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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Calibration Specification for Temperature Parameter of Passive
Medical Cold Boxes
(English Translation)**

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8 Re-school interval (4)

Appendix A Tests for Holding Time of Vaccine Refrigerated Containers and Vaccine Carrying Cases (5)

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Introduction

This specification was drafted in accordance with JJF 1071-2010 "Rules for the preparation of national metrological calibration specifications", in which measurement uncertainty the degree of assessment was conducted in accordance with JJF 1059.1-2012 Evaluation and Expression of Measurement Uncertainty.

This specification is the first release.

Passive medical refrigerator temperature parameter calibration specification

1 Scope

This specification applies to the temperature range of the insulation in the (-20~20) °C range, there is a temperature display and thermometer outside the temperature probe the calibration of the temperature parameters of the passive medical refrigerator and the calibration of the temperature parameters of the passive medical refrigerator in other temperature zones Also refer to this specification.

2 Terms

2.1 passive medical refrigerator box passivemedicalcoldbox Applied to the medical industry, relying solely on cold storage and insulation structure refrigerated insulation device.

2.2 Coolant Coolant

It can absorb and store a large amount of cold at low temperatures, and at the higher temperatures it can release a large amount of cold, which can be longer the substance that maintains a low temperature environment in and around itself.

3 Overview

Passive medical refrigerators are heat-insulating boxes made of highly efficient heat-insulating materials, and a certain amount of cold storage agent is placed inside.

In a closed state, it is possible to effectively maintain the device at a relatively low temperature in the case for a long time. Refrigerated boxes are usually used to save Items such as medicines, reagents, samples, blood and biological products stored and transported under low temperature conditions have different uses.

Also known as vaccine refrigerated containers, vaccine carrying cases, blood transport containers, drug refrigerated containers, specimen receiving containers, biosafety all

transport freezer and so on.

The passive medical refrigerated box with its own temperature display consists of an incubator, a cooling agent and a digital thermometer.

The internal volume is usually not more than 60L and the ambient temperature is not higher than 55°C. The insulation temperature zone of the refrigerator is due to its expectation Different from the requirements and the type of coolant, the temperature range of the passive medical refrigerator is usually no more than (-20~

20) °C, wherein the most commonly used temperature range is (2 ~ 8) °C.

The domestic refrigerator manufacturers claim that the temperature of the cold storage box is usually a multiple of 12h, such as 12h, 24h, 48h, 72h or 96h, etc., the test is usually carried out with reference to the vaccine refrigerated box or vaccine provided by the World Health Organization (WHO).

The test method for the box holding time (see Appendix A). Some refrigerator manufacturers provide free storage of cooling agent with the tank for the preservation time of the refrigerator, see Appendix B for the test method. The manufacturer's stated holding time is usually not when the coolant is not loaded.

6h or more.

4 Metrological characteristics and other requirements

4.1 Measurement Characteristics Temperature indication error. no more than $\pm 1^{\circ}\text{C}$ (or meet product specification requirements).

4.2 Other technical requirements

4.2.1 Passive medical refrigerator (hereinafter referred to as refrigerator) logo should be complete, clear, and has the following information.

Manufacturer name or trademark, model/specification, serial number, etc.; vaccine refrigerated containers and vaccine carrying containers should be in obvious positions (Box Cover or Box Front) Give an open box warning sign.