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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1233-2024

Cardiac troponin detection reagent kit (labelled immunoassay)

心肌肌钙蛋白测定试剂盒（标记免疫分析法）

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

Issued by: National Medical Products Administration

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1 Scope

YY/T 1233 is the product standard for the cardiac troponin assay kit by labelled immunoassay, the test that decides whether a patient with chest pain is having a myocardial infarction. It specifies the requirements, the marking, the labelling, the instructions for use, the packaging, transport and storage of the kit, and describes the corresponding test methods. Troponin is the assay where analytical performance translates most directly into clinical decisions: the diagnostic thresholds sit near the limit of detection, so precision at low concentration is not a specification detail but the basis of the rule-out pathway that keeps patients out of hospital beds. For a manufacturer or a distributor registering a troponin kit in China, this is the governing product standard.

This document specifies the requirements, labeling, instructions for use, packaging, transportation, and storage for Cardiac troponin detection reagent kit (labelling immunoassay), and describes the corresponding test methods. This document applies to kits intended for the in vitro quantitative detection of cardiac troponin I (hereinafter referred to as cTnI) and cardiac troponin T (hereinafter referred to as cTnT) in human serum, plasma, or whole blood. The methodologies covered include enzyme-linked immunoassay, enzymatic and non-enzymatic chemiluminescence, electrochemiluminescence, time-resolved fluorescence immunoassay, and others. This document does not apply to. -- Qualitative or semi-quantitative reagents labeled with colloidal gold or other methods (e.g., test strips, biochips, etc.); -- Various radioimmunoassay or immunoradiometric assay kits labeled with radioisotopes; -- cTnI or cTnT calibrators and quality control materials intended for separate sale.

2 Normative References

The contents of the following documents constitute indispensable provisions of this document through normative reference therein. For dated references, only the edition cited

applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

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

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

GB/T 29791.1 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part

3 Terms and Definitions

The terms and definitions defined in GB/T 29791.1, as well as the following terms and definitions, apply to this document.

3.1 High-sensitivity cardiac troponin detection; hs-cTn It is a measurement method that can consistently detect cardiac troponin (cTn) in the peripheral blood of more than 50% of healthy adult males and females, with the measurement results being greater than or equal to the limit of detection, and for which the coefficient of variation (CV) of the measurement results is less than or equal to 10% at the 99th percentile upper reference limit (99th URL) of the healthy population. Note

1.The 99th URL refers to the cTn concentration value obtained by arranging the cTn concentration values of apparently healthy individuals in ascending order; the value located at the 99th position (specifically, the mean of the values at the 99th and 100th positions) is termed the 99th percentile upper reference limit for apparently healthy individuals. Note

2.The 99th URL is a recognized cutoff point for myocardial injury and serves as an essential cutoff value for the diagnosis of myocardial infarction. Note

3.Both hs-cTn and conventional cTn detection methods (hereinafter referred to as con-cTn) target cTn as the analyte. The distinction lies in the sensitivity of the detection system, rather than in the substance being measured.

4 Requirements

4.1 Appearance The manufacturer shall establish appearance requirements for the product. These requirements shall include.

a) The kit shall contain all components; there shall be no liquid leakage; both the inner and outer packaging shall be intact; and labels and markings shall be clear.

b) Where applicable, liquid reagents shall be homogeneous solutions, free from precipitates and flocculent matter.

c) Where applicable, lyophilized products, upon reconstitution, shall form homogeneous

solutions free from precipitates, flocculent matter, etc.

4.2 Traceability In accordance with GB/T 21415 and relevant regulations, the manufacturer shall provide information regarding the source of the cTnI and/or cTnT calibrators used, the value assignment process for traceability, corresponding requirements, uncertainty estimates, and other relevant details.

4.3 Accuracy Accuracy shall meet one of the following requirements.

a) Relative Bias. When testing Certified Reference Materials (CRMs) or other recognized reference materials, the relative bias of the measurement results shall meet the acceptable criteria for cTn assays; alternatively, when testing accuracy control materials provided by the manufacturer that demonstrate commutability, the relative bias of the measurement results shall not exceed ±10%. Product calibrators associated with the reagent under evaluation, as well as quality control materials with assigned values specific to the reagent's detection system, shall not be used for accuracy evaluation.

b) Recovery. Within the range of [85.0%, 115.0%].

c) Comparison Study. When compared against an analytical system designated by the manufacturer that possesses metrological traceability, the correlation coefficient (r) shall be no less than 0.975, and the slope shall fall within the range of [0.9, 1.1].

Note. Where applicable, priority shall be given to the use of Certified Reference Materials (CRM) or other recognized reference materials as specified in 4.3a).

4.4 Detection Limit The manufacturer shall specify the detection limit of the product; the detection limit claimed by the manufacturer shall meet the following requirements.

a) For conventional cTnI assay kits (hereinafter referred to as con-cTnI), the detection limit shall not exceed

0.05 ng/mL.

b) For conventional cTnT assay kits (hereinafter referred to as con-cTnT), the detection limit shall not exceed