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

GB/T 44467-2024

**Molecular in vitro diagnostic examinations - Specifications for
pre-examination processes for saliva - Isolated human DNA**

分子体外诊断检验 唾液检验前过程的规范 提取人类DNA

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting is required.

This document is equivalent to ISO 4307:2021 "Specification for pre-testing procedures for molecular in vitro diagnostic tests - Extraction of saliva from human DNA".

Introduction

Medicine has made great progress due to the development of molecular in vitro diagnostic technology. Analyze nucleic acids, proteins and metabolic substances in human tissues and fluids New technologies that detect and analyze biomarkers hold great promise for further advances in medicine. However, the behavior of these molecules varies greatly during specimen collection, transportation, storage, and processing.

The condition may change significantly, making the diagnosis or research results unreliable or even impossible to analyze.

The analytical tests cannot reflect the patient's true condition.

Saliva contains microorganisms and foreign matter (eg, food particles), making the composition of a patient's or donor's saliva more complex and unique.

Therefore, it is necessary to explain the pre-collection preparations to patients or donors before collection and check whether they comply with them to reduce the variability of specimens.

Medical laboratories/IVD manufacturers need to be aware of specimen variability when performing validation and confirmation designs.

The DNA in saliva may become fragmented or degraded. In addition, bacteria in saliva samples can continue to grow and Dilute human DNA. The deoxyribonucleases secreted by these bacteria can also accelerate DNA degradation. All of these may affect DNA testing.

Sensitivity and reliability.

The entire process from specimen collection to DNA testing needs to be standardized to minimize factors such as DNA degradation and fragmentation after saliva collection.

This document contains the information required to obtain high-quality saliva specimens/samples and isolate human DNA from them for testing.

Special measures to be taken.

Molecular in vitro diagnostic test before saliva test Specification of the process for extracting human DNA

1 Scope

This document specifies how sputum intended for human DNA testing should be handled, stored, processed and recorded during the pre-test phase of molecular testing.

The requirements for liquid specimens are given and corresponding recommendations are provided.

This document applies to molecular in vitro diagnostic tests, including laboratory-developed tests performed by medical laboratories and molecular pathology laboratories;

For laboratory customers, in vitro diagnostic developers and manufacturers, biobanks, institutions and commercial organizations engaged in biomedical research, and Regulatory bodies.

This document does not cover the specific measures required for collecting saliva into absorbent materials or by gargling, as well as the storage and handling of saliva.

Measures of cell-free DNA in fluid, DNA of pathogens and other bacteria, or the entire microbiome.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies.

in this document.

ISO 15189 Medical laboratories - Requirements for quality and competence Note. GB/T 22576.1-2018 Requirements for quality and competence of medical laboratories Part 1: General requirements (ISO 15189:2012, IDT) ISO 15190 Medical laboratories-Requirements for safety Note. GB 19781-2005 Safety requirements for medical laboratories (ISO 15190:2003, IDT)

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in ISO 15189 and the following apply.

Ambient temperature

The temperature of the unconditioned ambient air.

[Source. GB/T 42080.1-2022, 3.2] 3.2 Analyte the component represented by the name of the measured quantity.

[Source. GB/T 21415-2008, 3.2, modified] 3.3 Analytical test performance the ability of a test procedure to measure or detect a specific analyte (3.2).

NOTE: Other test performance characteristics such as robustness, repeatability, etc. are also included.

[Source. GB/T 42080.1-2022, 3.4, modified]