AS/NZS 4308:2008

Australian/New Zealand Standard™

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

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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.
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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.
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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.

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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.

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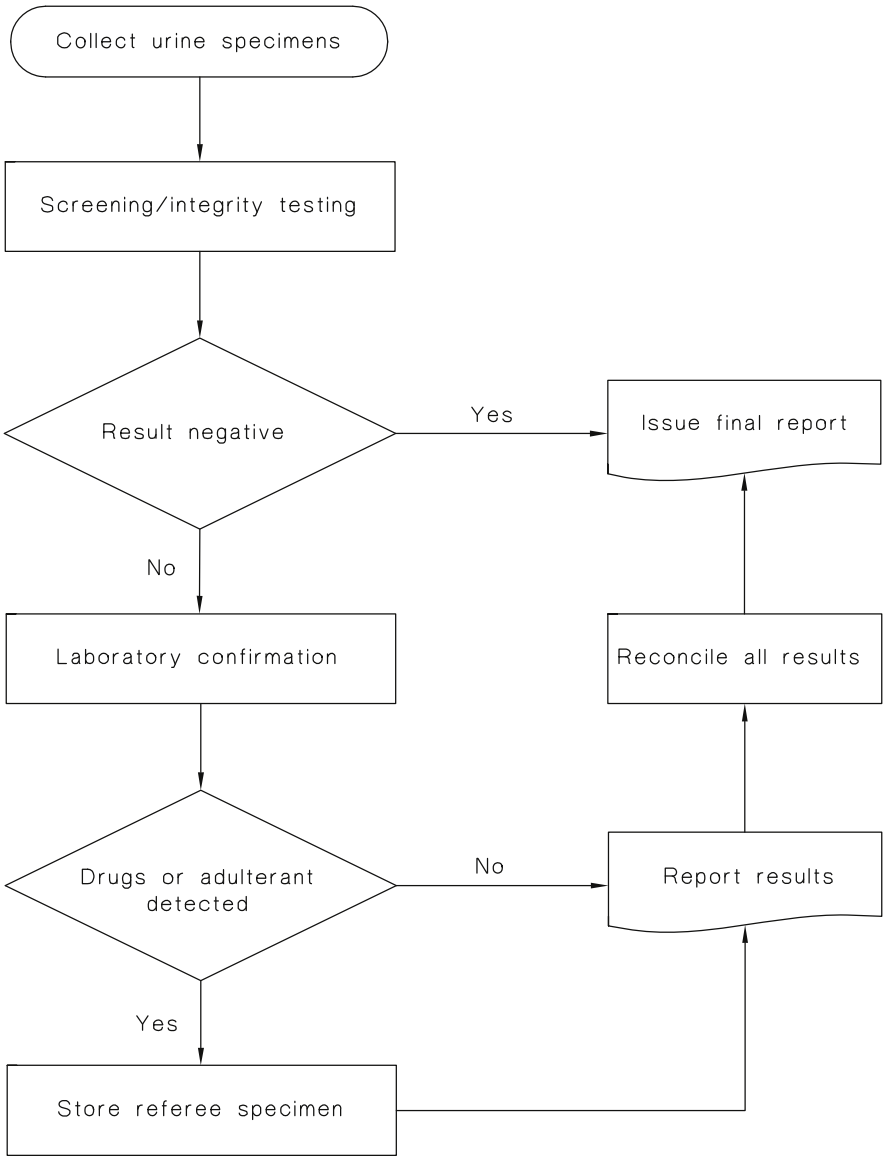

FIGURE 1 FLOWCHART

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Australian/New Zealand Standard

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

S E C T I O N 1 S C O P E A N D G E N E R A L

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

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ISO
3696 Water for analytical laboratory use—Specification and test methods

NPAAC (National Pathology Accreditation Advisory Council)
Retention of laboratory records and diagnostic material

1.3 DEFINITIONS

For the purpose of this Standard, the definitions below apply.

1.3.1 Accreditation

Assessment by a recognized body of the technical competence of a laboratory conducting specific analysis as laid down in the Standard, or a collecting agency where both collection procedures and on-site screenings are performed.

1.3.2 Adulterant

A substance used to compromise, or attempt to compromise, the integrity of a urine specimen.

1.3.3 Amphetamine type substances (Sympathomimetic amines)

Amphetamine, benzylpiperazine, ephedrine, methylamphetamine, methylenedioxyamphetamine (MDA), methylenedioxymethylamphetamine (MDMA), phentermine and pseudoephedrine.

1.3.4 Benzodiazepines

Alprazolam, clonazepam, diazepam, flunitrazepam, nitrazepam, oxazepam, temazepam and/or their metabolites.

1.3.5 Blind testing

Testing where the true result is unknown to the operator at the time of the analysis.

1.3.6 Calibration standard

A drug-free urine to which has been added a reference compound at a known concentration for the purpose of defining the calibration and linearity of the analytical method.

1.3.7 Cannabinoids

Any number of urinary metabolites of tetrahydrocannabinol.

1.3.8 Cannabis metabolite

11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid.

1.3.9 Chain-of-custody

A series of procedures to account for the integrity of each specimen by tracking its handling and storage from point of specimen collection to final disposal of the urine.

1.3.10 Chain-of-custody form

A form to be used from time of collection of the specimen to its receipt by the laboratory as well as dispatch between laboratories. Thereafter, appropriate documentation accounts for the urine or aliquots within the laboratory.

1.3.11 Cocaine metabolites

Benzoyl ecgonine and ecgonine methyl ester.

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1.3.12 Collecting agency

An organization assuming professional, organizational, educational and administrative responsibility for collection, on-site screening (if applicable), storage and dispatch of the urine specimen.

NOTES:

1 Responsibility for on-site screening is dependent on accreditation.

2 The requesting authority also may operate as a collecting agency.

3 Medical advisors such as a Medical Review Officer (MRO) may be used to provide advice.

1.3.13 Collecting site

A place where a donor provides a specimen of his/her urine.

NOTE: On-site screening may be conducted at the collecting site.

1.3.14 Collector

A person who has successfully completed a course of instruction for specimen collection and on-site screening (if applicable), handling, storage and dispatch of specimens and who has received a statement of attainment in accordance with The Australian Quality Training Framework or New Zealand Qualification Authority.

1.3.15 Concentration

Mass of a substance in a defined volume. Concentration may be expressed in micrograms per litre (μg/L). Where concentration is very low, the mass may be expressed as nanograms, or similar units as appropriate.

One microgram per litre (μg/L) is equivalent to one nanogram per millilitre (ng/mL).

1.3.16 Confirmatory test

An analytical procedure that uses mass spectrometry to unequivocally identify the presence of a specific drug and/or metabolite.

NOTE: This should be carried out on a fresh aliquot taken from the original specimen.

1.3.17 Control specimen

A specimen containing drugs or drug metabolites at a recognized concentration and prepared wherever possible from a different source to the calibration standard for the purpose of evaluating the acceptability of a test result.

1.3.18 Cut-off concentration

A value at or above which the drug/metabolite is deemed to be ‘detected’ and below which the drug/metabolite is deemed to be ‘not detected’.

NOTE: In some contexts the words positive and negative are used respectively for detected and not detected.

1.3.19 Donor

A person who provides a urine specimen to be assessed for the presence of drugs and/or metabolites.

1.3.20 Drug free

A urine specimen demonstrated to be free of all drugs and/or metabolites as related to this Standard.

1.3.21 Integrity testing

Tests for substances that affect the detection or quantitation of drugs or metabolites in the specimen.

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1.3.22 Laboratory

A testing facility accredited against AS/NZS 4308 at which the analytical procedures are carried out to screen for and/or confirm the presence of a specific drug or metabolite.

NOTE: The above definition excludes a collecting agency that performs on-site screening only.

1.3.23 On-site drug screening device

An immunoassay device used to exclude the presence of drugs and/or metabolites in urine at the site of specimen collection and which has been verified in accordance with Appendix B.

1.3.24 On-site screening

A screening test carried out at the point of collection.

1.3.25 Opiates

6-acetylmorphine, codeine, morphine.

1.3.26 Permanent record system

A system in which identifying data on each specimen collected at the collecting site are permanently recorded in the sequence of collection.

1.3.27 Proficiency testing program

A series of tests to ensure that a laboratory or organizations conducting on-site screening can operate at a level of proficiency in accordance with this Standard.

1.3.28 Referee specimen

An aliquot of the original specimen that has been decanted into a separate container which is to be sealed at the point of collection and subsequently transported and securely stored at the laboratory for analysis in the event of any disputed result(s).

1.3.29 Reference compound

Primary material of certified purity or secondary material traceable to a primary standard.

1.3.30 Requesting authority.

An individual, agency or organization that requests and ensures that collection and testing of a donor's urine for the presence of drugs and the reporting of results are in compliance with this Standard.

NOTE: In some organizations medical advisors such as a Medical Review Officer (MRO) may be used to review test results.

1.3.31 Sample

A portion or aliquot taken from the specimen, on which the test or assay is actually carried out.

1.3.32 Screening tests

Methods used to exclude the presence of a drug or class of drugs and to identify whether specimen integrity is compromised.

1.3.33 Specimen

Urine collected from the donor.

1.3.34 Thermometer

A device used to determine the temperature of the collected specimen without contaminating it.

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1.3.35 Uncertainty of measurement

A parameter associated with the result of a measurement that characterizes the dispersion of the values of analyte concentration that could reasonably be attributed to the analytical procedure.

1.3.36 Verification of on-site devices

A process independent of the manufacturer to ensure that the device is fit-for-purpose in accordance with this Standard. (See Appendix B.)

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SECTION 2 SPECIMEN COLLECTION, STORAGE, HANDLING AND DISPATCH

2.1 GENERAL

This Section sets out procedures for collection, storage, handling and dispatch of a urine specimen for testing by the laboratory. The procedure requires the provision of a referee specimen in case the resolution of disputed results is required.

WARNING: THE COLLECTION AND HANDLING OF HUMAN SPECIMENS MAY CONSTITUTE AN INFECTION HAZARD. HANDLE IN ACCORDANCE WITH APPENDIX D AND AS/NZS 2243, PARTS 1, 2 AND 3.

2.2 COLLECTING SITE

2.2.1 General

A collecting site shall have all the necessary personnel, procedures manuals, materials, equipment, facilities and supervision for the collection, security, on-site screening if applicable, temporary storage and transportation of specimens to a laboratory.

2.2.2 Privacy

Procedures for collecting urine specimens shall allow for individual privacy. Observed collections may be conducted in situations where there is an unacceptable risk to the integrity of the specimen.

2.2.3 Security

Procedures shall be in place to provide for the designated collecting site to be secure. If a collecting site cannot be dedicated to the collection of urine, then that portion of the facility used shall be secured during collection.

2.2.4 Chain-of-custody

Chain-of-custody forms shall be properly completed by a collector and donor. Handling and transportation of urine specimens from one individual or place to another shall always be accomplished through chain-of-custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

The chain-of-custody form shall have as a minimum the following information:

(a) Verification of donor's identity.

(b) Two identifiers unique to the donor.

(c) Date and time of collection.

(d) Confirmation by the donor that the specimen was their own and was correctly taken.

(e) Name and signature of collector.

(f) Declaration by the collector that the specimen has been collected and if applicable tested on-site in compliance with this Standard.

(g) Requesting authority details.

(h) Results of specimen integrity checks carried out at the point of collection.

NOTE: An example of a chain-of-custody form is provided in Appendix C.

2.2.5 Access

Personnel not authorized by the collecting agency shall not be permitted in any part of the collecting site where the urine specimen is being collected and stored.

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2.3 INTEGRITY AND IDENTITY OF THE COLLECTED SPECIMEN

2.3.1 General

Precautions shall be taken to ensure that a specimen is not adulterated, substituted or diluted during the collection procedure and that information on the urine container, chain-of-custody form and in the permanent record system can identify the individual from whom the specimen was collected.

2.3.2 Precautions

The following precautions should be taken to ensure the integrity of the specimen.

To deter the dilution of specimens at the collecting site, toilet colouring agents should be used, so the water in the toilet bowl remains coloured. There should be no other accessible source of water in the enclosure where the urine is voided. Where these procedures are not possible other measures should be taken to protect the integrity of the sample.

2.3.3 Collection procedure

The procedure shall be as follows:

(a) When a donor arrives at the collecting site, the collector shall request identification. If the individual's identity cannot be established unequivocally, then the collector shall not proceed with the collection.

(b) After washing hands, the donor remains in the presence of the collector and does not have access to any water fountain, tap, soap dispenser, cleaning agent or any other materials that might be used to compromise the integrity of the urine specimen.

(c) The donor provides the specimen in an area such that individual privacy is maintained.

(d) The donor does not flush the toilet until the urine specimen has been handed to the collector.

(e) In the presence of the donor, the collector shall ensure that the specimen is secure at all times prior to being sealed and labelled.

(f) The integrity of the specimen shall be checked by the following:

NOTE: No device should be placed into the original collected urine unless it can be shown that the device does not contaminate the specimen.

(i) Visual inspection of the colour or lack thereof.

NOTE: A colourless urine may indicate excessive hydration.

(ii) Measuring the temperature within 4 minutes of voiding. The acceptance criterion shall be a temperature between 33°C and 38°C.

NOTES:

1 Insufficient urine may invalidate temperature reading with some types of thermometers.

2 Extremes of temperature may affect the above temperature range. In these circumstances, the collector may use discretion to accept the specimen.

(iii) An on-site creatinine test.

NOTE: Additional integrity testing may be performed, e.g. pH and adulterants.

(g) Any unusual or abnormal finding shall be noted in the permanent record system and on the chain-of-custody form.

(h) If the integrity of the specimen cannot be established, then another urine specimen shall be collected and both forwarded to the laboratory for drug and specimen integrity testing. Both the original and further specimens shall be uniquely labelled and accompanied by their individual chain-of-custody forms which are cross referenced in the permanent record system.

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(i) If on-site screening is to be conducted, then it shall take place at this point using the procedure specified in Appendix A.

2.4 PREPARATION FOR DISPATCH

The procedure shall be as follows:

(a) The specimen is split between at least 2 containers, one of which shall be the referee specimen.

The collector shall ensure that each container is labelled in such a manner that it can be traceable to the donor and the chain-of custody form.

(b) The tamper-evident seals shall be initialled by the donor and placed on the container.

(c) The chain-of-custody form shall be completed by the collector and signed by the donor.

(d) The collector shall enter into the permanent record system all information identifying the specimen.

(e) The urine containers and the chain-of-custody form are now ready for transportation. If the specimens are not dispatched immediately, they shall be refrigerated during temporary storage.

Transportation shall occur as soon as possible.

2.5 TRANSPORTATION TO THE LABORATORY

The procedure for transportation of specimens to the laboratory shall incorporate the following:

(a) The collector shall place the test and referee specimens in a container designed to minimize the possibility of damage and contamination during transport.

(b) The container shall be securely sealed to ensure any tampering would be detected.

(c) The collector shall ensure that the chain-of-custody form with testing instructions is inside the sealed container in which the specimens are transported to the laboratory.

(d) Transportation shall occur in accordance with appropriate legislation.

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SECTION 3 GENERAL LABORATORY REQUIREMENTS

3.1 GENERAL

This Section sets out procedures for laboratory testing of human urine for drugs and specimen integrity.

Drug screening procedures should be conducted using immunoassay and confirmatory testing shall be conducted using mass spectrometry.

The laboratory undertaking analyses of this nature shall—

(a) be accredited to the relevant Section of this Standard, i.e. screening procedures Section 4, confirmatory procedures Section 5; and

(b) participate in a recognized external proficiency testing program.

NOTE: Principles of operation involving immunoassay and mass spectrometry are outlined in Appendix E.

If a drug class cannot be excluded after the screening procedure, the specimen shall undergo laboratory confirmatory testing.

WARNING: THE COLLECTION AND HANDLING OF HUMAN SPECIMEN MAY CONSTITUTE AN INFECTION HAZARD. HANDLE IN ACCORDANCE WITH APPENDIX D AND AS/NZS 2243, PARTS 1, 2 AND 3.

3.2 REAGENTS

All reagents shall be of analytical reagent grade and Grade 1 water as defined in ISO 3696 shall be used throughout.

3.3 APPARATUS

3.3.1 Volumetric glassware

Laboratory calibrated volumetric glassware shall be used throughout. Volumetric flasks shall comply with AS 2164 and pipettes shall comply with AS 2166 and AS 2167. The use of volumetric apparatus shall conform with AS 2162, Parts 1 and 2.

3.3.2 Piston operated volumetric apparatus

Shall be used in accordance with AS 2162.2.

3.4 LABORATORY SECURITY

The following shall be observed:

(a) The laboratory shall be secure at all times and shall have in place sufficient security measures to control access to the premises and to ensure that only authorized personnel handle specimens or gain access to the laboratory processes or areas where records are kept.

(b) Access to the secured areas shall be limited to specifically authorized individuals whose authorization is documented.

(c) All authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, time of entry, the purpose of entry and the time of departure shall be maintained.

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(d) Receipt of specimens shall be documented on the chain-of-custody form or in the laboratory's information system such that the specimen identity, integrity and security is assured.

(e) Laboratories shall maintain control and chain of custody of specimens from the time of receipt through to the completion of testing, reporting of results, storage and disposal.

(f) The handling and transfer of a specimen, including aliquots, shall be dated and documented appropriately and every individual in the chain shall be identified.

3.5 SPECIMEN RECEPTION

The laboratory shall develop and document criteria for acceptance or rejection of specimens.

When specimens are received, laboratory personnel shall—

(a) inspect each package and each specimen for evidence of tampering;

(b) compare information on containers within each package with the information on the accompanying chain-of-custody form; and

(c) store specimens not being used for analysis, including the referee specimen.

NOTE: Any discrepancies should be noted (see Clauses 4.11.2(i) and 5.15).

3.6 SPECIMEN INTEGRITY TESTING

3.6.1 General

A urinary creatinine concentration shall be measured. Drug testing shall be conducted regardless of the creatinine concentration. Where there is a discrepancy between on-site and laboratory creatinine results, then the laboratory result shall take precedence.

3.6.2 Creatinine concentration greater than 50 mg/L but less than 200 mg/L

A creatinine concentration greater than 50 mg/L (5 mg/dL, 0.44 mmol/L) but less than 200 mg/L (20 mg/dL, 1.76 mmol/L), may indicate dilution in some individuals. This does not necessarily represent a deliberate attempt at dilution.

A repeat specimen should be requested. The laboratory report should indicate the dilute nature of the specimen without implying a deliberate attempt to affect its integrity.

NOTE: Caution should be exercised in interpreting low creatinine values as certain populations may have physiologically low levels.

3.6.3 Creatinine less than 50 mg/L

If the creatinine is less than 50 mg/L, further testing for dilution shall be undertaken using specific gravity or an alternative measure. The laboratory report should indicate that the specimen characteristics are not consistent with human urine. The laboratory performing this test shall be appropriately accredited.

3.6.4 Other substances

Tests for other substances including acids, alkalis, oxidants and other chemicals capable of affecting the integrity of the specimen should be performed. Any abnormality shall be confirmed by a validated method prior to being reported.

3.7 RECONCILIATION OF TEST RESULTS

The requesting authority shall determine the process for reconciling the screening and confirmatory test results, including integrity testing.

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3.8 STORAGE OF SPECIMEN

3.8.1 Short-term storage

Specimens shall be refrigerated on receipt by the laboratory, unless subject to immediate processing. Specimens shall be kept refrigerated at all times unless being analysed or transferred to long-term storage. The negative specimens should be discarded after testing. The following storage conditions apply:

(a) Refrigeration shall be secure.

(b) Refrigeration unit temperature shall be monitored and should operate in a range of 2–8°C.

3.8.2 Long-term storage

All specimens in which drugs have been detected or for which integrity cannot be established and their respective referee specimens shall be stored in a locked freezer at the confirmatory laboratory for at least 3 months from the date of reporting of the results, unless written authority for disposal is received.

It is recommended that emergency power be available in case of prolonged power failure. However, transfer to another secure location is acceptable. Such transfer shall be fully documented.

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SECTION 4 LABORATORY SCREENING PROCEDURES

4.1 GENERAL

This Section sets out laboratory procedures for the screening of drugs in human urine, as follows:

(a) Amphetamine type substances.

(b) Benzodiazepines.

(c) Cannabis metabolites.

(d) Cocaine metabolites.

(e) Opiates.

4.2 METHOD

The approved method should be immunoassay although other more specific or sensitive techniques may be used where appropriate. The manufacturer's instructions shall be followed for reagent constitution and storage. The laboratory shall validate and document the accuracy, precision, specificity and sensitivity of the analytical method where such a method differs from the manufacturer's validated method. Such documentation shall show that the cut-off levels are consistently achievable using the selected method.

When immunoassay is not suitable for detecting some of the drugs covered by this Standard, an alternative technique to immunoassay shall be used. Cut-off values of these compounds are listed in Table 2.

The laboratory shall disclose to the requesting authority any limitations regarding the detection of any drugs/metabolites within a class being tested and as listed in Table 1.

4.3 LABORATORY SECURITY, SPECIMEN RECEPTION, SPECIMEN INTEGRITY TESTING AND STORAGE OF SPECIMENS

For laboratory security, specimen reception, specimen integrity testing and storage of specimens, refer to Clauses 3.4, 3.5, 3.6 and 3.8 respectively.

4.4 PERSONNEL

4.4.1 Laboratory supervisor

The laboratory supervisor is responsible for day-to-day operations and supervision of the technical analyst(s). The laboratory supervisor shall have at least a Bachelor's Degree in the chemical or biological sciences or medical technology or equivalent and shall have sufficient training and experience in the theory and practice of screening for drugs of abuse in urine. The person shall have adequate expertise in the following areas:

(a) Quality control practices and procedures, detecting aberrant test or quality control results.

(b) Remedial actions to be taken in response to test systems being out of control limits.

(c) Review, interpretation and reporting of test results.

(d) Maintenance of the chain of custody.

(e) Training of technical analysts.

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4.4.2 Screening analyst

The laboratory shall have a qualified individual with adequate training to assume responsibility for screening for drugs of abuse using an immunoassay method or other technique where appropriate.

4.4.3 Access to expertise

The laboratory shall have access to an expert who has appropriate training and experience in applications of analytical toxicology, e.g. publications, court testimony, research concerning analytical toxicology of drugs or other factors that qualify the individual as an expert in toxicology.

4.4.4 Acceptance of results

On a day-to-day basis a minimum of two qualified personnel (see Clauses 4.4.1 and 4.4.2) shall be present in the screening laboratory, and shall ensure the results meet the acceptance criteria.

4.4.5 Accreditation

The laboratory shall have an individual responsible for ensuring the facility is fully accredited to this Section 4 and that it participates in a recognized external proficiency testing program.

4.5 NUMBER OF DETERMINATIONS

The screening procedure has been written for a single determination.

4.6 BLANK DETERMINATION

A blank test shall be carried out in parallel with the analysis using the same procedure as for the analysis and in the same quantities for all the reagents but using a known drug-free urine. The blank shall be run with a frequency of at least once per batch and positioned immediately after a positive calibrator or positive quality control to test for carry-over.

4.7 QUALITY CONTROL

Every batch of samples for testing shall contain a minimum of 10% or two quality controls, whichever is the greater in number. Further, the concentration of analytes shall be as follows:

(a) The high control shall be within 25% above the cut-off concentration.

(b) The low control shall be within 25% below the cut-off concentration.

The compound used for quality control shall be the same as that used for calibration.

4.8 SCREENING TEST CUT-OFF LEVELS

The procedure for the screening test should be an immunoassay technique that meets the screening test cut-off concentrations listed in Table 1. Laboratories shall demonstrate that they can reliably detect the drugs at the cut-off concentrations listed in Table 1. Where a non-immunoassay technique is used for screening, then the cut-off concentrations shall be as listed in Table 2.

4.9 ACCEPTANCE CRITERIA

The laboratory shall have defined and documented acceptance criteria for all quality control results. If these criteria are not met, then the batch of affected samples shall be reanalysed. As a minimum, the following criteria shall be used:

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(a) The value of the high control(s) shall be greater than the cut-off in Table 1 or Table 2 as appropriate.

(b) The value of low control(s) shall be less than the cut-off in Table 1 or Table 2 as appropriate.

(c) The value of the blank shall be less than that of the low control and shall differ from the value of that control by more than three standard deviations of the mean of the control value.

(d) The value obtained for both controls shall be at or within ± 20% of the expected value.

4.10 CONFIRMATORY TESTING

If a result is less than the screening cut-off, then the drug class shall be reported in accordance with Clause 4.11.1.

Specimens with results equal to, or greater than the cut-off in Table 1, shall be subjected to confirmatory testing. The stored specimens, including the referee specimen, shall be forwarded for confirmatory testing.

TABLE 1

IMMUNOASSAY SCREENING TEST
CUT-OFF LEVELS

Class of drug*	Cut-off level, g/L
Amphetamine type substances	300
Benzodiazepines	200
Cannabis metabolites	50
Cocaine metabolites	300
Opiates	300

* For drugs that may be optionally tested within each class, the specified cut-off levels may not apply and other methodologies may be more appropriate.

4.11 REPORTING OF RESULTS

4.11.1 Conditions for reporting

The conditions for reporting are as follows:

(a) If all requested drug classes are not detected (negative) and the integrity of the specimen is not in question then a final report shall be issued.

(b) If any requested drug class returns a result that is not negative or the integrity of the specimen is in question then an interim report may be issued that can only advise that the specimen requires further testing.

(c) When confirmatory test results are available they shall be reconciled with the screening results and reported in accordance with Clause 5.15.

4.11.2 Test report

The test report shall contain, as a minimum, the following information:

(a) Donor identification.

(b) Date of specimen collection.

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(c) Date of receipt of specimen in the laboratory.

(d) Laboratory identification number.

(e) Date of reporting of analysis.

(f) Results as described in Clause 4.11.1.

(g) Identification of the person with the authority to issue the report.

(h) Any observation or results of integrity testing which may have affected the drug test.

(i) Any discrepancies noted.

(j) For screen only results reference to Section 4 of this Standard, i.e. Section 4 of AS/NZS 4308.

NOTE: If a major discrepancy exists the final report cannot state compliance with or reference to this Standard. Laboratories making a statement of compliance with this Australian/New Zealand Standard are advised to ensure that such compliance is capable of being verified.

4.12 RECORD KEEPING

Records shall be kept in a secure location for a period consistent with the requesting authority's policy or as per National Pathology Accreditation Advisory Council (NPAAC) Guidelines or equivalent.

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SECTION 5 LABORATORY CONFIRMATORY PROCEDURES

5.1 GENERAL

This Section sets out the confirmatory procedures for the unequivocal identification and quantitation of drugs and/or their metabolites in human urine in those classes of drugs listed as follows:

(a) Amphetamine type substances.

(b) Benzodiazepines.

(c) Cannabis metabolites.

(d) Cocaine metabolites.

(e) Opiates.

5.2 PRINCIPLE

Confirms by mass spectrometry the presence of drugs and/or their metabolites in those classes of drugs listed in Clause 5.1.

5.3 APPARATUS

5.3.1 Gas chromatograph/mass spectrometer

5.3.2 Liquid chromatograph/mass spectrometer

5.3.3 Tandem mass spectrometry

NOTE: Appendix E provides information on methodologies for apparatus listed in Clauses 5.3.1, 5.3.2 and 5.3.3.

5.4 LABORATORY SECURITY, SPECIMEN RECEPTION, SPECIMEN INTEGRITY TESTING AND STORAGE OF SPECIMENS

For laboratory security, specimen reception, specimen integrity testing and storage of specimens, refer to Clauses 3.4, 3.5, 3.6 and 3.8 respectively.

5.5 PERSONNEL

5.5.1 Laboratory management

The laboratory shall have a qualified individual to assume professional, organizational, educational and administrative responsibility for the laboratory's urine drug testing facility.

The individual shall have appropriate formal qualifications, and experience with the analysis of biological material for drugs of abuse. The individual shall also have appropriate training and experience in applications of analytical toxicology, e.g. publications, court testimony, research concerning analytical toxicology of drugs of abuse or other factors that qualify the individual as an expert in toxicology. A laboratory may designate more than one qualified employee to be responsible for management or operation of the laboratory.

5.5.2 Laboratory supervisor

The laboratory supervisor is responsible for day-to-day operations and to supervise the technical analyst(s). The laboratory supervisor shall have at least a Bachelor's Degree in the chemical or biological sciences or medical technology or equivalent and shall have sufficient training and experience in the theory and practice of confirmatory testing for drugs of abuse in urine. The person shall have adequate expertise in the following areas:

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(a) Quality control practices and procedures, detecting aberrant test or quality control results.

(b) Remedial actions to be taken in response to test systems being out of control limits.

(c) Review, interpretation and reporting of test results.

(d) Maintenance of the chain of custody.

(e) Training of technical analysts.

5.5.3 Analyst

The laboratory shall have a qualified individual to assume responsibility for routine analysis. This person shall have appropriate tertiary qualifications and adequate training.

5.5.4 Review results

The laboratory shall have a qualified individual who reviews all pertinent data and quality control results to attest to the validity of the laboratory test reports. This individual shall not be the same person as the analyst conducting the testing.

5.5.5 Accreditation

The laboratory shall have an individual responsible for ensuring the facility is fully accredited to this Section 5 and furthermore it participates in a recognized external proficiency testing program.

5.6 CONFIRMATION CRITERIA

The following criteria are applicable for confirmatory testing:

(a) All confirmatory tests shall be done on a fresh aliquot taken from the specimen.

(b) All quantitation shall be done using internal standards added to the sample before any analytical procedures are commenced. Isotopically labelled internal standards should be used if available.

(c) As an adjunct to confirmatory testing, the laboratory may undertake additional screening tests.

(d) All concentration measurements shall be for total drug calculated as the sum of free and deconjugated compound.

(e) Where a drug has more than one metabolite and one of which is equal to or greater than the cut-off in Table 2, then only that metabolite need be reported.

(f) Confirmatory testing of any specimen integrity parameter shall be performed using a validated method. The laboratory shall establish acceptance criteria in relation to confirmation of the presence of substances, which may affect the integrity of the specimen.

5.7 INSTRUMENTATION

GC/MS, GC/MS/MS, and LC/MS/MS are the only acceptable confirmation methods for cocaine metabolites, cannabis metabolites, opiates, amphetamine type substances, and benzodiazepines. Confirmation may be made by identification and quantitation of the target drug and/or metabolite but derivatization of the drug and/or metabolite is acceptable.

5.8 NUMBER OF DETERMINATIONS

If the laboratory also has conducted screening tests, the laboratory shall process each specimen for confirmatory testing in batches which are derived from a second aliquot taken from the original specimen.

Replicate determinations are recommended but single determinations are permitted.

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5.9 BLANK DETERMINATION

A blank test shall be carried out in parallel with the analysis using the same procedure as for the analysis and in the same quantities for all the reagents but using a known drug-free urine.

5.10 INSTRUMENT SETUP

This shall be as follows:

(a) The instrument shall be tuned in accordance with the manufacturer's guidelines or according to documented laboratory procedures.

(b) Quantitation shall be performed using internal standardization.

(c) A minimum of three calibration points not including the blank shall be used and the resulting range shall incorporate both the cut-off concentration and the expected values of the high and low controls.

(d) Calibration shall be performed with each batch.

5.11 QUALITY CONTROL

Every batch of samples for confirmatory testing shall contain a minimum of 10% or two quality controls containing the drug and/or metabolite being confirmed, whichever is the greater in number. Further, the concentration of analytes shall be as follows:

(a) The high control shall be within 25% above the cut-off from Table 2.

(b) The low control shall be within 25% below the cut-off from Table 2.

5.12 CALCULATIONS

A calibration curve shall be prepared using the peak area (or height) ratio of the reference standard to internal standard in the calibration standard plotted against their respective drug and/or metabolite concentrations. The concentration of the drugs and/or metabolites present shall be determined in μg/L by comparing the peak area (or height) ratio of the sample with the calibration curve.

5.13 ACCEPTANCE CRITERIA

Results shall be reported as 'detected' (positive) if the following criteria are met:

(a) The concentration detected at or above the specified cut-off concentration in Table 2 by an amount equal to or greater than the laboratory's determined uncertainty of measurement using a coverage factor of 2 as calculated using a single tail test.

(b) The concentration of drugs or their metabolites that exceed the highest calibration point of the standard curve shall be documented in the laboratory records as 'greater' than the highest standard curve value.

(c) Peaks shall not be reported unless their signal to noise ratio is at least 3:1.

(d) The retention time of a compound shall be at or within ± 2% of that of the calibration standard.

(e) If using GC/MS in the Selected Ion Monitoring (SIM) mode or its equivalent, a minimum of three specific and significant ions shall be used. No ion with m/z less than 50 shall be used. The common low mass ions, m/z 58, 86, 91, 105 shall not be considered as specific. The relative ratio of the ion intensities in the unknown shall be at or within ± 20% of the corresponding ratios in the extracted calibration standard at the closest calibration point.

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(f) If compounds are examined using full scan mode, then the scan range shall be from m/z 50 to a value above the molecular weight of the compound or its derivative. All significant ions present in the calibration standard also shall be present in the sample, and the relative ratio of the ion intensities shall be at or within ± 30% of the corresponding ratios in the extracted calibration standard. The presence of significant ions in the spectrum of the unknown which are not in the spectrum of the calibration standard is acceptable provided that their presence can be explained and discounted.

(g) If using Tandem Mass Spectrometric detection (MS^n), e.g. LC/MS/MS and GC/MS/MS, data can be acquired in either full scan or selected reaction monitoring (SRM) mode. The combination of mass selection of the precursor ion followed by a potentially unique collision-induced dissociation and mass selection of the product ion gives MS^n increased specificity. A minimum of two product ions shall be monitored. The relative intensities of any of the monitored ions shall not differ by more than ± 30% from the relative intensities of any of the same ions acquired from a positive control or reference compound analysed contemporaneously. For full scan spectral data, 5.13(f) applies. The signal to noise ratio of the least intense diagnostic ion shall be greater than 3:1.

(h) If sufficient unique diagnostic ions are not available, a different derivative that yields a different precursor and/or product ions shall be prepared, or a second form of ionization or fragmentation technique used.

(i) The concentration of both controls shall be at or within ± 20% of the expected value.

(j) The laboratory shall demonstrate the effectiveness of its deconjugation procedures in determining measurement of total drug. Laboratories shall ensure that any drug detected is not as a result of analytical artefact.

5.14 UNCERTAINTY OF MEASUREMENT

The laboratory shall ensure that the uncertainty of measurement is determined. The results of this determination shall be applied to the interpretation of the result with respect to the cut-off levels in Table 2.

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TABLE 2

CONFIRMATORY TEST CUT-OFF CONCENTRATIONS (AS TOTAL DRUG)

Compound	Cut-off level g/L
Codeine	300
Morphine	300
6-Acetylmorphine*	10
Amphetamine	150
Methylamphetamine	150
Methylenedioxymethylamphetamine	150
Methylenedioxyamphetamine	150
Benzylpiperazine*	500
Phentermine*	500
Ephedrine*	500
Pseudoephedrine*	500
11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid	15
Benzoylecgonine	150
Ecgonine methyl ester	150
Diazepam	200
Nordiazepam	200
Oxazepam	200
Temazepam	200
α-hydroxy-alprazolam	100
7-amino-clonazepam	100
7-amino-flunitrazepam	100
7-amino-nitrazepam	100

* These drugs may be optionally tested within each class and the specified cut-off levels shall apply.

5.15 TEST REPORT

The test report shall contain as a minimum, the following information:

(a) Donor identification.

(b) Date specimen collected.

(c) Date of receipt of specimen in the laboratory.

(d) Laboratory identification number.

(e) Date of reporting of analysis.

(f) All drug classes tested and not detected (negative), and individual drugs and/or metabolites confirmed as detected (positive).

(g) If urine is tested for drugs or metabolites other than those listed in Table 2, the method of testing also shall be reported.

(h) Drugs and/or metabolites not listed in Table 2 shall be reported as ‘detected’ (positive) if their presence is confirmed by mass spectrometry. For these drugs or metabolites the laboratory shall determine its own cut-off levels. Clause 5.13(b) to (j), however, still applies. The reporting of such drugs shall state that the confirmatory cut-off is not specified within the Standard.

(i) Identification of the person with the authority to issue the report.

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(j) Any observation or integrity measurement that may have affected the test result.

(k) Reference to this Section, i.e. Section 5 of AS/NZS 4308.

(l) If initial screening has been conducted by the confirming laboratory, reference shall be made to Section 4 of AS/NZS 4308.

NOTE: If a major discrepancy exists the final report cannot state compliance with or reference to this Standard. Laboratories making a statement of compliance with this Australian/New Zealand Standard are advised to ensure that such compliance is capable of being verified.

5.16 RECORD KEEPING

Records shall be kept in a secure location for a period consistent with the laboratory policy or as per National Pathology Accreditation Advisory Council (NPAAC) Guidelines or equivalent.

5.17 DISPUTED RESULTS

In the event of results being challenged, the referee specimen shall be made available for testing only with the consent of the donor. Testing shall be carried out by a laboratory accredited to Section 5 of AS/NZS 4308. Reports shall be sent to the requesting authority. Due to possible degradation of specimen over time, re-testing of the disputed result using mass spectrometry need only detect the presence of the drug or metabolite. Accordingly, no confirmatory test cut-offs apply. Clause 5.13(b) to (j), however, still apply. Replicate analysis is recommended for confirmation of disputed results.

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APPENDIX A

ON-SITE SCREENING PROCEDURE

(Normative)

A1 GENERAL

This Appendix sets out the procedure for on-site screening for drugs of abuse in human urine.

The on-site device and the controls shall be used and stored strictly in accordance with manufacturer's instructions and the collector shall ensure that no contamination of the specimens is possible by the testing procedure.

If the presence of drugs cannot be excluded in the specimen, the collector may request that the specimen proceeds directly to confirmatory testing. Further screening tests are at the discretion of the laboratory conducting the confirmatory testing.

A2 PERSONNEL

The collecting agency shall have access to an expert who has appropriate training and experience in applications of analytical toxicology, e.g. publications, court testimony, research concerning analytical toxicology of drugs or other factors that qualify the individual as an expert in toxicology.

A3 PROCEDURE

A3.1 General

The collector may carry out an on-site test to exclude the presence of any or all of the classes of drugs designated in AS/NZS 4308, or identify specimens that require laboratory testing.

The collecting agency shall disclose to the requesting authority any limitations regarding the detection of any drugs/metabolites within a class being tested and as listed in Table 1.

A3.2 Requirements for on-site screening

The requirements are as follows:

(a) The cut-off concentrations for the on-site device shall be equivalent to the cut-off concentrations for the classes of drugs listed in Table 1.

(b) The collecting agency and requesting authority shall ensure that verification of the device has been performed in compliance with Appendix B of this Standard. If the manufacturer modifies the device, the verification procedure shall be repeated.

(c) The collecting agency shall be able to demonstrate that the collectors are proficient in the use of the device.

(d) The collector shall ensure that the on-site device is within its use-by-date and record the test date, the batch number and expiry date of the device in the permanent record system together with two unique identifiers for the donor.

(e) Each day, immediately prior to the testing of the specimens at the collecting site and for each new lot number, a minimum of one above cut-off and one below cut-off quality control for each drug class on the device used shall be run.

Further, at least one quality control shall be run after each subsequent 25 specimens. Above and below cut-off controls shall be used alternately.

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The below cut-off control shall be a urine specimen containing drugs or metabolites relevant to this Standard at a concentration between 25% and 50% below the cut-off concentration.

The above cut-off control shall be a urine specimen containing drugs or metabolites relevant to this Standard at a concentration between 25% and 50% above the cut-off concentration. The results of all quality control tests shall be recorded in the permanent record system using 'Control' as a unique identifier.

The collecting agency shall have a written protocol in the event of a quality control failure.

(f) On-site screening shall be carried out in the presence of the donor.

(g) The results obtained from the device shall be interpreted strictly in accordance with the manufacturer's instructions.

(h) The results of the test shall be recorded in the permanent record system.

(i) If the on-site device indicates the possible presence of a drug class, the collector shall dispatch the specimens to a laboratory in accordance with Section 2.

(j) The collecting agency shall participate in an external proficiency testing program. Where such a program is not available, the collecting agency shall arrange a program with a laboratory to demonstrate on-going reliability of the screening process.

(k) All quality control and proficiency testing results obtained shall be used to assess the on-going performance of on-site screening and shall be available to accrediting and requesting authorities.

(l) Specimens not submitted to the laboratory shall be disposed of in accordance with waste disposal requirements and appropriate legislation.

A3.3 Acceptance of results

A result shall be accepted only if the below cut-off control does not indicate the presence of any drug or drug group and furthermore, the above cut-off control does not indicate the absence of any drug or drug group. If either control fails on a repeat test, then all further testing shall cease and corrective action shall be undertaken, in compliance with the collecting agency's written protocol.

A4 REPORTING OF RESULTS

A4.1 Test report

The test report shall include as a minimum the following:

(a) Donor identification.

(b) Date of testing.

(c) Date of reporting if different to date of testing.

(d) Results of on-site testing—

  (i) If all requested drug classes are excluded and the integrity of the specimen is not in question then a final report is issued.

  (ii) If any requested drug class returns a result that is not negative or the integrity of the specimen is in question then an interim report may be issued that can only advise that the specimen requires further testing.

  (iii) When confirmatory test results are available they shall be reconciled with the screening results and reported in accordance with Clause 5.15.

(e) Identification of the person with the authority to issue the report.

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(f) Statement of compliance with Appendix A of this Standard, i.e. Appendix A of AS/NZS 4308.

NOTE: Collecting agencies making a statement of compliance with this Australian/New Zealand Standard are advised to ensure that such compliance is capable of being verified.

A report relating to any screening test shall not indicate that the specimen is positive.

A4.2 Record keeping

Records shall be kept in a secure location for a period consistent with the requesting authority's policy or as per National Pathology Accreditation Advisory Council (NPAAC) Guidelines or New Zealand equivalent.

A4.3 RECONCILIATION OF TEST RESULTS

The requesting authority shall determine the process for reconciling the screening and confirmatory test results, including integrity testing.

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APPENDIX B

VERIFICATION OF PERFORMANCE OF ON-SITE DEVICES AROUND THE CUT-OFF

(Normative)

In order for on-site devices to be used, there has to be a procedure for ensuring the trueness of results with respect to the cut-offs as specified in Table 1. This is achieved by adopting an acceptable level of performance for readings within +25% and –30% of the screening cut-offs.

Verification is to be performed by a laboratory accredited to AS ISO/IEC 17025 or AS 4633 and the relevant Standard, AS/NZS 4308, or equivalent. The procedure is carried out by blind-testing a minimum of 20 different urine specimens containing the substance used by the manufacturer to calibrate the device for each drug class.

There shall be a minimum of 10 urine specimens spiked and confirmed by mass spectrometry analysis at concentrations –30% of the cut-off and a minimum of 10 urine specimens at +25% of the cut-off for each drug class tested by the device. It is acceptable to spike multiple substances into each urine specimen. For each of the drug classes tested, not more than a total of 10% shall return either a positive at –30% of the cut-off and/or a negative at +25% of the cut-off. All urine drug concentrations shall be checked using mass spectrometry.

Results of the verification to assess compliance of the device shall be documented and available to the requesting authority and accrediting agency.

As an example, if 20 devices are tested, no more than two failures in total (either false positives or false negatives) are permitted for each drug class tested.

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APPENDIX C

CHAIN-OF-CUSTODY FORM

(Informative)

TEST REQUEST

To be completed by the collecting agency.

Donor Name or Primary identifier ……..

Date of birth or other secondary identifier ……..

Requesting Authority..... ... Contact Name: .....

COLLECTOR CERTIFICATION

To be completed by the Collector

Collecting site location ..... Date/Time of collection .....

Serial number of seals .....

Results of integrity testing.....

Collection comments .....

I certify that the donor's identification has been verified and that the specimen identified on this form is that provided to me by the donor providing the certification above, that it bears the same identification as set forth above and that it has been collected, divided, labelled and sealed in compliance with AS/NZS 4308.

Name of Collector .....

Signature of Collector: .....Date: . .....

TEST(S) REQUIRED: .....

DONOR CERTIFICATION

To be completed by Donor

I certify that the specimen accompanying this form is my own and was provided by me to the collector. Further, I certify that the containers were sealed with tamper-evident seals in my presence and that the information provided on this form and on the labels is correct. Also, I consent to the analysis of the specimen for drugs specified above and the release of these results to my employer, prospective employer or their authorized representative.

Signature of Donor: ..... Date: .....

LABORATORY USE ONLY

Duplicate specimen received by	Date/Time Received	Seal Intact		Labels Match		Identification Number
		Yes	No	Yes	No	

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APPENDIX D

RECOMMENDED PRECAUTIONS FOR HANDLING BIOLOGICAL SPECIMENS

(Informative)

D1 GENERAL RECOMMENDATIONS

Body fluids from all individuals should be considered infective. Consequently, adequate precautions should be taken with all specimens of body fluid. Precautions should be implemented universally as follows:

(a) Gloves should be worn when handling urine specimens or any object, material or surface that has been exposed to such specimens. Gloves should be carefully removed and changed when they are visibly contaminated.

(b) If the outside of the container appears contaminated with urine, the container should be cleaned with a suitable disinfectant, such as a freshly prepared 1:10 dilution of 5% sodium hypochlorite in water.

(c) All spills should be cleaned promptly with a disinfectant such as sodium hypochlorite solution.

(d) Mouth pipetting is not permitted. Mechanical pipetting devices should be used for the manipulation of all liquids in the laboratory.

(e) Suitable laboratory aprons or gowns, masks and goggles should be worn while handling potentially infectious material with these items of clothing being discarded appropriately before leaving the laboratory.

(f) The handling of potentially infectious material should be done in a manner that minimizes the creation of droplets and aerosols. Procedures such as opening specimen containers, pipetting, centrifuging and vigorous mixing should be carried out in a biological safety cabinet Class 1.

(g) Potentially contaminated materials and equipment should be decontaminated by means of autoclaving or soaking in hypochlorite solution before disposal of specimens or disposable laboratory ware, or reuse in the case of non-disposable laboratory equipment.

(h) Hands should be washed after removing protective clothing and gloves.

(i) Persons with cuts and abrasions should not handle biological material.

D2 DISINFECTION OF SPILLS

In the event of a spill, the following procedure should be followed:

(a) Use absorbent material to contain and remove the bulk of the spill and place the waste into a suitable container (see Paragraph D4).

(b) Wipe down the spill site with disposable towels soaked in disinfectant solution such as a freshly prepared 1:10 dilution of 5% sodium hypochlorite in water.

(c) Using a detergent solution, clean the spill site thoroughly.

(d) Dispose of all contaminated waste material into leakproof biohazard bags.

NOTES:

1 Commercial laundry bleach contains approximately 5% available chlorine and may be diluted 1 in 10 with tap water.

2 Hypochlorite solutions should be prepared daily.

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D3 DISINFECTION OF EQUIPMENT

Instruments and equipment should be used in a manner that minimizes surface contamination or the production of droplets (aerosols). Spillage should be immediately decontaminated. In the event of a breakage or leakage within a centrifuge, the centrifuge should be decontaminated.

Equipment surfaces exposed to potential contamination should be disinfected daily. If necessary the equipment manufacturer's advice should be sought regarding compatibility of disinfectants with surfaces or functions. All instruments and equipment that require service or repair should be cleaned and disinfected before leaving the laboratory.

D4 WASTE DISPOSAL

The disposal of laboratory waste should be in compliance with legislation. Needles should not be bent, broken or recapped after use. All 'sharps' should be discarded into puncture-proof containers. Infectious waste should be disposed of in leak proof biohazard containers.

D5 BIBLIOGRAPHY

[1] N.S.W. Health Department *Infection control policy*. 2005.

[2] World Health Organisation, *Laboratory Biosafety* Manual, 3rd edition, Geneva 2004.

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APPENDIX E

PRINCIPLES OF OPERATION

(Informative)

E1 GAS CHROMATOGRAPHY

Drugs present in urine are extracted into an organic solvent. An aliquot of this solvent is injected into the gas chromatograph. The separation is performed on a column containing the liquid stationary phase which is maintained in an oven and has a controlled flow of carrier gas. Compounds are partitioned between the mobile phase and the stationary phase. Molecules with a greater affinity for the stationary phase spend more time in that phase and take longer to reach the detector. The detector measures the amount of compound exiting the column. The signal from the detector is processed by a chart recorder, integrator or data handling system. Each compound will have a characteristic retention time which is defined as the time in minutes from injection to peak maximum at the detector.

E2 GAS CHROMATOGRAPHY/MASS SPECTROMETRY

Drugs are extracted from urine and injected into a GC/MS system. The column operates as described in Paragraph E1 but uses a mass spectrometer as a detector. The mass spectrometer ionizes the compounds eluting from the GC column, either by electron impact (EI), or in conjunction with a chemical reagent gas (CI). The ionized compounds fragment in patterns directed by the functional groups in the molecule. The fragmentation pattern of a particular compound is characteristic of its structure (although related drugs may have similar patterns). After fragmentation, the fragmented ions are detected and quantitated according to their mass to charge ratios. The chromatographic and mass spectrometric data are stored in a data system where they can be compared to spectra of known compounds already stored.

E3 HIGH PRESSURE LIQUID CHROMATOGRAPHY

Drugs are separated on columns filled with small particles (the stationary phase) by elution with a liquid (the mobile phase) under high pressure. Separation of the compounds may occur as a result of adsorption chromatography, where interactions occur between solutes and the surface of the stationary phase; partition chromatography, where the compounds partition between the mobile phase and a bound liquid stationary phase according to their relative affinities for each phase; ion-exchange chromatography, where charged solute molecules are attracted to anionic or cationic groups on the surface of a solid stationary phase and size exclusion chromatography, where a solid stationary phase with controlled pore size excludes larger molecules which are preferentially eluted. After separation, compounds are detected with the retention time of a drug measured as for GC above. The retention time of a compound is characteristic under conditions of fixed mobile phase, temperature and column conditions.

E4 IMMUNOASSAY

Classes of drugs are identified using an antibody specific for the drug class being assayed and a labelled form of the drug. The method depends on the ability of the drug being assayed to compete in the reaction between antibody and the labelled drug. A fixed quantity of the antibody is reacted with a fixed quantity of the labelled drug and the specimen to be assayed. The specific binding sites on the antibody bind both labelled drug and unlabelled drug present in the specimen. The proportion of labelled drug molecules bound is inversely proportional to the number of unlabelled drug molecules. The label may be a radioisotope, an active enzyme or a fluorescent label or detection may rely on some other measurable phenomenon such as agglutination. A suitable analytical measurement is made of the label and the results compared to a calibration curve prepared using a urine matrix.

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All performance criteria provided by the reagent manufacturer should be met and calibration performed at least daily unless documented calibration stability for longer periods has been demonstrated.

The assay raw data at the cut-off should differ from the blank response by more than four standard deviations of the cut-off value. Reagents and calibrators should be used before the manufacturer's expiry date and be stored according to their recommendations.

E5 LIQUID CHROMATOGRAPHY/MASS SPECTROMETRY

Drugs are extracted from urine and injected into a LC/MS system. The column operates as described in Paragraph E3 but uses a mass spectrometer as a detector. The mass spectrometer ionizes the compounds eluting from the LC column, either by electrospray ionization (ESI) or by atmospheric pressure chemical ionization (APCI). The ionized compounds may fragment in patterns directed by the functional groups in the molecule. The fragmentation pattern of a particular compound is characteristic of its structure (although related drugs may have similar patterns). After fragmentation, the ions are detected and quantified according to their mass to charge ratios. The chromatographic and mass spectrometric data are stored in a data system where they can be compared to spectra of known compounds already stored.

E6 TANDEM MASS SPECTROMETRY(GC/MS/MS, LC/MS/MS)

A technique using an additional mass spectrometric stage that further fragments ions from the gas or liquid chromatograph mass spectrometer.

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