

Australian/New Zealand Standard™

**Procedure for specimen collection and
the detection and quantification of
drugs in oral fluid**



AS/NZS 4760:2019

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Australian/New Zealand Standard™

Procedure for specimen collection and the detection and quantification of drugs in oral fluid

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CH-039, Detection of Drugs in Oral Fluid, to supersede AS 4760—2006.

This Standard incorporates Amendment No. 1 (September 2020). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.

The objective of this Standard is to ensure that the detection of drugs in oral fluid meets the expectations for testing of specimens for applications such as workplace, medico-legal, or court-directed purposes. This Standard is not intended for clinical use or for drug exposure detection in sport, but it may be used if deemed relevant. This Standard addresses procedures for the collection of oral fluid, on-site drug testing, handling and dispatch of specimens to the laboratory for screening tests (if applicable) and confirmatory testing.

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

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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FOREWORD

An oral fluid specimen may be used to provide an indication of relatively recent drug exposure at a workplace or at the roadside for drivers, but may also have other applications. For some drugs, there is a relationship between a blood or plasma concentration of drug and oral fluid concentration which may allow an inference of relatively recent exposure to drugs to be made (within hours) compared to the longer window of detection in urine (days to weeks). There is no relationship between oral fluid concentration and urine concentration and it is not appropriate to relate the presence of drugs in oral fluid to impairment, but rather to relatively recent exposure.

This Standard sets out the procedures for the collection and testing of oral fluid for drugs and its packaging and transportation to a laboratory. It allows for the screening test of oral fluid at the site of collection (on-site testing) 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 and appropriate mass spectrometry method.

Oral fluid can be obtained by ‘spitting’ or by absorption onto an absorbent material or through employing a device that stimulates production of oral fluid. A number of such devices are available to facilitate the collection process. Due to the relative ease of obtaining oral fluid, collection does not require specialist medical or paramedical experience (c.f. blood collection) or special collection facilities (c.f. urine collection). The volume of oral fluid is invariably low and this will often restrict the number of tests that can be conducted without the need for repeat collection. Occasionally, subjects will be unable to provide oral fluid when required.

The techniques available for testing of oral fluid are similar to urine testing but the target analytes may be different. The most convenient technique for a screening test is immunoassay and devices are available for on-site screening tests. Laboratory-based screening tests and confirmatory testing procedures are similar to those used for other biological fluids.

As the results of both on-site and laboratory screening are used as part of the evidentiary process together with confirmatory testing, it is necessary to ensure that on-site and laboratory screening tests are equally fit-for-purpose with their results deemed to be substantially similar. For on-site screening tests, this necessitates the implementation of procedures, such as quality controls, proficiency testing, verification of collection, testing and transportation devices as fit-for-purpose and competency based training. A hard copy of the initial test results if available may be retained for evidentiary purposes, e.g. photograph or print out.

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

A report is issued to a nominated representative of the requesting authority and/or collection facility. It is recommended that all negative and confirmed positive results are managed by a suitably qualified person or expert with appropriate training in drug testing and result interpretation.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Procedure for specimen collection and the detection and quantification
of drugs in oral fluid**

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE AND APPLICATION**1.1.1 Scope**

This Standard sets out procedures for oral fluid specimen collection, storage, handling, on-site screening tests and, if required, dispatch to the laboratory. It also covers applicability of oral fluid for drug testing and general issues related to drug screening on-site and drug screening and/or confirmation in the laboratory.

1.1.2 Application

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

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)

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 safety and containment

AS ISO

- 15189 Medical laboratories—Requirements for quality and competence

AS/NZS ISO/IEC

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

ISO

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

ISO/IEC

- Guide 98-3 Uncertainty of measurement
- Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

IATA

- International Air Transport Association
- Guidelines for shipping infectious substances and diagnostic specimens

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 Adulteration

A substance used to compromise, or attempt to compromise, the integrity of an oral fluid specimen.

1.3.2 Amphetamine-type substances (Sympathomimetic amines)

Amphetamine-type substances (ATS) may include, but are not necessarily limited to, the following: amphetamine, methylamphetamine, methylenedioxymethylamphetamine (MDMA), methylenedioxyamphetamine (MDA), phentermine and pseudoephedrine.

1.3.3 Batch

A set of laboratory samples and controls together with calibrators as appropriate that are analysed contemporaneously.

1.3.4 Benzodiazepines

Benzodiazepines may include but are not necessarily limited to the following: alprazolam, clonazepam, diazepam, flunitrazepam, lorazepam, nitrazepam, oxazepam, temazepam and/or their metabolites.

1.3.5 Blind testing

Testing that replicates field conditions for an on-site device where the true result is not known to the person who performs the testing.

1.3.6 Calibration sample

A sample matrix containing an analyte at a known concentration used for defining the calibration and linearity of the analytical method.

1.3.7 Cannabinoids

This Standard refers to Δ^9 -tetrahydrocannabinol (THC) as the target compound.

1.3.8 Chain-of-custody

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

1.3.9 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 oral fluid samples or aliquots within the laboratory.

1.3.10 Cocaine and metabolites

Cocaine, benzoylecgonine and ecgonine methyl ester.

1.3.11 Collection device

A device that consists of one or more components designed to collect oral fluid and be verified as fit-for-purpose in accordance with Appendix C.

NOTES:

- 1 The device may contain a fluid designed to facilitate testing and to maintain the integrity of the specimen.
- 2 It may include absorbent material or a tube to directly receive the oral fluid.
- 3 The device may incorporate an adequacy indicator to collect a known amount of oral fluid.

1.3.12 Collection facility

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

NOTE: The requesting authority also may operate as a collection facility.

1.3.13 Collection site

A place at which the specimen collection occurs and where on-site screening test procedures may be conducted.

1.3.14 Collector

A person who has successfully completed a course of instruction on oral fluid collection and on-site drug screening (if applicable), handling, storage and dispatch of specimens and demonstrates ongoing competence.

NOTE: Courses may be those provided by the Vocational Education and Training (VET) Quality Framework, the Faculty of Clinical Forensic Medicine (RCPA), the New Zealand Qualification Authority, or courses that would be recognized as providing equivalent training.

1.3.15 Concentration

Quantity of a substance in a defined volume or mass. Concentration is expressed in nanograms per millilitre (ng/mL) or other units, as appropriate, e.g. micrograms per litre (µg/L) or nanograms per gram (ng/g).

1.3.16 Confirmatory test

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

1.3.17 Confirmed positive result

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

1.3.18 Control specimen

An oral fluid specimen, or synthetic oral fluid, containing drugs and/or drug metabolites at known concentrations.

1.3.19 Cut-off concentration

Confirmatory testing: A value at or above which the drug and/or metabolite is deemed to be 'confirmed positive' and below which the drug and/or metabolite is deemed to be a 'negative'.

NOTES:

- 1 In some contexts the words 'positive' may be used in place of 'confirmed positive'.
- 2 In some contexts the words 'not detected' may be used in place of 'negative'.

Screening tests: A value at or above which the drug class, drug and/or metabolite is deemed to be 'not-negative' and requires further testing and below which the drug class, drug and/or metabolite is deemed to be negative.

1.3.20 Donor

A person who provides an oral fluid specimen to be assessed for the presence of drugs and/or metabolites.

1.3.21 Drug

A substance that has a physiological effect on the body either itself or through its metabolite(s). The term 'drug' refers to the drug and/or its metabolite(s) for the purpose of detecting a target drug in oral fluid.

1.3.22 Drug-free specimen

A1 | An oral fluid specimen or synthetic matrix matched equivalent demonstrated to be free of all drugs and drug metabolites being tested.

1.3.23 Expert

A person with formal qualifications, training and experience with the analysis of oral fluid and interpretation of results. Examples include but are not limited to: toxicologist (clinical or forensic); physician; medical review officer (MRO).

1.3.24 Fit-for-purpose

A device that has been verified by conformance to Appendix C to be suitable for use in testing to this Standard.

1.3.25 Laboratory

A testing facility that conducts testing in accordance with this Standard (AS/NZS 4760), including analytical procedures for screening tests and/or confirmatory testing to detect the presence of a specific drug and/or metabolite. This definition excludes a collection facility that performs screening testing only.

1.3.26 Laboratory analyst

A person who has training, experience and competence to perform laboratory drug testing of biological fluids.

1.3.27 Laboratory record system

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

1.3.28 Laboratory specimen

A specimen prepared for sending to the laboratory.

1.3.29 Limit of detection (LOD)

The lowest concentration at which a laboratory can reliably detect the presence of a drug and/or metabolite.

1.3.30 Limit of reporting (LOR)

The concentration above the limit of quantification (LOQ) at which a laboratory reports the presence of a drug and/or metabolite. The LOQ is the lowest concentration at which a laboratory can reproducibly measure a drug and/or metabolite.

1.3.31 Negative result

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

1.3.32 Not-negative (unconfirmed) result

A 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. A result that requires confirmatory testing of the specimen to unequivocally determine the presence or absence of a drug. A not-negative result may be reported as 'unconfirmed' or 'requires further testing'.

1.3.33 On-site

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

1.3.34 On-site screening test device

A device used to exclude the presence of drugs and/or metabolites in oral fluid at the site of specimen collection and which has been verified as fit-for-purpose in accordance with Appendix C.

1.3.35 On-site testing

A screening test carried out at the point of collection.

1.3.36 Opioids

Opioids may include but are not necessarily limited to the following: morphine, codeine, oxycodone, methadone and 6-acetylmorphine.

1.3.37 Oral fluid specimen

Fluid collected from the oral cavity of the donor.

1.3.38 Permanent record system

A system in which identifying data on each specimen collected (and tested on-site if applicable) are permanently recorded by the collection facility.

1.3.39 Proficiency testing program

A 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 accordance with this Standard.

1.3.40 Quality control

A series of tests designed to establish whether the method of analysis has performed in accordance within pre-defined performance criteria.

1.3.41 Referee specimen

An additional specimen collected contemporaneously, or a second portion of the original specimen, which is sealed at the point of collection and subsequently transported to and securely stored at the confirmatory testing laboratory for analysis in the event of a disputed result. Both specimens are transported to the laboratory together.

1.3.42 Requesting authority

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

1.3.43 Sample

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

1.3.44 Screening test

A method used to exclude the presence of a drug or class of drugs. May also be referred to as an initial test.

1.3.45 Specimen dilution

The volume of neat oral fluid collected, divided by the total volume of both the neat oral fluid and the diluent contained in the device.

1.3.46 Transportation device

The device used to transport the oral fluid specimen(s) to the laboratory and which has been verified as fit-for-purpose in accordance with Appendix C. This device may be a collection device and/or the on-site testing device, provided it can be shown that the device does not contaminate the specimen.

1.3.47 Uncertainty of measurement

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

1.3.48 Verification of devices

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

SECTION 2 COLLECTION, STORAGE, HANDLING AND DISPATCH

2.1 GENERAL

This Section sets out procedures for specimen collection, storage, handling and dispatch of oral fluid specimens to the laboratory. The procedure requires the provision of a referee specimen should the resolution of disputed results be required.

WARNING: THE COLLECTION AND HANDLING OF HUMAN SPECIMENS MAY CONSTITUTE AN INFECTION HAZARD. REFER TO APPENDIX D AND AS/NZS 2243.1, AS/NZS 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, on-site screening tests (if applicable), temporary storage and transportation of oral fluid specimens to a laboratory that are necessary to carry out the procedures specified in this Standard.

2.2.2 Privacy

Procedures for collection and screening tests of oral fluid specimens shall allow for individual privacy. Collection shall be witnessed by the collector.

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 whilst stored onsite and during transportation.

2.2.4 Informed consent

Specimen collection and testing shall be conducted only after the donor signs a written informed consent form. This form may be either a document separate from the chain-of-custody form or a component of the chain-of-custody form.

The informed consent document shall have as a minimum the following information:

- (a) The reason for testing; e.g. random, blanket, post-incident, pre-employment, employment, workplace, unspecified/unknown, work health and safety, etc.
- (b) The testing procedures will be conducted in accordance with this Standard.
- (c) The drug/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 their specimen will be in accordance with the relevant privacy 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 read and/or had explained to them the information outlined in (a) to (g).

Informed consent may include the option for the donor to voluntarily provide the collector with the identity of recently used prescription or non-prescription medications. This information may assist with the interpretation of results or may be required by an organization's policy. The provision of any information provided must be treated and managed in accordance with relevant privacy legislation.

2.2.5 Chain-of-custody

Chain-of-custody forms shall be completed by the collector and donor. Handling and transportation of oral fluid specimens from one individual or place to another shall always be accomplished through chain-of-custody procedures. The number of persons handling specimens shall be kept to a minimum.

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

- (a) Written informed consent or a notation that a separate informed consent form has been completed.
- (b) A notation about the means used to unequivocally verify the donor's identity (e.g. driver's licence, passport, company ID or other appropriate measure).
- (c) Two identifiers unique to the donor (e.g. name and date of birth).
- (d) Date and time of specimen collection.
- (e) Device information and lot number.
- (f) Confirmation by the donor that the specimen was their own.
NOTE: This may require the donor's signature or initials on both the chain-of-custody form and the sealed specimens to be dispatched to the laboratory.
- (g) Identification and signature of collector.
- (h) Declaration by the collector that the collection and, if applicable, on-site testing of the specimen has been performed in accordance with this Standard.
- (i) Requesting authority details.
- (j) Results (if any) of any on-site specimen testing carried out at the point of collection.
- (k) Required laboratory testing (e.g. drug/drug classes to be tested).

2.3 INTEGRITY AND IDENTITY OF THE COLLECTED SPECIMEN

2.3.1 General

Precautions shall be taken to ensure the following:

- (a) The oral fluid specimen is not adulterated during the collection procedure.
- (b) Information on the oral fluid container(s) and in the permanent record system identifies the individual from whom the specimen was collected.

2.3.2 Precautions

To ensure that unadulterated oral fluid specimens are obtained and the donor is correctly identified, as a minimum, the donor and the collector shall witness at all times the collection and, if applicable, screening tests, until labelling and sealing of specimen(s) is completed.

2.3.3 Collection procedure

The procedure shall be as follows:

- (a) When a donor arrives at the collection site, the collector shall request identification (e.g. drivers licence, passport, company ID). If the individual's identity cannot be established unequivocally, then the collector shall not proceed with the collection.