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Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

Laboratoires d'analyses de biologie médicale et dispositifs médicaux de diagnostic in vitro — Exigences relatives aux systèmes d'autosurveillance des traitements par anti-coagulant oraux

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

This second edition cancels and replaces the first edition (ISO 17593:2007), which has been technically revised.

The main changes are as follows:

— Updated with more current state of the art information that has evolved over several years.

— Subclause 8.4 Validation of measurement precision: added a more robust study design.

— Subclause 8.5.8.2 and 8.5.8.3: updated examples were added to reflect changes in criteria.

— Subclause 8.6 Minimum acceptable system accuracy : Updated requirements/performance criteria.

— Clause 9 Lay person performance evaluation: added clarity, revised performance criteria and increased sample size.

— Removed Annex F listing of publications.

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

Oral-anticoagulation monitoring systems are in vitro diagnostic (IVD) medical devices that measure prothrombin time in fresh, untreated human blood specimens. Prothrombin time is an indicator of the ability of blood to clot. IVD medical devices for self-testing of oral-anticoagulation therapy are used predominantly by individuals who have heart valve replacements, or who are suffering from atrial fibrillation or deep vein thrombosis and are receiving oral anticoagulant therapy with vitamin K antagonist medicines (e.g. warfarin). Patients must maintain the level of anticoagulant in the blood high enough to reduce thrombin formation, yet low enough to avoid excessive bleeding. An oral-anticoagulation monitoring system allows the user to monitor anticoagulation therapy and take action to control the level of anticoagulant present in the blood. This document applies to oral-anticoagulation monitoring systems to be used by lay persons. The primary objectives are to establish requirements for oral-anticoagulation monitoring systems that will enable lay persons to achieve acceptable performance, and to specify procedures for manufacturers and other interested parties to demonstrate conformance of such systems to the requirements stated in this document.

Performance criteria for oral-anticoagulation monitoring systems were established, based on the state-of-the-art, which has been shown to offer significant benefit to patients [31]. The criteria are given in terms of "system accuracy", because metrological terms commonly used in International Standards (e.g. trueness and measurement uncertainty) would not be familiar to lay persons. System accuracy, which is affected by systematic bias and random effects (and is inversely related to measurement uncertainty), describes the degree to which the individual results produced by an oral-anticoagulation monitoring system agree with correct international normalized ratio (INR) values when the system is used as intended by lay persons. In setting the performance criteria, it is assumed that users will be properly selected and will receive the necessary training and that operating and control procedures will be followed in accordance with the manufacturer's instructions for use. It is also assumed that manufacturers will anticipate and mitigate the effects of reasonably foreseeable misuse, including reasonably foreseeable deviations from recommended operating and control procedures by the intended users.

Requirements that are unique to self-testing with oral anticoagulation monitoring systems, including specific content of information supplied by the manufacturer, are addressed in this document. General requirements that apply to all IVD medical devices and which are covered by other standards (e.g. IEC 61010-1, IEC 61010-2-101, ISO 13485, ISO 14971, ISO 23640 and ISO 18113-1, ISO 18113-4, ISO 18113-5) are incorporated by reference, when appropriate. While the goal is to standardize these requirements, it is also recognized that current national and regional usage by patients and regulatory authorities should be taken into consideration.