

Australian Standard[®]

**Procedures for specimen collection and
the detection and quantitation of drugs
in oral fluid**



This Australian Standard® was prepared by Committee CH-039, Detection of Drugs in Oral Fluid. It was approved on behalf of the Council of Standards Australia on 10 October 2006. This Standard was published on 1 November 2006.

The following are represented on Committee CH-039:

- Australian Industry Group
 - Australian Worker's Union
 - Forensic Science South Australia
 - Institute of Environmental Science & Research, New Zealand
 - Monash University
 - National Institute of Forensic Science
 - National Measurement Institute
 - Royal College of Pathologists of Australasia
 - Royal Melbourne Institute of Technology
 - Transport Workers' Union of Australia
 - Victorian Institute of Forensic Medicine
 - The Western Australia Centre of Pathology and Medical Research
-

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the detection and quantitation of drugs
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PREFACE

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee CH-039, Detection of Drugs in Oral Fluid. After consultation with stakeholders of both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard, rather than an Australian/New Zealand Standard.

The objective of this Standard is to provide requirements and guidance on the mechanisms of incorporation of drugs in oral fluid, factors that might affect drug concentration, applicability of oral fluid for drug testing and general issues related to drug detection on-site and in the laboratory. Also to ensure that the preliminary (if not already conducted on-site) and confirmatory laboratory procedures meet the needs for the detection and quantitation of drugs in oral fluid.

The collecting agency and laboratory should maintain the utmost confidentiality of test results and should not disclose results to another party other than the requesting authority or donor.

The term ‘informative’ has been used in this Standard to define the application of the appendix to which it applies. An ‘informative’ appendix is only for information and guidance.

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STANDARDS AUSTRALIA

Australian Standard

Procedures for specimen collection and the detection and quantitation of drugs in oral fluid

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE AND APPLICATION

1.1.1 Scope

This Standard provides requirements and guidance on the mechanisms of incorporation of drugs into oral fluid, factors that might affect drug concentration, procedures for specimen collection, storage, handling, on-site initial testing and, if relevant, dispatch of human oral fluid to the laboratory. It also covers applicability of oral fluid for drug testing and general issues related to drug detection on-site and quantitation in the laboratory.

The laboratory method is intended for, but not limited to, workplace, medico-legal or court-directed detection of any or all of the following classes of drugs:

- (a) Opiates.
- (b) Amphetamine-type stimulants.
- (c) Cannabis.
- (d) Cocaine and metabolites.

NOTE: Although the use of test results is outside the scope of this Standard, where oral fluid testing is used for employment purposes, consideration should be given to the development of policies in consultation with all relevant parties, specifically in relation to the basis of requesting, testing, reporting and the proper application of results.

1.1.2 Application

The Standard addresses only the testing of specimens for workplace, medico-legal or court-directed purposes. The testing of specimens for clinical use or in sport is not covered. Oral fluid specimens collected under this Standard should only be used for the specific purpose of drug analysis, e.g. they are not to be used for DNA testing.

1.2 REFERENCED AND RELATED DOCUMENTS

1.2.1 Referenced documents

The following documents are referred to in this Standard:

AS

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

AS/NZS

2243 Safety in laboratories

2243.1 Part 1: Planning and operational aspects

2243.2 Part 2: Chemical aspects

2243.3 Part 3: Microbiological aspects and containment facilities

ISO

3696 Water for analytical laboratory use—Specification and test methods

IATA International Transport Association

Guidelines for shipping infectious substances and diagnostic specimens

1.2.2 Related documents

Attention is drawn to the following documents:

NSW Health Department, *Infection control policy* 1999.

World Health Organization, Geneva, *Laboratory Biosafety Manual*, 2nd edition, 1993.

1.3 DEFINITIONS

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

1.3.1 Accreditation

Independent attestation related to a collecting agency or laboratory conveying formal demonstration of its technical competence.

1.3.2 Adulteration

The addition of a substance in-vivo or in-vitro, excluding those integral to the on-site collection and or testing process, which may compromise the integrity of the specimen.

1.3.3 Amphetamine-type stimulants

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

1.3.4 Analyst

A person with a suitable tertiary qualification who has appropriate training and experience to perform laboratory drug testing of biological fluids.

1.3.5 Calibrator

A sample matrix containing an analyte at a known concentration used to determine the response of an assay.

1.3.6 Cannabis

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

1.3.7 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.

1.3.8 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.

NOTE: Within the laboratory appropriate documentation can account for the specimen or specimen aliquots.

1.3.9 Cocaine and metabolites

Cocaine, benzoyl ecgonine and ecgonine methyl ester.

1.3.10 Collecting agency

An accredited organization to assume professional, organizational, educational and administrative responsibility for collection, initial testing if applicable, storage and dispatch of the oral fluid specimen.

1.3.11 Collection device

A device that consists of one or more components designed to collect oral fluid and incorporates an adequacy indicator.

NOTES:

- 1 The device may contain a fluid designed to facilitate the analysis.
- 2 It may include absorbent material or a tube to directly receive the oral fluid.

1.3.12 Collection site

A place at which the specimen collection occurs and where initial testing procedures may be conducted.

1.3.13 Collector

A person who has successfully completed a course of instruction in compliance with this Standard for specimen collection, storage, handling and dispatch and received a statement of attainment in accordance with the Australian Quality Training Framework.

1.3.14 Concentration

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

1.3.15 Confirmation

Process that unequivocally determines the presence of a specific drug or metabolite above the relevant target concentration.

1.3.16 Confirmatory test

An analytical procedure that uses mass spectrometry to identify and quantify unequivocally a specific drug or metabolite.

1.3.17 Confirmed negative

A result at or below the target concentration following confirmatory testing.

1.3.18 Confirmed positive

A result above the target concentration following confirmatory testing.

1.3.19 Control specimen

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

1.3.20 Donor

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

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 demonstrated to be free of all drugs and drug metabolites being tested.

1.3.23 Initial testing

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

NOTE: This is also known as a screening test.

1.3.24 Laboratory

A place at which the analytical procedures are conducted.

NOTES:

- 1 The laboratory could include a laboratory service with a uniform quality system under the same administration.
- 2 The laboratory or laboratory service undertaking analysis according to this Standard should be accredited to the Standard or forensic equivalent.

1.3.25 Laboratory specimen

A specimen prepared for sending to the laboratory and intended for inspection and testing.

1.3.26 Laboratory record system

A book in which identifying data on each specimen collected are permanently recorded.

NOTE: Other systems which permanently record these data may be used in place of the permanent record book.

1.3.27 Negative result

A result at or below the nominated or target concentration used for initial testing.

1.3.28 Nominated concentration

A concentration expressed in units such as ng/mL, above which the drug is deemed to be 'unconfirmed', and at which a manufacturer or laboratory can show that a drug or a drug metabolite can be reliably detected by the initial testing and for which performance specifications are available.

NOTE: See Clause 1.5 and Sections 4 and 5 for further information.

1.3.29 On-site

A place at which the specimen collection occurs and where initial testing procedures may be conducted.

1.3.30 Opiates

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

1.3.31 Oral fluid specimen

Secretions in the oral cavity emanating predominantly from the major and accessory salivary glands.

1.3.32 Permanent record system

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

1.3.33 Proficiency testing program (Initial testing)

A series of qualitative tests to ensure that a collecting agency performing initial testing can operate at a level of proficiency in accordance with this Standard.

1.3.34 Proficiency testing program (Laboratory)

A series of both qualitative and quantitative tests to ensure that a laboratory can operate at a level of proficiency in accordance with this Standard.

1.3.35 Referee specimen

A second container of the collected specimen or additional specimen collected contemporaneously which is sealed at the point of collection and subsequently transported and securely stored at the confirmatory testing laboratory for analysis in the event of a disputed analysis.

1.3.36 Requesting authority

An individual, agency 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.

1.3.37 Target concentration

A concentration expressed in units such as ng/mL, that is sufficient to detect drug use by the donor.

NOTE: See Clause 1.5 and Sections 4 and 5 for further information.

1.3.38 Technician

A person who conducts on-site testing. This person has successfully completed a course of instruction in compliance with this Standard for on-site testing and received a statement of attainment in accordance with the Australian Quality Training Framework.

1.3.39 Test portion

The portion of material taken from the laboratory specimen on which the test or assay is actually carried out.

1.3.40 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.

1.3.41 Unconfirmed result

A result that requires confirmatory testing of the specimen to unequivocally determine the presence or absence of a drug.

1.4 GENERAL

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 initial testing of oral fluid at the site of collection (on-site testing) or the conduct of initial testing in an accredited laboratory using the nominated or target concentration. Negative results from initial testing are reported at this stage. Confirmatory testing of an unconfirmed result shall be performed in an accredited laboratory using a validated mass spectrometric method. Figure 1 shows a flow chart of the steps involved in specimen collection, testing and reporting results.

In comparison with other collection methods, e.g. for blood or urine specimens, the collection of oral fluid is accepted as a more convenient procedure and less intrusive to the donor's privacy. Oral fluid derives from a number of accessory glands including the parotid, submaxillary, and sublingual, and by other small glands such as labial, buccal and palatal glands, and is sometimes referred to as saliva. Oral fluid production is mediated by a number of physiological factors such as age, gender, and food intake, but some drugs may also affect the production of oral fluid. Drugs are present in oral fluid by combination of one or more processes including passive diffusion, pinocytosis, ultrafiltration, entrapment and active transport. In contrast to urine, the predominant substance present in oral fluid is often the parent drug, e.g. Δ^9 -tetrahydrocannabinol (THC). Concentrations of some drugs in oral fluid are much lower than for blood (e.g. benzodiazepines), whereas for others concentrations are higher, e.g. amphetamine-type stimulants and opiates.

An oral fluid specimen may be used to establish recent drug use at a workplace or at the roadside for drivers, but may also have other applications. There is a relationship between a blood or plasma concentration of drug and oral fluid concentration, which may allow an inference of relatively recent use of drugs to be made (within hours) compared to only being able to establish past use through urine concentrations (days to weeks). However, there is no relationship between oral fluid concentration and urine concentration. It is not appropriate to relate the presence of drugs in oral fluid to impairment, but rather, to recent use.

Oral fluid can be obtained by 'spitting' or by absorption onto an absorbent material or through employing a device that stimulates production of oral fluids. 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 on demand.

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 initial testing is immunoassay and devices are available for on-site initial testing. Laboratory-based initial and confirmatory testing procedures are similar to those used for other biological fluids.