



SLOVENSKI STANDARD SIST EN ISO 21572:2013

01-junij-2013

Nadomešča:

SIST EN ISO 21572:2004

SIST EN ISO 21572:2004/AC:2005

Živila - Analiza molekularnih biomarkerjev - Metode na osnovi proteinov (ISO 21572:2013)

Foodstuffs - Molecular biomarker analysis - Protein-based methods (ISO 21572:2013)

Lebensmittel - Untersuchung von molekularen Biomarkern - Proteinverfahren (ISO 21572:2013)

Produits alimentaires - Analyse des biomarqueurs moléculaires - Méthodes basées sur les protéines (ISO 21572:2013)

Ta slovenski standard je istoveten z: EN ISO 21572:2013

ICS:

67.050	Splošne preskusne in analizne metode za živilske proizvode	General methods of tests and analysis for food products
--------	--	---

SIST EN ISO 21572:2013 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21572:2013

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>

EUROPEAN STANDARD

EN ISO 21572

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2013

ICS 67.050

Supersedes EN ISO 21572:2004

English Version

Foodstuffs - Molecular biomarker analysis - Protein-based methods (ISO 21572:2013)

Produits alimentaires - Analyse des biomarqueurs
moléculaires - Méthodes basées sur les protéines (ISO
21572:2013)

Lebensmittel - Untersuchung von molekularen Biomarkern -
Proteinverfahren (ISO 21572:2013)

This European Standard was approved by CEN on 12 January 2013.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

[SIST EN ISO 21572:2013](https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013)

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....3

**iTeh STANDARD PREVIEW
(standards.iteh.ai)**

[SIST EN ISO 21572:2013](https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013)

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>

Foreword

This document (EN ISO 21572:2013) has been prepared by Technical Committee ISO/TC 34 "Food products" in collaboration with Technical Committee CEN/TC 275 "Food analysis - Horizontal methods" 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 August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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

This document supersedes EN ISO 21572:2004.

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Endorsement notice

The text of ISO 21572:2013 has been approved by CEN as EN ISO 21572:2013 without any modification.

[SIST EN ISO 21572:2013](https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013)

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21572:2013

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>

INTERNATIONAL
STANDARD

ISO
21572

Second edition
2013-02-01

**Foodstuffs — Molecular biomarker
analysis — Protein-based methods**

*Produits alimentaires — Analyse des biomarqueurs moléculaires —
Méthodes basées sur les protéines*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 21572:2013](https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013)

[https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-
f02b431a91f2/sist-en-iso-21572-2013](https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013)



Reference number
ISO 21572:2013(E)

© ISO 2013

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21572:2013

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2013

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 General.....	1
3.2 Terms relating to antibodies.....	2
3.3 Terms relating to techniques.....	2
3.4 Terms relating to control.....	3
3.5 Terms relating to validation.....	3
4 Principle	6
5 Reagents	6
6 Laboratory equipment	6
7 Sampling	6
8 Procedure	7
8.1 General.....	7
8.2 Preparation of sample solution.....	7
8.3 Extraction.....	7
8.4 Preparation of calibration curves, positive controls and reference materials.....	7
8.5 Assay procedure.....	7
9 Interpretation and expression of results	8
9.1 General.....	8
9.2 Quantitative and semiquantitative analysis.....	8
9.3 Qualitative analysis.....	8
10 Specific parameters which may influence results	8
10.1 General.....	8
10.2 Special considerations.....	9
10.3 Assay applicability.....	9
11 Confirmation method	10
12 Test report	10
Annex A (informative) Detection of a protein by ELISA	12
Annex B (informative) Detection of protein(s) by lateral flow devices	22
Bibliography	29

ISO 21572:2013(E)**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 21572 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

This second edition cancels and replaces the first edition (ISO 21572:2004), which has been technically revised. It also incorporates the Technical Corrigendum ISO 21572:2004/Cor. 1:2005.

ITEH STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21572:2013

<https://standards.iteh.ai/catalog/standards/sist/5851a79a-ad0b-4065-8ad5-f02b431a91f2/sist-en-iso-21572-2013>

Foodstuffs — Molecular biomarker analysis — Protein-based methods

WARNING — Follow all instructions provided by the kit/reagent manufacturers and other standard laboratory safety procedures. Read and implement the material safety data sheets (MSDS).

1 Scope

This International Standard provides general guidelines and performance criteria for methods for the detection and/or quantification of specific proteins or protein(s) of interest [POI(s)] in a specified matrix.

These general guidelines address existing antibody based methods. Methods other than those described in [Annex A](#) or [Annex B](#) can also detect the POI. The same criteria as outlined in this International Standard apply generally.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 24276, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 24276 and the following apply.

3.1 General

3.1.1

sample

subset of a population made up of one or more sampling units

[SOURCE: ISO 3534-2:2006, 1.2.17]

3.1.2

laboratory sample

sample (3.1.1) as prepared for sending to the laboratory and intended for inspection or testing

[SOURCE: ISO 78-2:1999, 3.1]

3.1.3

test sample

sample (3.1.1) as prepared for testing or analysis, the whole quantity or part of it being used for testing or analysis at one time

[SOURCE: ISO 3534-2:2006, 5.3.11]

3.1.4

test portion

part of a *test sample* (3.1.3) which is used for testing or analysis at one time

[SOURCE: ISO 3534-2:2006, 5.3.12]

ISO 21572:2013(E)**3.1.5****matrix**

products submitted for analysis, which might have differences in chemical composition and physical state

[SOURCE: ISO 22174:2005, 3.1.4]

3.1.6**denaturation of proteins**

physical and/or (bio)chemical treatment which destroys or modifies the structural, functional, enzymatic, or antigenic properties of the POI or the analyte

3.2 Terms relating to antibodies**3.2.1****antibody**

protein (immunoglobulin) produced and secreted by B lymphocytes in response to a molecule recognized as foreign (antigen) and capable of binding to that specific *antigen* (3.2.2)

3.2.2**antigen**

substance that stimulates the production of *antibodies* (3.2.1) and reacts with them

3.2.3**clone**

population of identical cells derived from a single cell

3.2.4**cross-reactivity**

binding of the *antibody* (3.2.1) to substances other than the analyte of primary interest

3.2.5**monoclonal antibody**

antibody (3.2.1) produced from a single hybridoma *clone* (3.2.3) and directed to a single *antigen* (3.2.2) determinant

3.2.6**polyclonal antibody**

mixture of immunoglobulin molecules, secreted against a specific immunogenic substance, each recognizing a different epitope

[SOURCE: ISO 19001:2013, 3.11]

3.2.7**selectivity of an antibody**

ability of an *antibody* (3.2.1) to specifically bind to an *antigen* (3.2.2) determinant and not to other similar structures or other antigens

3.3 Terms relating to techniques**3.3.1****conjugate**

material produced by attaching two or more substances together by covalent bond via chemical groups

EXAMPLE Conjugates of antibodies with fluorochromes (e.g. chemical entity, such as a molecule or group, which emits light that is in response to being stimulated by absorption of incident light), radiolabelled substances, gold or enzymes are often used in immunoassays.