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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 1177-2010

Cancer antigen CA72-4 quantitative detection reagent (kit)-Chemiluminescent immunoassay

癌抗原 CA72-4 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 according to the rules specified in GB/T 1.1-2009

Which is the basis for evaluation of CA72-4 (Cancer Antigen 72-4, CA72-4) quantitative determination reagent (kit) (chemiluminescent immunoassay) product quality.

Please note that some contents in this document may involve in the patent. The issuing authority of this document will not bear the responsibilities of these patents.

This Standard is proposed by the National Medical Clinical Testing Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC 136).

This Standard shall be under the jurisdiction of the National Medical Clinical Testing Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC 136).

Participating drafting organizations of this Standard: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd and Roche Diagnostic Products (Shanghai) Co., Ltd.

Main drafters of this Standard: Zhang Xinmei, Cheng Yinghao, Tao Yuan and Du Haiou.

Cancer antigen CA72-4 quantitative detection reagent (kit)-Chemiluminescent immunoassay

1 Scope

This Standard specifies the classification, requirements, test method, marks, labels, operating instructions, packaging, transportation and storage of the cancer antigen CA72-4 quantitative detection reagent (kit) (chemiluminescent immunoassay).

This Standard is applicable to test cancer antigen CA72-4 reagent (kit) [hereinafter referred to as “CA72-4 reagent (kit)”] based on the principles of chemiluminescent immunoassay, including the enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) in the carrier of microplates, pipes, magnetic particles, microbeads and plastic beads.

The Standard does not apply to:

a) The tumor marker calibration product and tumor marker quality control materials intended for separate sale.

b) Biochip in the principle of chemiluminescent 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 Classifications

CA72-4 reagent (kit) can be divided into enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) according to different chemiluminescence principles; According to different solid phase carriers, it can be divided into enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) in the carrier of microplates, pipes, magnetic particles, microbeads and plastic beads; According to

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