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

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**Criterion on quality control of laboratories -- Molecular
biological testing of food
(English Translation)**

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1 Scope

This Standard specifies the management requirements, technical requirements, testing process control requirements, and test result quality control requirements for laboratories for molecular biological testing of food.

This Standard applies to the quality control of laboratories that primarily use molecular biology techniques (such as nucleic acid technology) to test food products. Laboratories in other fields conducting molecular biology testing may also refer to this Standard.

2 Normative references

The following documents contain the provisions which, through reference in this Standard, become the provisions of this Standard. For dated references, their subsequent amendments (excluding corrigendum) or revisions do not apply to this

Standard. However, the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest versions of these documents are applicable.

For undated reference documents, the latest versions apply to this Standard.

GB/T 15483.1, Proficiency testing by interlaboratory comparisons -- Part 1.

Development and operation of proficiency testing schemes (GB/T 15483.1-1999, idt ISO/IEC Guide 43-1.1997)

GB/T 19000, Quality management systems -- Fundamentals and terminology (GB/T 19000-2000, idt ISO 9000.2000)

GB 19489, Laboratories -- General requirements for biosafety

GB/T 27000, Conformity assessment -- Vocabulary and general principles (GB/T 27000-2006, ISO/IEC 17000.2004) IDT)

VIM International General Metrology Terminology [published by the International Bureau of Weights and Measures (BIPM), the International Electrotechnical

Commission (IEC), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Organization for Standardization (ISO), the International Union of Theoretical and Applied Chemistry (IUPAC), the International Union of Theoretical and Applied Physics (IUPAP), and the International Organization of Legal Metrology (OIML)]

3.1 Terms and definitions

The terms and definitions defined in GB/T 19000, GB/T 27000 and VIM, as well as the following terms and definitions, apply to this Standard.

NOTE: GB/T 19000 specifies general definitions related to quality. GB/T 27000 specifically specifies definitions related to certification and laboratory accreditation. If there are differences between the definitions given in GB/T 19000 and GB/T 27000 and VIM, the definitions in GB/T

27000 and VIM shall prevail.

3.1.1

molecular biological testing laboratories of food

A laboratory that uses molecular biology techniques (such as nucleic acid technology) as its main means and food as its testing object.

3.1.2

top management of laboratory

One person or group of people commanding and controlling the laboratory at the highest level.

3.1.3

management personnel of laboratory

Personnel responsible for managing laboratory activities under the leadership of the laboratory's top manager.

3.1.4

laboratory competence

The materials, environment, information resources, personnel, technology, and expertise required for the laboratory to conduct the corresponding tests.

3.1.5

sample

One or more parts are taken from a whole and are intended to provide relevant information about the whole, usually serving as the basis for judging the whole.

3.1.6

testing report

A document that provides test results and other relevant information regarding the test.

3.1.7

polymerase chain reaction; PCR

This is a molecular biology experimental method for the in vitro enzymatic synthesis of specific DNA fragments. It mainly consists of a repeated thermal cycle of three steps.

high-temperature denaturation, low-temperature annealing, and optimal-temperature extension. First, the template DNA is denatured into single strands at high temperature.

Then, under the catalysis of DNA polymerase and at a suitable temperature, two primers

4.1.1 Laboratories conducting molecular biological testing of food (hereinafter referred

to as laboratories) or their affiliated organizations shall have a clear legal status.

Laboratories are generally independent legal entities; laboratories that are not independent legal entities must be authorized by the legal entity.

4.1.2 Laboratory testing services shall meet the needs of clients and their organizations.

4.1.3 Laboratories shall comply with the relevant provisions of this Standard when conducting work in their fixed facilities or in external locations.

4.1.4 The top management of laboratory shall be responsible for the design, establishment, maintenance, and improvement of the organizational management system, including at least the following aspects.

- a) Staff the laboratory adequately. Provide all personnel with the necessary authority and resources to perform their duties;
- b) Establish policies and procedures to prevent institutions and individuals from becoming involved in any activities that could impair their judgment, technical expertise, honesty, or impartiality;
- c) Establish policies and procedures to ensure that clients' confidential information is protected;
- d) Clearly define the laboratory's organizational and management structure, as well as its relationship with other relevant institutions;
- e) Define the responsibilities, powers, and relationships among all personnel;
- f) Establish a technical management team to oversee technical operations (the head of the