



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 15195:2003

ICS 11.100

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Tel: (01) 807 3838

**LABORATORY MEDICINE - REQUIREMENTS
FOR REFERENCE MEASUREMENT
LABORATORIES (ISO 15195:2003)**

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EUROPEAN STANDARD
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English version

**Laboratory medicine - Requirements for reference measurement
laboratories (ISO 15195:2003)**

Médecine de laboratoires - Exigences pour les laboratoires
réalisant des mesurages de référence (ISO 15195:2003)

Laboratoriumsmedizin - Anforderungen an
Referenzmesslaboratorien (ISO 15195:2003)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 15195:2003 (E)

Foreword

This document (EN ISO 15195:2003) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2004, and conflicting national standards shall be withdrawn at the latest by April 2004.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15195:2003 has been approved by CEN as EN ISO 15195:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA
(normative)**Normative references to international publications
with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 17511	2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials	EN ISO 17511	2003
ISO 18153	2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials	EN ISO 18153	2003

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Laboratory medicine — Requirements for reference measurement laboratories

*Médecine de laboratoires — Exigences pour les laboratoires réalisant
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