

## Australian/New Zealand Standard™

# Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine



## **AS/NZS 4308:2008**

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee CH-036, Analysis of Body Fluids and Wastes. It was approved on behalf of the Council of Standards Australia on 21 January 2008 and on behalf of the Council of Standards New Zealand on 25 January 2008.  
This Standard was published on 19 March 2008.

---

The following are represented on Committee CH-036:

Air New Zealand  
Australasian Railway Association  
Australasian Association of Clinical Biochemists  
Australian Council of Trade Unions  
Australian Institute of Medical Scientists  
Institute of Environmental Science and Research, New Zealand  
Institute of Medical and Veterinary Science  
Medical Industry Association, New Zealand  
National Association of Testing Authorities  
National Drug and Alcohol Research Centre  
National Institute of Forensic Science  
National Measurement Institute  
Path West Laboratory Medicine, WA  
Pacific Laboratory Medicine Services  
Queensland Health Scientific Services  
Royal College of Pathologists of Australasia  
Royal Prince Alfred Hospital  
South Eastern Area Laboratory Services  
Victorian Institute of Forensic Medicine  
WorkCover New South Wales

Additional Interests:

NSW Nurses Association  
Rail, Tram and Bus Union

---

### **Keeping Standards up-to-date**

Standards are living documents which 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 Standards may also be withdrawn.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 which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at [www.standards.com.au](http://www.standards.com.au) or Standards New Zealand web site at [www.standards.co.nz](http://www.standards.co.nz) and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

---

*This Standard was issued in draft form for comment as DR 07317.*

---

# Australian/New Zealand Standard™

## **Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine**

Originated in Australia as AS 4308—1995.  
Previous edition AS/NZS 4308:2001.  
Third edition 2008.

### **COPYRIGHT**

© Standards Australia/Standards New Zealand

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.

Jointly published by Standards Australia, GPO Box 476, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 8564 6

## PREFACE

This Standard was prepared by the Standards Australia/Standards New Zealand Committee CH-036, Analysis of Body Fluids and Wastes to supersede AS/NZS 4308:2001, *Procedures for the collection, detection and quantitation of drugs of abuse in urine*.

The objective of this Standard is to ensure that the detection of drugs in urine meets the expectations for testing of specimens for medico-legal, workplace or court-directed purposes. This Standard addresses appropriate procedures for the collection of urine, on-site screening, handling and dispatch of specimens to the laboratory for screening and confirmatory tests. Testing for clinical use or in sport is not covered.

This revision provides additional requirements for collection procedures, laboratory screening procedures and quantitative laboratory confirmatory procedures. It also includes an appendix specifying the requirements for optional on-site screening since this procedure has become an established screening technique in a number of industries.

Statements expressed in mandatory terms in footnotes to tables are deemed to be requirements of this Standard.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is for information and guidance only.

## CONTENTS

	<i>Page</i>
FOREWORD.....	5
SECTION 1 SCOPE AND GENERAL	
1.1 SCOPE .....	7
1.2 REFERENCED DOCUMENTS .....	7
1.3 DEFINITIONS .....	8
SECTION 2 SPECIMEN COLLECTION, STORAGE, HANDLING AND DISPATCH	
2.1 GENERAL .....	12
2.2 COLLECTING SITE.....	12
2.3 INTEGRITY AND IDENTITY OF THE COLLECTED SPECIMEN .....	13
2.4 PREPARATION FOR DISPATCH .....	14
2.5 TRANSPORTATION TO THE LABORATORY.....	14
SECTION 3 GENERAL LABORATORY REQUIREMENTS	
3.1 GENERAL .....	15
3.2 REAGENTS .....	15
3.3 APPARATUS.....	15
3.4 LABORATORY SECURITY .....	15
3.5 SPECIMEN RECEPTION .....	16
3.6 SPECIMEN INTEGRITY TESTING .....	16
3.7 RECONCILIATION OF TEST RESULTS.....	16
3.8 STORAGE OF SPECIMENS .....	16
SECTION 4 LABORATORY SCREENING PROCEDURES	
4.1 GENERAL .....	18
4.2 METHOD.....	18
4.3 LABORATORY SECURITY, SPECIMEN RECEPTION, SPECIMEN INTEGRITY TESTING AND STORAGE OF SPECIMENS.....	18
4.4 PERSONNEL .....	18
4.5 NUMBER OF DETERMINATIONS.....	19
4.6 BLANK DETERMINATION .....	19
4.7 QUALITY CONTROL.....	19
4.8 SCREENING TEST CUT-OFF LEVELS.....	19
4.9 ACCEPTANCE CRITERIA .....	19
4.10 CONFIRMATORY TESTING .....	20
4.11 REPORTING OF RESULTS.....	20
4.12 RECORD KEEPING .....	21
SECTION 5 LABORATORY CONFIRMATORY PROCEDURES	
5.1 GENERAL .....	22
5.2 PRINCIPLE.....	22
5.3 APPARATUS.....	22
5.4 LABORATORY SECURITY, SPECIMEN RECEPTION, SPECIMEN INTEGRITY TESTING AND STORAGE OF SPECIMENS.....	22
5.5 PERSONNEL .....	22
5.6 CONFIRMATION CRITERIA .....	23
5.7 INSTRUMENTATION .....	23
5.8 NUMBER OF DETERMINATIONS.....	23

	<i>Page</i>
5.9 BLANK DETERMINATION .....	24
5.10 INSTRUMENT SETUP.....	24
5.11 QUALITY CONTROL.....	24
5.12 CALCULATIONS.....	24
5.13 ACCEPTANCE CRITERIA .....	24
5.14 UNCERTAINTY OF MEASUREMENT.....	25
5.15 TEST REPORT .....	26
5.16 RECORD KEEPING .....	27
5.17 DISPUTED RESULTS.....	27
APPENDICES	
A ON-SITE SCREENING PROCEDURE.....	28
B VERIFICATION OF PERFORMANCE OF ON-SITE DEVICES AROUND THE CUT-OFF .....	31
C CHAIN-OF-CUSTODY FORM .....	32
D RECOMMENDED PRECAUTIONS FOR HANDLING BIOLOGICAL SPECIMENS .....	33
E PRINCIPLES OF OPERATION.....	35

## FOREWORD

This Standard sets out the procedures for specimen collection, packaging and transportation to a laboratory and the detection and quantitation of drugs in urine. This edition of the Standard introduces the option of on-site screening.

After collection of the specimen, the Standard allows for either screening at the collecting site or at a laboratory using the cut-off levels as specified in the Standard. If all test results for drugs are negative and specimen integrity is not a question, then a final report is issued at this stage.

As the results of screening are used for evidentiary purposes, it is necessary to ensure that on-site and laboratory screenings are substantially equivalent.

For on-site screening, this necessitates the implementation of procedures such as quality controls, proficiency testing, verification of testing devices, competency based training and accreditation.

These procedures have been a requirement for laboratory testing in this Standard since its inception and provide confidence in the quality of results obtained.

Any unconfirmed result requires laboratory confirmatory testing using mass spectrometry.

Figure 1 provides a flowchart showing the steps involved in specimen collection, screening, confirmation and reporting results.

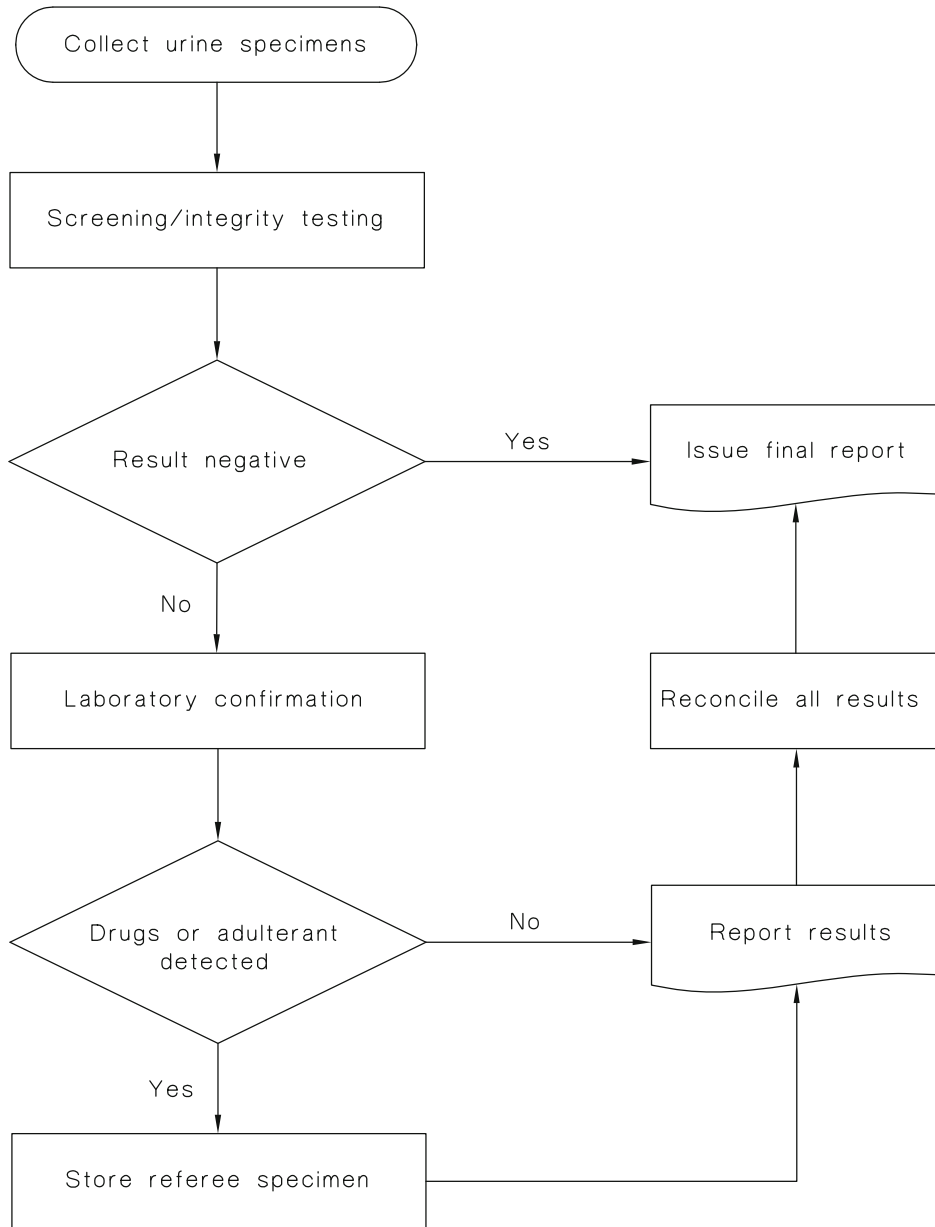


FIGURE 1 FLOWCHART



## STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

---

**Australian/New Zealand Standard**
**Procedures for specimen collection and the detection and quantitation  
of drugs of abuse in urine**


---

## SECTION 1 SCOPE AND GENERAL

**1.1 SCOPE**

This Standard sets out procedures for specimen collection, screening, confirmation, quantitation and reporting of drugs in human urine as well as integrity testing of the specimen. The procedures are intended for but not limited to medico-legal, workplace, correctional services or court directed testing of any or all of the following classes of drugs:

- (a) Amphetamine type substances.
- (b) Benzodiazepines.
- (c) Cannabis metabolites.
- (d) Cocaine metabolites.
- (e) Opiates.

## NOTES:

- 1 The detection and reporting of drugs other than those listed in Table 2 is not precluded.
- 2 This Standard has no relevance to the issue of impairment.

**1.2 REFERENCED DOCUMENTS**

The following documents are referred to in this Standard.

## AS

- 2162 Verification and use of volumetric apparatus
- 2162.1 Part 1: General—Volumetric glassware
- 2162.2 Part 2: Guide to the use of piston-operated volumetric apparatus (POVA)
- 2164 Laboratory glassware—One-mark volumetric flasks
- 2166 Laboratory glassware—One-mark pipettes
- 2167 Graduated straight pipettes
- 4633 Medical laboratories—Particular requirements for quality and competence

## AS ISO/IEC

- 17025 General requirements for the competence of testing and calibration laboratories

## AS/NZS

- 2243 Safety in laboratories
- 2243.1 Part 1: Planning and operational aspects
- 2243.2 Part 2: Chemical aspects
- 2243.3 Part 3: Microbiological aspects and containment facilities



The remainder of this document  
is available for purchase online at

➤ [www.saiglobal.com/shop](http://www.saiglobal.com/shop) ◀

SAI Global also carries a wide range of publications from a wide variety of Standards Publishers:



Click on the logos to search the database online.