

**Piim. Somaatiliste rakkude arvu  
määramine. Osa 2: Elektrooniline  
osakeste lugemise meetod**

Milk - Enumeration of somatic cells - Part 2:  
Guidance on the operation of fluoro-opto-electronic  
counters

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 13366-2:2006 sisaldab Euroopa standardi EN ISO 13366-2:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 24.11.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 13366-2:2006 consists of the English text of the European standard EN ISO 13366-2:2006.</p> <p>This document is endorsed on 24.11.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p><b>Käsitlusala:</b> See ISO 13366 osa määrab kindlaks meetodi somaatiliste rakkude arvu määramiseks nii toorpiimas kui ka keemiliselt konservitud piimas, kasutades elektroonilist osakeste loendurit.</p>	<p><b>Scope:</b> This part of ISO 13366 IDF 148 gives guidance on the operating conditions for counting somatic cells, in both raw and chemically preserved milk, using fluoro-opto-electronic somatic cell counters in which either a rotating disc technique or flow cytometry is applied in the counting section.</p>
---	--

**ICS** 67.100.10

**Võtmesõnad:** bioloogilised katsed, elektrooniline meetod, katsed, loendamine, piim, põllumajandustooted, rakud, toiduainetooted

English Version

Milk - Enumeration of somatic cells - Part 2: Guidance on the  
operation of fluoro-opto-electronic counters (ISO 13366-2:2006)

Lait - Dénombrement des cellules somatiques - Partie 2:  
Lignes directrices pour la mise en oeuvre des compteurs  
fluoro-opto-électroniques (ISO 13366-2:2006)

Milch - Zählung somatischer Zellen - Teil 2: Leitfaden zum  
Betrieb fluoreszenzoptoelektronischer Zählgeräte (ISO  
13366-2:2006)

This European Standard was approved by CEN on 29 September 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

## Foreword

This document (EN ISO 13366-2:2006) has been prepared by Technical Committee ISO/TC 34 "Agricultural food products" in collaboration with Technical Committee CEN/TC 302 "Milk and milk products - Methods of sampling and analysis", the secretariat of which is held by NEN.

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 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.

This document supersedes EN ISO 13366-2:1997.

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

### Endorsement notice

The text of ISO 13366-2:2006 has been approved by CEN as EN ISO 13366-2:2006 without any modifications.

---

---

**Milk — Enumeration of somatic cells —**

Part 2:

**Guidance on the operation  
of fluoro-opto-electronic counters**

*Lait — Dénombrement des cellules somatiques —*

*Partie 2: Lignes directrices pour la mise en œuvre des compteurs  
fluoro-opto-électroniques*



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor the IDF accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and IDF national committees. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat at the address given below.

© ISO and IDF 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO or IDF at the respective address below.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

International Dairy Federation  
Diamant Building • Boulevard Auguste Reyers 80 • B-1030 Brussels  
Tel. + 32 2 733 98 88  
Fax + 32 2 733 04 13  
E-mail [info@fil-idf.org](mailto:info@fil-idf.org)  
Web [www.fil-idf.org](http://www.fil-idf.org)

Published in Switzerland

## Contents

Page

Foreword.....	iv
Foreword.....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions.....	1
4 Principle.....	2
5 Factors affecting the results of measurements.....	2
5.1 Sample bottles .....	2
5.2 Sampling.....	2
5.3 Preservation .....	3
5.4 Sample storage and transport.....	3
5.5 Interfering substances .....	3
5.6 Sample quality at analysis .....	4
5.7 Applied chemicals .....	4
5.8 Instrument condition .....	4
5.9 Working factor.....	5
5.10 Testing volumes.....	5
6 Calibration .....	5
6.1 Reference materials.....	5
6.2 Calibration procedure.....	6
7 Sampling.....	8
8 Determination.....	8
9 Checks on performance in routine operation.....	8
9.1 Blank checks .....	8
9.2 Carry-over effect .....	8
9.3 Ratio of reagent volume and test sample volume.....	9
9.4 Pilot checks .....	9
9.5 Additional instrument surveillance.....	9
9.6 Repeatability.....	9
9.7 Intralaboratory reproducibility .....	10
9.8 External comparisons .....	10
10 Specific remarks for the use with milk from different species .....	10
10.1 General.....	10
10.2 Cow milk .....	10
10.3 Goat milk.....	10
10.4 Sheep milk.....	11
10.5 Buffalo milk .....	11
11 Precision.....	11
11.1 Repeatability.....	11
11.2 Intralaboratory reproducibility .....	11
11.3 Reproducibility.....	12
12 Test report .....	12
Bibliography .....	13

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 13366-2|IDF 148-2 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF). It is being published jointly by ISO and IDF.

This edition of ISO 13366-2|IDF 148-2 cancels and replaces ISO 13366-2:1997 and ISO 13366-3:1997, which have been technically revised.

ISO 13366 consists of the following parts, under the general title *Milk — Enumeration of somatic cells*:

- *Part 1: Microscopic method (Reference method)*
- *Part 2: Guidance on the operation of fluoro-opto-electronic counters*



## Foreword

**IDF (the International Dairy Federation)** is a worldwide federation of the dairy sector with a National Committee in every member country. Every National Committee has the right to be represented on the IDF Standing Committees carrying out the technical work. IDF collaborates with ISO in the development of standard methods of analysis and sampling for milk and milk products.

Draft International Standards adopted by the Action Teams and Standing Committees are circulated to the National Committees for voting. Publication as an International Standard requires approval by at least 50 % of the IDF National Committees casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. IDF shall not be held responsible for identifying any or all such patent rights.

ISO 13366-2|IDF 148-2 was prepared by the International Dairy Federation (IDF) and Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*. It is being published jointly by IDF and ISO.

All work was carried out by the Joint ISO-IDF Action Team on *Automated methods*, of the Standing Committee on *Quality assurance, statistics of analytical data and sampling*, under the aegis of its project leaders, Mrs S. Orlandini (IT) and Mr H.J.C.M. van den Bijgaart (NL).

This edition of ISO 13366-2|IDF 148-2 cancels and replaces IDF 148A:1995, methods B and C of which have been technically revised.

ISO 13366 consists of the following parts, under the general title *Milk — Enumeration of somatic cells*:

- *Part 1: Microscopic method (Reference method)*
- *Part 2: Guidance on the operation of fluoro-opto-electronic counters*

# Milk — Enumeration of somatic cells —

## Part 2:

# Guidance on the operation of fluoro-opto-electronic counters

## 1 Scope

This part of ISO 13366|IDF 148 gives guidance on the operating conditions for counting somatic cells, in both raw and chemically preserved milk, using fluoro-opto-electronic somatic cell counters in which either a rotating disc technique or flow cytometry is applied in the counting section.

The guidance is applicable to the counting of somatic cells in raw cow milk. The guidance is also applicable to raw milk of other species, such as goat, sheep and buffalo, if the specified prerequisites are met.

## 2 Normative references

The following referenced documents are indispensable for the application 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 8196-1|IDF 128-1, *Milk — Definition and evaluation of the overall accuracy of indirect methods of milk analysis — Part 1: Analytical attributes of indirect methods*

ISO 8196-2|IDF 128-2, *Milk — Definition and evaluation of the overall accuracy of indirect methods of milk analysis — Part 2: Calibration and quality control in the dairy laboratory*

ISO 13366-1|IDF 148-1, *Milk — Enumeration of somatic cells — Part 1: Microscopic method (Reference method)*

ISO Guide 34, *General requirements for the competence of reference material producers*

ISO Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8196-1|IDF 128-1, ISO 8196-2|IDF 128-2 and the following apply.

### 3.1

#### reference method

method described in ISO 13366-1|IDF 148-1 for the counting of somatic cells

### 3.2

#### somatic cells

those cells that show more than a threshold intensity of fluorescence due to the staining of DNA in their nuclei

NOTE The number of somatic cells is expressed in cells per millilitre.