



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

STANDARDS
Australia



This Australian Standard® was prepared by Committee CH-041, Forensic Analysis. It was approved on behalf of the Council of Standards Australia on 1 February 2017. This Standard was published on 24 February 2017.

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.

Keeping Standards up-to-date

Australian Standards® are living documents that reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued.

Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments that may have been published since the Standard was published.

Detailed information about Australian Standards, drafts, amendments and new projects can be found by visiting www.standards.org.au

Standards Australia welcomes suggestions for improvements, and encourages readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to Standards Australia, GPO Box 476, Sydney, NSW 2001.

Australian Standard[®]

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

Originally as AS 5483—2012.
Revised and redesignated as AS ISO 18385:2017.

COPYRIGHT

© Standards Australia Limited

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968.

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 1 76035 676 7

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 apply:

- (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 number.

CONTENTS

1	Scope	1
2	Terms and definitions	2
3	Abbreviated terms	5
4	Types of products	5
	4.1 General	5
	4.2 Products that come into direct contact with biological stains or material potentially containing human DNA	5
	4.3 Chemicals, reagents, solvents, and some disposables involved in the analysis of human DNA	6
	4.4 Protective barrier products that are used during the collection and analysis of biological material	6
5	Quality management systems	6
	5.1 General	6
	5.2 Documents and records	6
	5.3 Authorization	7
	5.4 Subcontracting of work and purchase of components	7
	5.5 Control of nonconforming product	7
	5.6 Corrective and preventive action	8
	5.7 Staff contamination detection provision	8
6	Human DNA contamination risk management	8
	6.1 General	8
	6.2 Risk assessment	8
	6.3 Risk mitigation	10
	6.4 Risk control measures	10
	6.4.1 Equipment	10
	6.4.2 Personnel	10
	6.4.3 Cleaning and maintenance	10
7	Environmental human DNA monitoring	11
8	Requirements for products subject to post-production treatment	11
9	Requirements for products not subject to post-production treatment	12
	9.1 Product testing	12
	9.2 Batch records	12
10	Product packaging, labelling, and documentation	12
	Annex A (normative) Compliance testing	13
	Annex B (informative) Guidance on the effectiveness of post-production treatments currently used in the manufacture of products	15
	Annex C (informative) Relevant markers for DNA profiling	17
	Bibliography	18

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.

Currently in preview, click buy full version

AUSTRALIAN STANDARD

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

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](#).