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PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国医药行业标准

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

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Foreword

This Standard is 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 issued institution of this file should not bear the responsibility to identify these patents.

This Standard is proposed by the China Food and Drug Administration.

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

This Standard is drafted by: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd., Roche Diagnostic Products (Shanghai) Co., Ltd., 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) (chemiluminescence 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 chemiluminescence immunoassay. It includes the enzymatic and non-enzymatic chemiluminescence immunoassay detection reagent (kit) with carriers of microwell plates, tubes, magnetic particles, microbeads and plastic beads.

The 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 chemiluminescence immunoassay.

2 Normative references

The articles contained in the following documents have become 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 21415-2008In 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 chemiluminescence immunoassay reagent (kit) according to different chemiluminescence principles; According to different solid phase carriers, it can be divided into microwell plates, tubes, magnetic particles, microbeads and plastic beads as the carrier of

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