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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 1247-2014

# Hepatitis B virus surface antigen (HBsAg) detection reagent (kit) (Chemiluminescent immunoassay)

# 乙型肝炎病毒表面抗原测定试剂（盒）（化学发光免疫分析法）

Issued on June 17, 2014 Implemented on July 1, 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 National Institutes for Food and Drug Control, Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd, Beijing Yuande Bio-Medical Engineering Co., Ltd, Roche Diagnostics (Shanghai) Limited and Abbott Trading (Shanghai) Co., Ltd.

The main drafters of the Standard: Zhou Cheng, Wang Ruixia, Du Haiou, Cheng Yinghao, Cai Xiaorong, Wang Yunfeng and Wang Xuefeng.

# Hepatitis B virus surface antigen (HBsAg) detection reagent (kit)
# (Chemiluminescent immunoassay)

## 1 Scope

This standard specifies the technical requirements, test method, identification, labels, instructions, packaging, transportation and storage etc. of the hepatitis B virus surface antigen (HBsAg) detection reagent (kit) (chemiluminescence immunoassay).This standard is appropriate for the reagent(box) that utilizing the chemiluminescence analysis technique, and adopting the double antibody sandwich method, qualitatively or quantitatively measuring the surface antigen of hepatitis B virus in human's serum and plasma (hereinafter referred as "HBsAg"). Including chemiluminiscence, electrochemiluminescence and time resolved luminescence, etc.

The Standard does not apply to:

a) Preparing to be used for the calibrator of surface antigen of hepatitis B virus which is marketed alone and the quality control product of surface antigen of hepatitis B virus;

b) Biochip in the principle of chemiluminescent immunoassay.

## 2 Normative references

The articles contained in the following documents have become this document 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.

GB/T 21415 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

## 3 Requirements

### 3.1 Quantitative determination reagent (kit)

#### 3.1.1 Appearance

The following requirements shall be fulfilled:

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