

AS/NZS 4308:2023



Australian/New Zealand Standard™

Procedures for specimen collection and the detection and quantification of drugs in urine



AS/NZS 4308:2023

This Joint Australian/New Zealand Standard™ was prepared by Joint Technical Committee CH-039, Detection and Analysis of Drugs in Specimens of Human Origin. It was approved on behalf of the Council of Standards Australia on 18 October 2023 and by the New Zealand Standards Approval Board on 04 October 2023.

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- Asia Pacific Healthcare Group
- Australasian Association for Clinical Biochemistry and Laboratory Medicine
- Australasian Medical Review Officers Association
- Australian Chamber of Commerce and Industry
- Australian Council of Trade Unions (ACTU)
- Forest Industry Contractors Association (FICA)
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- NZISM
- Pathology Technology Australia
- Royal Australasian College of Physicians
- Royal College of Pathologists of Australasia
- Sober Check
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- Workplace Drug Testing Association

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Australian/New Zealand Standard™

Procedures for specimen collection and the detection and quantification of drugs in urine

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Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CH-039, Detection and Analysis of Drugs in Specimens of Human Origin, to supersede AS/NZS 4308:2008, *Procedures for specimen collection and the detection and quantification of drugs of abuse in urine*.

The inclusion of roles and responsibilities in AS/NZS 4308:2023, was approved by the Standards Australia Production Management Group on 14 December 2021.

The objective of this document 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 document addresses appropriate procedures for the collection of urine, onsite drug screening, handling and dispatch of specimens to a laboratory for drug screening (if relevant) and confirmatory tests.

This document is not intended for clinical use or for drug exposure detection in sport, but it may be used if deemed relevant.

The major changes in this edition are as follows:

- (a) The onsite drug testing procedure has been incorporated into the body of the document.
- (b) Additional requirements have been included for the following
 - (i) Collection procedures.
 - (ii) Onsite screening test procedures.
 - (iii) Laboratory screening procedures.
 - (iv) Laboratory confirmatory procedures.
 - (v) Device verification procedures.

AS/NZS 4308:2008 will also remain current for 36 MONTHS after the date of publication of this document and after this time it will be superseded by AS/NZS 4308:2023. Regulatory authorities that reference this document in regulation may apply these requirements at a different time. Users of this document should consult with these authorities to confirm their requirements.

The terms “normative” and “informative” are used in Standards to define the application of the appendices 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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Introduction

A urine specimen may be used to provide an indication of drug exposure for workplace, medico-legal or court-directed purposes but may also have other applications. There is no relationship between urine concentration and oral fluid concentration, and only relates to exposure not impairment.

This document sets out the procedures for the collection and testing of urine for drugs and its packaging and transportation to a laboratory. It allows for the screening test of urine at the site of collection (onsite drug screening test) or the conduct of a screening test in a laboratory. Negative results from screening tests are reported at this stage. Confirmatory testing of a not-negative or unconfirmed result is performed in a laboratory using a validated, mass spectrometric method. A report is issued to a nominated representative of the requesting authority or collection facility.

Australian/New Zealand Standard

Procedures for specimen collection and the detection and quantification of drugs in urine

Section 1 Scope and general

1.1 Scope

This document sets out procedures for urine specimen collection, storage, handling, onsite drug screening tests and, if required, dispatch to the laboratory. It also covers applicability of urine for drug testing and general issues related to drug screening onsite and drug screening or confirmation in the laboratory.

1.2 Application

1.2.1 Drug analysis

Urine specimens collected under this document shall only be used for the specific purpose of drug analysis and not for other purposes such as DNA testing.

1.2.2 Transitional period

This document (AS/NZS 4308:2023) and its previous edition (AS/NZS 4308:2008) will both be current for 36 months after the date of publication of this document. It is not intended for the requirements of this document to be interchangeable with the requirements of the previous edition. Users seeking to make a statement of conformity to either this document or to the previous edition shall be able to demonstrate that they fulfil the relevant requirements of that edition.

This document will supersede the previous edition after 36 months.

1.3 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document:

NOTE Documents for informative purposes are listed in the Bibliography.

AS ISO 15189, *Medical laboratories—Requirements for quality and competence*

AS ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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

1.4 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

1.4.1

adulteration

method used to compromise, or attempt to compromise, the integrity of a urine specimen

1.4.2

amphetamine-type substances

sympathomimetic amines

drug class that may include but is not necessarily limited to amphetamine, methylamphetamine, methylenedioxymethylamphetamine (MDMA), methylenedioxyamphetamine (MDA), phentermine and pseudoephedrine

1.4.3**batch**

set of laboratory samples and controls together with calibrators as relevant that are analyzed contemporaneously

1.4.4**benzodiazepines**

drug class that may include but is not necessarily limited to alprazolam, clonazepam, diazepam, flunitrazepam, nitrazepam, oxazepam, temazepam and their metabolites

1.4.5**blind testing**

testing that replicates field conditions for an onsite drug screening device where the true result is not known to the person who performs the testing

1.4.6**calibration sample**

drug-free urine containing an analyte at a known concentration used for defining the calibration and linearity of the analytical method

1.4.7**chain-of-custody**

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

1.4.8**chain-of-custody documentation**

documentation used from time of collection of the specimen to its receipt by the laboratory, as well as dispatch between laboratories

Note 1 to entry: Thereafter, appropriate documentation accounts for the urine specimens, samples or aliquots within the laboratory.

1.4.9**cocaine metabolite**

benzoylecgonine as the target compound

1.4.10**collection device**

device consisting of one or more components for collecting urine

1.4.11**collection facility**

organization assuming professional, organizational, educational and administrative responsibility for collection, onsite drug screening (if relevant), storage and dispatch of the urine specimen

Note 1 to entry: The requesting authority also may operate as a collection facility.

1.4.12**collection site**

place at which the specimen collection occurs and where onsite drug screening test procedures may be conducted

1.4.13**collector**

person who has successfully completed a course of instruction on urine collection and onsite screening (if relevant), handling, storage and dispatch of specimens and who demonstrates ongoing competence

Note 1 to entry: Examples of courses may include those provided by the Vocational Education and Training (VET) Quality Framework, the New Zealand Qualification Authority, or other courses that would be recognized as providing equivalent training.

1.4.14**competent person**

person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills enabling that person to perform a specified task

Note 1 to entry: See [Appendix E](#) for information on specific competent persons.

1.4.15**concentration**

quantity of a substance in a defined volume

Note 1 to entry: Concentration is expressed in nanograms per millilitre (ng/mL) or equivalent units, e.g. micrograms per litre (µg/L).

1.4.16**confirmatory test**

analytical procedure that uses chromatography and mass spectrometry, or other validated technology, that unequivocally determines the presence of a drug or metabolite

1.4.17**confirmed positive result**

result at or above the cut-off concentration following confirmatory testing

1.4.18**control sample**

urine containing drugs or drug metabolites at a known concentration

1.4.19**cut-off concentration****cut-off level**

<screening tests> value at or above which the drug class, drug or metabolite is deemed to be “not-negative” and requires further testing and below which the drug class, drug or metabolite is deemed to be negative

Note 1 to entry: In some contexts, the words “not detected” may be used in place of “negative”.

<confirmatory testing> value at or above which the drug or metabolite is deemed to be “confirmed positive” and below which the drug or metabolite is deemed to be a “negative”

Note 2 to entry: In some contexts, the word “positive” may be used in place of “confirmed positive”.

1.4.20**donor**

person who provides a urine specimen to be tested for the presence of drugs or metabolites

1.4.21**donor specimen**

urine collected from the donor

1.4.22**drug**

substance that has a physiological effect on the body either directly or through its metabolite(s)

Note 1 to entry: The term “drug” refers to the drug or its metabolite(s) for the purpose of detecting a target drug in urine.

1.4.23**drug class**

group of pharmacologically related compounds sharing a similar chemical structure or mode of action

1.4.24**drug-free specimen**

urine demonstrated to be free of all relevant drugs and drug metabolites

Note 1 to entry: See [Table 6.1](#) for a non-exhaustive list of examples of relevant drugs.

1.4.25**drug screening test**

method used to exclude the presence of a drug or class of drugs

Note 1 to entry: This may also be referred to as an initial test.

1.4.26**expert**

person with formal qualifications, training, and experience with the toxicological analysis of urine and interpretation of results

Note 1 to entry: Examples include but are not limited to toxicologist (clinical or forensic); physician; certified medical review officer (MRO).

Note 2 to entry: Expert experience may include publications, court testimony, research concerning analytical toxicology of drugs.

1.4.27**fit-for-purpose device**

device that has been verified as suitable for use in collection, transportation, testing and storage of urine specimens

Note 1 to entry: See [Appendix B](#) for verification procedures.

1.4.28**integrity testing**

tests for substances or other forms of adulteration that affect the detection or quantification of drugs or metabolites in the urine specimen

1.4.29**laboratory**

testing facility that conducts testing in conformance to this document, including analytical procedures for drug screening tests or confirmatory testing to detect the presence of a drug or metabolite

Note 1 to entry: This definition excludes a collection facility that performs onsite drug screening tests only.

1.4.30**laboratory analyst**

person identified by the laboratory as being responsible for performing the laboratory's testing and analysis

1.4.31**laboratory manager**

person identified by the laboratory as being responsible for professional, organizational, educational and administrative tasks for the laboratory's urine drug testing facility

[SOURCE: ISO/IEC 9646-5:1994(en), 3.6 [modified]]

1.4.32**laboratory supervisor**

person identified by the laboratory as being responsible for day-to-day laboratory operations and supervision of laboratory analysts

1.4.33**laboratory specimen**

specimen prepared for sending to the laboratory

1.4.34**limit of detection****LOD**

lowest concentration at which a laboratory can reliably detect the presence of a drug or metabolite

1.4.35**limit of quantification****LOQ**

lowest concentration at which a laboratory can reproducibly quantify a drug or metabolite

1.4.36**limit of reporting****LOR**

concentration at or above the limit of quantification at which a laboratory reports the presence of a drug or metabolite

1.4.37**lot**

devices or quality control material manufactured in the same manufacturing event identified by a unique lot number

1.4.38**matrix effects**

combined effect of all components of the sample other than the drug in determining the drug concentration

Note 1 to entry: This may include preparation, clean up procedures or analysis steps.

1.4.39**may**

indicates the existence of an option

1.4.40**negative result**

result below the relevant cut-off concentration or limit of reporting

1.4.41**new psychoactive substances**

compounds developed either in a pure form or a preparation which may mimic the effects of existing substances

Note 1 to entry: Examples of new psychoactive substances may include those that mimic cannabis, cocaine or methylenedioxymethylamphetamine.

1.4.42**not-negative result****unconfirmed result**

screening test result that is at or above the relevant cut-off concentration and therefore does not exclude the presence of a drug or class of drugs

Note 1 to entry: A not-negative result may be reported as “unconfirmed” or “requires further testing”.

1.4.43**onsite**

place at which the specimen collection occurs and where drug screening test procedures may be conducted

Note 1 to entry: This may be at a fixed or mobile site.

1.4.44**onsite drug screening device**

device used to exclude the presence of drugs and metabolites in urine at the specimen collection site and which has been verified as fit-for-purpose

Note 1 to entry: See [Appendix B](#) for verification procedures.

1.4.45**drug screening test**

screening test carried out at the point of specimen collection or in a laboratory

1.4.46**opiates**

drug class that may include but is not necessarily limited to morphine, codeine, oxycodone, methadone and 6-acetylmorphine

1.4.47**proficiency testing program**

series of blind samples, prepared by an external provider, to ensure that a facility conducting drug testing can operate at a level of proficiency in conformance to this document

1.4.48**quality control**

series of tests designed to establish whether the method of analysis has been performed in accordance with pre-defined performance criteria

1.4.49**record system**

system in which identifying data on each specimen received are permanently recorded

1.4.50**referee specimen**

aliquot of the original specimen that has been transferred into a separate container, which is sealed at the point of collection and subsequently transported and securely stored at the laboratory for analysis in the event of a disputed result

Note 1 to entry: The original and referee specimens are transported to the laboratory together.

1.4.51**reference material**

primary material of certified purity or secondary material traceable to a primary material

1.4.52**requesting authority**

individual, facility or organization that requires assessment of a donor's urine for the presence of drugs and to which the result of the assessment is reported

1.4.53**sample**

portion or aliquot taken from the urine specimen on which the test or assay is carried out

1.4.54**shall**

indicates that a statement is mandatory

1.4.55**should**

indicates a recommendation

1.4.56**temperature indicator**

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

1.4.57**THC metabolites**

urinary metabolites of Δ^9 -tetrahydrocannabinol (THC)

EXAMPLE Carboxy-tetrahydrocannabinol (THC-COOH)

1.4.58**transportation device**

device that is used to transport the urine specimen to the laboratory

Note 1 to entry: This device may be a collection device or the onsite drug screening device, provided it can be shown that the device does not contaminate the specimen.

1.4.59**uncertainty of measurement**

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

1.4.60**verification of onsite devices**

process independent of the manufacturer, distributor or vendor to ensure that a device is fit-for-purpose

Note 1 to entry: See [Appendix B](#) for verification procedures.

Section 2 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 a 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. FOR FURTHER INFORMATION, SEE [APPENDIX C](#) AND AS 2243.1, AS 2243.2 AND AS/NZS 2243.3.

2.2 Collection site

2.2.1 General

A collection site shall have all the personnel, procedures, materials, equipment, facilities and supervision for the collection, security, onsite drug screening tests (if relevant), temporary storage and transportation of urine specimens to a laboratory that are necessary to carry out the procedures specified in this document. Where a specimen is collected and transported directly to the laboratory, the device shall be verified as fit-for-purpose in conformance to [Clause B.1](#), [B.2](#) and [B.3](#).

2.2.2 Privacy

Procedures for collecting urine specimens shall allow for individual privacy.

Increased supervision or directly observed collections may be conducted where required by policy, other medico-legal requirements or reasonable cause is determined to suspect that the integrity of the specimen collected is in doubt or the purpose of the test is of a high legal or safety risk. Reasonable cause shall be recorded on the chain-of-custody record.

Reasonable cause may include a prior record of specimen tampering (e.g. low creatinine or unacceptable temperature of first collection) or high risk such as post-incident collections or court mandated testing. Observed collections may also be required in some industries e.g. heavy industry, law enforcement.

An observed collection may involve —

- (a) indirect observation of the donor providing the specimen (e.g. standing directly behind the donor);
- (b) direct observation of the donor providing the specimen (e.g. standing in front of the donor); or
- (c) the use of a mirror to observe the passage of urine.

2.2.3 Security

Procedures shall be in place to provide security for specimens that require laboratory testing to ensure the integrity of the specimens while stored onsite and during transportation.

2.2.4 Informed consent

Specimen collection and testing shall be conducted only after documentation of informed consent has been obtained and documented. This may be a component of the chain-of-custody documentation or separate from the chain-of-custody documentation.

The informed consent shall include as a minimum the following information:

- (a) The reason for testing.

NOTE 1 Examples of reasons for testing may include random, blanket, post-incident, pre-employment, employment, workplace, unspecified/unknown, work health and safety.

- (b) The testing procedures that will be conducted in conformance to this document.
- (c) The drug or drug classes being tested for.
- (d) The requirement to provide unequivocal verification of identification to the collector.
- (e) A statement that collection, storage and exchange of information relating to the drug testing of the specimen will be in accordance with relevant privacy policy/legislation.
- (f) A statement that results will only be used for the purpose for which they were obtained. This includes confidential communication of results to the requesting authority.
- (g) The right to dispute a result and the availability of the referee specimen, which is held at the laboratory, to be tested on request.
- (h) A statement that the donor has either read or had explained to them the information outlined in Items (a) to (g).

Informed consent may include the option for the donor to voluntarily provide the collector with the identity of recently used prescription medications or non-prescription, over-the-counter drugs and supplements. This information may assist with the interpretation of results or may be required by an organization's policy.

NOTE 2 Refer to relevant privacy legislation for requirements relating to the treatment and management of any personal information that has been provided.

2.2.5 Chain-of-custody

Chain-of-custody documentation shall be completed. Chain-of-custody procedures shall be followed when handling and transporting urine specimens from one individual or place to another. The number of persons handling specimens shall be kept to a minimum.

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

- (a) Documented informed consent or a notation that a separate informed consent document has been completed.
- (b) A notation about the means used to unequivocally verify the donor's identity.

NOTE 1 Examples of identity verification may include driver licence, passport, company ID or other appropriate measure.

- (c) Two identifiers unique to the donor.

NOTE 2 Examples of unique identifiers may include name and date of birth, or in the case of an anonymized sample a unique identifier traceable back to the donor.

- (d) Date and time of specimen collection.
- (e) Onsite testing device information, expiry date and lot number (if relevant).
- (f) Confirmation by the donor that the specimen is their own and has been sealed in their presence.

NOTE 3 This may require the donor's signature or initials on both the chain-of-custody documentation and the sealed specimens to be dispatched to the laboratory.

- (g) Identification and signature of the collector.