

STN	Diagnostická analýza zdravia zvierat Kontrola diagnostických činidiel <i>in vitro</i> Časť 1: Súbor aplikácií na počiatočnú kontrolu a kontrolu medzi dávkami	STN EN 18000-1 96 9051
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Animal health diagnostic analyses - Control of in vitro diagnostic reagents - Part 1: Application file for the initial and the batch-to-batch control

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 1: Application file for the initial and the batch-to-batch control

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro - Partie 1 : Dossier de présentation pour le contrôle initial et le contrôle lot à lot

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen Reagenzien - Teil 1: Antragsunterlagen für die Zulassungs- und die Chargenprüfung

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN 18000-1:2026 (E)

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European foreword

This document (EN 18000-1:2026) 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of an identical text or by endorsement, at the latest by July 2026, and conflicting national standards shall be withdrawn at the latest by July 2026.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.

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EN 18000-1:2026 (E)**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* for a given disease.

The EN 18000 series establishes 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 *control* organization for *control* and approval. Its purpose is to provide the *applicant* submitting an animal disease *in vitro diagnostic reagent* to *control* with the general input for the preparation of the *control* application file. It describes the optimal administrative and technical information regarding the *applicant* and the *reagent* required for the application file for *initial control* and for a *batch-to-batch control*, respectively. It specifies, in particular, the validation parameters of the *test method* using the *reagent* (objectives, methodology, criteria and results) according to international *standards*.

Parts 2 and 3 concern the specific aspects of the *control* by such organization of an immunological *diagnostic reagent* and of a polymerase-chain reaction (PCR) *diagnostic reagent*, respectively.

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.

Many of the definitions in Clause 3 are derived from definitions presently or previously given in chapters or in the "Glossary terms" of the WOAHA (World Organisation for Animal Health) Manual. These WOAHA documents are revised on a regular basis. However, given the impossibility of tracing successive versions of WOAHA documents and thus guaranteeing access to archived versions, the WOAHA source has not been cited in the definitions used. These definitions are applicable in this document and have been agreed by all stakeholders.

The terms defined in Clause 3 are written in italics throughout the EN 18000 series.

1 Scope

This document specifies terms and definitions applicable to the EN 18000 series and requirements concerning information to be provided by applicants submitting animal health *in vitro diagnostic reagents to control*.

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 necessary, 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

There are no normative references in this document.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN