

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 151972003 In Vitro Diagnostic

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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ISO - ISO 15197:2003 - 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 15197:2003 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.

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.

SS-EN ISO 15197:2003 - In vitro diagnostic test systems ...

IS/ISO 15197: In Vitro DiAGNOSTIC Test Systems - Requirements for Bloos-Glucose Monitoring Systems for Self - Testing in Managing Diabetes Mellitus. In order to promote public education and public safety, equal justice for all, a better informed citizenry, the rule of law, world trade and world peace, this legal document is hereby made available on a noncommercial basis, as it is the right of all humans to know and speak the laws that govern them.

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ISO/ISO 15197: In Vitro DiAGNOSTIC Test Systems ...

ISO 15197:2003 In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus ... Clinical laboratory testing and in vitro diagnostic test systems — In vitro diagnostic medical devices for professional use — Summary of regulatory requirements for information supplied by ...

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 ...

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 ...

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 ...

NOTE 5 Users of this document can consider whether other standards and/or requirements also apply to the IVD medical device which is the subject of the clinical performance study, for instance, in the situation for which there is an IVD medical device and a medical device used in an integrated

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system (e.g. a lancet, an IVD test strip, and a ...

ISO - ISO 20916:2019 - In vitro diagnostic medical devices ...

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.

Clinical laboratory testing and in vitro diagnostic ... - ISO

III IS/ISO 15197:2003 Indian Standard IN VITRO DIAGNOSTIC TEST SYSTEMS — REQUIREMENTS FOR BLOOD-GLUCOSE MONITORING SYSTEMS FOR SELF-TESTING IN MANAGING DIABETES MELLITUS 1 Scope 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.

Full text of "IS/ISO 15197: In Vitro DiAGNOSTIC Test ...

nen-en-iso 15197:2003 en In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus This norm is withdrawn since 06-06-2013

NEN-EN-ISO 15197:2003 en - NEN

BS EN ISO 15197:2003: Title: In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus: Status: Revised, Superseded, Withdrawn: Publication Date: 27 May 2003: Withdrawn Date: 30 June 2013: Normative References(Required to achieve compliance to this standard)

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BS EN ISO 15197:2003 In vitro diagnostic test systems. ... (published 27/05/2003) BS EN ISO 15197:2003 is maintained by CH/212. This standard is available from the following sources: British Standards Shop (Shop) British Standards Online (BSOL) Other historical versions of this standard document also exist: BS EN ISO 15197:2013 [current until ...

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. EN ISO 15197:2003 E. [Google Scholar] 2. International Organization for Standardization.

Accuracy of a Blood Glucose Monitoring System

ISO 15197:2003, In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus Paperback - 23 Aug. 2007 by ISO/TC 212 (Author) See all formats and editions

ISO 15197:2003, 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 15197:2013 - Techstreet

In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. EN ISO 15197:2003.

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