Z316.7-12

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Primary sample collection facilities and medical laboratories — Patient safety and quality of care — Requirements for collecting, transporting, and storing samples

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Preface

This is the first edition of CSA Z316.7, *Primary sample collection facilities and medical laboratories — Patient safety and quality of care — Requirements for collecting, transporting, and storing samples*.

CSA Group acknowledges that the development of this Standard was made possible, in part, by the financial support of Alere Inc., BD — Canada (Preanalytical Systems), the Canadian Society for Medical Laboratory Science (CSMLS), the Clinical Laboratory Management Association Trillium Chapter, Copan Diagnostics, Covidien, Greiner Bio-One North America, Inc., Thermo Fisher Scientific, and the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, the Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Québec, Saskatchewan, and Yukon, as administered by the Canadian Agency for Drugs and Technologies in Health (CADTH).

This Standard was inspired by the following documents produced by the Ordre professionnel des technologistes médicaux du Québec (OPTMQ):

(a) *Prélèvement de sang par ponction capillaire aux fins d'analyse,* 3rd ed. (2011);
(b) *Prélèvement de sang par ponction veineuse pour fins d'analyse,* 6th ed. (2006); and
(c) *Transport et conservation des échantillons dans le domaine de la biologie médicale*, 4th ed. (2010).

This Standard was prepared by the Subcommittee on Specimen Procurement, under the jurisdiction of the Technical Committee on Medical Laboratory Quality Systems and the Strategic Steering Committee on Health Care Technology, and has been formally approved by the Technical Committee.

Notes:

(1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*

(2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*

(3) *This Standard was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*

(4) *To submit a request for interpretation of this Standard, please send the following information to* ***inquiries@csagroup.org*** *and include "Request for interpretation" in the subject line:*
(a) define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;
(b) provide an explanation of circumstances surrounding the actual field condition; and
(c) where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.
Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at* ***standardsactivities.csa.ca****.*

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(a) Standard designation (number);
(b) relevant clause, table, and/or figure number;
(c) wording of the proposed change; and
(d) rationale for the change.

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0 Introduction

0.1

The pre-examination phase in clinical laboratory testing is of utmost importance and needs to be well understood as it includes the initial stages of producing test results that drive relevant and informed clinical decisions. The pre-examination phase consists of all of the steps performed from the moment a healthcare provider generates a test request to the time that the sample is ready to be tested. Errors can occur in any of the numerous steps in this process, including collecting blood from the wrong patient, mislabelling the sample, or inappropriately storing the sample, which can lead to erroneous diagnosis and treatment of the patient. These types of errors can go unrecognized if pre-examination policies and procedures are not properly established, standardized, and followed. This Standard specifies quality requirements for sample collection, transport, and storage to ensure that a high level of patient safety and quality of care is achieved and to aid in the prevention of these errors.

0.2

This Standard may be used as a stand-alone document for facilities performing pre-examination activities or with ISO 15189 (see Clause 5) for facilities that also perform examination and post-examination activities.

0.3

The requirements of this Standard apply to facilities performing pre-examination activities. Facilities include, but are not limited to, medical laboratories performing pre-examination activities and primary sample collection services. Primary sample collection services include, but are not limited to, any organization or person that collects primary samples, e.g., hospitals and associated collection centres, bedside collections within hospital centres or other healthcare facilities, private and public collection service organizations, doctor's offices, and home collections. When the term "facility" is used to designate a medical laboratory, only pre-examination activities are included in the scope of the requirements of this Standard.

Note: *It is possible that national, provincial/territorial, or local requirements will apply.*

1 Scope

1.1

This Standard establishes quality requirements for sample collection, transport, and storage to ensure that patient safety and quality of care are at the forefront of the pre-examination process of laboratory testing.