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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 1197-2013

Alanine Aminotransferase Diagnostic Kit (IFCC Method)

丙氨酸氨基转移酶（ALT)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 Standard is mainly drafted by National Institutes for Food and Drug Control.

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

Alanine Aminotransferase Diagnostic Kit (IFCC Method)

1 Scope

This standard specifies the determination principle, requirements, test method, signs, instructions, packaging, transport and storage, etc. of alanine aminotransferase diagnostic kit (IFCC method).
This standard applies to the quality control of alanine aminotransferase diagnostic kit (IFCC method), and the product is used for quantitative determination of the alanine 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.
GB/T 191 Packaging-Pictorial Marking for Handling of Goods

3 Determination Principle

The alanine aminotransferase diagnostic kit (IFCC method) is among the modified methods recommended by the International Federation of Clinical Chemistry (IFCC). The principle of the method is that the lanine amino will be transferred to α-ketoglutaric acid to generate pyruvic acid and glutamic acid under the catalysis of ALT, and then the pyruvic acid will react with NADH to generate lactic acid and NAD- under the catalysis of LDH. NADH has characteristic absorption peak at the wavelength of 340 nm, and its oxidation rate is proportional to the activity of ALT in serum. Therefore, the activity of ALT can be calculated through determining the decrease rate of NADH absorbance at 340 nm.

4 Requirement

4.1 Appearance

Comply with the normal appearance required by the manufacturer.

4.2 Load

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

4.3 Reagent blank

4.3.1 Absorbance of reagent blank

Should be not less than 1.0 (wavelength of 340 nm, light path of 1 cm).

4.3.2 Rate of change for the absorbance of reagent blank

Should not be greater than 0.004/min (endpoint method is not applicable).

4.4 Linear interval

The upper limit of linear interval should be at least 500U/L; in the linear range, the linear correlation coefficient (r) of theoretical concentration and measured concentration should not be less than 0.99000 within the linear interval.

4.5 Accuracy

4.5.1 Provide reference material or carry out determination by using the serum whose value is determined by reference method; the deviation between measured value and marked value should be within ±15%.

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