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INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1176-2010

Cancer antigen CA15-3 quantitative detection reagent (kit) - Chemiluminescent immunoassay

癌抗原 CA15-3 定量测定 试剂 (盒) 化学发光免疫分析法

Issued on: December 27, 2010 **Implemented on: June 1, 2012**

Issued by: State Food and Drug Administration

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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 Food and Drug Administration.

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 organization of this standard: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd., Roche Diagnostic Products (Shanghai) Co., Ltd., and Beckman Coulter Commercial Enterprise (China) Co., Ltd.

The main drafters of this standard: Zhang Xinmei, Cheng Yinghao, Du Haiou, Huang Baixing, and Zhang Jinwen.

Cancer antigen CA15-3 quantitative detection reagent (kit) - Chemiluminescent immunoassay

1 Scope

This standard specifies the classification, requirements, test method, identification, labels, instructions, packaging, transportation and storage of the cancer antigen CA15-3 quantitative detection reagent (kit) (chemiluminescent immunoassay).

This standard is applicable to test cancer antigen CA15-3 reagent (kit) [hereinafter referred to as “CA15-3 reagent (kit)”], based on the principles of chemiluminescent immunoassay. It includes the enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) with carriers of microwell plates, tubes, magnetic particles, micro-beads and plastic-beads.

The Standard is not applicable to:

a) The tumor marker calibrators and tumor marker control materials that are intended for separate sales.

b) Biochip that uses the principle of chemiluminescent immunoassay.

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 Classification

CA15-3 reagent (kit) can be divided into enzymatic and non-enzymatic chemiluminescent immunoassay reagent (kit), according to different chemiluminescent principles. According to different solid-phase carriers, it can be divided into microwell plates, tubes, magnetic particles, micro-beads and plastic-beads as the carrier of chemiluminescent immunoassay reagent (kit). According to different operation processes, it can be divided

into manual operation method and instrument-automatic operation method.

4 Requirements

4.1 Appearance

The appearance shall comply with the following requirements:

a) Each component of reagent (kit) shall be complete, intact and no leakage of liquid;

b) The packaging labels shall be clear and easy to be identified.

4.2 Traceability

The manufacturer shall provide the contents such as source, assignment procedure and measurement uncertainty of the applied CA15-3 calibrators in accordance with GB/T21415-2008 and relevant regulations.

4.3 Accuracy

The accuracy shall comply with one of the following requirements:

a) Use the reference materials as the sample for detection. The relative deviation of the measurement results shall be within the range of ± 10%;

b) The recovery rate shall be within the range of (85% to 115%).

Note: If CA15-3 has the international reference materials or national standard products, detect in accordance with Term a); if there are no international reference materials or national standard products, then in accordance with b) for detection.

4.4 Minimum detection limit

The minimum detection limit shall not be greater than 1.0 U/mL.

4.5 Linearity

The upper limit of linear range shall not be less than 5 times the reference value. The lower limit shall not be greater than 1/5 times the reference value. The correlation coefficient r shall not be less than 0.9900 within the linear range prescribed by the manufacturer.

4.6 Repeatability

Use the samples with the concentrations of (30±6) U/mL and (150±30) U/mL to repeatedly and respectively test for 10 times. The coefficient of variation (*CV*) shall not be greater than 10% (instrument-automatic operation) or not be greater than 15% (manual operation).

SD — Standard deviation of 30-times measurement results;

M — Mean of 30-times measurement results.

5.8 Stability

The following methods can be used for verification:

a) Stability within the validity: Take the kit that has been expired to perform the detection in accordance with methods of 5.3-5.6. It shall comply with the requirements in 4.8 a);

b) Thermal stability test: A kit within the validity is placed for 3 days at 37°C. Perform the test according to methods of 5.3-5.6. The result shall comply with requirements of 4.8 b).

6 Marks, labels and instructions

6.1 Marks, labels for outer package of reagent (kit)

a) Product name and packaging specifications;

b) Name, address, contact details of the manufacturer 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.

6.2 Marks and labels on each component packing of reagent (kit)

It shall contain at least the following contents:

a) Product name and packaging specifications;

b) Name or trademark of the manufacturer;

c) Product batch number;

d) Expiration date;

e) Storage conditions.

7 Packaging, transportation and storage

7.1 Packaging

Reagent (kit) shall be packaged according to the requirements of the manufacturer.

7.2 Transportation

Reagent (kit) shall be transported according to the requirements of the manufacturer.

7.3 Storage

Reagent (kit) shall be stored under the conditions specified by the manufacturer.

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. GB/T 9969-2008 General principles for preparation of instructions for use of industrial products

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