SLOVENSKI STANDARD
SIST EN 12306:1999

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Biotehnologija - Navodilo za kontrolo kakovosti diagnostičnih kompletov, ki se uporabljajo v kmetijstvu, kontrola rastlinskih in živalskih škodljivcev, kontrola obolenj in onesnaževanja okolja

Biotechnology - Guidance for quality control of diagnostic kits used in agriculture, plant and animal pest and disease control and environmental contamination

Biotechnik - Leitfaden zur Qualitätsüberwachung von Diagnostikpackungen zur Verwendung in der Landwirtschaft, bei der Schädlingsbekämpfung, Bekämpfung von Krankheiten bei Pflanzen und Tieren sowie bei Kontaminationen der Umwelt

Biotechnologie - Guide pour le contrôle de qualité des trousses de diagnostic utilisées en agriculture pour la surveillance des maladies et des agents nuisibles pour les plantes et les animaux et des contaminations environnementales

Ta slovenski standard je istoveten z: EN 12306:1997

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
65.020.99	Drugi standardi v zvezi s kmetijstvom in gozdarstvom	Other standards related to farming and forestry

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English version

Biotechnology - Guidance for quality control of diagnostic kits used in agriculture, plant and animal pest and disease control and environmental contamination

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This European Standard was approved by CEN on 21 August 1997.

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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.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", 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of an identical text or by endorsement, at the latest by April 1998, and conflicting national standards shall be withdrawn at the latest by April 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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

Introduction

Diagnostic kits are manufactured as multicomponent products designed for the qualitative or quantitative detection of a target organism or substance.

Because the diagnostic kit includes more than one component (e.g. reagents, materials, accessories) it is important to assess the performance of the whole system. In this European Standard it is assumed that diagnostic kits are a homogeneous category of products, even though each assay procedure may be affected by specific experimental parameters.

1 Scope

This European Standard provides guidance for a quality control procedure of a diagnostic kit to assure that the assay results will fulfil the intended purpose of the test by both manufacturers and users.

This European Standard applies to diagnostic kits used in agriculture, plant and animal pest and disease control monitoring of feed and environmental contamination due to microorganisms. This standard does not apply to diagnostic kits used either in food industry or for human health monitoring, or control of non biological contaminants.

This European Standard does not concern single kit components such as reagents (i.e. monoclonal or polyclonal antibodies) or materials (i.e. ELISA plate). This standard does not concern any specific diagnostic method (such as ELISA, Dot blot, DNA probe).

This European Standard does not aim to establish a system of quality assurance but it is recommended that quality control procedures are in accordance with a system of quality assurance such as EN ISO 9000 series.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 375	*In vitro* diagnostic systems - Requirements for labelling of *in vitro* diagnostic reagents for professional use.
EN 1619	Biotechnology - Large-scale process and production - General requirements for management and organization for strain conservation procedures

3 Definitions

For the purposes of this standard, the following definitions apply :

3.1 accuracy

Closeness of agreement between a test result and the accepted reference value.

NOTE 1 : The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component [ISO 3534-1].

NOTE 2 : Accuracy of a diagnostic test is the probability of finding exact results.

3.2 diagnostic kit

Set of kit components and instructions for use packaged together and intended for *in vitro* measurement or detection of a specified analyte.

3.3 kit component

Reagent or another material intended to be part of a diagnostic kit.

3.4 microorganism

Any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE : For the purposes of this standard, the term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity .

3.5 precision

Closeness of agreement between independent test results obtained under stipulated conditions.

NOTE 1 : Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.

NOTE 2 : The measure of precision usually is expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

NOTE 3 : "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme stipulated conditions [ISO 3534-1].

3.6 sensitivity

Capacity to record small variation in concentration of a substance in the test material.

NOTE : Sensitivity of a diagnostic test is the probability of detecting a target organism (positive response) in an infected or contaminated test material.

3.7 specificity

Capacity to specifically recognize the analyte to be detected, distinguishing it from similar substances, impurities or degradation products.

NOTE : Specificity of a diagnostic test is the probability not to detect a target organism (negative response) in a non infected or non contaminated test material.

4 General considerations

The manufacturer of the diagnostic kit should implement a quality control procedure designed to :

- attest the performance characteristics of the diagnostic kit ;
- achieve the performance characteristics by preventing misuse of the diagnostic kit ;
- ensure the suitability for the intended purpose ;
- ensure consistency with the need for protection of human health, animal and environment safety ;
- ensure the performance characteristics are not affected by storage and transportation conditions.

Assessment of quality of a diagnostic kit is based on the reliability of the assay results. Diagnostic results may be considered reliable when the specific performance characteristics stated by the manufacturer, are achieved. Relevant parameters for performance characteristics may be sensitivity, specificity, precision or accuracy. These performance characteristics should be determined through appropriate tests already known from the state-of-the-art for each kind of assay.

The achievement of stated performances depends on the following :

- the sampling procedure ;
- the availability and commutability of control material ;
- the method of expressing the results.

5 Quality control procedures

5.1 Assay performance

The manufacturer and the user should implement quality control procedures designed to assure the achievement of the stated performance characteristics by referring to a control material or, if available, a certified reference material.

Control material should be made available by the manufacturer, preferably as a kit component. The nature of the control material should be defined. The traceability of values assigned to control material should be assured by the kit manufacturer through available certified reference materials and reference measurement procedures appropriate to actual assay conditions. In this regard, the manufacturer should assist the user by providing information about the source of control material.

NOTE : Examples of control materials are a plant extract, an animal serum which specifically reacts with a known pathogen isolate, a purified compound or a virus of a known concentration.

Control materials are processed according to the instructions for use of the diagnostic kit in the same fashion as any test material.

The results obtained, either qualitative or quantitative, are compared with the expected values indicated in the instructions. Correspondence with these results, and also with values generally agreed in the literature indicates the reliability of the results.

5.2 Packaging, labelling and instructions for use

The packaging of the diagnostic kit should include the kit components and the instructions for the use in accordance with EN 375. Labels should be placed on the outer container in which the kit components are packaged, as well as, on the immediate container in which each component is contained.

NOTE : Since a diagnostic kit can contain kit components which are chemical substances, attention is drawn to European (see annex A [4]) and national regulations.

a) The label on the outer container should state :

- product name ;
- name and address of the manufacturer ;
- intended use ;
- number of tests that can be performed ;
- storage information ;
- lot number ;
- expiry date ;
- danger or other symbols and warning, where appropriate.

b) The label on the immediate container should state :

- product name ;
- name of the manufacturer ;
- name and amount of the kit component ;
- intended use ;
- storage information ;
- lot number ;