# DIN EN 18000-2:2026-08 (E)

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

## Contents

Page


European foreword ..... 3

Introduction ..... 4

1 Scope ..... 5

2 Normative references ..... 5

3 Terms and definitions ..... 5

4 General control steps ..... 6

5 Prerequisites of the reagent control for the control organization ..... 6
5.1 General ..... 6
5.2 Reference materials ..... 6
5.3 Definition of the purposes of the reagents ..... 7
5.4 General design rules for controlling ELISA reagents ..... 7

6 Initial conformity control ..... 7
6.1 General ..... 7
6.2 Characterization of the reagents by the applicant and documentary review by the control organization ..... 7
6.2.1 General ..... 7
6.2.2 Definition of the interpretation method and threshold(s) ..... 9
6.2.3 Analytical sensitivity ..... 9
6.2.4 Coherence of the dose-response relationship ..... 9
6.2.5 Analytical specificity ..... 9
6.2.6 Diagnostic sensitivity and specificity ..... 10
6.2.7 Sensitivity and specificity verification panel ..... 10
6.2.8 Test repeatability ..... 10
6.2.9 Intermediate precision (within-laboratory reproducibility) ..... 10
6.2.10 Interlaboratory reproducibility ..... 11
6.2.11 Validation of the conditions of use/robustness ..... 11
6.2.12 Verification of the stability ..... 11
6.3 Initial control of the reagents by the control organization ..... 11
6.3.1 General ..... 11
6.3.2 Analytical sensitivity: verification of the minimum detection level ..... 12
6.3.3 Coherence of the dose-response relationship ..... 12
6.3.4 Analytical specificity ..... 12
6.3.5 Positive sample panel assessment (diagnostic sensitivity approach) ..... 12
6.3.6 Negative sample panel assessment (diagnostic specificity approach) ..... 12
6.3.7 Test repeatability ..... 12

7 Batch-to-batch control ..... 13
7.1 Control at the start of the batch shelf-life ..... 13
7.2 Control during the batch shelf life ..... 13
7.3 Derogations from systematic batch-to-batch control ..... 13

8 Special cases ..... 13
8.1 Multiple protocols ..... 13
8.2 Multiple matrices ..... 14

**8.3 Pooling of samples ..... 14**

**Bibliography ..... 15**