AS/NZS 4760:2019

Australian/New Zealand Standard™

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

STANDARDS Australia

STANDARDS NEW ZEALAND
PAEREWA AOTEAROA

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Australian/New Zealand Standard™

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

Originated in Australia as AS 4760—2006.
Jointly revised and redesignated as AS/NZS 4760:2019.

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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.

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.

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Australian/New Zealand Standard

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

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 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

An oral fluid specimen or synthetic 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.

(b) The collection shall take place in accordance with the device manufacturer's instructions to ensure maximum efficiency of transfer of any drugs in the specimen to the device and minimize degradation at the point of collection as well as during storage and transportation.

(c) The collector shall visually inspect the donor's oral cavity to ensure that the oral cavity is free from external substances, e.g. liquid, food.

NOTE: The oral cavity should be free of external substances for at least 10 minutes prior to specimen collection.

(d) For screening tests conducted on-site, testing shall take place at this point using the procedure specified in Appendix A.

(e) For screening tests conducted in a laboratory (i.e. not on-site) the collector shall determine that the specimen is suitable to enable all required laboratory testing to be performed. This includes the provision of a separate referee specimen at the point of collection.

If sufficient volume is available, the specimen shall be split and one of these becomes a referee specimen. If sufficient volume is not available, additional oral fluid shall be collected to ensure two specimens are available, one of which becomes the referee specimen. The additional specimen, or specimens, shall be collected without delay after the first to ensure specimen consistency.

(f) If following on-site screening tests, laboratory testing of the specimen is required then the collector shall proceed with Steps (g) to (j) after ensuring that two specimens are available for laboratory testing as outlined in (e) above.

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

(h) The collector shall securely attach labels to each container.

(i) The label shall list the date and time of collection and a minimum of two unique identifiers for the donor.

(j) The containers shall be sealed with tamper-evident seals that are signed or initialled by the donor. If the donor initials the tamper-evident seals on the containers, then the donor shall also initial the chain-of-custody form.

NOTE: Other devices or containers which can guarantee the integrity of the oral fluid specimen may be used in place of tamper-evident seals.

(k) The donor shall be required to provide written acknowledgment on the chain-of-custody form that the specimens are their own and are labelled such that they can identify the donor correctly and have been sealed in the donor's presence.

2.4 PREPARATION FOR DISPATCH

The procedure shall be as follows:

(a) Each container shall be labelled in such a manner that it is traceable to the donor and the chain-of custody form.

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

(c) A written indication of what laboratory testing is required and, if applicable, the results of any on-site testing performed shall be recorded for inclusion with the specimen.

(d) All information identifying the specimen shall be entered into the permanent record system.

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

(f) Specimen transportation shall occur as soon as practicable.

2.5 TRANSPORTATION TO THE LABORATORY

The procedure for transportation of the specimens to the laboratory comprises the following:

(a) Both the oral fluid specimens (test and referee specimen) shall be placed in shipping containers designed to minimize the possibility of damage or specimen degradation during shipment.

(b) The shipping containers shall be securely sealed to eliminate the possibility of tampering.

(c) The chain-of-custody form shall be submitted to the laboratory for all specimens that are shipped to the drug testing laboratory. Where transportation is facilitated by commercial couriers, and chain-of-custody is not practicable, the risk of not maintaining chain-of-custody should be assessed.

(d) Compliance with relevant legislation relating to transportation also applies.

NOTE: Refer to current IATA guidelines and legislation for procedures and requirements for packaging and shipping of biological material.

SECTION 3 GENERAL LABORATORY REQUIREMENTS

3.1 GENERAL

This Section sets out procedures for laboratory testing of oral fluid specimens for drugs.

Screening tests may be conducted by immunoassay or by mass spectrometry. Confirmatory testing shall be conducted using mass spectrometry.

The laboratory undertaking analyses of this nature shall participate in a proficiency testing program (if available).

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

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.

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. The use of volumetric apparatus shall be in accordance with the relevant Standard, e.g. AS 2162.1.

3.3.2 Piston operated volumetric apparatus

Piston operated volumetric apparatus shall be used in accordance with the relevant Standard, e.g. AS 2162.2.

3.4 LABORATORY SECURITY

The following requirements apply:

(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.

(d) Receipt of specimens shall be documented on the chain-of-custody form or in the laboratory's information management system such that the specimen identity, integrity, security and traceability 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 samples (aliquots), shall be dated and documented and every person in the chain shall be identified.

3.5 SPECIMEN RECEPTION AND GENERAL ACCEPTANCE CRITERIA

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

When specimens are received, they shall be inspected as follows to determine whether any tampering has occurred, or documentary chain-of-custody fatal flaws exist:

(a) Each package and each specimen shall be inspected for evidence of tampering.

(b) Information on containers within each package shall be compared with the information on the accompanying chain-of-custody form.

(c) Specimens not being used for analysis, including the referee specimen, shall be stored as per Clause 3.7.

NOTE: Any discrepancies should be noted (see Clause 4.12.2 and Clause 5.16).

Chain-of-custody fatal flaws cannot be corrected, and the specimen shall be rejected. Fatal flaws are as follows:

(i) No documentation received with the specimens.

(ii) No specimens accompany chain-of-custody documentation.

(iii) No written consent from the donor.

(iv) No tamper-evident seals.

(v) Tamper-evident seals broken or tampered with on the specimen collection/transport container(s).

(vi) Only a single specimen container received.

(vii) Insufficient or leaking of one or more specimen containers.

(viii) Items (b) to (d) and (f) in Clause 2.2.5 not provided.

3.6 RECONCILIATION OF TEST RESULTS

The requesting authority shall determine the process for reconciling the screening drug test results and confirmatory test results. The facility that performs screening tests and refers specimens for confirmatory testing shall have a documented protocol for reconciling the screen and confirmatory test results.

3.7 STORAGE OF SPECIMEN

3.7.1 Short-term storage

Specimens shall be refrigerated or frozen on receipt by the laboratory, unless subject to immediate processing. Testing should be performed without delay to minimize loss on storage and ensure results are available as soon as practicable. Specimens shall be kept refrigerated or frozen at all times unless being analysed or transferred to long-term storage. Negative specimens (but not the records) may be discarded after testing.

The following storage conditions apply:

(a) Refrigeration shall be secure.

(b) Refrigeration unit temperature shall be monitored.

(c) The unit should operate in a range of 2°C–8°C.

3.7.2 Long-term storage

All specimens in which drugs have been confirmed as positive (or when their integrity is in doubt), together with their respective referee specimens, shall be stored in a secure freezer at the confirmatory laboratory for at least 6 months from the date of reporting of the results, unless written authority for disposal is received from both the requesting authority and donor.

The following long-term storage conditions apply:

(a) Freezer unit shall be secure.

(b) Freezer unit temperature shall be monitored and operated at a temperature below 0°C.

SECTION 4 LABORATORY SCREEN TESTING

4.1 GENERAL

Screening tests may be carried out in the laboratory utilizing either method specified in Clause 4.2. Table 1 outlines the drugs and drug classes and cut-off concentrations when immunoassay is utilized for screening tests. Table 2 outlines the drugs and cut-off concentrations when chromatography is utilized for screening tests. One or more of the listed drugs and drug classes may be screened for.

Screening tests for additional drugs may be performed at the request of the requesting authority (see Appendix B). For any other drugs or drug classes not listed in Tables 1 or 2, the LOR established by the laboratory shall apply. These drugs or drug classes shall be reported as 'positive' ('detected') or 'negative' ('not detected').

WARNING: THE COLLECTION AND HANDLING OF HUMAN SPECIMENS MAY CONSTITUTE AN INFECTION HAZARD. REFER TO AS/NZS 2243.1, AS/NZS 2243.2 AND AS/NZS 2243.3.

4.2 METHOD

The screening test method shall be one of the following:

(a) Immunoassay.

(b) Chromatography-based techniques.

If immunoassay procedures are used when performing screening tests, the manufacturer's instructions should 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 instructions. Such documentation shall show that the cut-off concentrations are consistently achievable using the selected method.

4.3 LABORATORY SECURITY, SPECIMEN RECEPTION AND STORAGE OF SPECIMENS

For laboratory security, specimen reception and storage of specimens, refer to Clauses 3.4, 3.5 and 3.7 respectively.

4.4 RESPONSIBILITIES AND PERSONNEL

4.4.1 Laboratory supervision

Supervision of the laboratory includes the day-to-day operations and the laboratory analyst(s). Qualifications for this role would be, as a minimum, a bachelor's degree in the chemical or biological sciences or medical technology or equivalent in addition to sufficient training and experience in the theory and practice of testing for drugs in oral fluid. Sufficient training and experience would be evidenced by demonstrated 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 and assessment of competency of laboratory personnel.

(f) Participation in a proficiency program or suitable alternative with a satisfactory level of performance.

4.4.2 Laboratory analyst

Refer to Clause 1.3.26.

4.4.3 Analytical toxicologist

The laboratory shall have access to a qualified and experienced expert.

4.4.4 Acceptance of results

A process shall be in place that will ensure the results meet the acceptance criteria (see Clause 4.10).

4.5 NUMBER OF DETERMINATIONS

The testing procedure may involve a single determination.

4.6 CALIBRATION

Calibration shall be performed with each batch unless calibration stability has been validated for the method used between successive batches.

4.7 BLANK DETERMINATION

A blank which has been processed through the entire extraction and derivatization (if any) procedure shall be run using a known drug-free oral fluid sample(s) or a synthetic equivalent. The blank shall be run with a frequency of at least once per batch.

4.8 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 no greater than 50% above the cut-off concentration.

(b) The low control shall be no less than 50% below the cut-off concentration.

The matrix used for quality control shall be the same as that used for calibration, and shall be either pooled blank oral fluid or a synthetic equivalent.

4.9 SCREENING TEST CUT-OFF LEVELS

Where an immunoassay technique is used for the screening test, 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 the screening test, then the cut-off concentrations shall be as listed in Table 2.

4.10 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 re-analysed.

As a minimum, the following criteria shall be used:

(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 LOD.

(d) The value obtained shall be at or within ±20% of the expected value for the high control and at or within ±25% of the expected value for the low control.

4.11 INTERPRETATION OF RESULTS

Where immunoassay is utilized for screening tests, specimens with results equal to or greater than cut-off concentrations listed in Table 1 shall be subjected to confirmatory testing before final results are issued.

Where mass-spectrometry is utilized for screening tests, a specimen with results equal to or greater than the cut-off concentrations listed in Table 2 shall be subjected to additional confirmatory testing using a fresh aliquot taken from the specimen.

If a specimen result is less than the cut-off concentrations listed in Table 1 or Table 2, then the drug shall be reported as 'negative'. If a specimen result is equal to or greater than the cut-off concentrations listed in Table 1 or Table 2, it shall be indicated that this is a 'not-negative' or 'unconfirmed' result that requires further testing (RFT). This may be recorded and issued as an interim report.

TABLE 1

LABORATORY IMMUNOASSAY SCREENING TEST CUT-OFF CONCENTRATIONS

Class of drug	Cut-off concentration ng/mL
Amphetamine-type substances	50
Cannabinoids	15
Cocaine and metabolites	50
Opiates	50
Oxycodone	40

NOTES:

1 The cut-offs apply to the concentration in the neat oral fluid specimen (originally obtained from the donor). The specimen dilution of the particular device used to collect, store or transport the oral fluid specimen (as described in Appendix C1) shall be applied to calculate this concentration from the laboratory result.

2 Other drugs or drug classes not listed in Tables 1 or 2 can be added to the testing options provided the laboratory has established validated testing methods consistent with this Standard. If a cut-off concentration has not yet been established, the LOR for the methodology shall apply as specified in Appendix B.

TABLE 2

CHROMATOGRAPHY-BASED SCREENING TEST CUT-OFF CONCENTRATIONS

Compound	Cut-off concentration ng/mL
Amphetamine	25
Methylamphetamine	25
Methylenedioxymethylamphetamine	25
Methylenedioxyamphetamine	25
Δ^9-tetrahydrocannabinol (THC)	5
Cocaine	25
Benzoylecgonine	25
Codeine	25
Morphine	25
6-Acetylmorphine	10
Oxycodone	20

NOTES:

1 The cut-offs apply to the concentration in the neat oral fluid specimen (originally obtained from the donor). The specimen dilution of the particular device used to collect, store or transport the oral fluid specimen (as described in Appendix C1) shall be applied to calculate this concentration from the laboratory result.

2 Other drugs or drug classes not listed in Tables 1 or 2 can be added to the testing options provided the laboratory has established validated testing methods consistent with this Standard. If a cut-off concentration has not yet been established, the LOR for the methodology shall apply as specified in Appendix B.

4.12 REPORTING OF RESULTS

4.12.1 Conditions for reporting

The conditions for reporting are as follows:

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

(b) If any requested drug or 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 (RFT).

(c) A report relating to any screening test shall not indicate that the specimen is positive nor shall the measured concentration obtained for any drug class or drug be indicated on the report.

(d) When confirmatory test results are available, they should be reconciled with the screening test results and reported in accordance with Clauses 3.6 and 5.15.

4.12.2 Test report

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

(a) Donor’s identification.

(b) Statement that a completed chain-of-custody document was received and the specimen seals were intact.

(c) Date and time of specimen collection.

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

(e) Laboratory identification (accession) number.

(f) Date of reporting of results.

(g) Device(s) used for the collection, transportation and/or storage of the specimen.

(h) Method of analysis used for the screening test.

(i) For those drugs or drug classes tested, results are reported as described in Clause 4.12.1.

(j) For drugs or drug classes listed in Tables 1 and/or 2, reference to the cut-off concentrations listed in these tables.

(k) For drugs or drug classes not listed in Tables 1 and/or 2, inclusion of the LOR.

(l) Any observation made during the course of the testing which may have affected the test result, including discrepancies.

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

(n) Reference to Section 4 of this Standard, i.e. Section 4 of AS/NZS 4760:2019.

NOTE: Laboratories making a statement of conformance to this Standard, are advised to ensure that such conformance is capable of being verified.

4.13 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.

SECTION 5 LABORATORY CONFIRMATORY PROCEDURES

5.1 SCOPE

This Section sets out confirmatory procedures for the unequivocal identification and quantification of drugs and/or their metabolites in oral fluid specimens.

5.2 PRINCIPLE

Mass spectrometry is utilized to confirm the presence of drugs and/or their metabolites at or above the cut-off concentrations listed in Table 3 or the limit of reporting for additional drugs listed in Appendix B.

5.3 APPARATUS

5.3.1 Gas chromatograph/mass spectrometer

An instrument that includes a separation of compounds by gas chromatography coupled with one or more forms of mass spectral detection.

5.3.2 Liquid chromatograph/mass spectrometer

An instrument that includes a separation of compounds by high performance liquid chromatography coupled with one or more forms of mass spectral detection.

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

5.4 LABORATORY SECURITY, SPECIMEN RECEPTION AND STORAGE OF SPECIMENS

For laboratory security, specimen reception and storage of specimens, refer to Clauses 3.4, 3.5 and 3.7 respectively.

5.5 RESPONSIBILITIES AND PERSONNEL

5.5.1 Laboratory management

The laboratory manager shall assume professional, organizational, educational and administrative responsibility for the laboratory's oral fluid drug testing service.

More than one qualified employee may be designated to be responsible for management or operation of the laboratory.

5.5.2 Laboratory supervision

Supervision of the laboratory includes the day-to-day operations and the laboratory analyst(s). Qualifications for this role would be, as a minimum, a bachelor's degree in the chemical or biological sciences or medical technology or equivalent in addition to sufficient training and experience in the theory and practice of confirmatory testing for drugs in oral fluid. Sufficient training and experience would be evidenced by demonstrated 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 and assessment of competency of laboratory analyst(s) and other personnel.

(f) Participation in a proficiency program or suitable alternative with a satisfactory level of performance.

5.5.3 Laboratory analyst

Refer to Clause 1.3.26.

5.5.4 Acceptance of results

On a day-to-day basis a minimum of two qualified personnel (as defined in Clauses 5.5.2 and 5.5.3) shall ensure the results meet the acceptance criteria (see Clauses 4.10 and 5.14).

5.5.5 Review results

All pertinent data and quality control results shall be reviewed to attest to the validity of the laboratory reports. This shall not be performed by the laboratory analyst conducting the testing.

5.6 CONFIRMATORY PROCEDURES

The following procedures are applicable for confirmatory testing:

(a) All confirmatory tests shall be performed on a fresh aliquot from the original specimen container.

(b) Analytical technology that simultaneously tests for all compounds listed in Table 3 and that meets the analytical acceptance criteria of Clauses 5.10 to 5.14 may be used to analyse an oral fluid specimen without prior testing by either Section 4 or Appendix A of this Standard.

(c) If there has been no prior testing of the specimen, then replicate analysis using a fresh aliquot taken from the original specimen shall be performed before reporting a confirmed positive result.

(d) All quantification shall be performed using internal standards added to the sample before any analytical procedures are commenced.

NOTE: Isotopically labelled internal standards should be used if available.

(e) 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.

(f) Calibration shall be performed with each batch unless calibration stability has been validated for the method used between successive batches.

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

(h) All drugs and their metabolites listed in Table 3 that are present at a concentration equal to or greater than the cut-off shall be reported.

5.7 INSTRUMENTATION

Acceptable instrumentation for the separation of compounds by chromatography coupled with one or more forms of mass spectral detection includes but is not limited to the following: GC/MS, GC/MS/MS, GC/HRMS, GC/HRMS/MS, LC/MS/MS, LC/HRMS and LC-HRMS/MS. Confirmation may be made by identification and quantification 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 has conducted screening tests, the laboratory shall process each specimen for confirmatory testing using samples derived from a second aliquot taken from the original specimen.

Replicate determinations are recommended but single determinations are permissible.

5.9 INSTRUMENT SETUP

The instrument shall be tuned in accordance with the manufacturer's instructions or according to documented laboratory procedures.

5.10 BLANK DETERMINATION

A blank which has been processed through the entire extraction and derivatization (if any) procedure shall be run using a known drug-free oral fluid sample(s) or synthetic equivalent. The blank shall be run with a frequency of at least once per batch.

5.11 QUALITY CONTROL

Every batch of samples for confirmatory testing shall contain a minimum of 10% or two control samples 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 no greater than 50% above the cut-off level in Table 3.

(b) The low control shall be no less than 50% below the cut-off level in Table 3.

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 ng/mL (µg/L) by comparing the peak area (or height) ratio of the sample with the calibration curve.

If a drug or metabolite concentration exceeds the level of the highest calibrator, then a measured level shall not be reported unless a validated method has been used to obtain an extrapolated result. Diluting the sample extract so that the absolute response falls within the calibration range or extending linearity above the highest calibration standard using an additional control are both acceptable provided these approaches have been validated.

5.13 UNCERTAINTY OF MEASUREMENT

The uncertainty of measurement shall be determined in accordance with the relevant standard. Refer also to ISO/IEC Guide 98-3. The results of this determination shall be applied in conjunction with the specimen dilution to the interpretation of the measured value with respect to the cut-off levels in Table 3 whereby specificity is given precedence over sensitivity in the reporting of confirmed positive results.

The concentration of the high and low controls shall respectively be above and below the specified cut-off concentration.

Uncertainty of measurement shall not be applied to control values for the purpose of satisfying acceptance criteria (see Clause 5.14).

TABLE 3

CONFIRMATORY TEST CUT-OFF CONCENTRATIONS

Compound	Cut-off concentration ng/mL
Amphetamine	25
Methylamphetamine	25
Methylenedioxymethylamphetamine	25
Methylenedioxyamphetamine	25
Δ^9-tetrahydrocannabinol (THC)	5
Cocaine	25
Benzoylecgonine	25
Codeine	25
Morphine	25
6-Acetylmorphine	10
Oxycodone	20

NOTES:

1 The cut-offs apply to the concentration in the neat oral fluid specimen (originally obtained from the donor). The specimen dilution of the particular device used to collect, store or transport the oral fluid specimen, as specified in Appendix C1, shall be applied to calculate this concentration from the laboratory result.

2 Other drugs or drug classes not listed in Tables 1, 2 or 3 can be added to the testing options provided the laboratory has established validated testing methods consistent with this Standard. The LOR for the methodology shall apply as specified in Appendix B.

5.14 ACCEPTANCE CRITERIA

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

(a) The concentration detected shall be at or above the specified cut-off concentration in Table 3 by an amount equal to or greater than the laboratory's determined uncertainty of measurement with a minimum coverage factor of 1.65 as calculated using a single tail test.

NOTE: The concentration of drugs or their metabolites that exceed the highest calibration point of the standard curve may be documented in the laboratory records as 'greater' than the highest standard curve value.

(b) The signal to noise ratio (S/N) of any ion used for identification shall be at least greater than 3:1.

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

(d) The value obtained shall be at or within ±20% of the prepared quantitative value of the high control and at or within ±25% of the prepared quantitative value of the low control.

(e) The concentration of the high and low controls shall respectively be above and below the specified cut-off concentration.

(f) The value of the blank shall be less than that of the LOD.

(g) Uncertainty of measurement shall not be applied to control values for the purpose of satisfying acceptance criteria.

(h) Measures shall be taken to ensure that any drug or metabolite detected is not as a result of analytical artefact.

(i) Mass spectrometric detection

If the full scan mode is used, then the scan range shall be from m/z 50 to a value above the molecular weight of the compound or its derivative. However, when necessary, a partial scan may be used which begins at a m/z value greater than any abundant ion arising from a derivatizing agent, chemical ionization reagent or mobile phase component. All significant ions present in the corresponding mass spectrum from a calibration standard, a control sample or a reference analyte shall be present in the mass spectrum from the sample. In addition, the relative abundances of three diagnostic ions in the sample spectrum shall not exceed the tolerances specified in Table 4. The presence of significant ions in the spectrum from the sample which are not present in the spectra from the calibration, control or reference samples is acceptable provided that their presence can be explained and discounted. Background subtraction, if applied, shall be performed uniformly on the batch of specimens analysed.

(j) Selected ion monitoring mode (SIM)

In some cases it may be necessary to monitor selected ions in order to detect analytes at low concentrations. A minimum of three diagnostic ions shall be monitored. No ion with m/z below 50 Da shall be used. The common low mass ions, m/z 58, 86, 91, 105 shall not be considered as diagnostic. Ions shall have a signal to noise ratio greater than 3:1. The relative abundances of these ions shall not exceed the tolerances specified in Table 4.

(k) Tandem mass spectrometry (MS^n)

MS^n 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 ions gives MS^n increased specificity. A minimum of two product ions shall be monitored. The relative abundances of these ions shall not exceed the tolerances specified below. For MS^n, product ions with m/z below 50 are acceptable, however non-characteristic transitions, such as the loss of water or derivatizing agent groups, are not suitable. The signal to noise ratio of the least abundant product ion shall be greater than 3:1.

(l) High resolution (accurate mass) mass spectrometry

In general, when compared with mass spectra obtained using unit mass resolution and nominal mass assignment, the use of accurate mass data (resolution >10 000 FWHM) (full width at half maximum) provides additional confidence in the attribution of a mass peak or ion chromatogram to a confirmatory analyte. This increased confidence allows some relaxation in the criteria applied to confirmatory analysis. For example, in MS^n, a precursor ion and a diagnostic product ion can be used instead of two product ions provided that mass accuracy for both ions is within ±2 mDa or 5 ppm (whichever is greater). It also allows ions in the spectrum from the sample which are not present in the spectra from the calibration, control or reference samples to be discounted on the basis of their incompatible accurate mass.

TABLE 4

RELATIVE ABUNDANCE CRITERIA FOR MASS SPECTROMETRY

Relative abundance (% of base peak) in reference mass spectrum	Tolerance range for all MS methods
50–100	±10 (absolute)
25–50	±20% (relative)
1–25	±5 (absolute)

(m) If diagnostic ions with relative abundances less than 5% are used, then they shall at least be detected in the sample spectrum (S/N > 3:1).

If sufficient unique diagnostic ions are not available, a derivative or a second form of ionization/fragmentation which provides additional different mass spectra may be used.

The use of any of the mass spectrometric criteria does not preclude the laboratory from applying more stringent criteria as judged necessary by the laboratory either routinely or on a case-by-case basis.

5.15 TEST REPORT

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

(a) Donor identification.

(b) Statement that a completed chain-of-custody document was received and the specimen seals were intact.

(c) Date and time of specimen collection.

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

(e) Laboratory specimen identification (accession) number.

(f) Date of reporting of results.

(g) Device(s) used for the collection, transportation and/or storage of the specimen.

(h) All drugs or drug classes determined to be below the cut-off concentration shall be reported as negative, and individual drugs and/or metabolites determined to be at or above the cut-off concentration shall be reported as confirmed positive or positive or detected. Measured levels of a drug and/or metabolite below the cut-off concentration are not reported.

NOTE: For a confirmed positive, the routine reporting of the measured drug and/or metabolite level is not recommended. If the measured level of a drug and/or metabolite is reported, the results should be reviewed and interpreted by an expert (see Clause 1.3.23).

(i) Reference to the cut-off concentrations for drugs listed in Table 3. If a cut-off concentration has not been established, a statement referring to the LOR for the methodology as specified in Appendix B.

(j) Drugs and/or metabolites not listed in Table 3, and for which an agreed cut-off concentration has not been established, shall be reported as ‘positive’ (detected) if their presence is confirmed by mass spectrometry. For these drugs or metabolites the laboratory shall determine its own LOR. Clause 5.14 Items (b) to (g), however, still apply.

NOTE: Refer to Note to Clause 5.15(h) for recommendations on the reporting of measured drugs and/or metabolite levels.

(k) Any observation or discrepancy that may have affected the test result.

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

(m) Reference to Section 5 of this Standard, i.e. Section 5 of AS/NZS 4760:2019.

NOTE: Laboratories making a statement of conformance to this Standard are advised to ensure that such conformance is capable of being verified.

5.16 RECORD KEEPING

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

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 chosen by the donor that meets the requirements of AS/NZS ISO/IEC 17025 or AS ISO 15189 or equivalent and conforms to Section 5 of this Standard. Reports shall be sent to the donor, the requesting authority, as well as the laboratory reporting the original result. In the event that results are challenged, due to possible degradation of specimen over time, re-testing in the case of a disputed result using mass spectrometry need only detect the presence of the drug or metabolite. Accordingly, no confirmatory test cut-offs apply. Clause 5.14 Items (b) to (m), however, still applies. Replicate analysis is recommended for confirmation of disputed results.

APPENDIX A

ON-SITE SCREENING TEST PROCEDURE

(Normative)

A1 GENERAL

This Appendix sets out the procedure for on-site screening tests for drugs in oral fluid specimens.

Immunoassay devices have been developed to allow the immediate testing of oral fluid on-site. These devices allow the collector to determine the outcome of a reaction with the oral fluid that is interpreted by the collector or read by an instrument. The collector shall be trained to conduct the on-site test procedure in accordance with this Appendix, see also Clause 1.3.14.

The basis of on-site immunoassay devices is similar to that used in other applications of drug testing. It is important to note that it does have limitations due to its reliance on recognizing molecular configuration and chemical functionality. This means that this form of testing can never definitively identify a drug. It is this difference in analysis which makes it important to consider the chance of a false ‘negative’ result or a false ‘not-negative’ result due to cross-reactivity with structurally similar molecules or other factors affecting immunoreactivity. Therefore, this technique is only suitable for screening tests and requires the careful selection of an immunoassay device that is fit-for-purpose in accordance with Appendix C.

Manufacturers of on-site screening test devices should provide performance specifications at the concentrations listed in Table A1 for each of the analytes. An on-site device shall be verified as fit-for-purpose in accordance with Appendix C.

The on-site device and the quality controls shall be used and stored strictly in accordance with manufacturer’s instructions. The collector shall ensure that no aspect of the procedure causes contamination of the specimen.

If the presence of drugs cannot be excluded in the specimen, the specimen shall be split and one of these becomes a referee specimen. If sufficient volume is not available an additional specimen shall be collected and this becomes the referee specimen. The second specimen shall be collected without delay after the first to ensure specimen consistency. Both specimens shall be dispatched to the laboratory for confirmatory testing. Further screening tests are at the discretion of the laboratory conducting the confirmatory testing.

A2 PERSONNEL

The collection facility shall have access to an expert (see Clause 1.3.23).

A3 PROCEDURE

A3.1 General

An on-site test may be carried out to exclude the presence of any or all of the drugs/drug classes of drugs designated in Table A1, i.e. one or more of the listed drugs and drug classes may be screened for.

The collection facility 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 A1.

Specimen collection and on-site screening shall be conducted only after the donor signs a written informed consent form (refer to Clause 2.2.4 for details). Chain-of-custody forms shall be completed by the collector and donor (refer to Clause 2.2.5). Section 2 also covers handling and transportation of oral fluid specimens.

A3.2 Requirements for on-site drug testing

The requirements are as follows:

(a) The cut-off concentrations for the on-site device shall be those listed in Table A1.

(b) The collection facility and requesting authority shall ensure that verification of the device has been performed in accordance with Appendix C, as specified in Paragraph A1. If the manufacturer modifies the device, the verification procedure shall be repeated to confirm the device is fit-for-purpose. Re-verification of devices in accordance with Appendix C is required and shall be performed at intervals of no more than 36 months.

(c) The collection facility shall be able to demonstrate that the collector is proficient in the use of the device to carry out the on-site test.

(d) The collector shall follow the manufacturer's instructions.

(e) The on-site device shall be within its use-by-date and the test date, batch number of the oral fluid collection and/or testing device and expiry date of the device shall be recorded in the permanent record system together with evidence of two unique identifiers for the donor.

(f) The collector shall ensure that the quality control and quality assurance requirements details in Paragraph A3.3 have been undertaken and documented.

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

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

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

(j) If the on-site device cannot exclude the presence of a drug or drug class in accordance with the designated cut-off protocols, the specimens shall be dispatched to a laboratory in accordance with Section 2.

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

(l) All quality control and proficiency testing results obtained shall be used to assess the ongoing performance of the device and shall be available to requesting authorities.

A3.3 Requirements for quality control and quality assurance, including proficiency testing

On-site quality control testing upon the arrival of each batch of devices to the main or multiple storage sites shall be carried out as follows:

(a) Quality control testing shall be performed if appropriate control fluids for on-site drug testing devices are commercially available to the collection facility. In the absence of commercially available control fluids, evidence that devices are working as intended shall be established.

(b) Quality control samples shall contain all drug classes being tested for, at 50% above (high control) and 50% below (low control) the cut-off concentrations listed in Table A1.

(c) One high control and one low control sample shall be performed before use after delivery of each new lot/batch of testing devices to the end user's place of storage (e.g. collection facility). If multiple lots/batches of devices arrive in the same delivery, all batches/lots shall be evaluated.

(d) One high and one low control shall be performed each month for each batch of drug test devices that are stored in the same location. If multiple storage locations are used, this shall be replicated at each storage location.

NOTE: Where possible, devices selected for quality control testing should be drawn from separate packages of devices.

(e) Quality control testing is not required for devices that are stored and handled in accordance with the manufacturer's instructions and transported from the main storage site to remote locations for use within 14 days.

(f) The results of all quality control tests shall be recorded in the permanent record system (see Clause 1.3.38).

NOTE: The performance of quality controls should as far as possible simulate the process used with a device for testing a donor specimen including the addition of diluent as appropriate.

(g) The following procedure shall be followed in the event of a failed control test:

(i) Where a control test does not produce the expected test results for all drug classes included, a second device from the same batch shall be tested.

(ii) If the second test also does not produce the expected response for all drug classes included, the entire lot/batch transported and stored together is to be withdrawn from testing. If the second test gives the expected result, the lot/batch may continue to be used.

(iii) Withdrawal from use of faulty devices will have no effect on test results issued prior to quality control testing.

(iv) Where a lot/batch has been deemed to have failed quality control testing, an investigation into their transport and storage shall occur to minimize the chance of recurrence of this event. The facility shall have a documented procedure to carry out such an investigation and record its outcome.

(v) Where no usable on-site drug testing devices remain, specimens may still be collected, stored and transported appropriately for laboratory testing and confirmation as required.

(h) Where a suitable proficiency testing program exists, the collection facility shall participate and demonstrate a satisfactory level of performance. Where such a program is not available, the collection facility shall arrange a program with a laboratory to demonstrate on-going reliability of the on-site testing process.

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

(j) Any unacceptable proficiency results shall lead to a review of the results which may include the devices selected, device transportation and storage, staff training and competency, and on-site quality control. This process will have no effect on screening test results issued prior to the unacceptable proficiency testing.

(k) The collection facility shall have a written protocol for ensuring the integrity of specimen results in the event of a quality control or proficiency testing failure.

A4 REPORTING OF RESULTS

A4.1 General

Where on-site testing is utilized for screening tests, specimens with results equal to, or greater than cut-off concentrations listed in Table A1 shall be subjected to confirmatory testing. A confirmatory test shall be performed on such specimens before final results are issued.

TABLE A1

ON-SITE IMMUNOASSAY SCREENING TEST CUT-OFF CONCENTRATIONS

Class of drug	Cut-off concentration ng/mL
Amphetamine-type substances	50
Cannabinoids	15
Cocaine and metabolites	50
Opiates	50
Oxycodone	40

NOTE: The cut-offs apply to the concentration in the neat oral fluid specimen (obtained from the donor).

A4.2 Conditions for reporting

The conditions for reporting are as follows:

(a) A result shall be accepted only during the period of satisfactory quality control and proficiency testing. If either control fails on a repeat test, then all further testing shall cease and corrective action shall be undertaken, in accordance with the collection facility's written protocol.

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

(c) If any requested drug or 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 advises that the specimen requires further testing (RFT).

(d) A report relating to any immunoassay-based screening test shall not indicate that the specimen is 'positive' nor shall the measured concentration obtained for any drug class or drug be indicated on the report.

(e) When confirmatory test results are available they shall be reconciled with the screening test results and reported in accordance with Paragraph A4.5 and Clause 5.15.

A4.3 Test report

The test report shall include as a minimum the following:

(a) Donor identification.

(b) Statement, where applicable, that a chain-of-custody document was completed and the specimen seals were intact.

(c) Date and time of specimen collection and screening test result.

(d) Date of reporting if different to date of screening test.

(e) Device (or method) used for the collection and on-site screening test (if the same device) including lot number and expiry date.

(f) Device (or method) used for the on-site screening test [if different from Item (e)] including lot number and expiry date.

(g) The drugs or drug classes tested and the results reported, as described in Paragraph A4.2 Items (a) to (d).

(h) Reference to the cut-off concentrations listed in Table A1.

(i) Any observation made during the course of the screening test which may have affected the test result, including discrepancies.

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

(k) Statement of conformance with Appendix A of this Standard, i.e. Appendix A of AS/NZS 4760:2019.

NOTE: Collection facilities making a statement of conformance to this Standard are advised to ensure that such conformance is capable of being verified.

A4.4 Record keeping

Records shall be kept in a secure location for a period consistent with the relevant legislation or as per National Pathology Accreditation Advisory Council (NPAAC) Guidelines, or New Zealand equivalent.

A4.5 Reconciliation of test results

The process for reconciliation of the initial drug test results and confirmatory test results is the subject of agreement between the collection agency and the requesting authority.

APPENDIX B

ADDITIONAL TESTING

(Normative)

Drug use patterns including the types of drugs being used by individuals are constantly changing. Testing for drugs not listed in Tables 1 to 3 and A1 of this Standard may be required in a number of circumstances. This may be due to the regional use of a drug such as LSD or kava or due to the emergence and use of drugs such as synthetic cannabinoids or cathinone derivatives.

Drugs other than those listed in Tables 1 to 3 and A1 of this Standard may also be tested for utilizing suitably validated techniques. This testing shall occur in a laboratory, using a validated method of analysis and by applying the criteria for identification described in Sections 4 and 5 as a minimum standard. Results of testing will be reported as 'positive' ('detected') or 'negative' ('not detected'). A positive result will be a concentration at or above the LOR. The limit of reporting will be established by the laboratory and shall be included on the test report in accordance with Clause 5.15.

The table below is a non-exhaustive list of drugs and compounds that are presented as examples of compounds that may be tested for in consultation with the laboratory.

Interpretation of results by an expert (see Clause 1.3.23) is recommended.

TABLE B1

EXAMPLES OF ADDITIONAL DRUGS AND DRUG CLASSES THAT MAY BE TESTED FOR

Class of drug
Synthetic Cannabinoids
Synthetic Cathinones
Ketamine
LSD or metabolites
Fentanyl and derivatives
Methadone
Kava (kavain)
NBOMe Derivatives
Tramadol
Zolpidem
Zopiclone
Benzodiazepines

APPENDIX C

VERIFICATION OF PERFORMANCE OF DEVICES USED FOR THE COLLECTION, ON-SITE TESTING, TRANSPORT AND STORAGE OF ORAL FLUID SPECIMENS

(Normative)

C1 GENERAL

Verification of the performance of devices in accordance with this Standard shall be performed by a laboratory that shall meet the requirements of AS/NZS ISO/IEC 17025 or AS ISO 15189 or equivalent, and this Standard (AS/NZS 4760:2018 Section 5 and Appendix C). The laboratory shall use matrix-matched validated mass spectrometry methods for the relevant drug. Verification shall be performed with matrix-matched oral fluid specimens fortified with the drug for which the manufacturer has designed the device, or fortified with the drug used by the manufacturer of the on-site testing device to calibrate the device for that class of drug. Results of the verification shall be documented and available to the requesting authority, and to assess conformance. Manufacturers of devices shall inform the end user of changes to production or design that affect the performance of their products, in which case these devices shall be subject to re-verification. Laboratories which promote, sell or distribute specific devices shall not carry out validation of those devices.

Irrespective of production and design changes, re-verification of devices shall be performed at intervals of no more than 36 months.

C2 COLLECTION DEVICES

Analytical cut-offs outlined in this Standard are contingent on the dilution of the oral fluid specimen at the point of collection, and contingent on the recovery of drugs from the matrix and devices used at collection.

The collection facility shall be able to provide evidence of verification of the minimum recovery of drug (drug metabolite) from the matrix and devices used for collection and transport of the specimen to the laboratory.

Devices shall achieve minimum recovery of 70% of drug (drug metabolite).

The minimum recovery of drug (drug metabolite) to be tested shall be verified using a minimum of 10 devices. Spiking of multiple drugs (drug metabolites) into the same blank matrix is acceptable.

For each drug (drug metabolite) not more than 10% of devices shall return a recovery of less than 70%.

Verification of recovery shall be performed at concentrations above the cut-off to no more than +50% of the cut-off.

Verification shall be performed using conditions (temperature and time) relevant to those expected during routine use of the device used for collection and transport of the specimen to the laboratory and as per the manufacturer’s instructions/specifications.

When applicable, the specimen dilution shall be verified using a minimum of 20 devices by a procedure such as a gravimetric or colourimetric method. The specimen dilution of 90% of individual devices in that verification group shall be no more than ±10% of the manufacturer’s specifications.

For example, if the product or manufacturer's specifications state that one part of oral fluid is collected in three parts of diluent in the device, then the specimen dilution is [1/(1 + 3)] = 0.25. For a group of 20 such devices to be verified as fit-for-purpose, the specimen dilution of at least 18 devices shall be between 0.225 and 0.275 inclusive.

Where the collection device is used for transportation and storage, including where the collection procedure or the collection device dilutes neat oral fluid, Paragraph C4 shall also apply.

C3 ON-SITE TESTING DEVICES

The collection facility shall be able to provide evidence of verification that on-site testing devices are fit-for-purpose, i.e. returning a 'negative' result when a drug is absent or below the relevant cut-off concentration and a 'not-negative' result when a drug is present at or above the relevant cut-off concentration.

Blank matrix-matched samples shall be spiked at two concentrations, with a minimum of 10 devices for each concentration—

(a) below the cut-off, to no less than −50% of the cut-off; and

(b) above the cut-off, to no more than +50% of the cut-off.

Concentrations of drug in the fortified samples shall be confirmed by mass spectrometry. Spiking of multiple drugs into the same blank matrix is acceptable.

The device shall be subjected to blind testing using a minimum of 20 spiked samples. For each drug class tested, not more than a total of 10% shall return either false 'negative' or false 'not-negative' results. For example, if 20 devices are tested, no more than two failures in total (either false 'not-negatives' or false 'negatives') are permitted for each drug class tested.

Where the on-site testing device is used for transport and storage, including where the collection procedure or the collection device dilutes neat oral fluid, Paragraph C4 shall apply.

C4 TRANSPORTATION AND STORAGE DEVICES

The collection facility shall be able to provide evidence of verification that drugs are stable during transport and storage of the oral fluid specimen in accordance with use of the device as per the manufacturer's instructions/specification. The collection facility shall be able to provide evidence that the specimen can be transported to the laboratory under the conditions specified by the manufacturer, and if other conditions apply, performance shall be able to be demonstrated to conform for the alternative conditions. Conditions for stability studies shall also consider temperature during short term storage in the laboratory.

Verification shall be performed at two concentrations, with a minimum of 20 devices for each concentration—

(a) below the cut-off to no less than −50% of the cut-off; and

(b) above the cut-off to no more than +50% of the cut-off.

To demonstrate stability, the average concentration of the drug shall not deviate by more than 20% of the prepared quantitative concentration.

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 oral fluid 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 oral fluid, 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 leak-proof 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.

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 is required to comply 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

Further information may be found in the following:

NSW Health, *Infection control policy*, 2007.

World Health Organization, *Laboratory Biosafety Manual*, 3rd edition, Geneva 2004.

APPENDIX E

PRINCIPLES OF OPERATION

(Informative)

E1 IMMUNOASSAY (IA)

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 an oral fluid matrix.

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.

E2 GAS CHROMATOGRAPHY (GC)

Drugs present in oral fluid 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 a high boiling point 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. Each compound will have a characteristic retention time, which is defined as the time in minutes from injection to peak maximum at the detector.

E3 GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS)

Drugs are extracted from oral fluid and injected into a GC/MS system. The column operates as described in Paragraph E2 but uses a mass spectrometer as a detector. The mass spectrometer ionizes the compounds eluting from the GC column, either by electron impact (E2), 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.

E4 HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC or LC)

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.

E5 LIQUID CHROMATOGRAPHY/MASS SPECTROMETRY (LC/MS)

Drugs are extracted from oral fluid and injected into a LC/MS system. The column operates as described in Paragraph E4 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.

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. It is usual practice to monitor at least two secondary ions from at least one characteristic or diagnostic fragment ion.

E7 HIGH RESOLUTION AND ACCURATE MASS SPECTROMETRY

A mass spectral technique that enables highly accurate determination of the molecular weight of ions that is most useful in drug screening to detect unknown compounds, and uses either gas or liquid chromatography to separate drugs.

NOTES

NOTES

Standards Australia

Standards Australia is an independent company, limited by guarantee, which prepares and publishes most of the voluntary technical and commercial standards used in Australia. These standards are developed through an open process of consultation and consensus, in which all interested parties are invited to participate. Through a Memorandum of Understanding with the Commonwealth government, Standards Australia is recognized as Australia's peak national standards body.

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