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Basic semen examination — Specification and test methods

Analyse de base du sperme — Spécifications et méthodologie analytique

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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.

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).

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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.

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).