AS/NZS 4760:2019

Australian/New Zealand Standard™

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

STANDARDS Australia

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PAEREWA AOTEAROA

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The following are represented on Committee CH-039:

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This Standard was issued in draft form for comment as DR AS/NZS 4760:2018.

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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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