

Australian Standard[®]

**Minimizing the risk of contamination in
products used to collect and analyse
biological material for forensic DNA
purposes**



This Australian Standard® was prepared by Committee CH-041, Forensic Analysis. It was approved on behalf of the Council of Standards Australia on 17 May 2012. This Standard was published on 18 June 2012.

The following are represented on Committee CH-041:

- Australia New Zealand Policing Advisory Agency, National Institute of Forensic Science
- Australian and New Zealand Forensic Science Society
- Australian Association of Forensic Pathologists
- Australian Federal Police
- Chemistry Centre, WA
- Consumer Action
- Expertise, Evidence and Law Program, School of Law, University of New South Wales
- National Association of Testing Authorities, Australia
- New South Wales Police Force
- Queensland Police Service
- University of Canberra
- Victoria Police Forensic Services Department
- Victorian Institute Forensic Medicine
- Western Australia Police

Additional Interests:

- Medical Technology Association of Australia
-

This Standard was issued in draft form for comment as DR AS 5843.

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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First published as AS 5483—2012.

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

ISBN 978 1 74342 149 9

PREFACE

This Standard was prepared by the Standards Australia Committee CH-041, Forensic Analysis. This Standard is the result of a consensus among the representatives of the Committee to produce it as an Australian Standard.

The objective of this Standard is to provide provisions for the manufacture of products used in forensic analysis in order to minimize contamination with human DNA during the production process.

The Standard may be used in conjunction with other Standards that detail quality assurance methods, such as ISO 9001.

The term 'informative' has been used in this Standard to define the application of the appendix to which it applies. An 'informative' appendix is only for information and guidance.

The Committee wishes to acknowledge the support provided by the Attorney General's Department in the development of this Standard as an Australian Government initiative.

The Committee also acknowledges the assistance of the following organizations:

- (a) Environmental Science, Research Forensic Services, New Zealand.
- (b) PathWest Laboratory Medicine, WA.
- (c) American Society of Crime Lab Directors, United States of America.
- (d) Bundeskriminalamt, Germany.
- (e) Health Services Authority, Singapore.
- (f) Office of the Forensic Regulator, United Kingdom.

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STANDARDS AUSTRALIA

Australian Standard

Minimizing the risk of contamination in products used to collect and analyse biological material for forensic DNA purposes**1 SCOPE**

This Standard specifies provisions for the manufacture of products used in forensic DNA collection and analysis. Products covered by the scope of this Standard include consumables used for evidence collection (including those used in DNA kits), such as swabs, containers and packaging, and also products used in the analysis of DNA samples, such as tubes and other plastic ware, disposable laboratory coats, gloves, masks and other consumables.

This Standard does not cover technical product specifications.

WARNING: THIS STANDARD CALLS FOR THE USE OF PROCEDURES THAT MAY BE A HEALTH HAZARD OR CAUSE INJURY IF ADEQUATE PRECAUTIONS ARE NOT TAKEN.

The quality guidelines for human DNA testing specified in this Standard are applicable to all other biological testing of products used to collect and analyse biological material for forensic purposes, excluding microbiological testing.

This Standard applies to the production specifications for single-use material only and excludes items used in the DNA analysis process post-amplification.

2 REFERENCED AND RELATED DOCUMENTS**2.1 Referenced documents**

The following documents are referred to in this Standard:

ISO

9001 Quality management systems—Requirements

10993 Biological evaluation of medical devices

10993-7 Part 7: Ethylene oxide sterilization residuals

ISO/IEC

17025 General requirements for the competence of testing and calibration laboratories

2.2 Related documents

Further information may be found in the following Standards:

AS

2030 Gas cylinders (series)

AS/NZS

2161 Occupational protective gloves (series)

2243 Safety in laboratories (series)

4501 Occupational protective clothing

4501.1 Part 1: Guidelines on the selection, use, care and maintenance of protective clothing

4501.2 Part 2: General requirements

14644 Cleanrooms and associated controlled environments

14644.2 Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)

14644.3 Part 3: Test methods (ISO 14644-3:2005, MOD)