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Osnovne preiskave semena - Specifikacija in preskusne metode (ISO/DIS 23162:2020)

Basic semen examination - Specification and test methods (ISO/DIS 23162:2020)

Grundlegende Samenanalyse - Spezifikation und Testmethoden (ISO/DIS 23162:2020)

Analyse de base du sperme - Spécifications et méthodologie analytique (ISO/DIS 23162:2020)

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Contents

Page

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).

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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

This document was developed in response to worldwide demand for standards for reliable examination of human semen. The WHO has published a manual on human semen examination in five editions between 1980 and 2010 providing general recommendations for laboratory procedures. These recommendations have become increasingly detailed and succinct [13].

However, a formal standard, based on best available evidence and global consensus, would facilitate any laboratory seeking accreditation for semen examination using laboratory procedures most likely to give reliable results. Subjects would benefit from fewer random factors influencing the choice of treatment modality. Costs for using suboptimal treatments could be expected to decrease. Also, the development of clinical science would prosper by the use of proper procedures allowing the development of both diagnostic and therapeutic strategies to benefit from well-defined laboratory techniques. This includes both the symptomatic treatment of infertility of the couple (Assisted Reproductive Technology – ART; In Vitro Fertilization - IVF) and the follow-up of often causative treatments of disorders in the male (e.g. hypogonadism, varicocele). Furthermore, for validation and evaluation of new methods to improve diagnosis and treatment of infertility the here defined standard 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 the Computer-Aided Sperm Analysis (CASA). The standardized handling and preparation of semen samples is essential to the quality of the data obtained.

In this document, the following verbal forms are used:

- ‘shall’ indicates a requirement;
- ‘should’ indicates a recommendation;
- ‘may’ indicates a permission;
- ‘can’ indicates a possibility or capability.

Further details can be found in the ISO/IEC Directives, Part 2:2018, 7

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).

3.3
CASA
computer-aided sperm analysis
automated examination of *ejaculates* (3.4) with equipment using imaging technology

Note 1 to entry: Examination based on image analysis of video sequences to obtain information on sperm concentration (3.18) and motility, more seldom sperm morphology.

Note 2 to entry: There are CASA systems commercially available, but no common standard for validation, evaluation, reliability in analyses or contents of reports. The scope of this document is not to provide a standard for CASA, although the pre-examination aspects can be useful also to developers, manufacturers and users of CASA equipment.

3.4
ejaculate
semen or semen sample obtained by masturbation, intercourse, vibratory stimulation or electro-ejaculation

Note 1 to entry: The ejaculate is a mixture of spermatozoa and secretions, mainly from the seminal vesicles, the prostate and the epididymides.

3.5
ejaculate collection container
primary sample container

Note 1 to entry: Ejaculate collection container should be not toxic to spermatozoa.

Note 2 to entry: If an *ejaculate* (3.4) can only be collected at sexual intercourse, a non-toxic, silastic condom can be used. The *ejaculate* (3.4) shall be transferred to an ejaculate sample container upon receipt by the laboratory; this shall be noted in the report form.

3.6
ejaculate viscosity
property of an *ejaculate* (3.4) describing its resistance to flow like water after *liquefaction* (3.10)

Note 1 to entry: Incompletely liquefied semen is not a homogenous liquid due to the contents of gelatinous structures in the ejaculate fluid.

3.7
interlaboratory comparison
external quality control
proficiency testing
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3.8
high power field
area of a slide which is visible in the microscope under high power magnification (×400)

Note 1 to entry: This is not a standard field area as the size varies according to the type of oculars used (e.g. standard or wide field) (See Annex B).

3.9
immotile
total lack of active tail movements

3.10
liquefaction
process of change in the consistency of the *ejaculate* (3.4) from gel-like or coagulum-like into a liquid phase

Note 1 to entry: Liquefaction occurs due to degradation of the gel-like or coagulum-like property, by enzymatic action on macromolecules.

3.11
non-progressive sperm motility
active tail movements leading to a sperm propagation of less than approximately 5 µm/s

Note 1 to entry: A normal head length is approximately 5 µm.

3.12
positive displacement pipette
common laboratory pipette working by piston-driven displacement within a capillary, not the displacement of air within an enclosed chamber

Note 1 to entry: The piston in the pipette tip is in direct contact with the liquid specimen.

Note 2 to entry: Use to avoid major volume errors with viscous liquids like semen.

3.13
progressive sperm motility
forward motility of a spermatozoon of > 5 µm/s

Note 1 to entry: See also slow progressive sperm motility (3.17) and rapid progressive sperm motility (3.14).

3.14
rapid progressive sperm motility
forward motility of a spermatozoon of at least 25 µm/s

3.15
seminal plasma
mixture of secretions, mainly from the seminal vesicles, the prostate and the epididymides, without spermatozoa

3.16
sexual abstinence
time between *ejaculate* (3.4) collection and the most recent previous ejaculation

3.17
slow progressive sperm motility
forward motility of a spermatozoon of 5 µm/s to24 µm/s

3.18
sperm concentration
number of spermatozoa per unit volume

Note 1 to entry: Sperm concentration is expressed as millions or thousands/millilitre).

Note 2 to entry: It shall not to be confused with sperm density (mass/volume).

3.19
sperm vitality
percentage of vital spermatozoa, independent of their ability to move

3.20
total sperm number
calculated total number of spermatozoa in the *ejaculate* (3.4)

Note 1 to entry: Total sperm number = sperm concentration × *ejaculate* (3.4) volume.

Note 2 to entry: Total sperm number is not the same as sperm concentration.

3.21
Tygerberg strict criteria
sperm morphology criteria based on the morphology of spermatozoa able to penetrate into and migrate within cervical mucus

3.22
typical spermatozoon
spermatozoon with the morphology typical of spermatozoa able to penetrate into and migrate within cervical mucus and reach the site of fertilization

[SOURCE: Menkveld, et al., 1991[7], Menkveld and Kruger, 1995[8]]

3.23
Teratozoospermia Index
TZI
average number of defective regions (head, neck/midpiece, tail, and/or cytoplasmic droplet) in abnormal spermatozoa

Note 1 to entry: This index is, by definition, never outside the interval of [1.00;4.00].

4 Staff Training and Competence

4.1 General Aspects

General requirements for staff training and competence are covered in ISO 15189:2012. How these requirements are applied to human semen analysis are covered here.

4.2 Training

Semen examination involves many analytical steps that require operator training to minimize operator subjectivity in order to provide accurate reliable results (MacLeod and Gold, 1951[6], Mortimer, 1994[10],Barratt, et al., 2011[1]).

All personnel performing assessments of sperm motility, sperm concentration, sperm vitality and/or sperm morphology shall receive training using either commercial, in-house or EQA-derived validated reference materials to ensure that their results conform to the laboratory's pre-determined measurement error limits. Without such training staff cannot be expected to be able to provide accurate or reliable results for these assessments, and participation in EQA schemes is pointless.

NOTE Effective goal-oriented reiterative training procedures for these assessments have been published (Mortimer, 1994[10], Björndahl, et al., 2010[2]); a ±10% range of measurement error is expected between novices upon completion of their training and the laboratory's experienced staff (See also Annex C).

4.3 Maintenance of Competence

Ongoing verification of competence shall be demonstrated by all personnel performing these assessments at regular intervals as defined in the laboratory's quality framework.

NOTE As per subclause 4.2, the same ±10% range of measurement error is expected for ongoing verification of competence by all trained staff performing these assessments.

5 Semen Characteristics, Sampling and Pre-Examination Handling

5.1 General Characteristics

Examination of the ejaculate is in some important aspects different from investigations of other human bodily fluids. The subject is expected to accomplish the collection of the ejaculate. Results are dependent on ejaculation frequency before collection, as well as on the time and temperature before initiation of investigations. In case of infertility diagnosis, clear reference limits are missing due to the fact that the desired outcome is dependent on the particular clinical situation of each couple trying to achieve a pregnancy.

