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# Medical laboratories — Requirements for collection and transport of samples

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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# Foreword

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

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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.



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



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.

This document provides requirements for all activities related to collection, labelling, sample integrity, stability, storage, packaging 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 - Medical laboratories — Requirements for quality and competence.

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 that enabled more testing for COVID to occur. Temporary collection facilities may not be able to meet all the requirements in this document, however, as far as possible it should be complied with in order to reduce potential risks to patients. Local jurisdictions can provide further guidance on minimum best practice for specimen 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 its direct control and/or responsibility.

To ensure the pre-examination processes covered by the scope of this document meet the needs of patients and the clinical personnel responsible for the care of those patients such services are required to be performed according to documented policies and procedures for patient preparation, patient identification, collection of samples and transportation of samples to a medical laboratory.

This document is a revision of ISO/TS20658:2017 Medical laboratories – Requirements for collection, transport, receipt and handling of samples. It has been significantly amended with the scope now limited to activities occurring before samples are received by a laboratory for examination. It is also

closely aligned with ISO 15189 Medical laboratories — Requirements for quality and competence and now has this document as a normative reference.

# Medical laboratories — Requirements for collection and transport of samples

## 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, that may 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 may 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 may 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, *Medical laboratories — Requirements for quality and competence*



## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and 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* (3.14) 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]

**3.3**
**biobanking**
*process* (3.15) 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 may also be included: processing, testing and analysing.

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

[SOURCE: ISO 20387:2018]

**3.4**
**capillary puncture**
*procedure* (3.14) that involves the collection of blood from capillaries by puncturing the skin

**3.5**
**cleaning**
*process* (3.15) to remove any type of contamination, visible or not

[SOURCE: ISO 15190:2020, 3.6]

**3.6**
**decontamination**
*procedure* (3.14) 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, 3.9]



**3.7**
**disinfection**
*process* (3.15) 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 is 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]

**3.9**
**facility**
entity(ies) 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 type of accommodation whether purpose built, pop-up, mobile, permanent and/or temporary facilities.

**3.10**
**hand hygiene**
general term referring to any action of hand cleansing

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

**3.11**
**medical laboratory**
**laboratory**
an 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) including test ordering, interpretation of results and advice on further examinations.

[SOURCE: ISO 15189 amended to omit list of types of examinations]

**3.12**
**patient**
individual undergoing *sample collection* (3.19) who is the source of material for *examination* (3.8)

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

Note 2 to entry: It should be noted that an individual who undergoes *sample collection* (3.19) may not have an ongoing disease and therefore may not be a patient as such. They can be clients or employees being tested for reasons other than to receive medical care, such as health or community screening.



**3.13**
**pre-examination processes**
**pre-analytical phase**
*process* (3.15) which starts, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s) and transportation to the laboratory and end when the *examination* (3.8) begins



[SOURCE: ISO 15189]

**3.14**
**procedure**
specified way to carry out an activity or a *process* (3.15)

[SOURCE: ISO 9000:2015, 3.4.5]

**3.15**
**process**
set of interrelated or interacting activities that use inputs to deliver an intended result

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

[SOURCE: ISO 9000:2015, 3.4.1]

**3.16**
**personal protective equipment**
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]

**3.17**
**primary sample**
**specimen**
discrete portion of material, intended for *examination* (3.8), study or analysis of one or more quantities or properties and assumed to apply for 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* (3.11).

[SOURCE: ISO 15189]

**3.18**
**sample**
one or more parts taken from a *primary sample* (3.17)

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

**3.19**
**sample collection**
process of obtaining a *primary sample* (3.17)

**3.20**
**user(s)**
an individual or entity requesting services of the collection facility

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

**3.21**
**venepuncture**
*procedure* (3.14) that involves the collection of venous blood by penetrating a vein with a needle or other collection apparatus

**3.22**
**warm ischemia**
ischemia of cells and tissues under normothermic conditions.

# 4 General requirements

## 4.1 General

The organisation(s) providing collection and transport services (hereinafter referred to as 'the facility(ies)') 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 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 comply with all relevant requirements of ISO 15189 relating to collection and transport of samples to a medical laboratory.

## 4.2 Ethical conduct

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

### 4.2.1 Impartiality

Processes for the collection and transport of samples shall be undertaken impartially and structured and managed so as to safeguard impartiality.

The facility shall be responsible for the impartiality of its pre-examination activities and shall not allow commercial, financial or other pressures to compromise impartiality.

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 users, etc. Such relationships do not necessarily present the facility with a threat to impartiality.

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

### 4.2.2 Confidentiality



#### 4.2.2.1 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.

#### 4.2.2.2 Release and disclosure of information

When the facility is required by law or authorised by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released and provide consent, unless prohibited by law.

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.

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

#### 4.2.2.3 Personnel responsibility

Personnel, including any committee members, 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.