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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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Detection Kit for Human Immunodeficiency Virus 1 Type (HIV-1) P24 Antigen and Antibodies to Human Immunodeficiency Virus (Chemiluminescence Immuno-Assay)

人类免疫缺陷病毒抗原抗体联合检测试剂盒（发光类）

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Detection Kit for Human Immunodeficiency Virus 1 Type (HIV-1) P24 Antigen and Antibodies to Human Immunodeficiency Virus (Chemiluminescence Immuno-Assay)

1 Scope

This Standard specifies the requirements, test methods, mark, label and use instructions, package, transportation and storage of detection kit for antigen and antibodies to human immunodeficiency virus (chemiluminescence immuno-assay).

This Standard is applicable to the kit perform qualitative detection of human immunodeficiency virus 1 (HIV-1), p24 antigen and (HIV-1 p24) and HIV (including HIV-1 and HIV-2) antibodies in the human serum and/or plasma through the light source (including chemiluminescence analysis, immunofluorescence analysis, time-resolved immunofluorescence analysis) excited by special substance based on the sandwich method; namely, detection kit for antigen and antibodies to human immunodeficiency virus.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB/T 191-2008 Packaging – Pictorial Marking for Handling of Goods

GB/T 29791.2-2013 In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) - Part 2: In Vitro Diagnostic Reagents for Professional Use

3 Requirements

3.1 Appearance

reference product of minimum detection limit; the requirements for minimum detection quantity is no higher than 2.5IU/mL (≤2.5IU/mL); and its matrix serum is negative.

3.3.4 Precision

Test with a national precision reference product or a standardized precision reference product; the results are both positive, the coefficient of variation of *CV*≤15% (*n*=10).

3.4 Stability

Verification of shelf life stability and thermal stability:

a) Shelf life stability: the period of shelf life for the products specified by the manufacturer. Take the reagent (kit) for a certain period of time before the expiration of valid date; detect the appearance, positive reference product compliance rate, negative reference product compliance rate, minimum detection limit, and precision, and the like items; the results shall meet the requirements of 3.2 and 3.3.

b) handle the reagent (kit) under the specified heating conditions (37°C); detect the appearance, positive reference product compliance rate, negative reference product compliance rate, minimum detection limit, precision, and the like items; the results shall meet the requirements of 3.2 and 3.3.

NOTE 1: Thermal stability cannot be used to derive the valid date of the product; unless it is from a derivation formula based on a large number of stability studies.

NOTE 2: Generally, a product with a valid period of 1 year and no more than 1 month is selected; the valid period shall be half a year; and so on. However, if it exceeds the specified time, when the product meets the requirements, it is also acceptable.

4 Test Methods

4.1 Appearance

Take visual examination with normal or corrected visual acuity under natural light, the results shall meet the requirements of 3.1.

4.2 HIV antibody detection

4.2.1 Negative reference product compliance rate

Test with a national negative reference product or a standardized negative reference product; operate as per the product instructions; the results shall meet the requirements of 3.2.1.

4.4.1 Shelf life stability: take the reagent (kit) for a certain period of time before the expiration of valid date; operate as per the product instructions; the results shall meet the requirements of 3.4 a).

4.4.2 Thermal stability: place the reagent (kit) for certain time under certain temperature conditions (generally 37°C); operate as per the product instructions; the results shall meet the requirements of 3.4 b).

5 Mark, Label and Use Instructions

It shall conform to the provisions of GB/T 29791.2-2013.

6 Package, Transportation and Storage

6.1 Package

The packaging and transporting pictorial signs shall conform to the provisions of GB/T 191-2008. The packaging container shall ensure the good sealing, completeness, and no leakage, no damage.

6.2 Transportation

The kit shall be transported as required by the manufacturer. During the transportation, it shall be protected from moisture; prevent heavy loads from piling up; avoid direct sunlight, rain and snow; prevent contact with acid and alkali substances; prevent the damage to the inner and outer package.

6.3 Storage

The kit shall be stored under the conditions specified by the manufacturer.

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