Translated English of Chinese Standard: YY/T1178-2010
Translated by: www.ChineseStandard.net
Wayne Zheng et al.
Email: Sales@ChineseStandard.net

YY

ICS 11.100
C 44

INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1178-2010

Carbohydrate antigen CA19-9 quantitative detection reagent (kit) – Chemiluminescent immunoassay

糖类抗原 CA19-9 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

Table of Contents

Foreword 3

1 Scope 4

2 Normative references 4

3 Classification 4

4 Requirements 5

5 Test methods 6

6 Marks, labels and instructions 9

7 Packaging, transportation and storage 11

Bibliography 12

Foreword

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

Please note that some contents in this file may involve patents. The issuing organization of this file 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 organization of this standard: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd., Johnson & Johnson Medical (Shanghai) Ltd, and Beijing Office of Switzerland Abbott Co., Ltd.

The main drafters of this standard: Zhang Xinmei, Cheng Yinghao, Qi Xin, and Wang Xuefeng.

Carbohydrate antigen CA19-9 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 carbohydrate antigen CA19-9 quantitative detection reagent (kit) (chemiluminescent immunoassay).

This standard is applicable to test carbohydrate antigen (CA19-9) reagent (kit) [hereinafter referred as “CA19-9 reagent (kit)”], based on the principles of chemiluminescent immunoassay. It includes the enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) with the carriers of microwell plates, tubes, magnetic particles, micro-beads and plastic beads.

This standard is not applicable to:

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

b) Biochip in 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

CA19-9 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 carriers of chemiluminescent

4.7 Within-batch difference

Use 3 batches of reagent kits to respectively test the samples with concentrations of (40±8) U/mL and (150±30) U/mL. The coefficient of variation (*CV*) among the 3 batches of kits shall not be greater than 15%.

4.8 Stability

The following methods can be used for verification:

a) Stability within the validity: The manufacturer shall stipulate the validity of reagent (kit). Use the kits that have been expired to test the accuracy, minimum detection limit, linearity and repeatability. It shall comply with requirements of .4.3-4.6.

b) Thermal stability test: A kit within the period of validity is placed for 3 days at 37°C. Test the accuracy, minimum detection limit, linearity and repeatability. The results shall comply with the requirements of 4.3-4.6.

Note 1: Thermal stability test cannot be used to derive the validity of products, unless it uses the derivation formula that is established and based on a large number of stability study data.

Note 2: According to the product characteristics, it can choose Method a) and Method b) for arbitrary combination, but the method selected shall verify the stability of the products, in order to ensure the product performance to comply with the standard requirements within the validity.

5 Test methods

5.1 Appearance

Use corrected-visual-acuity to visually inspect, under the natural light. It shall meet the requirements of 4.1.

5.2 Traceability

Traceability information provided by the manufacturer shall comply with the requirements of 4.2.

5.3 Accuracy

Accuracy may select one of the following test methods:

a) Prepare the concentration of the reference material. Make its final concentration to be about 100 U/mL (concentration deviation of ±20% is allowed). Take it as the sample. Perform the detection according to the procedures of instructions. Repeat for 3 times repeatedly. Record the average result as *M*. Calculate the relative deviation *B* of the measured concentration according to Formula (1). The result shall comply with the requirements of 4.3 a).

It shall include at least the following contents:

a) Product name;

b) Packaging specifications;

c) Intended use;

d) Inspection principle;

e) Main compositions;

f) Storage conditions and expiration date;

g) Applicable instrument;

h) Sample requirements;

i) Inspection methods;

j) Reference value (Reference range);

k) Explanation to the inspection results;

l) The limitations of inspection methods;

m) Product performance index;

n) Instructions of analytical interference (hemolysis, lipemia, jaundice, etc.);

o) Instructions for analytical specificity (cross-reactants);

p) Precautions;

q) References;

r) Name, address, contact details of the manufacturer or after-sales service organization;

s) License number of medical device manufacturer (limited to domestic enterprises);

t) Medical device registration certificate number;

u) Product standard number;

v) Instructions approval and date of modification.

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

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

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

_____ END _____