

ICS 11.100
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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 1206-2013

Total cholesterol kit (COD-PAP method)

总胆固醇测定试剂盒（氧化酶法）

Issued on October 21, 2013

Implemented on October 1, 2014

Issued by China Food and Drug Administration

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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: Liu Yan, Sun Nan, Wang Yumei, Zhang Chuntao and Gao Shangxian.

Total cholesterol kit (COD-PAP method)

1 Scope

This standard specifies the determination principle, requirements, test method, signs, instructions, packaging, transport and storage, etc. of total cholesterol kit (COD-PAP method).

This standard applies to the quality control of liquid-type total cholesterol kit (COD-PAP method) of single reagent and double reagent used for quantitative inspection in medical laboratory.

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.

YY/T 0466.1 Medical Devices. Symbols to Be Used with Medical Device Labels, Labeling and Information to Be Supplied. Part 1:General Requirements

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 for the kits of double reagent and single reagent shall not be greater than 0.080 and 0.100 respectively at the wavelength of 55nm~550nm.

3.4 Linear interval

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