



National Standards Authority of Ireland

IRISH STANDARD

**I.S. EN ISO 15195:2003**

ICS 11.100

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

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
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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)

This European Standard was approved by CEN on 24 July 2003.

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## **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of an identical text or by endorsement, at the latest by April 2004, and conflicting national standards shall be withdrawn at the latest by April 2004.

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### **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        |

# INTERNATIONAL STANDARD

**ISO**  
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## Laboratory medicine — Requirements for reference measurement laboratories

*Médecine de laboratoires — Exigences pour les laboratoires réalisant  
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