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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 1727-2020

Human immunodeficiency virus antibody detection kit for oral mucosal transudate (colloidal gold immunochromatography)

口腔黏膜渗出液人类免疫缺陷病毒抗体检测试剂盒（胶体金免疫层析法）

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Foreword

This standard is a mandatory industry standard. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. Please note that certain contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This standard was proposed by the State Drug Administration. This standard is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). Drafting organizations of this standard. China Institute for Food and Drug Control, Beijing Institute of Medical Device Inspection, Guangzhou Wanfu Biotechnology Co., Ltd. Company, Beijing Manuo Biopharmaceutical Co., Ltd., Chengdu Xiehe Biotechnology Co., Ltd. The main drafters of this standard. Xu Sihong, Zhang Chuntao, Song Aijing, Sun Li, Li Meilan, Tang Xiangjun, Xiao Ling. Oral mucosa exudate human immunodeficiency virus antibody Detection kit (Colloidal gold immunochromatography)

1 Scope

YY 1727 is the mandatory Chinese standard for oral fluid HIV antibody rapid tests using colloidal gold immunochromatography. The oral fluid format is what makes HIV self-testing and community outreach testing possible: no blood, no needle, no laboratory, and a result in minutes. That reach is also the risk, because the test is performed and read by someone with no training and the consequence of a false result is either an undiagnosed infection or a devastating false positive. The document sets out how such a kit is classified, the technical requirements it has to meet, the test methods that demonstrate them, and the labelling and storage rules. Being a YY standard without the /T suffix, compliance is compulsory in China. It took effect in June 2022.

This standard specifies the requirements for the human immunodeficiency virus antibody detection kit (colloidal gold immunochromatography) for oral mucosal exudate, Test methods, labels and instructions for use, packaging, transportation and storage. This standard is applicable to the detection of human immunodeficiency virus type 1 and human immunodeficiency virus in human oral mucosal exudate based on the principle of colloidal gold immunochromatography. A human immunodeficiency virus antibody detection kit for

qualitative detection of type 2 (HIV-1/2) antibodies (hereinafter referred to as "kit").

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article Pieces. For undated references, the latest version (including all amendments) applies to this document.

GB/T 191 Packaging, storage and transportation pictorial signs

GB/T 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Requirements

3.1 Appearance The appearance should meet the following requirements.

a) Each component of the kit should be complete and complete, with no liquid leakage;

b) Chinese packaging labels should be clear and free from wear.

3.2 Physical inspection The physical inspection should meet the following requirements.

a) The width of the film strip should be >=2.5mm;

b) The liquid moving speed should be >=10mm/min.

3.3 Compliance rate of antibody negative reference products Use the national negative reference product for testing, the positive reaction should not be more than 2 copies, the negative reference product compliance rate (-/-) should be >=18/20; or use After the standardized negative reference product is tested, the result should meet the corresponding requirements.

3.4 Compliance rate of antibody positive reference products Use national positive reference materials (see Appendix A) for testing, the HIV-1 positive reference product conformance rate (/) should be 18/18, HIV- The conformity rate of type 2 positive reference product (/) should be 2/2; or use a standardized positive reference product for testing, and the result should meet the corresponding requirements.

3.5 Lowest detection limit Use the national minimum detection limit reference product for detection, the positive reaction shall not be less than 3 (>=3/5) and the diluted matrix (S1) shall be a negative reaction;