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 1232-2014

γ-Glutamyl transpeptadase test reagent kit (Method of GPNA)

γ -谷氨酰基转移酶测定试剂（盒）（GPNA 底物法）

Issued on June 17, 2014 **Implemented on July 01, 2015**

Issued by China Food and Drug Administration

Contents

Foreword

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

Please note that some content of the Document may involve any patent. The issuing authority of the Document will not undertake the responsibility of identifying these patents.

The Standard is proposed by China Food and Drug Administration.

The Standard is 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.

The Standard is mainly drafted by Beijing Institute of Medical Device Testing, Shanghai Fosun Long March Medical Science Co., Ltd, InTec Products (Xiamen) Technology Co., Ltd, Beijing Chemclin Biotech Co., Ltd and Merit Choice Bio-Engineering Co., Ltd.

The main drafters of the Standard: Wang Jun, Wu Jie, Bi Chunlei, Du Jiao, Cheng Yinghao and Xu Donghuan.

γ-Glutamyl transpeptadase test reagent kit（Method of GPNA)

1 Scope

This standard specifies the technical requirements, test method, labeling, instructions for use, packaging, transport and storage ofγ-Glutamyl transpeptadase test reagent kit (Method of GPNA)

This standard applies to the γ-glutamyl transpeptadase test reagent (kit) used to carry out quantitative determination of the γ-glutamyl transpeptadase activity in serum and plasma with the method of L-γ glutamyl-3-carboxyl-paranitroaniline, including hand reagent and reagents used in semi-automatic and full-automatic biochemical analyzer.

This standard does not apply to the dry γ-glutamyl transpeptadase test reagent (kit).

2 Normative References

The following document is indispensable for the application of this document. For dated references, only dated edition applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB 3100 The international system of units and its application

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

YY /T 0316 Medical devices—Application of risk management to medical devices

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

YY/T 0638 In Vitro Diagnostic Medical Devices. Measurement of Quantities in Biological Samples. Metrological Traceability of Values Assigned to Enzymatic Concentration of Calibrators and Control Materials

3 Requirement

3.1 Appearance

Comply with the normal appearance required by the manufacturer.

3.2 Load

The load of liquid reagent shall not be less than the labeled amount.

3.3 Absorbance of reagent blank

The absorbance of reagent blank shall be within the range given by the manufacturer.

3.4 Sensitivity analysis

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.