Translated English of Chinese Standard: YY/T1161-2009
Translated by: www.ChineseStandard.net
Wayne Zheng et al.
Email: Sales@ChineseStandard.net

YY

ICS 11.100
C44

PROFESSIONAL STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1161-2009

Tumor Associated Antigen CA125 Quantitative Detection Reagent (Kit) (Chemiluminescent Immunoassay)

肿瘤相关抗原 CA125 定量测定试剂（盒）（化学发光免疫分析法）

Issued on: December 30, 2009 **Implemented on: June 1, 2011**

Issued by: State Food and Drug Administration

Table of Contents

Foreword

The preparation of this standard follows the basic regulations of the GB/T 1.1-2000 *Directives for Standardization Part 1: Rules for the Structure and Preparation of Standards.* It is the basis of product quality to evaluate tumor associated antigen CA125 quantitative determination reagent (kit) (chemiluminescence immunoassay).

This standard was proposed by the China Food and Drug Administration.

This standard shall be centralized by the National Medical Clinical Testing Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC 136).

Drafting organizations of this standard: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd, Beijing Yuande Biomedical Engineering Co., Ltd, Beckman Coulter Co., Ltd., and Siemens Diagnostics Medical (Shanghai) Corporation.

The main drafter of this standard: Zhang Xinmei, Cheng Yinghao, Sun Xudong, Hu Guomao, Ying Xitang, Zhang Jinwen, and Zhu Weizan.

Tumor Associated Antigen CA125 Quantitative Detection Reagent (Kit) (Chemiluminescent Immunoassay)

1 Scope

This standard specifies the terms and definitions, classification, requirements, test methods, inspection rules, identification, labels, instructions, packaging, transportation and storage of tumor associated antigen CA125 quantitative determination reagent (kit) (chemiluminescence immunoassay).

This standard is applicable to quantitative detection of tumor associated antigen (CA125) reagent (kit) [hereinafter referred to as “CA125 reagent (kit)”], based on the principles of chemiluminescence immunoassay. It includes the enzymatic and non-enzymatic chemiluminescence immunoassay detection reagent (kit) with carriers of micro-plates, tubes, magnetic particles, micro-beads and plastic beads.

This standard is not applicable to the requirements of calibrators and quality control products in the kit.

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 standard, the following terms and definitions shall apply.

3.1

Chemiluminescence, CL

Because that the chemical reaction can generate the substances of electronic energy

level to be in the excited state, the latter can generate photon by transition release energy, thereby to cause the luminescence phenomenon.

3.2

Chemiluminescent immunoassay, CLIA

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

Minimum detectable concentration / detection limit, limit of detection

It refers to the measured minimum value that can be declared as varying from zero at a certain probability in the sample. [ISO/DIS 18113-1]

Note 1: Sometimes it is incorrectly referred to as a sensitivity of analysis.

Note 2: The minimum detection limit in this standard is the minimum concentration which differs from zero and is at the confidence interval of not less than 95%.

3.4

Analytical specificity

The capability of measurement procedure that only measures the sample to-be-measured.

[GB/T 19702-2005/ISO 15193:2002, 3.8]

Note 1: Lack of specificity may be referred to the analytical interference.

Note 2: The lack of specificity may be referred as due to cross reaction in the immunochemical measurement procedure.

Note 3: The specificity of the measurement procedure shall not be confused with the diagnostic specificity.

3.5

Linearity of a measuring system

The directly proportional capacity between the given measuring result and the measured value in the sample. [ISO/DIS 18113-1]

Note 1: For in vitro diagnostic (IVD) medical devices, the linearity-related results of measurement are the measurement values after correction or linearization.

can only be sold after the inspection is qualified.

7.3 Reagent (kit) must be submitted to ex-factory inspection in batches. Each material-feeding batch is deemed as one batch of products.

7.4 Ex-factory inspection

7.4.1 Sampling quantity

The sampling quantity of ex-factory inspection shall be 3 times as the quantity of inspection items. It includes inspection quantity, reinspection quantity and retained-sample quantity.

7.4.2 Inspection items

The items of ex-factory inspection shall be clear.

7.4.3 Eligibility determination

If any item is unqualified in the process of inspection, reinspection shall be carried out. If any item is unqualified in the reinspection, the batch of reagent (kit) is deemed as unqualified.

7.4.4 The retained-sample reagent (kit) is used for reinspection in particular cases, such as quality complaints by the users. If the retained-sample is not used for reinspection, then the reagent (kit) shall be destroyed in two months after the validity period.

7.5 Type inspection

7.5.1 Type inspection shall be conducted in case of one of the following conditions:

a) Production of new products;

b) When there is significant change to the material, formula or process;

c) Not less than once a year during continuous production;

d) When production is resumed after the long-term shutdown;

e) When it is required by the contract provision or the administrative department.

7.5.2 Sampling quantity

The sampling quantity of type inspection shall be three times as the quantity of inspection items. It includes the inspection quantity, reinspection quantity and retained-sample quantity.

7.5.3 Inspection items

For type inspection, it shall conduct full-inspection. All inspection results shall be qualified.

7.5.4 Eligibility determination

If all inspection items are qualified, the type inspection is deemed as qualified. If the type inspection is not qualified, it must not start mass-production.

8 Marks, labels and instructions

8.1 Outer package of reagent (kit)

It shall contain at least the following contents:

a) Product name and specification;

b) Name, address and contact details of the manufacturer;

c) Number of medical device registration certificate number and product standard;

d) Product batch number;

e) The period of validity;

f) Storage conditions.

8.2 Each component of reagent (kit)

It shall contain at least the following contents:

a) Product name and specification;

b) Name or trademark of the manufacturer;

c) Product batch number;

d) The period of validity.

8.3 Instructions of reagent (kit)

It shall contain at least the following contents:

a) Product name;

b) Packaging specifications;

c) Intended use;

d) Inspection principle;

Bibliography

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

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

3. YY 0466-2003 Medical devices - Symbols to be used with medical device labels labelling and information to be supplied

4. GB/T 19702-2005 In vitro diagnostic medical devices-Measurement of quantities in samples of biological origin-Presentation of reference measurement procedures

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

_____ END _____