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STN	**Základné vyšetrenie spermiového semena Špecifikácia a skúšobné metódy (ISO 23162: 2021)**	**STN EN ISO 23162** 85 6507

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/21

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EUROPEAN STANDARD
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EN ISO 23162

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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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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of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by July 2024.

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

INTERNATIONAL STANDARD

ISO 23162

First edition
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Basic semen examination — Specification and test methods

Analyse de base du sperme — Spécifications et méthodologie analytique

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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.

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.

INTERNATIONAL STANDARD **ISO 23162:2021(E)**

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*

