ICS 11.100
C 44

YY

PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国医药行业标准

YY/T 1162-2009

Alpha-fetoprotein quantitative detection reagent (kit) (Chemiluminescent immunoassay)

甲胎蛋白（AFP）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 China Food and Drug Administration

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;*

Which is the basis for evaluation of Alpha-Fetoprotein, AFP quantitative determination reagent (kit) (chemiluminescence immunoassay) product quality.

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

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

This Standard is drafted by: Beijing Institute of Medical Device Testing, Beijing Yuande Biomedical Engineering Co., Ltd, Beijing Chemclin Biotech Co., Ltd, Shanghai Abbott Pharm Co, Ltd, Siemens Diagnostics Medical (Shanghai) Corporation.

The main drafter of this Standard: Zhang Xinmei, Sun Xudong, Cheng Yinghao, Yang Xiaolin, Wang Xuefeng and Zhu Weizan.

Alpha-fetoprotein 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 alpha-fetoprotein quantitative detection reagent (kit) (chemiluminescence immunoassay).

This Standard is applicable to the quantitative determination of the alpha-fetoprotein quantitative detection reagent (kit) (hereinafter referred to as “AFP reagent (kit)”) in the human blood matrix or other body fluid components based on the principle of chemiluminescence immunoassay. It includes the enzymatic and non-enzymatic chemiluminescence immunoassay detection reagent (kit) in carriers of microplates, tubes, magnetic particles, microbeads and plastic beads.

The 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 this standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 21415-2008In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511: 2003, IDT)

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

北京文心雕语翻译有限公司
Beijing Lancarver Translation Inc.

完整版本请在线下单/Order Checks Online for Full version

联系我们/or Contact:

TEL: 400-678-1309

QQ: 19315219 | Skype: Lancarver

Email：info@lancarver.com

http://www.lancarver.com

线下付款方式：

I. 对公账户：

单位名称：北京文心雕语翻译有限公司

开 户 行：中国工商银行北京学清路支行

账　　号：0200 1486 0900 0006 131

II. 支付宝账户：info@lancarver.com

III. Paypal: info@lancarver.com

注: 付款成功后，请预留电邮，完整版本将在一个工作日内通过电子 PDF 或 Word 形式发送至您的预留邮箱，如需索取发票，下单成功后的三个工作日内安排开具并寄出，预祝合作愉快！

NOTE All documents on the store are in electronic Adobe Acrobat PDF format, there is not sell or ship documents in hard copy. Mail the order and payment information to info@lancarver.com , you will shortly receive an e-mail confirming your order.