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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 1198-2013

Aspartate aminotransferase diagnostic kit(IFCC method)

天门冬氨酸氨基转移酶测定试剂盒(IFCC法）

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

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 main drafters of the Standard: Wang Yumei, Huang Jie, Liu Yan and Gao Shangxian.

Aspartate aminotransferase diagnostic kit (IFCC method)

1 Scope

This standard specifies the determination principle, requirements, test method, identifications, signs, instructions,packaging, transport and storage of aspartate aminotransferase diagnostic kit (IFCC method).

This standard applies to the quality control of aspartate aminotransferase diagnostic kit (IFCC method), and the product is used for quantitative determination of the aspartate aminotransferase activity in human serum or plasma.

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.

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.

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

GB/T 191 Packaging-Pictorial Marking for Handling of Goods

3 Determination Principle

The method is among the methods recommended by IFCC. The reaction equation of determination principle is as follows:

L-aspartic acid +α-ketoglutaric acid⟶ oxaloacetic acid+ L-glutamic acid

Oxaloacetic acid +NADH+- malic acid+ NAD+

In the above coupled reaction, the oxidation rate of NADH is proportional to the enzymatic activity of the specimen, and NADH has characteristic absorption peak at the wavelength of 340 nm. Therefore, the activity of ALT can be calculated through measuring the decrease rate of NADH absorbance.

The amino of L-aspartic acid will be transferred to malic dehydrogenase (MDH) under the catalysis of AST, and then carry out coupled reaction, oxidizing the NADH to NAD+. NADH has characteristic absorption peak at the wavelength of 340 nm, and its oxidation rate is proportional to the activity of AST in serum. Therefore, the activity of ALT (U/L) can be calculated through measuring the decrease rate of NADH absorbance at 340 nm.

4 Requirement

4.1 Appearance

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