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PROFESSIONAL STANDARD

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Quantitative detection reagent (kit) for tumor markers - Chemiluminescent immunoassay

肿瘤标志物定量测定试剂（盒）化学发光免疫分析法

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Foreword

This standard was drafted in accordance with the rules specified in GB/T 1.1-2009.

Please note that some contents in this document may involve patents. The issuing organization of this document does not bear the responsibility to identify these patents.

This standard was proposed by the China Clinical Laboratory Testing and In vitro Diagnostic Test System of Standardization Administration of China (SAC/TC 136).

This standard shall be under the jurisdiction of the China Clinical Laboratory Testing and In vitro Diagnostic Test System of Standardization Administration of China (SAC/TC 136).

Drafting organizations of this standard: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd., Beijing Yuande Bio-Medical Engineering Co., Ltd, Roche Diagnostic Products (Shanghai) Co. Ltd., and Siemens Healthcare Diagnostics (Shanghai) Co., Ltd.

The main drafters of this standard: Zhang Xinmei, Cheng Yinghao, Yang Xiaolin, Du Haiou, Cai Xiaorong, and Zhu Weizan.

Quantitative detection reagent (kit) for tumor markers - Chemiluminescent immunoassay

1 Scope

This standard specifies the terms and definition, classification, requirements, test method, marks, labels, instructions, packaging, transportation and storage etc. of quantitative detection reagent (kit) [herein after referred to as “reagent (kit)”] for tumor markers (chemiluminescent immunoassay).

This standard applies to the reagent (kit) used for quantitative detection of human tumor markers taking the chemiluminescent immunoassay as the principle. It includes the enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) in the carrier of micro-plates, tubes, magnetic particles, micro-beads and plastic beads.

This standard does not apply to:

a) The calibrator and quality control product of tumor markers intended for separate sale;

b) Biochip that uses chemiluminescent immunoassay as the principle.

2 Normative references

The articles contained in the following documents have become part of this document when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this document.

GB/T 21415-2008 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

Tumor marker, TM

During the tumor generation and reproduction, the certain kind of substances (including

proteins, hormones, enzymes and polyamines) that are generated or secreted by tumor cells or other cells; released into the blood, body fluids, cells or tissues; reflect the tumor's presence and growth; and that are measurable by using methods such as biochemistry, immunology and molecular biology.

3.2

Chemiluminescence, CL

The luminescence phenomenon that is caused by – because of chemical reactions, the substances with generated electron energy-level at excited state unleash energy and produce the photons through transition.

3.3

Chemiluminescent immunoassay, CLIA

It is the technology combined with chemiluminescence and immunoassay. Conduct a series of immunoreactions through marked antigen or antibody with products to be measured. Finally measure the luminous intensity to get the content of the product to be measured.

3.4

Kit for tumor markers

A group of components that are packed together, for the purpose of completing detection of tumor markers.

3.5

Batch (lot)

The materials produced in one process or a series of processes, which are of consistent properties and specified amount.

Note: It can be initial-material, intermediate material and final product.

[ISO/FDIS 18113-1, Definition 3.5]

3.6

Batch code, lot number

A combination of particular numbers and (or) letters that can specifically identify one batch and that has the traceability of manufacturing, packaging, marks and transportation process.

[ISO/FDIS 18113-1, Definition 3.6]

(*SD*) of the 10-times measurement results. Coefficient of variation (*CV*) is obtained and based on Formula (3). The results shall be in accordance with the requirements of 5.6.

$$CV = SD/M \times 100\% \quad \cdots\cdots (3)$$

Where:

CV — Coefficient of variation

SD — Standard deviation of the measuring results for 10 times;

M — Mean value of the measuring results for 10 times.

6.7 Within-batch difference

Use 3 batches of reagents (kits) to respectively detect the samples with at least 2 levels for 10 times. Work out mean value (*M*) and standard deviation (*SD*) of the 30-times measurement results. Coefficient of variation (*CV*) is obtained and based on Formula (4). The results shall be in accordance with the requirements of 5.7.

$$CV = SD/M \times 100\% \quad \cdots\cdots (4)$$

Where:

CV — Coefficient of variation

SD — Standard deviation of the measuring results for 30 times;

M — Mean value of the measuring results for 30 times.

6.8 Stability

The following methods can be used for verification:

a) Stability within the validity: Take the reagent kit that has been expired for detection in accordance with methods in 6.3-6.6. It shall comply with the requirements in 5.8 a);

b) Thermal stability test: The reagent kit within the period of validity shall be detected by methods of 6.3-6.6 according to thermal stability conditions stated by the manufacturing enterprise. The results shall be in accordance with the requirements of Clause 5.8 b).

7 Marks, labels and instructions

7.1 Marks and labels on the outer package of the reagent (kit)

It shall contain at least the following contents:

a) Product name and packaging specifications;

b) Name, address, contact information of the manufacturing enterprise or after-sales service organization;

c) Medical device registration certificate number;

d) Product standard number;

e) Product batch number;

f) Expiration date;

g) Storage conditions.

7.2 Marks and labels of each component package of reagent (kit)

It shall contain at least the following contents:

a) Product name and packaging specifications;

b) Name or trademarks of the manufacturing enterprise;

c) Product batch number;

d) Expiration date.

7.3 Instructions of reagent (kit)

It shall contain at least the following contents:

a) Product name;

b) Packaging specifications;

c) Intended use;

d) Detection principle;

e) Main compositions;

f) Storage conditions and expiration date;

g) Applicable instrument;

h) Sample requirement;

i) Detection method;

Bibliography

1. YY/T 0316-2008 Medical devices — Application of risk management to medical devices (ISO 14971: 2007, IDT)

2. YY/T 0466.1-2009 Devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1:General requirements (ISO 15223.1-2009, IDT)

3. GB/T 191-2008 Packaging - Pictorial marking for handling of goods

4. JJF 1001-1998 General Terms in Metrology and Their definitions

5. ISO/FDIS 18113-1 Clinical laboratory testing and in vitro diagnostic medical systems — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

6. ISO 3534-1: 1993 Statistics Vocabulary and symbols — Part 1: General statistical terms and terms used in probability — Second Edition

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