SLOVENSKI STANDARD
SIST EN ISO 21572:2020

01-januar-2020

Nadomešča:
SIST EN ISO 21572:2013

Živila - Analiza molekulskih biomarkerjev - Imunokemijske metode za odkrivanje prisotnosti in kvantifikacijo beljakovin (ISO 21572:2019)

Foodstuffs - Molecular biomarker analysis - Immunochemical methods for the detection and quantification of proteins (ISO 21572:2019)

Lebensmittel - Untersuchung auf molekulare Biomarker - Proteinverfahren (ISO 21572:2019)

Produits alimentaires - Analyse des biomarqueurs moléculaires - Méthodes immunochimiques pour la détection et la quantification des protéines (ISO 21572:2019)

Ta slovenski standard je istoveten z: **EN ISO 21572:2019**

ICS:

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

SIST EN ISO 21572:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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English Version

Foodstuffs - Molecular biomarker analysis - Immunochemical methods for the detection and quantification of proteins (ISO 21572:2019)

Produits alimentaires - Analyse des biomarqueurs moléculaires - Méthodes immunochimiques pour la détection et la quantification des protéines (ISO 21572:2019)

Lebensmittel - Untersuchung auf molekulare Biomarker - Proteinverfahren (ISO 21572:2019)

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

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European foreword

This document (EN ISO 21572:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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

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The text of ISO 21572:2019 has been approved by CEN as EN ISO 21572:2019 without any modification.

INTERNATIONAL STANDARD

ISO 21572

Third edition
2019-10

Foodstuffs — Molecular biomarker analysis — Immunochemical methods for the detection and quantification of proteins

Produits alimentaire — Analyse des biomarqueurs moléculaires — Méthodes immunochimiques pour la détection et la quantification des protéines

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

This third edition cancels and replaces the second edition (ISO 21572:2013), which has been technically revised. The main changes compared with the previous edition are as follows:

— the title has been changed to specify that the document is focused on immunochemical protein detection methods;

— an introduction has been added;

— terms, definitions and references have been updated;

— the text has been modified to improve the document's applicability to general protein analysis applications.

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

Analytical techniques based on highly specific immunochemical-binding interactions have become key tools for analysing many different chemical and macromolecular analytes, including proteins. Methods utilizing these techniques are widely accepted in the scientific and regulatory communities. Immunochemical assay methods are most commonly used to detect (presence or absence) and/or quantify specific protein analytes such as allergenic proteins, disease marker proteins or newly expressed proteins in biotech crops.

Prior to analysis, samples generally need to be ground or processed in a manner that facilitates extraction of the analyte from the sample matrix. An important step in analytical method development is therefore the selection of a suitable extraction buffer that does not interfere with the analytical method performance and that ensures an appropriate level of analyte stability during the analytical process.

The immunochemical assay process generally incorporates at least two steps:

— binding or capturing the analyte of interest present in samples with an antibody targeted specifically to the analyte;

— detection of the antibody-analyte complex using a technique that signals the specific interaction.

Once an analytical method has been developed and optimized, it should be validated to demonstrate that its performance is reliable and suitable for the intended use and to characterize the method limitations. This involves performing several experiments with real samples to evaluate parameters such as accuracy, precision, sensitivity, selectivity and the detection or quantification limits. Validation also allows for the establishment of method performance criteria, against which routine analytical performance can be compared to ensure that acceptable analytical results are consistently reported.

This document provides a set of general procedures and analytical considerations for using immunochemical techniques to analyse target proteins. It discusses aspects of sample processing, extraction, assay set-up, interpretation and reporting of results, and relevant assay performance parameters. Two annexes are included containing example procedures that can be followed when analysing a protein of interest (POI) in a variety of background matrices using methods based on enzyme-linked immunosorbent assays (ELISAs) and lateral flow devices (LFDs).