

## Iso 151972003 In Vitro Diagnostic Test Systems Requirements For Blood Glucose Monitoring Systems For Self Testing In Managing Diabetes Mellitus

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**ISO - ISO 15197:2003 - In vitro diagnostic test systems ...**

BS EN ISO 15197:2003. Title. In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes

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mellitus. Status. Revised, Superseded, Withdrawn. Publication Date. 27 May 2003. Withdrawn Date.

## **BS EN ISO 15197:2003 - In vitro diagnostic test systems ...**

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2003) (Swedish Standard) This International Standard specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples and procedures for the verification and the validation of performance by the intended users.

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ISO 15197:2003 specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples and procedures for the verification and the validation of performance by the intended users. These systems are intended for self-testing by laypersons for management of diabetes mellitus.

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## **IS/ISO 15197: In Vitro DiAGNOSTIC Test Systems ...**

ISO 15197 was prepared by Technical Committee ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems. Introduction Blood-glucose monitoring systems are in vitro diagnostic medical devices used predominantly by individuals affected by diabetes mellitus.

## **ISO 15197:2003(en), In vitro diagnostic test systems ...**

ISO 15197:2013 specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus.

## **ISO - ISO 15197:2013 - In vitro diagnostic test systems ...**

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## **ISO - 11.100.10 - In vitro diagnostic test systems**

ISO 15197 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 15197:2003 ), the clauses, subclauses and annexes of which have been technically revised.

## **ISO 15197:2013(en), In vitro diagnostic test systems ...**

Creation date: 1994 Scope. Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.

## **ISO/TC 212 - Clinical laboratory testing and in vitro ...**

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## **DS/EN ISO 15197:2003 - In vitro diagnostic test systems ...**

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