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Australian STANDARD

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

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Australasian Association of Clinical Biochemists
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Australian Institute of Medical Scientists
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National Association of Testing Authorities Australia
National Coalition of Public Pathology
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Medical laboratories — Requirements for collection, transport, receipt, and handling of samples

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Preface

This Standard was prepared by Standards Australia Committee HE-029, Clinical Laboratory Testing and *in vitro* Diagnostic Test Systems.

The objective of this Standard is to specify requirements and good practice recommendations for the collection, transport, receipt and handling of samples intended for medical laboratory examinations.

This Standard is applicable to medical services, not under the direct control of an accredited medical laboratory, involved in laboratory pre-examination processes that include the examination request, patient preparation and identification, sample collection, transport, receipt and storage. This Standard may also be applicable to some biobanks.

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

This Standard is identical with, and has been reproduced from, ISO/TS 20658:2017, *Medical laboratories — Requirements for collection, transport, receipt, and handling of samples*.

As this document has been reproduced from an International Technical Specification, a full point substitutes for a comma when referring to a decimal marker.

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The terms "normative" and "informative" are used in Standards to define the application of the appendices or annexes to which they apply. A "normative" appendix or annex is an integral part of a Standard, whereas an "informative" appendix or annex is only for information and guidance.

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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).

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

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

Introduction

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

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

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

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

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

Australian Standard®

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

1 Scope

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

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

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

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

3.2
biobank
entity that performs *biobanking* (3.3)

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

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

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

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

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

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

[SOURCE: ISO 15190:2003, 3.5]

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

[SOURCE: ISO 15190:2003, 3.7]