AS ISO 18385:2017
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Australian STANDARD

Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes—Requirements

STANDARDS Australia

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The following are represented on Committee CH-041:

- Australian and New Zealand Policing Advisory Agency
- Australian Association of Forensic Physicians
- Australian Federal Police
- National Association of Testing Authorities Australia
- National Council of the Australian and New Zealand Forensic Science Society
- NSW Police Force
- Queensland Police Service
- Victorian Institute of Forensic Medicine
- WA Forensic Science Laboratory
- Western Australia Police
- Western Sydney University

This Standard was issued in draft form for comment as DR AS ISO 18385:2016.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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PREFACE

This Standard was prepared by the Standards Australia Committee CH-041, Forensic Analysis, to supersede AS 5483—2012, *Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes*, three years from the publication of this Standard. For this period, either Standard may be used. At the end of three years, it is anticipated that AS 5483—2012 will be withdrawn.

The objective of this Standard is to specify requirements for the production of products used in the collection, storage and analysis of biological material for forensic DNA purposes, but not those consumables and reagents used in post-amplification analysis.

This Standard is identical with, and has been reproduced from ISO 18385:2016, *Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes—Requirements*.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

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INTRODUCTION

This International Standard was produced with the aim to create global standards for manufacturers of forensic products used in human DNA analysis. Inadvertent contamination by manufacturers of consumables and reagents, when combined with the improved sensitivity of DNA testing methods, increasingly interferes with forensic analysis.

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WARNING — This International Standard calls for the use of procedures that may be a health hazard or cause injury if adequate precautions are not taken.

1 Scope

This International Standard specifies requirements for the production of products used in the collection, storage, and analysis of biological material for forensic DNA purposes, but not those consumables and reagents used in post-amplification analysis.

The consumables and reagents covered by this International Standard include those used for evidence collection (sampling kits), such as swabs, containers, and packaging, and also products used in the analysis of DNA samples, such as tubes and other plasticware, disposable laboratory coats, gloves, and other consumables.

This International Standard applies to the production of consumables and reagents which do not require cleaning for continued use. This International Standard does not cover technical product specifications (i.e. product design).

This International Standard excludes microbiological testing.

This International Standard specifies a requirement for manufacturers to minimize the risk of occurrence of detectable human nuclear DNA contamination in products used by the global forensic community.

An overview of the International Standard is provided in Figure 1.