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STN	**Diagnostická analýza zdravia zvierat** **Kontrola diagnostických činidiel *in vitro*** **Časť 2: Činidlá pre imunologické techniky**	**STN** **EN 18000-2** 96 9051

Animal health diagnostic analyses - Control of in vitro diagnostic reagents - Part 2: Reagents for immunological techniques

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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English Version

Animal health diagnostic analyses - Control of in vitro diagnostic reagents - Part 2: Reagents for immunological techniques

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro - Partie 2 : Réactifs pour les techniques immunologiques

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen Reagenzien - Teil 2: Reagenzien für immunologische Verfahren

This European Standard was approved by CEN on 4 August 2025.

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

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European foreword

This document (EN 18000-2:2026) has been prepared by Technical Committee CEN/TC 469 “Animal health diagnostic analyses”, 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of an identical text or by endorsement, at the latest by July 2026, and conflicting national standards shall be withdrawn at the latest by July 2026.

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.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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

Introduction

The purpose of the EN 18000 series is to facilitate the mutual recognition of the work of the animal health in vitro *diagnostic reagent control organizations* at the European level (or even more widely) and thus to eventually allow the use of strategic *reagents* controlled by a single *control organization (CO)* for a given disease.

The EN 18000 series establishes the requirements for the *control* of in vitro *diagnostic reagents* in animal health. This series is divided into three parts.

Part 1 concerns terms and definitions and the submission of a *reagent* dossier to a *CO* for *control* and approval.

Part 2 concerns the specific aspects of the control by such organization of an immunological *diagnostic reagent*. It describes the *control* of in vitro *reagents* for immunological analyses with a qualitative expression of *test results* used in animal health. It involves *CO* and *applicants* (including their subcontractors, when relevant).

Part 3 concerns the specific aspects of the *control* by such organizations of a polymerase-chain reaction *diagnostic reagent* for the detection or quantification of pathogen-specific nucleic acids.

Like any *standard*, this document is intended to be voluntary and, if its use is prescribed by a competent authority or any other animal health stakeholder, it will be up to them to determine for which diseases and to which extent this document will be applied by the *control* bodies they have designated for this purpose.

The terms defined in Clause 3 and the terms of EN 18000-1 are written in italics throughout the EN 18000 series.

1 Scope

This document specifies the *control* and approval of in vitro *diagnostic reagents* used in animal health for immunological analyses with a qualitative expression of *test results*.

This document is applicable to *diagnostic reagents*, as a priority for infectious (bacterial, viral, fungal or parasitic) or prion diseases and associated animal species for which harmonization of practices in this area is needed, i.e. those for which the national, regional or international regulatory framework provides for the control of trade in animals and/or animal products and/or the definition of a health status (absence of infection) of areas, establishments or individuals. While all *reagents* designated by the competent authorities fall under the scope of this document, the authorities or any other animal health stakeholder can choose to derogate in specific and exceptional situations such as emerging, exotic or rare diseases.

This document is not applicable to all existing *diagnostic reagents*, in particular those for which certain parameters described in this document cannot be validly evaluated in accordance with international requirements, due, e.g. to the absence of a specific *reference method* and/or accessible and duly validated *reference materials (RMs).*

This document does not cover the step in which the *user* verifies a *reagent* (*analysis method adoption*).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

EN 18000-1:2025, *Animal health diagnostic analyses — Control of in vitro diagnostic reagents — Part 1: Application file for the initial and the batch-to-batch control*