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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).

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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*.

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.