SVENSK STANDARD
SS-EN ISO 23162:2021

Grundläggande spermaundersökning – specifikation och testmetoder (ISO 23162:2021)

Basic semen examination – Specification and test methods (ISO 23162:2021)

Svenska Institutet för Standarder

Language: engelska/English

Edition: 1

Svenska Institutet för Standarder

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Standarden är framtagen av kommittén för Laboratoriemedicin, SIS/TK 331.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

Fastställd: 2021-07-19
ICS: 11.100.01

Svenska Institutet för Standarder

Europastandarden EN ISO 23162:2021 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 23162:2021.

The European Standard EN ISO 23162:2021 has the status of a Swedish Standard. This document contains the official version of EN ISO 23162:2021.

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LÄSANVISNINGAR FÖR STANDARDER

I dessa anvisningar behandlas huvudprinciperna för hur regler och yttre begränsningar anges i standardiseringsprodukter.

Krav
Ett krav är ett uttryck i ett dokuments innehåll som anger objektivt verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas. Krav uttrycks med hjälpverbet **ska** (eller **ska inte** för förbud).

Rekommendation
En rekommendation är ett uttryck i ett dokuments innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet **bör** (eller **bör inte** för avrådanden).

Instruktion
Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

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En förklaring är ett uttryck i ett dokuments innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet **får**. Inom standardiseringen saknas rekommenderad nekande motsats till hjälpverbet får, förbud uttrycks med **ska inte** enligt reglerna för krav. Möjlighet och förmåga uttrycks med hjälpverbet **kan** (eller motsatsen **kan inte**).

READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

Requirement
A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary **shall** (or **shall not** for prohibition).

Recommendation
A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary **should** (or **should not** for dissuasion).

Instruction
An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

Statement
A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary **may**. There is no recommended opposite expression for the auxiliary may in standardization, prohibition is expressed by the use of **shall not** in accordance with the rules for requirements. Possibility and capability are expressed by the auxiliary **can** (its opposite being **cannot**).

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23162

July 2021

ICS 11.100.01

English Version

Basic semen examination - Specification and test methods (ISO 23162:2021)

Analyse de base du sperme - Spécifications et méthodologie analytique (ISO 23162:2021)

Grundlegende Samenanalyse - Spezifikation und Testmethoden (ISO 23162:2021)

This European Standard was approved by CEN on 11 June 2021.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 23162:2021: E

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

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.

European foreword

This document (EN ISO 23162:2021) 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 January 2022, and conflicting national standards shall be withdrawn at the latest by July 2024.

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Any feedback and questions on this document should be directed to the users’ national standards body/ national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23162:2021 has been approved by CEN as EN ISO 23162:2021 without any modification.

Introduction

This document was developed in response to global demand for standards for reliable examination of human semen. The five editions of a laboratory manual for human semen analysis published by the WHO between 1980 and 2010 have provided general recommendations for suitable laboratory procedures, but even the latest edition (World Health Organization 2010 [16]) does not constitute a Technical Standard adequate for use under ISO 15189.

A Technical Standard based on best available evidence and global consensus regarding laboratory procedures most likely to give reliable results will facilitate any laboratory seeking accreditation for human semen examination. Subjects, and biomedical science in general, would benefit from fewer random factors affecting the accuracy of results. Clinically this would support improved diagnoses as well as provide more objective grounds for choosing between possible management strategies or alternative treatment modalities. Furthermore, to support the evaluation and validation of new methods to improve the diagnosis and treatment of infertility, these standardized techniques can serve as reference methods.

The pre-examination preparation of human semen is important not only in manual basic semen examination, but also for Computer-Aided Sperm Analysis (CASA). Standardized handling and preparation of semen samples is essential to the quality of the data obtained.

Basic semen examination — Specification and test methods

1 Scope

This document specifies the minimum requirements for equipment and critical aspects of the test methods for best practice in laboratories performing basic examination of human semen collected by ejaculation.

This document is applicable to the entire process of basic manual semen examination and also to sample preparation for Computer-Aided Sperm Analysis (CASA).

This document does not apply to the post-vasectomy assessments.

NOTE Given the medico-legal ramifications surrounding the evaluation of post-vasectomy ejaculates, the methodology in this document is in all likelihood inadequate to establish an ejaculate as being completely "clear" (i.e. no spermatozoa in the ejaculate).

2 Normative References

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189, *Medical laboratories — Requirements for quality and competence*

ISO/TS 20914, *Medical laboratories — Practical guidance for the estimation of measurement uncertainty*

3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
air displacement pipette
common laboratory pipette with disposable tips where the volume aspirated is controlled by the displacement of an equivalent volume of air inside an enclosed chamber inside the pipette handle

Note 1 to entry: An air displacement pipette can only give accurate volumes for liquids with viscosity close to that of water.

3.2
azoospermia
complete absence of spermatozoa in the *ejaculate* (3.4)

Note 1 to entry: The term azoospermia is not a clinical diagnosis but a description of a laboratory finding. Complete lack of spermatozoa is difficult to determine in absolute terms. Since only parts of an *ejaculate* (3.4) can be examined, the modern definition is based on probability calculations derived from data obtained from investigations of random aliquots from an *ejaculate* (3.4) (See Annex A).