YY

ICS 11.100

C 44

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1216-2013

Alpha-fetoprotein quantitative labelling immunoassay kit

甲胎蛋白定量标记免疫分析试剂盒

Issued on: October 21, 2013 **Implemented on: October 1, 2014**

Issued by: State Food and Drug Administration

Table of Contents

Foreword

This Standard is drafted according to the rules specified in GB/T 1.1-2009.

Please note that some contents of this Standard may involve patents. The issuing authority of this Standard does not undertake the responsibility of identifying these patents.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of National Technical Committee (SAC/TC 136) on System of Medical Clinical Test Lab and in Vitro Diagnostic System of Standardization Administration of China.

Drafting organization of this Standard: National Institutes for Food and Drug Control.

The main drafters of this Standard: Liu Yan, Huang Ying, and Gao Shangxian.

Alpha-fetoprotein quantitative labelling immunoassay kit

1 Scope

This Standard specifies the classification, requirements, test method, marks, labels, operating instructions, packaging, transportation, and storage of the alpha-fetoprotein quantitative labelling immunoassay kit.

This Standard is applicable to the quantitative detection of alpha-fetoprotein labelling immunoassay kit (hereinafter referred to as AFP kit). It includes AFP immunoassay kit of quantitative detection by using labelling methods such as enzyme labelling, (electrical) chemiluminescent labelling, (time resolution) fluorescence labelling AS capture antibody; and using microplates, pipes, magnetic particles, microbeads, plastic beads and others AS the carrier coated antibody.

This Standard does not apply to:

a) Colloidal gold labelled AFP test strip;

b) Various types of radio-immunity or IRMA reagent kit labelled with ^{125}I and other radioactive isotopes.

2 Normative references

The articles contained in the following documents have become part of this Standard 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.

YY/T 0466.1-2009 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

3 Classifications

The AFP kits can be divided into ELISA reagent kit, chemiluminescent reagent kit, time resolution fluorescence reagent kit etc., according to the various labelling methods. It can be divided into different kinds of AFP kits with carriers such as microplates, pipes, magnetic particles, microbeads and plastic beads, according to the various solid-phase carriers. The AFP kits can be divided into manual operation method and automatic

4.6 Specificity

DETECT at least 10 normal serums. The detection results shall not be higher than 20.0 ng / mL.

4.7 Measured value of quality control material

Within the linear range of the kit, SET 2 or 3 quality control materials with different concentrations. The measured results shall be within the allowable interval of the measured value of quality control products.

4.8 Stability

The following methods may be selected:

4.8.1 Stability at the end of validity

The reagent kit is preserved until the end of the validity under a specified condition. The measured results shall comply with the provisions of 4.1, 4.2, 4.3, 4.4, 4.5.1, 4.5.2, 4.6 and 4.7.

4.8.2 Thermal stability

According to the period of validity of the kit, the kit is usually placed under the condition of 37°C for some time (usually 3 days - 7 days). The inspection results shall comply with the provisions of 4.1, 4.2, 4.3, 4.4, 4.5.1, 4.5.2, 4.6, and 4.7.

Note 1: The thermal stability cannot be used to derive the period of validity of products, unless it uses the derivation equation that is established based on a large number of stability study data;

Note 2: One of the above methods can be selected according to the product characteristics. However, the selected method shall be capable of verifying the stability of the product, so as to ensure that the performance of the product can comply with the standard requirements within the period of validity.

5 Test methods

5.1 Appearance

USE visual inspection method. Visually INSPECT under natural light and bright place. It shall comply with the provision of 4.1.

5.2 Minimum detection limit

DETERMINE the signal values of zero-value calibrator or sample diluent for not less than 10 times. CALCULATE the mean ($\bar{x}$) and standard deviation (*SD*). And CALCULATE the value of ($\bar{x}$ + *2SD*). The sample concentration corresponding to that value is the minimum detection limit of the kit. It shall comply with the provision of 4.2.

Bibliography

[1] GB 3100 The international system of units and its application

[2] GB/T 19702 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Presentation of reference measurement procedures

[3] GB/T 19703 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin -- Description of reference materials

[4] *Ye Yingwu. National Clinical Test Operation Specification. Edition 3, Nanjing: Southeast University Press, 2006*

[5] WS/T 124-1999 Inspection criteria of the quality of clinical chemistry in vitro diagnostic kits - General guideline

[6] GB/T 29791.1-2013 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

_____ END _____

This is an excerpt of the PDF (Some pages are marked off intentionally)

------ The End ------