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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

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

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

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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.

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

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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.

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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.

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

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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.

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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

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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*

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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.]

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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

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[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

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[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.

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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.]

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3.13
patient
person undergoing *sample collection* (3.20) who is the source of material for *examination* (3.8)

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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.]

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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.]

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3.20
sample collection
process of obtaining a *primary sample* (3.18)

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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.

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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.

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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.

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NOTE ISO 15189 provides further details on requirements regarding patients.

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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.

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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.

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5.3.4 Risk management

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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

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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.

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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;

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— 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.

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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.

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6.2.5 Personnel records

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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.

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