collection of venous blood by penetrating a vein with a needle or other collection apparatus

3.23

warm ischemia

ischemia of cells and tissues under normothermic conditions

4 General requirements

4.1 General

The organisation(s) providing collection and transport services shall ensure activities are performed in such a way as to meet the requirements of this document. This shall include activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a user's location.

Where collections are performed outside of the direct control of a medical laboratory, such as by healthcare workers or by an independent collection company, the requirements of this document shall be met.

There shall be close cooperation between the medical laboratory and the facility providing collection and transport of samples, including the exchange of information, to ensure the harmonization of processes and procedures, where appropriate.

Facilities shall conform with all relevant requirements of ISO 15189 relating to collection and transport of samples to a medical laboratory.

4.2 Ethical conduct

4.2.1 General

Facility management shall have arrangements in place to ensure that sound ethical conduct is upheld at all times and that undue pressure, conflicts of interest and impartiality are considered.

4.2.2 Impartiality

- a) Facility activities shall be undertaken impartially. The facility shall be structured and managed to safeguard impartiality.
- b) The facility management shall be committed to impartiality.
- c) The facility shall be responsible for the impartiality of its facility activities and shall not allow commercial, financial or other pressures to compromise impartiality.
- d) The facility shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel.

NOTE A relationship that threatens the impartiality of the facility can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding) and payment of a sales commission or other inducement for the referral of new laboratory users, etc. Such relationships do not necessarily present the facility with a threat to impartiality.

- e) If a threat to impartiality is identified, the effect shall be eliminated or minimized so that the impartiality is not compromised. The facility shall be able to demonstrate how it mitigates such a threat.

4.2.3 Confidentiality

4.2.3.1 Management of information

The facility shall be responsible, through legally enforceable commitments, for the management of all patient information obtained or created during the performance of facility activities. Management of patient information shall include privacy and confidentiality taking cybersecurity into account. The facility shall inform the user in advance, of the information it intends to place in the public domain. Except for information that the user makes publicly available, or when agreed between the facility and the user (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

Confidentiality of patient information shall be respected and maintained by all personnel.

4.2.3.2 Release and disclosure of information

When the facility is required, for whatever reason, to release confidential information, the patient concerned shall be notified of the information released and provide consent, where applicable.

Information about the patient from a source other than the user (e.g. complainant, regulator) shall be kept confidential by the facility. The identity of the source shall be kept confidential by the facility and shall not be shared with the user, unless agreed by the source.

NOTE Statutory and regulatory requirements can apply for release and disclosure of information.

The facility shall have a process for disclosure of a patient safety incident, medical error, or incident related to a medical device involved in either the collection or transport, or both, of samples that did result or could have resulted in harm to that patient.

4.2.3.3 Personnel responsibility

Personnel, contractors, personnel of external bodies, or individuals acting on the facility's behalf, shall keep confidential all information obtained or created during the performance of facility pre-examination activities.

4.2.4 Requirements regarding patients, facility personnel and others

Facility management shall ensure that the well-being, safety and rights of all persons who interact with the facility during sample collection and transport are a primary consideration.

During sample collection and transport, patients and their samples shall be treated in an ethical manner with due care and consideration at all times. This includes assuring privacy, being courteous and respectful and taking into account cultural diversity and disabilities.

Precautionary measures for dealing with violent or uncooperative persons shall be in place to ensure personnel and public safety.

NOTE ISO 15189 provides further details on requirements regarding patients.

5 Structural requirements

5.1 Legal entity

The facility shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its activities.

5.2 Facility manager

5.2.1 Facility manager competence

The facility shall be directed by a person with the competence, delegated authority and responsibility, and resources to fulfil the requirements of this document.

5.2.2 Delegation of duties

The facility manager can further delegate either selected duties or responsibilities, or both, to competent personnel and such delegation shall be documented. However, the facility manager shall maintain the ultimate responsibility for the overall operation and administration of the facility.

5.3 Facility responsibilities and activities

5.3.1 Facility activities

The facility shall establish objectives and policies to ensure that the service is meeting the needs and requirements of patients and users.

The facility shall specify and document the range of its activities, including activities performed at sites other than the main location.

NOTE ISO 15189 provides further details on requirements regarding objectives and policies.

5.3.2 Structure and authority

5.3.2.1 Structure

The facility shall clearly define its structure, including its place in any parent organisation and the collection sites, when applicable.

5.3.2.2 Authority

The facility shall specify the responsibility, authority and interrelationship of all personnel who manage and perform activities related to the collection and transport of samples.

The facility shall clearly define who is responsible for what activities in the context of cooperation between medical laboratory and collection facility, where different.

NOTE ISO 15189 provides further details on requirements regarding the structure and authority of the facility.

5.3.3 Advisory services

Facility management shall ensure appropriate information is available to meet the needs of patients and users who use the pre-examination services provided.

5.3.4 Risk management

Facility management shall establish, implement and maintain processes for identifying risks of harm to patients and personnel associated with its sample collection and transport activities.

These risks shall be assessed, eliminated or mitigated and communicated to users as appropriate.

The identified risks and effectiveness of the mitigation processes shall be monitored and evaluated according to the potential impact to the patient.

5.3.5 Emergency situations

The facility shall establish emergency preparedness plans to ensure the recovery of management systems and continued operations after a disruption, in the event of emergency situations (e.g. fire, flood or response to a pandemic).

NOTE 1 ISO 22367 provides details for managing risk in medical laboratories.

NOTE 2 ISO 15190 provides details for laboratory security.

NOTE 3 ISO 35001 provides details on biorisk management for laboratories.

NOTE 4 ISO 15189 provides details on continuity and emergency preparedness planning.

6 Resource requirements

6.1 General

The facility shall have available the personnel, facilities, equipment, consumables and support services necessary to manage and perform its sample collection and transport activities. The facility manager

shall be responsible for ensuring such resources are available in accordance with management system requirements.

6.2 Personnel

6.2.1 General

The facility shall have access to a sufficient number of qualified and competent persons to perform the work of collecting and transporting samples.

Facility management shall define and document the education, professional qualifications, training, skills and experience required for each position/function.

When new or amended procedures are introduced, the facility shall ensure that all relevant personnel are made aware of the changes, are trained and assessed as competent as necessary.

Job descriptions shall be available that define the duties, responsibilities and authorization of all personnel. Facility management shall communicate the job description to all personnel involved in sample collection and transport.

6.2.2 Training

Facility personnel involved in sample collection and transport shall be trained to ensure that facility activities are performed competently.

Personnel training shall include a general induction into the facility which covers:

- an introduction to the facility and facility personnel;
- the terms and conditions of employment;
- personnel policies;
- health and safety requirements (including fire and emergency), and any occupational health services;
- patient privacy expectations and confidentiality of patient information.

Specific training shall include, but not be limited to, procedures for:

- accurate patient and sample identification;
- proper collection techniques for the sample types likely to be encountered;
- proper handling techniques for sample collection and ancillary devices likely to be used for each sample type;
- sample storage, handling, packaging and transport 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;
- assigned work processes and procedures;
- use of computers and other relevant information technology;
- safety and infection control for protection of the personnel and patients.

Personnel undergoing training shall be supervised at all times.

The effectiveness of the training programme shall be periodically reviewed.

6.2.3 Competence assessment

The facility shall have a process for managing competence of its personnel, including personnel working outside of the facility.

The competence of each person to perform assigned tasks shall be assessed following initial training and periodically thereafter.

Reassessment shall take place within a defined time period and retraining shall occur when necessary.

Examples of competence assessment methods that can be used in any combination include:

- direct observation of routine work and safety processes and procedures;
- direct observation of equipment maintenance and functional checks;
- review of work records;
- assessment of problem-solving skills;
- performance against quality indicators.

6.2.4 Continuing education and/or continuing professional development

Where provided, either continuing education or continuing professional development, or both, for personnel should be directed toward the activities of the pre-examination processes and should not be too general in nature.

6.2.5 Personnel records

Personnel records for all personnel shall be available.

NOTE ISO 15189 provides further details on personnel records requirements.

6.3 Facilities and environmental conditions

6.3.1 General

The facilities and environmental conditions shall be suitable for collection of samples to ensure that the quality of work, safety of personnel and patient care services are not compromised.

The materials and equipment shall be fit for purpose for supporting the activities of the facility and be maintained in functional and reliable condition at least to manufacturer's requirements.

Access to and use of areas affecting the quality of pre-examination processes shall be controlled.

Appropriate measures shall be taken to safeguard samples and resources from unauthorized access.

NOTE ISO 15190 provides details for laboratory security.

6.3.2 Design

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.

In some circumstances, the design of the collection location is outside of the control of the organisation providing the service, e.g. mobile or home collections, however in all circumstances where collection occurs, the risk of injury and occupational illness shall be considered and minimised.

When designing locations for sample collection, consideration shall be given to accessibility, comfort needs (e.g. disabled access, washroom facility), safety, privacy, confidentiality and appropriate environmental conditions for patients and personnel.

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 or bowl and clean water 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, also fitted for disabled access where appropriate;
- 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) ability for adequate physical distancing (e.g. space between seats in the patient waiting area to minimize risk of airborne infection of respiratory tract infection to other patients);
- i) equipment for resuscitation, whenever possible;
- j) access to first aid supplies;
- k) visible 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;
- o) separate patient reception and collection areas;
- p) comfortable waiting area.

6.3.3 Privacy and confidentiality

Patient privacy and confidentiality shall be protected.

In some cases, protecting the privacy and confidentiality of patients can be difficult, i.e. sample collection in a public place, but still should be considered as far as possible.

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

- a) provides personal privacy for the patient during reception and sample collection (e.g. during a blood draw or collection of a urine sample and when removal of clothing is necessary);
- b) has a secure place for storage of a patient's personal property if needed;
- c) protects confidentiality of information.

6.3.4 Equipment, supplies and storage

When relevant, the facility design shall be able to accommodate storage space for:

- a) all the required materials and supplies used in sample collection;
- b) materials and equipment needed for the collection and stabilization of samples for transport and storage.

6.3.5 Facility maintenance

Work areas shall be clean and well maintained with measures taken to ensure good housekeeping.

The facility shall design and verify a cleaning and disinfection process, with emphasis on infection control, which includes special procedures for decontamination, as well as training for personnel involved in housekeeping tasks.

6.3.6 Personnel facilities

There shall be adequate access to amenities such as washrooms, drinking water and for storage of personal protective equipment (PPE) and clothing.

Safety of personnel working alone shall be considered.

6.4 Equipment, reagents, and consumables

6.4.1 General

Personnel shall have access to all equipment, reagents and consumables needed to perform its sample collection and transport activities.

For supplies that are removed from their containers for later use, a mechanism shall be in place to allow traceability of the individual items for lot number, expiry date, or other relevant information.

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

6.4.2 Verification and storage

Equipment used to perform collection and transport of samples shall be shown upon installation and during routine use to be capable of achieving the performance required to ensure proper functioning and to prevent contamination or deterioration of the samples.

Reagents and consumables shall be verified on receipt and accepted or rejected in accordance with the facility's specified requirements, then stored and maintained under controlled conditions and according to manufacturer's specifications.

Equipment and supplies shall be available in sufficient quantities and suitable for their intended use in sample collection, stabilization, transport and storage processes.

6.4.3 Inventory management

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

- a) supplies are not used after their expiry date;

In emergency situations and/or when the supply chain is interrupted, supplies may be used after expiry date if acceptable performance of such supplies / devices is validated.

- b) sufficient supplies are available to meet the needs of the operation;

c) safety data sheets are available, where relevant.

6.4.4 Equipment maintenance and repair

6.4.4.1 Current instructions on the use, safety and maintenance of equipment, including any documentation provided by the manufacturer of the equipment used in sample collection, processing and transport shall be easily accessible to the personnel using them. Procedures for calibration of equipment used in pre-examination activities shall be provided.

6.4.4.2 Documented processes and procedures for preventive maintenance that, at a minimum, follows the manufacturer's recommendations shall be available to personnel.

6.4.4.3 Equipment used in sample collection, processing and transport shall 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.

NOTE This applies to beds, chairs and countertops under the direct control of the facility. In some cases, they are not under control of the facility, e.g. patient's home.

6.4.4.4 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 impact of the defect shall 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.

6.4.4.5 Reasonable measures shall be taken to decontaminate equipment before service, repair or decommissioning. Repair shall take place in safe working conditions and appropriate PPE shall be provided.

NOTE Statutory and regulatory requirements can apply to the decontamination and disposal measures of used equipment.

6.4.5 Equipment operation and instructions for use

6.4.5.1 Only trained and competent personnel shall operate equipment and devices. 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.

6.4.5.2 Temperature ranges for refrigerators and freezers shall meet the requirements of the items stored in them. Temperatures shall be monitored and recorded with action taken if they do not meet requirements for the supplies stored in them.

6.4.5.3 Centrifuges shall have the timing mechanism and rotation speed checked periodically as well as internal temperature verification for refrigerated centrifuges. Instructions for decontaminating centrifuges after tube breakages shall be available.

6.4.5.4 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.

6.4.6 Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment, reagents or consumables used in sample collection, processing and/or transport shall be investigated and reported

to all relevant authorities, as required, where the nature of the adverse incident can compromise the integrity of the sample.

NOTE Relevant authorities can include the manufacturer and/or supplier of the equipment, reagents or consumables, the laboratory to which samples are provided or other notifiable bodies.

6.4.7 Computer equipment

When computers or automated pre-examination equipment are used for the collection, processing and recording of data, the facility 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, taking cybersecurity into account;
- e) any software upgrades are adequately documented and validated for its functional specifications and intended use.

Facilities collecting samples can have access to the Medical Laboratory Information System (MLIMS) for directly accessioning samples. In such cases the communication between the facility collecting samples and the medical laboratory is important and should be documented with appropriate access rights outlined.

If the collection facility has a separate information technology system, the interface between this system and the MLIMS shall be regularly checked, especially after software upgrades.

NOTE ISO 15189 provides further details on control of data and information management.

6.4.8 Records

Records shall be maintained for equipment, reagents, consumables and the storage conditions which contribute to the performance of pre-examination activities.

These records shall be available for a defined period.

NOTE 1 Statutory and regulatory requirements can apply to the maintenance of records.

NOTE 2 ISO 15189 provides further details on the control of records.

7 Process requirements

7.1 General

Any deviation from the established collection procedures shall be clearly recorded and communicated to the appropriate personnel, e.g. the requester or medical laboratory personnel.

The facility shall document acceptance and rejection criteria for collection processes. Where any part of the process fails acceptance criteria, the medical laboratory shall be notified for direction.

7.2 Test selection and requesting

Medical laboratories are responsible for providing information to and requesting information from users of their services, including the collection facility, regarding the examinations they perform to facilitate test selection and test requesting.

Where this information is not forthcoming from the medical laboratory, the collection facility shall liaise with the medical laboratory in order to obtain it.

Where the facility has not collected all required information, the medical laboratory shall be notified for direction.

NOTE 1 ISO 15189 provides further details on pre-collection information.

NOTE 2 The following information on test requesting and sample submission is information that the medical laboratory usually provides:

- Recommendations for test selection. Appropriate laboratory tests selection is based on patient's clinical situation.
- Timing and frequency of test ordering. Laboratory can provide consultation and advice to physicians or other healthcare workers for test selection, if applicable, considering test specifications, intended use, implications of test results and limitations.
- The examinations offered by the medical laboratory including, as appropriate, information concerning type of samples required, sample volumes, special precautions, turnaround times, biological reference intervals and clinical decision values.
- Factors known to significantly affect the performance of the examination or the interpretation of results.

The following information on what shall be collected can include:

- clinical information, and when applicable, the patient's race/ethnicity;
- either family history or pedigree, or both;
- patient consent information;
- date and time of sample collection;
- storage conditions;
- transport conditions.

7.3 Request information

7.3.1 General

The facility performing pre-examination services shall establish and periodically review agreements for providing these services with the users.

The requirements of both parties entering into an agreement shall be adequately defined and understood.

Users shall be informed of any changes to an agreement that can affect examination results.

Each request accepted by the facility for examination(s) shall be considered an agreement.

A request to perform an examination in a medical laboratory shall be provided by an authorised person.

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

The examination request shall provide sufficient information to ensure traceability of the patient to the request and sample at all times and validity of the results of the examination.

Where necessary, the facility shall communicate with either the requester or medical laboratory, or both, to clarify the request.

7.3.2 Request to perform sample collection for subsequent laboratory examination

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

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

NOTE 1 The examination request information can be in any format or medium as deemed appropriate by the laboratory and its users.

NOTE 2 The request to perform a sample collection for a subsequent laboratory examination is usually referred to as a "request form", however defined, e.g. hard copy, electronic, oral.

Requests shall be fully and accurately completed with the relevant patient, clinical and test information.

Requests 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.

When information is unable to be completed, the facility shall assess the risk to the patient outcome and initiate rejection or acceptance of the request as appropriate. This should be in consultation with the receiving medical laboratory.

The sample and any accompanying information, e.g. request form, shall be traceable to the patient at all times.

The collection facility shall record at least the following:

- date and time of sample collection;
- identity of the person who collected the sample;
- any deviations from the request, device failures, or occurrences of special interest during sample collection, storage, and transport;
- the type and number of samples collected, e.g. type of tube EDTA, Plain.

Additional information to be collected by the collection facility shall be as requested by the medical laboratory and can include:

- patient identification including:
 - first and last name of the patient or equivalent information if these are not available;
 - date of birth;
 - sex at birth and gender identity (optional) of the patient;
 - location/contact details of the patient;
 - a unique patient identifier.

NOTE 3 Unique identification includes either an alpha or numerical identifier, or both, such as a hospital number, medical record number, or personal health number.

- name or other unique identifier of the physician or other person legally authorized to request examinations or use medical information;
- an address and contact details where results can be delivered and emergency contact information for reporting critical results;

- type of sample and, where relevant, the anatomic site of origin;
- examinations requested;
- clinically relevant information about the patient and the request.

NOTE 4 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.

7.3.3 Oral requests

The laboratory shall have a procedure for managing oral requests for examinations that includes the provision of documented confirmation of the examination request to the laboratory, within a given time.

7.3.4 Handling urgent requests

There shall be instructions for prioritising and triaging requests deemed to be urgent.

The instructions shall include details of any special labelling of the request and sample.

7.4 Patient identification and reception

7.4.1 Transcription

Where information provided on a request form is transcribed into a record system or an information system, the facility 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.

7.4.2 Information for patients and users

The information shall be sufficiently detailed to provide users with a comprehensive understanding of the facility's scope of activities and requirements.

The facility shall provide sufficient information to patients 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 1 Genetic counselling can be a requirement prior to the examination.

NOTE 2 Statutory and regulatory requirements can apply for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals).

Patients shall be given information on the facility's policy on protection of personal information.

7.4.3 Patient identification

7.4.3.1 General

Procedures for the determination of patient identification prior to sample collection shall include a requirement for at least two and preferably three, identifiers attributable to the patient and specified

by the facility which allow for conclusive traceability to the patient. When one of these identifiers is an ID document it is preferable that this includes a photo ID.

NOTE More than two identifiers can 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 for outpatients, inpatients, and home patients.

7.4.3.2 Routine patient identification

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

- a) The patient is asked to state his or her full name and another identifier (e.g. date of birth), the information provided in the response shall be compared to the information on the request form and the unique identifiers specified by the medical laboratory.

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

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

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

- the identity should 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 traceable.

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

When more than one person is involved in the collection of samples, the patient ID shall be verified at each point of exchange.

7.4.3.3 Patient identification in a medical emergency situation

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, personnel shall:

- a) assign a master identification number (temporary) to the patient in accordance with facility policy;
- b) select the appropriate request forms and record with the master ID number;
- c) complete the necessary labels either by hand or by computer and apply the labels to 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 shall 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.

7.4.3.4 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 sex;
- d) the child's hospital number, medical record number, personal health number or other unique identifier;
- e) the mother/father'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.

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

NOTE Different jurisdictions can have different definitions of what constitutes the age of young children. International, national or regional regulations or requirements can apply to this definition.

7.5 Patient preparation

Clear and precise instructions shall be given to patients with regard to preparation before sample collection. These instructions are usually provided by the person who requested either the test or medical laboratory, or both, prior to sample collection.

Some tests require special patient preparation and shall be considered before taking samples for examination as they can have marked effects on the results. These factors include where relevant:

- a) time period for fasting before collection;
- b) time period and contents of any special diet before collection;
- c) medications and supplements 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) resting prior to sample collection;
- g) requirement for collecting the sample at a precise time.

The facility shall confirm that the patient strictly followed the instructions given by the person who requested either the test or medical laboratory, or both, prior to sample collection. Any failure or deviations from these instructions shall be recorded.

7.6 Sample collection

7.6.1 General

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

NOTE This is usually provided in the form of a sample collection manual or medical laboratory handbook, in either hard copy or electronic format.

When deviations or exclusions from, or additions to the documented procedures for sample collection occur for any reason, this information shall be recorded and communicated to the appropriate personnel, e.g. medical laboratory personnel.

This information may need to be included in reports containing examination results and it is therefore important that the medical laboratory should be informed.

7.6.2 Informed consent before sample collection

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 venepuncture. Patients in a hospital bed should be given the opportunity to refuse.

In emergency situations, consent is not always 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.

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.

7.6.3 Instructions for collection activities

Procedures for sample collection shall define the steps of each collection technique. The information shall also include:

- a) appropriate type of sample(s) to be collected;
- b) where relevant, appropriate anatomical sample collection site;
- c) volume or amount of sample required, (e.g. volume of sample required to ensure the optimal blood to anticoagulant ratio, volume of sample required for examination procedures);
- d) collection container or device to be used (e.g. evacuated sample collection tubes, tubes with specific anticoagulant or preservatives, specific cups or tubes containing sterile tissue culture media, buccal swabs);
- e) any special timing of sample collection, when needed;
- f) proper mixing of tubes following sample collection;
- g) recording time of sample collection and stabilisation (e.g. time placed in 10 % neutral buffered formalin);

- h) when applicable, recording patient demography, disease stage and, whether samples are being collected before, during or after treatment, time from diagnosis;
- i) safe disposal of materials used in the sample collection process;
- j) preventing and handling of adverse events related to collection (e.g. fainting, nerve puncture or any other threats to patient's safety).

All relevant procedures shall be available to every collector.

7.6.4 Patient-collected samples

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

Plain language shall be used to convey information at a level that 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) should be used to complement verbal communication. Consideration shall also be given to translation into other languages, depending on local population needs.

NOTE [Annex D](#) provides information on the collection of sample types other than blood.

7.7 Blood sample collection

7.7.1 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 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 can 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 medical laboratory's requirements.

NOTE The use of plastic tubes is preferred.

- c) All additive tubes shall be filled in accordance with manufacturer's instructions.

NOTE ISO 6710 provides information about single-use containers for human venous blood sample collection

- 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) Approved transfer devices shall be used to fill blood tubes. Closures should not be removed to fill a tube.
- f) Blood shall not be transferred from one collection tube to another.
- g) There shall be procedures for the care of patients who experience adverse reactions during the sample collection process.
- h) There shall be proper disposal of the lancet/incision device and other contaminated materials, such as gauze and gloves.

7.7.2 Order of draw

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

NOTE 1 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.

An example order of draw for venous samples is as follows:

1. Blood culture bottle
2. Sodium citrate tube
3. Serum tube
4. Heparin tube
5. EDTA tube
6. Sodium fluoride or potassium oxalate with glycolytic inhibitor tube

When using winged blood collection set (butterfly devices) the order of draw stays the same, however a discard tube shall be used to prime the tubing, when the first tube to be drawn according to the order of draw is affected by the fill volume, such as Sodium citrate tubes.

NOTE 2 The order of draw for a capillary blood collection is slightly different than the order of draw for a venous blood collection.

A sample order of draw for capillary samples is as follows:

1. Heparin (for capillary blood gas analysis only when requested)
2. No additive (for blood smear haematology counts only)
3. EDTA tube
4. Heparin tube
5. Other tube containing anticoagulants
6. Serum tube
7. Plain (No additive)

Heparin for blood gas shall be taken first only if the puncture site was warmed for arterialisation. If it is requested but the site is not warmed, the collection falls under No 4 in the order.

7.7.3 Special considerations when performing venepuncture

The following circumstances shall be considered when performing venepuncture:

- 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) whether the patient has a history of vasovagal reaction such as fainting or convulsion shall be asked before venepuncture;
- d) any medication causing bleeding tendency, such as anticoagulants or anti-platelet drugs, should be verified; tourniquet application time should not exceed 1 min;

- e) patients shall be instructed not to pump their fist or perform repetitive closing and opening of hand;
- f) the site chosen for venepuncture should minimize the risk of nerve injury;

NOTE 1 The preferred site for venepuncture is antecubital veins. In case that these veins are unavailable, dorsal veins of hands can be used for venepuncture. Veins from the wrist are not recommended.

- g) the number of attempts at venepuncture should be limited;
- h) 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;
- i) areas with evidence of fistulas shall be avoided;
- j) areas with evidence of oedema, haematoma, extensive scarring, fresh tattoos, burns, damaged or occluded veins shall be avoided, whenever possible;
- k) an arm on the same side as a mastectomy or one with paralysis, should also be avoided;
- l) blood shall not be collected from an arm that is being infused with any fluid, unless appropriate precautions are taken and recorded;
- m) confirm that bleeding has stopped before releasing the patient.

NOTE 2 The use of sharps device with flash visualization can be helpful, especially with non-experienced staff, or in children and patients with difficult veins.

7.7.4 Adult capillary puncture

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

- a) selection of an appropriate puncture site (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;

7.7.5 Paediatric blood collection

7.7.5.1 General

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

Only personnel experienced in paediatric blood collection (venous and capillary) shall perform these activities.

Instructions for the choice of the site for paediatric venepuncture or capillary puncture should be provided to the collector.

7.7.5.2 Patient preparation

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

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

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

7.7.5.3 Collection technique

An appropriate blood sample collection technique (i.e. venepuncture 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 should be considered when appropriate, when collecting blood samples from paediatric patients.

Collection procedures shall minimize discomfort for the child as much as practically possible. Excessive crying should be recorded, as it can 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.

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 can be needed in children with illnesses that impair the replenishment of blood volume or haemoglobin.

7.7.5.4 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 can puncture the heel bone of a new-born and therefore, shall not be used.

7.7.6 Vascular access devices (VAD)

Only experienced personnel who have completed thorough and documented training shall perform collection from vascular access devices (VADs).

Blood samples drawn from a VAD should only be considered if a direct venepuncture is not feasible.

When collecting blood from VADs, the initial volume of blood shall be discarded taking into account solution content and length of line.

NOTE 1 VADs include a variety of infusion catheters and ports which are used to provide access to a patient's circulatory system for administration of fluids and medications.

NOTE 2 It is recognised that collection from some VADs increases the potential for sample haemolysis or contamination with fluids or medications.

7.7.7 Arterial puncture

7.7.7.1 General

An arterial blood sample is collected from an artery and shall only be performed by competent healthcare workers and when absolutely necessary. The sample can be obtained either through a catheter placed in the artery, or by using a needle and syringe to puncture the artery.

Although several different arteries can be used for blood collection, the usual site of choice is the radial artery as it is more superficial and therefore easier to locate than the alternatives. Alternatives to the radial artery are the brachial or femoral arteries, however, these can be harder to locate, have poor collateral circulation and have a higher risk of damage to surrounding structures such as nerves.

7.7.7.2 Special considerations when performing arterial blood sampling

There are several potential complications which shall be considered when performing arterial blood sampling, these include:

- a) Bruising (haematoma) at the puncture site, occurring more often in brachial and femoral artery puncture sites. Bleeding disorders (coagulopathy) can exacerbate the risk of haematoma.
- b) Thrombosis, which is more common in radial artery puncture.
- c) Involuntary transient arterial contraction (Arteriospasm).
- d) Nerve damage from inadvertent needle redirection or needle insertion into the nerve bundle.
- e) Acute drop in blood pressure leading to dizziness or feeling faint and possible loss of consciousness.

7.7.7.3 Considerations when performing arterial blood sampling for blood gas analysis

The most common test for which arterial blood samples are used is blood gas analysis (BGA). The procedure shall be performed to minimise air exposure of the sample as this can cause significant changes to the blood gas values. In addition, the following should be considered:

- a) withdraw the needle and hold pressure on the site of collection;
- b) protect personnel from needlestick injury by removing or placing cover over needle;
- c) remove any air bubbles from syringe;
- d) gently mix the sample by rolling between palms of hand;
- e) transport to medical laboratory immediately;
- f) if the sample is unable to be tested within 1 h, place the sample on ice and send to the laboratory as soon as possible.

NOTE 1 Points a) to e) are applicable to any arterial procedure.

NOTE 2 [Annex D](#) provides requirements for collection of sample types other than blood.

7.8 Identification of samples

7.8.1 General

Unique labelling of samples to ensure traceability in a manner that provides an unequivocal link with the patients from whom they are collected shall be used to identify samples. This requires the use of at least two patient specific identifiers on all labels.

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

Additional information 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.

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

The preferred practice is for labelling sample containers immediately after collection and in the presence of the patient.

Labelling collection containers prior to sample collection are associated with additional risks.

Regardless of the method used, risks shall be defined and controls included in the process to preclude errors.

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

7.8.2 Handling urgent samples

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 sample, the mechanism of transport and any special reporting requirements.

7.9 Sample integrity and stability

7.9.1 Sample integrity

To avoid compromising sample integrity, which in turn can affect examination results:

- a) collection tubes and containers shall be stored according to manufacturer's instructions;
- b) use of small-bore needles can cause haemolysis and should be avoided;
- c) the appropriate puncture site shall be chosen;
- d) traumatic or repeated attempts at venepuncture should be avoided;
- e) sample tubes shall be adequately mixed immediately following collection;
- f) excessive mixing of sample shall be avoided;
- g) correct sample volume shall be specified and collected;

- h) correct volume for acceptable sample to additive ratio shall be collected;
- i) correct container or additives (e.g. stabilising agents/preservatives) 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 afterwards in case additional examinations are requested.

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

For solid tissue, time of collection and sample type shall be recorded. Depending on the type of specimen and the clinical setting, warm ischemia time, cold ischemia time, fixation type, or time specimen placed in fixative may be recorded.

Procedures to maintain sample integrity throughout the pre-examination process shall be validated and periodically reviewed for ongoing suitability.

7.9.2 Stability

Instructions provided by the medical laboratory on the type of tube in which the sample is to be stored, test specific information for storage conditions (e.g. temperature, protection from light, freeze-thaw cycles and acceptable length of storage time for all samples for examination) shall be followed.

The sample will maintain a specified property value within specified limits for a specified period of time. Therefore, the timeframe between sample collection and examination shall be monitored and controlled.

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, humidity, gas diffusion, contamination, time, temperature and leakage. For example, some analytes (e.g. bilirubin, beta-carotene and porphyrins) break down in the presence of light (photosensitivity) and need protection from light. The temperature of the sample post collection can also be important. Some analytes are required to be kept cold if not analysed within a specific timeframe (4° C) (blood gases within 1 h) or warm (body temperature) (Cryoglobulins) during storage and transport. Some analytes require immediate freezing to preserve the analyte.

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

7.9.3 Stabilization of samples

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

Examples of stabilization include use of sample collection devices with stabilization reagents, 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.

Instructions provided by the testing laboratory concerning which samples require stabilization and how long these samples can be stored before stabilization is performed, shall be followed.

7.10 Package and transport of samples

7.10.1 General

Instructions provided by the testing laboratory concerning packaging and transport of samples shall be followed. Such procedures shall be available and include appropriate storage conditions of collected samples until transport.

The facility shall document procedures for each mode of transport of samples, e.g. by foot, by air and by road. Samples shall be transported in a manner, to:

- protect the safety of everyone involved in sample handling during transportation;
- ensure that the samples are maintained under suitable conditions.

NOTE 1 The medical laboratory can provide advice on safe and reliable transport of samples.

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

7.10.2 Sample transport

7.10.2.1 General

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

- a) Transport containers shall be validated to ensure that the required specifications are met. This shall include ensuring appropriate physical conditions, e.g. temperature, light, humidity, and testing for freeze-thaw cycling during transport.
- b) When samples are transported outside of the facility, safeguarding the people responsible for transporting the samples and security of the public shall be taken into consideration since medical laboratory samples are considered to be biohazardous. Contact information of a designated person and biohazard signage shall be provided on the outside of a leak-proof container for sample transport.
- c) Contact information shall be readily available.

NOTE This information allows authorities such as first responders to know whom to contact in an emergency situation, such as a vehicle collision causing a spill.

- d) Sample transport shall 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.
- e) To avoid contamination in case of leakage, sample request forms and any other documentation shall not be in direct contact with samples.
- f) Patient confidentiality shall be protected in the transportation process.
- g) Any deviations from the established environmental conditions or delays shall be recorded and included in the examination report.

7.10.2.2 Pneumatic tube systems (PTS)

Prior to its introduction, a risk assessment shall be performed to determine what types of samples can be transported via the pneumatic tube system.

In general, the following specimens should be hand-delivered to the laboratory:

- respiratory specimens;
- specimens collected in glass anaerobic transport tubes;
- cytology and histology specimens with formaldehyde;

- specimens in syringes/capillary tubes;
- specimens with needles;
- all body fluid specimens;
- stool specimens;
- any irreplaceable specimen or those not easily recollected.

Transport of samples and blood products by PTS shall be validated prior to use.

NOTE Certain analytes have been observed to be compromised in blood samples transported by PTS; the medical laboratory can provide advice.

Procedures shall be in place for dealing with blockages, leakage and decontamination in the PTS.

There shall be procedures in place for notification of samples and blood products sent and received through the PTS, especially critical samples.

7.10.3 Quality and safety monitoring

Transportation of samples shall be monitored to ensure they are transported

- a) within a timeframe appropriate to the requested examinations,
- b) within a temperature interval and other physical conditions 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 safety of the carrier, the general public and the receiving medical laboratory, in compliance with established requirements.

7.11 Infection prevention and control (biosafety)

NOTE ISO 35001 provides details on bio-risk management for laboratories.

7.11.1 Personal protective equipment (PPE)

Personal protective equipment (PPE) shall be available for persons collecting and handling samples. The PPE shall be appropriate to the level of risk and properly fitted. Basic PPE includes facility 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 contaminated with hazardous materials.

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

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.

7.11.2 Hand hygiene

Hand hygiene shall, at a minimum, be performed before and after patient contact, between patients, as well as after glove removal ([Annex A](#) contains guidelines for hand hygiene). In circumstances where hands look or feel dirty, they shall be washed with soap and water, wherever possible. At all other times alcohol-based hand sanitizer can be used.

Hand hygiene stations (including alcohol-based hand sanitizers) shall be easily accessible in areas for patients.

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

Alternatives such as chlorhexidine-based products shall be available for patients and personnel allergic to alcohol-based sanitizers.

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

7.11.3 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.

7.11.4 Safe disposal

Single-use equipment shall be disposed of after each collection.

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.

The minimum standard for segregating healthcare waste 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.

7.11.5 Patient protection

Sterile single-use supplies shall be used in sample collection, e.g. needles.

Any reusable equipment shall be cleaned and disinfected regularly.

In order to prevent either sensitization or anaphylactic reactions, or both, in sensitized individuals (persons collecting and handling samples, and patients) alternative supplies for patients allergic to substances such as latex and adhesive bandages shall be considered with non-latex medical devices and accessories available, wherever possible.

NOTE Natural rubber latex (NRL) is known to be a potent allergenic substance. NRL can be found in numerous medical devices, including needles, catheters, syringes, tube stoppers, tourniquets, adhesive tapes. People in at-risk groups, sensitized and/or allergic to natural rubber latex are at risk of exposure by inhalation and through the hematogenous route if NRL medical devices are used. This risk is not resolved solely by using non-latex devices for sample collections in people with a confirmatory diagnosis of latex allergy, because sensitized people who do not know their condition are at risk of being treated with natural latex devices.

Disposable surgical masks should be worn by 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. These should be made available to patients by the organisation in emergency situations, e.g. COVID pandemic statutory.

7.11.6 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 (e.g. tables, desks, counters, floors) 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 (e.g. bed rails or surfaces, arm rests) shall be cleaned at least daily and between patients when soiled;
- d) washrooms 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.

NOTE Public health recommendations can apply to the frequency of cleaning and disinfection in some circumstances such as during a pandemic.

The facility shall consider the need for air purification after a risk-based assessment. Such consideration shall be recorded.

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 ([Annex B](#) contains guidelines for manufacturer's instructions).

7.11.7 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.

8 Management system requirements

8.1 General requirements

The facility shall establish, implement and maintain a management system that is capable of supporting and demonstrating the quality of the samples collected for medical laboratory testing.

The management system should reflect the size and complexity of the facility and its operations and need not be overly complex.

Where the facility is operated by a wider organisation such as a medical laboratory it shall be part of the management system of the medical laboratory.

NOTE ISO 15189 provides further details on the requirements of a management system.

8.2 Evaluation of pre-examination processes

8.2.1 General

The facility shall periodically review procedures to ensure that they are current and fulfil the requirements of the medical laboratory to which samples are sent.

These should include sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that they are appropriate, and that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the analyte.

8.2.2 Quality indicators

The facility shall establish quality indicators to evaluate performance throughout critical aspects of pre-examination processes. Indicators of quality and performance shall be monitored.

The indicators shall be periodically reviewed, to ensure their continued appropriateness.

NOTE Some examples of quality indicators for pre-examination processes are

- a) number of samples improperly labelled,
- b) number of requests with either erroneous patient identification or incorrect data, or both,
- c) number of samples with insufficient volumes,
- d) number of samples collected in incorrect containers,
- e) urine culture contamination rates,
- f) blood culture contamination rates,
- g) number of samples haemolysed,
- h) number of samples clotted,
- i) number of samples unaccounted for or missing,
- j) number of samples damaged during transport,
- k) Indicative turnaround times,
- l) number of health and safety incidents for personnel and public e.g. needlestick injury, falls,
- m) number of samples not properly stored before analysis,
- n) number of samples transported at inappropriate temperature,
- o) number of samples with excessive transport time, and
- p) number of requests for examinations modified for proven inappropriateness

The data shall be collected in a specified time period and measured against previous performance or an external benchmark. Sources of unacceptable samples shall also be collected so that appropriate action can be taken where needed.

In order for this data to be collected, the facility shall liaise with the receiving medical laboratory.

8.3 Facility user and personnel feedback

The facility shall seek feedback, both positive and negative, from its patients and users and its personnel. The feedback shall be analysed and used to reduce risk and improve the management system, facility activities and facility services to users.

EXAMPLES User satisfaction surveys, communication records, review of reports with users and personnel suggestions for improvement.

Records of feedback shall be maintained, including the action taken. Communication shall be provided to personnel on actions taken arising from their feedback.

8.4 Customer satisfaction

The facility shall establish, document, implement and maintain a system to enhance customer satisfaction and include processes to improve the system.

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 facility's processes and services. Customers can be the patient whose samples have been collected, the health care professional requesting sample collection and/or the medical 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.

Annex A (normative)

Your five moments for hand hygiene

1	Before patient contact	What? Clean your hands before touching a patient when approaching them. Why? To protect the patient against harmful germs carried on your hands.
2	Before an aseptic task	What? Clean your hands immediately before any aseptic task. Why? To protect the patient against harmful germs, including the patient's own germs, entering their body.
3	After body fluid exposure risk	What? Clean your hands immediately after an exposure risk to body fluids (and after glove removal). Why? To protect yourself and the healthcare environment from harmful germs carried by the patient.
4	After patient contact	What? Clean your hands after touching a patient and their immediate surroundings when leaving. Why? To protect yourself and the healthcare environment from harmful germs carried by the patient.
5	After contact with patient surroundings	What? Clean your hands after touching any object or furniture in the patient's immediate surroundings when leaving, even without touching the patient. Why? To protect yourself and the healthcare environment from harmful germs carried by the patient.
NOTE This table is based on the WHO reference [44] .		

Annex B (informative)

Disinfectants

B.1 General

Disinfectants are used to clean and decontaminate work areas.

A number of different disinfectants are available for cleaning surfaces and spills. These include:

- alcohol;
- chlorine compounds;
- quaternary ammonium compounds;
- phenolic compounds;
- iodophore compounds.

Properties of an ideal disinfectant include (see [Table B.1](#) for the properties of the most commonly used disinfectants):

- a) broad spectrum, i.e. it should have a wide antimicrobial spectrum;
- b) fast acting, i.e. it should produce a rapid kill;
- c) not affected by environmental factors, i.e. it should be active in the presence of organic matter (e.g. blood, sputum, faeces) and compatible with soaps, detergents and other chemicals encountered in use;
- d) nontoxic, i.e. should not be harmful to the user or patient;
- e) surface compatibility, i.e. it should not corrode instruments and metallic surfaces and should not cause the deterioration of cloth, rubber, plastics and other materials;
- f) residual effect on treated surfaces, i.e. it should leave an antimicrobial film on the treated surface;
- g) easy to use with clear label directions;
- h) odourless, i.e. it should have a pleasant odour or no odour to facilitate its routine use;
- i) economical, i.e. it should not be prohibitively high in cost;
- j) solubility, i.e. it should be soluble in water;
- k) stability, i.e. it should be stable in concentrate and use-dilution;
- l) cleaner, i.e. it should have good cleaning properties;
- m) environmentally friendly, i.e. it should not damage the environment on disposal.

Table B.1 — Properties of the most commonly used disinfectants

	Alcohol	Chlorine compounds	Quaternary ammonium compounds
Commonly available form	Ethyl or isopropyl alcohol; 70 % in water is most effective	Liquid, powder and tablet	Wide variety available with built-in detergent action
Advantages	— non-toxic — low cost — rapid action — non-staining — no residue	— low cost — rapid action	— non-corrosive, non-toxic, low irritant. — good cleaning ability, usually have detergent properties.
Disadvantages	— Flammable — store in cool, well-ventilated area. — Longer contact time is difficult to achieve due to evaporation. — Variable compatibility with certain materials (e.g. can harden rubber and deteriorate glues and some plastics).	— Solutions are light-sensitive and should be prepared fresh and stored in light-protected containers. Should be used immediately once diluted. — Irritant to skin and mucous membranes. — Highly corrosive to metals. — Neutralized by organic material.	— Decreased activity in hard water. — Reduced effectiveness in the presence of organic matter due to detergent-like properties. — Can make surfaces (including floors) slippery, which can be a hazard.
Effective against:			
Vegetative bacteria	+	+	+
Mycobacteria (TB)	+	+	—
Bacterial spores	—	+	—
Viruses — enveloped	+	+	+
Viruses — non-enveloped	±	+	—
Fungi	+	+	+
Fungal spores	—	+	—
Contact time	10 min to 30 min	10 min to 30 min	10 min to 30 min
Concentration of active ingredient	70 % to 85 %	0,01 % to 5 % (usually 5 000 ppm chlorine)	0,1 % to 2 %