YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1183-2024

Detection reagent kits for enzyme-linked immunosorbent assay

酶联免疫吸附法检测试剂盒

Issued on: September 29, 2024 **Implemented on: October 15, 2025**

Issued by: National Medical Products Administration

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 "Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents". This document replaces YY/T 1183-2010 "Detection reagent (kit) for enzyme-linked immunoabsorbent assay (ELISA)". Compared with YY/T 1183-2010, in addition to structural adjustments and editorial changes, the main technical changes are as follows: - ADD "analytical specificity"; DELETE the terms and definitions of "immediate container, primary container", "outer container (sales packaging)", "label", "batch (lot)", "batch code, lot number", "metrological traceability", "accuracy", "recovery", "detection limit, limit of detection", "linearity of a measuring system", "repeatability", "expiry date", "stability" and "cutoff value" (see

3.3 of this document, 3.3 ~

3.16 of the 2010 edition); - DELETE the classification (see Clause 4 of the 2010 edition); - MODIFY the requirements for the accuracy of quantitative detection and the corresponding detection methods (see

5.1.3 of this document,

6.1.3 of the 2010 edition); - MODIFY the requirements for the detection limit of quantitative detection and the corresponding detection methods (see

5.1.4 of this document,

6.1.4 of the 2010 edition); - MODIFY the requirements for the linearity of quantitative detection and the corresponding detection methods (see

5.1.5 of this document,

6.1.5 of the 2010 edition); - ADD the requirements for the analytical specificity of quantitative detection and the corresponding detection methods (see

5.1.6 of this document); - MODIFY the requirements for the repeatability of quantitative detection and the corresponding detection methods (see

5.1.7 of this document,

6.1.6 of the 2010 edition); - MODIFY the requirements for the inter-batch variability of quantitative detection and the corresponding detection methods (see

5.1.8 of this document,

1 Scope

YY/T 1183 is the general product standard for ELISA detection kits in China, covering the format rather than a single analyte. It sets the requirements for enzyme-linked immunosorbent assay kits and the corresponding test methods, which makes it the reference under which a large part of the Chinese IVD catalogue sits: infectious disease serology, hormone panels and antibody testing all reach the market as ELISA kits. Because it is generic, it is the document that defines what a manufacturer has to demonstrate for any ELISA product before analyte-specific requirements are added. It is the reagent counterpart of YY/T 1529 for the analyser. For a manufacturer or a distributor registering an ELISA kit in China, this is the standard the specification and the registration testing are built on.

This document specifies the requirements, identification, labeling and instructions for use, packaging, transportation and storage of detection reagent kits for enzyme-linked immunoabsorbent assay, and describes the corresponding test methods. This document applies to quantitative or qualitative detection reagent kits (hereinafter referred to as "reagent kits") based on the principle of enzyme-linked immunoabsorbent assay in medical laboratories.

2 Normative references

The following referenced documents are indispensable for the application 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.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB/T 21415 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

3.1 enzyme-linked immunoabsorbent assay; ELISA A solid phase adsorption test method that uses enzymes as marker indicators, antigen- antibody reactions as the basis, and the results are judged by the degree of color development of the chromogen.

3.2 detection reagent kit for enzyme-linked immunoabsorbent assay A set of components used to complete specific in vitro diagnostic tests based on the principle of enzyme-linked immunoabsorbent assay.

4 Requirements

4.1 Requirements for quantitative detection reagent kits for enzyme-linked immunoabsorbent assay

4.1.1 Appearance The appearance shall meet the following requirements.

4.1.2 Traceability The manufacturer shall provide the source, assignment process and uncertainty of the calibration standards used in accordance with GB/T 21415 and relevant regulations.

4.1.4 Detection limit It shall comply with manufacturer claims.

4.1.5 Linearity Within the linear range specified by the manufacturer, the correlation coefficient (r) of reagent kits shall not be less than 0.9900.

4.1.6 Analytical specificity Test negative samples containing cross-reactants/degradation products/impurities at a certain concentration/level 3 times, and the test results shall be consistent with their claimed values.

4.1.7 Repeatability Repeat the test 10 times using references/samples with high and low concentrations/levels respectively, and the coefficient of variation (CV) of the test results shall not be higher than 10 %.

4.2 Requirements for qualitative detection reagent kits for enzyme-linked immunoabsorbent assay

4.2.1 Appearance The appearance shall meet the following requirements.

4.2.2 Conformity rate of negative references Test different references/samples that are used to evaluate the negative conformity rate of reagents once each, and the test results shall all be negative. The setting of negative references follows the following principles (taking pathogenic microorganisms as an example).

4.2.5 Detection limit The manufacturer shall specify the detection limit level of reagent kits. Test references/samples with different concentrations/level gradients respectively, and the results shall comply with manufacturer claims. The concentration/level setting and preparation of references/samples shall follow the following principles.

4.2.6 Repeatability Test negative and weak positive references/samples with indicated

concentrations/levels at least 10 times, and the conformity rate of positive and negative results shall be 95 %.

4.2.8 Stability The shelf life stability and thermal stability can be verified.

5 Test methods

5.1 Test methods for quantitative detection reagent kits for enzyme-linked immunoabsorbent assay

5.1.1 Appearance Visually inspect with corrected vision under natural light.

5.1.2 Traceability The manufacturer shall provide traceability information.

5.1.4 Detection limit According to the information such as blank limit, detection limit and reference range of reagent kits provided by the manufacturer, test 5 low-value samples with concentrations close to the detection limit. Each sample is tested 5 times. The test results are sorted by size. If the following conditions are met, the blank limit and detection limit provided by the manufacturer can be considered to be basically reasonable.

5.1.5 Linearity The high-value samples close to the upper limit of the linear range are diluted to at least 5 concentrations in a certain proportion, among which the low-value concentration samples shall be close to the lower limit of the linear range. Operate according to the instructions of the reagent kit, test the sample of each concentration 3 times, calculate the average value of its concentration, linearly fit the average value of the result and the dilution ratio by the least squares method, and calculate the linear correlation coefficient (r). In special cases, such as the determination of bound and free states where dilution may cause changes in binding, dilution linear detection should not be used.

5.1.6 Analytical specificity Test negative samples containing cross-reactants/degradation products/impurities with indicated concentrations/levels 3 times.

5.1.9 Stability

5.1.9.1 Shelf life stability After a reagent kit is stored under the conditions specified in

4.1.9 a), test it according to methods of

5.1.9.2 Thermal stability Take a reagent kit within the shelf life, based on the thermal stability conditions claimed by the manufacturer, test it according to methods of

5.2 Test methods for qualitative detection reagent kits for enzyme-linked immunoabsorbent assay

5.2.1 Appearance Visually inspect with corrected vision under natural light.

5.2.2 Conformity rate of negative references Test negative references once each.

5.2.3 Conformity rate of positive references Test positive references once each.