ICS 13.310
CCS A 92

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 41844-2022

Specifications for prevention and control of human DNA contamination in DNA testing products

Issued on: October 12, 2022 **Implemented on: May 1, 2023**

Issued by: State Administration for Market Regulation, China National Standardization Administration

Table of Contents

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.

This document is modified to adopt ISO 18385.2016 "Minimizing the use of forensic science applications to collect, store and analyze biological materials

Necessary Guidelines for the Risk of Human-Origin DNA Contamination on Products".

Compared with ISO 18385.2016, this document has made the following structural adjustments.

--- Chapter 1 and Chapter 5 correspond to Chapter 1 of ISO 18385.2016;

--- Chapter 3 corresponds to Chapter 2 of ISO 18385.2016;

--- Chapter 4 corresponds to Chapter 3 of ISO 18385.2016;

--- Chapter 6 corresponds to Chapter 4 of ISO 18385.2016;

--- Chapter 7 corresponds to Chapter 5 of ISO 18385.2016;

--- Chapter 8 corresponds to Chapter 6 of ISO 18385.2016;

--- Chapter 9 corresponds to Chapter 7 of ISO 18385.2016;

--- Chapter 10 corresponds to Chapter 8 of ISO 18385.2016;

--- Chapter 11 corresponds to Chapter 9 of ISO 18385.2016;

--- Chapter 12 corresponds to Chapter 10 of ISO 18385.2016;

---Appendix A corresponds to Appendix C of ISO 18385.2016;

---Appendix B corresponds to Appendix A of ISO 18385.2016;

---Appendix C corresponds to Appendix B of ISO 18385.2016.

The technical differences between this document and ISO 18385.2016 and their reasons are as follows.

--- Changed the term "forensic science DNA level" (see 3.13), which increases operability and is more in line with my country's national conditions;

---Changed the "Staff Contamination Detection Regulations" and added "Manufacturers should consult with customers about potential staff DNA contamination

Quality control query and comparison method" (see 7.7), to meet the needs of my country's use of DNA pollution prevention;

---Increase the content of "aerosol pollution" in the risk assessment [see 8.2g)], and consider the risks of all production links as comprehensively as possible

factor;

--- Change "14 or more markers" to "21 or more markers" [see B.4.3a)], which is more applicable to the Chinese population.

The following editorial changes have been made to this document.

--- In order to coordinate with the existing standards, the name of the standard was changed to "Code for the Prevention and Control of Human-derived Pollution of DNA Testing Products";

--- Added the chapter "Normative References";

--- Added Chapter 5 "General Provisions", covering the content of the mandatory clauses in Chapter 1 of ISO 18385.2016.

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

As the sensitivity of DNA testing techniques increases, unintentional contamination from manufacturers of DNA testing reagents and consumables poses a threat to forensic science.

DNA analysis caused more disruption. The purpose of this document is to establish standards for the manufacture of forensic science human DNA testing products.

Consumables used in forensic DNA testing may introduce human-derived DNA contamination during the production process. In the production process of reagents and consumables

The quality control and pollution traceability in the industry are very important.

Specifications for the prevention and control of human-originated contamination of DNA testing products

WARNING. If adequate precautions are not taken, performance of this document may result in damage to health or personal injury.

1 Scope

This document specifies the general provisions for the prevention and control of human-originated contamination of products used in DNA testing, product types, quality management systems, human-originated

DNA pollution risk management, monitoring of human-derived DNA contamination in the environment, product requirements that require post-production treatment, no need for post-production

Handled product requirements, product packaging, labeling and supporting documents.

This document applies to the production of consumables and reagents that can be used without cleaning. This document does not cover product specifications (such as product

product design).

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

allele alele

DNA fragments with primary structural differences at the same locus.

3.2

Amplification

The process of exponentially replicating segments of a DNA sequence.

NOTE. Also known as polymerase chain reaction (PCR).

3.3

Blank samples without DNA components are used to verify that there is no contamination (3.7) during the amplification (3.2) process.

3.4

Samples containing known DNA components are used to verify that the amplification (3.2) process is normal.

3.5

Analytical threshold analyticalthreshold

The minimum peak height requirement that can be reliably identified as an amplification product peak from background noise.

3.6

Batch release test batchreleasetest

The test conducted by the manufacturer (3.15) or entrusted by the manufacturer before the release of the same batch of products and the test is qualified.

[Source. ISO /T S21003-7.2008, 3.1.9]

3.7

pollution contamination

The presence of DNA of human origin that could be detected during manufacturing or packaging could affect forensic science DNA analysis.