



SLOVENSKI STANDARD SIST EN ISO 17099:2017

01-december-2017

Radiološka zaščita - Merila za delovanje laboratorijev, ki za biološko dozimetrijo uporabljajo analizo tvorjenja mikrojedr s citokinetskim blokom v perifernih krvnih limfocitih (ISO 17099:2014)

Radiological protection - Performance criteria for laboratories using the cytokinesis block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry (ISO 17099:2014)

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Radioprotection - Critères de performance pour les laboratoires pratiquant la dosimétrie biologique par le test des micronoyaux avec blocage de la cytotédièrese (CBMN) dans les lymphocytes du sang périphérique (ISO 17099:2014)

Ta slovenski standard je istoveten z: EN ISO 17099:2017

ICS:

13.280	Varstvo pred sevanjem	Radiation protection
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

SIST EN ISO 17099:2017

en,fr,de

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EUROPEAN STANDARD

EN ISO 17099

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2017

ICS 13.280

English Version

Radiological protection - Performance criteria for
laboratories using the cytokinesis block micronucleus
(CBMN) assay in peripheral blood lymphocytes for
biological dosimetry (ISO 17099:2014)

Radioprotection - Critères de performance pour les
laboratoires pratiquant la dosimétrie biologique par le
test des micronoyaux avec blocage de la cytotérière
(CBMN) dans les lymphocytes du sang périphérique
(ISO 17099:2014)

This European Standard was approved by CEN on 13 September 2017.

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European foreword

The text of ISO 17099:2014 has been prepared by Technical Committee ISO/TC 85 “Nuclear energy, nuclear technologies, and radiological protection” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 17099:2017 by Technical Committee CEN/TC 430 “Nuclear energy, nuclear technologies, and radiological protection” the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by April 2018, and conflicting national standards shall be withdrawn at the latest by April 2018.

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INTERNATIONAL
STANDARD

ISO
17099

First edition
2014-11-15

**Radiological protection —
Performance criteria for laboratories
using the cytokinesis block
micronucleus (CBMN) assay in
peripheral blood lymphocytes for
biological dosimetry**

iTeh STANDARD PREVIEW

(standard.iteh.ai)
*Radioprotection — Critères de performance pour les laboratoires
pratiquant la dosimétrie biologique par analyse des micronoyaux
par blocage de la cytokinèse (CBMN) dans les lymphocytes du sang
périphérique*

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Reference number
ISO 17099:2014(E)

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Published in Switzerland

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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).

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 WTO principles in the Technical Barriers to Trade (TBT), see the following URL: [Foreword — Supplementary information](#).

The committee responsible for this document is ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

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ISO 17099:2014(E)

Introduction

The purpose of this International Standard is to define the use of the cytokinesis block micronucleus (CBMN) assay with human peripheral blood lymphocytes for biological dosimetry of exposure to ionizing radiation. This assay is intended to be applied for accidental or malevolent exposures involving a) up to a few casualties to provide individual full dose estimates or b) in a triage mode to populations to provide interim dose estimates for individuals.

The CBMN assay is an alternative cytogenetic technique, which is possibly simpler and faster to perform than the dicentric assay (ISO 19238:2014, ISO 21243:2008). It is also routinely used to demonstrate exposure to genotoxic agents, other than ionizing radiation, which is not covered in this International Standard. Although culture of the blood samples is slightly longer than for dicentrics, the scoring of micronuclei in binucleated lymphocytes is easier.

As was done with the dicentric assay, the CBMN assay has been adapted for the emergency triage of large-scale multi casualty radiation accidents. The blood volume required for sufficient number of scorable binucleated cells is similar than required for the dicentric assay. Again, the faster counting speed for micronuclei compensates for the extended culture time. In addition, the CBMN assay can be performed in an automated mode.

This International Standard provides a guideline on how to perform the CBMN assay for dose assessment using documented and validated procedures. Dose assessment using the CBMN assay has relevance in medical management, radiation-protection management, record keeping, and medical/legal requirements. This International Standard is divided into two parts, according to the use of CBMN assay: radiation exposure of a few individuals or population triage in a large radiological event.

A part of the information in this International Standard is contained in other international guidelines and scientific publications, primarily in the International Atomic Energy Agency's (IAEA) technical reports series on biological dosimetry. However, this International Standard expands and standardizes the quality assurance and quality control, the criteria of accreditation and the evaluation of performance. This International Standard is generally compliant with ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" with particular consideration given to the specific needs of biological dosimetry. The expression of uncertainties in dose estimations given in this International Standard complies with the "ISO-guide for the expression of uncertainty in measurement" (former GUM) and the ISO 5725-all parts.

Radiological protection — Performance criteria for laboratories using the cytokinesis block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry

1 Scope

This International Standard addresses the following:

- a) confidentiality of personal information for the customer and the laboratory;
- b) laboratory safety requirements;
- c) radiation sources, dose rates, and ranges used for establishing the calibration reference dose-effect curves allowing the dose estimation from CBMN assay yields and the minimum resolvable dose;
- d) performance of blood collection, culturing, harvesting, and sample preparation for CBMN assay scoring;
- e) scoring criteria;
- f) conversion of micronucleus frequency in binucleated cells into an estimate of absorbed dose;
- g) reporting of results;
- h) quality assurance and quality control;
- i) informative annexes containing examples of a questionnaire, instructions for customers, a microscope scoring data sheet, a sample report and advice on strengths and limitations of current automated systems for automated micronucleus scoring.

2 Terms and definitions

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

2.1

acentric

chromosome fragment of varying size

Note 1 to entry: When it is formed independently of a dicentric or centric ring chromosome aberration, it is usually referred to as an excess acentric.

2.2

background level

spontaneous yield (or number) of micronuclei recorded in control samples or individuals

2.3

bias

statistical sampling or testing error caused by systematically favouring some outcomes over others

2.4

binucleated cells

cells that have completed one nuclear division after mitogen stimulation and cell type in which micronuclei are scored

Note 1 to entry: These cells are accumulated in culture using cytochalasin-B which is an inhibitor of cytokinesis.