



# Guidelines for Oral Fluid

Version 001, March 2011

## Foreword

The following guidelines for oral fluid were adapted from the draft United Kingdom Guidelines for Legally Defensible Workplace Drug and Alcohol Testing. The European Workplace Drug Testing Society (EWDTTS) acknowledges the substantive work completed by the steering group members of the United Kingdom Workplace Drug Testing Forum (UKWDTF).

The EWDTTS recommends that all European laboratories that undertake legally defensible workplace drug testing should use these guidelines as a template for accreditation, in addition to meeting the general requirements of the international standard ISO/IEC 17025.

## Contents

1	General.....	3
1.1	Introduction.....	3
1.2	Objectives .....	3
1.3	Chain of Custody Procedures .....	3
1.4	Laboratory Security .....	3
1.5	Laboratory Personnel.....	4
2	Oral Fluid Collection .....	4
2.1	Introduction.....	4
2.2	Oral Fluid Collector .....	5
2.3	Oral Fluid Collection Kits.....	5
2.4	Chain of Custody Forms .....	5
2.5	Oral Fluid Collection Procedures .....	6
3	Laboratory Analysis Procedures.....	6
3.1	Introduction.....	6
3.2	Sample Receipt (Accessioning) .....	6
3.3	Sample Processing .....	7
3.4	Oral Fluid Validity Testing.....	7
3.5	Testing for Other Adulterants .....	8
3.6	Laboratory Screening Tests .....	8
3.7	Standardisation of Laboratory Screening Assays .....	9
3.8	Confirmation Tests .....	9
3.9	Authorisation and Reporting of Results.....	9



## Guidelines for Oral Fluid

Version 001, March 2011

3.10	Long-Term Storage of Samples .....	10
3.11	Records .....	10
4	Quality Assurance and Quality Control.....	11
4.1	Quality Assurance.....	11
4.2	Quality Control .....	11
4.3	Laboratory Screening Tests .....	12
4.4	Laboratory Confirmation tests .....	12
4.5	External Quality Assessment.....	12
4.6	Sub-contracting.....	13
5	Interpretation of Results .....	13
5.1	Toxicology Review.....	13
6	Challenges to Drug Test Results.....	13
	Appendix A Laboratory Organisation.....	15
	Appendix B Oral Fluid Collection Protocol .....	18
	Appendix C Example of a Donor's Statement of Informed Consent .....	21
	Appendix D Some Examples of Fatal Flaws in the Chain of Custody .....	22
	Appendix E Acceptable Screening Techniques .....	23
	Appendix F Recommended Maximum Cut-Off Concentrations for Screening Tests .....	24
	Appendix G Recommended Cut-Off Concentrations for Confirmation Tests .....	25
	Appendix H Medical Review.....	26



# Guidelines for Oral Fluid

Version 001, March 2011

## 1 General

### 1.1 Introduction

These guidelines represent an overview of the best practice for European laboratories providing oral fluid workplace drug testing services. They are designed to ensure that the entire drug testing process is conducted to give accurate and reliable information about a donor's drug use. These guidelines represent the best practice to maintain the legal defensibility of a drug test when tested by either an employment tribunal or a court of law.

### 1.2 Objectives

- To provide a common framework for European providers of oral fluid workplace drug testing services.
- To promote and harmonise standards by providing guidelines which are accepted at a European level.
- To ensure that the processes undertaken are capable of legal scrutiny.
- To provide safeguards to protect the dignity of the specimen donors and the validity of the specimen.
- To define for laboratories common quality assurance and quality control criteria that are capable of being accredited by an external body.

### 1.3 Chain of Custody Procedures

Laboratories must use chain of custody procedures to maintain control and accountability of samples from receipt through completion of testing, reporting of results, during storage, and continuing until final disposal of samples.

Chain of custody records may be maintained on paper or in computerised form, for a minimum accessible period of 5 years or as recommended by a recognised body.

### 1.4 Laboratory Security

Drug testing laboratories must have a robust security system to ensure that no unauthorised personnel gain access to the laboratory processes or to areas where samples or records are stored.

Unescorted access to these secured areas must be limited to authorised individuals. The laboratory must maintain a record that documents the entry and exit of all visitors to the secured laboratory



## Guidelines for Oral Fluid

Version 001, March 2011

areas.

The laboratory must maintain a record of all staff who are authorised to enter the secure laboratory areas. This list must be reviewed and updated on a regular basis.

### 1.5 Laboratory Personnel

Only staff who are suitably qualified and whose competence has been formally assessed can work within the laboratory. The key roles, qualifications and responsibilities are outlined in Appendix A. It is acceptable for individuals to have responsibility to carry out more than one role.

The laboratory must keep records that establish the individual's competency for the functions performed. The individual's file must include an up-to-date *curriculum vitae* listing qualifications and previous employment experience, training and competence assessment records for the current tasks performed.

All laboratory personnel must have received training in Health and Safety issues, the Control of Substances Hazardous to Health (COSHH) Regulations and other relevant legislation.

## 2 Oral Fluid Collection

### 2.1 Introduction

This is the first link in the chain of custody process which, when reconstructed at a later date, can be used to prove that the final result belongs to the specimen collected.

The collection process must be carried out by someone formally assessed as competent and authorised to carry out the collection. Standard Operating Procedures (SOPs) must be written for the collection process, the storage of collection devices, the training of Collecting Officers and the shipping of the collected specimen to the laboratory. These procedures must be followed precisely.

Collection procedures must cover the following aspects:

- Privacy and security of the specimen collection site
- Steps to ensure that the specimen collection is observed
- Steps to protect against tampering and adulteration
- Identification of the individual giving the specimen
- Evidence of the written informed consent of the individual to the analysis of the specimen (an example is given in Appendix C).



## **Guidelines for Oral Fluid**

Version 001, March 2011

- Disclosure of recent medication, or evidence that the individual was advised of the significance of recent medication

All specimens for legally defensible drug testing must be collected under circumstances that respect the dignity of the individual and guarantee the validity of the sample.

Suitable records must be made when the specimen is collected to prove that the specimen collected and the sample received by the laboratory is one and the same.

### **2.2 Oral Fluid Collector**

The manufacturer of the collection device must demonstrate that the device in no way impairs the ability of the laboratory to detect the drugs at the cut off levels recommended in these guidelines.

The collection device should not contain additives that will stimulate saliva production.

It is recommended that the device used to collect the oral fluid sample collects a known volume.

This may be achieved through an inbuilt volume indicator or measurement of the volume on submission to the laboratory.

It must be demonstrated by the manufacturer that the device will collect the stated known volume within +/- 10%.

The laboratory should be able to clearly identify which collection device has been used to collect the sample.

### **2.3 Oral Fluid Collection Kits**

The collection kit should comprise the following components:

- Specimen collection device(s)
- Chain of custody form.
- A unique identifier that links the chain of custody form and sample containers.
- At least two sample containers, demonstrably clean and unused.
- Tamper-evident seal for each container
- Packaging components that satisfy current postal and courier regulations.

### **2.4 Chain of Custody Forms**

The minimum information required on the Chain of Custody Form is:

- Unique identification to link the form to the specimen container(s) (typically a barcode)



## Guidelines for Oral Fluid

Version 001, March 2011

label).

- Information uniquely identifying the donor.
- Evidence that the donor identity has been confirmed.
- Evidence that the donor has given informed consent for the specimen to be tested.
- Date and time of collection.
- Names and signatures of all individuals who had custody of the specimen during the collection process.
- The opportunity to record any medication prescribed or non-prescribed that may have been taken in the days prior to the specimen being collected.

### 2.5 Oral Fluid Collection Procedures

One sample is collected and then split in the presence of the donor into two separate containers labelled sample A and sample B. However it is acknowledged that oral fluid samples are limited in volume and therefore it may be necessary to collect two samples at the same time and label them as sample A and B. If two samples are collected then they must be sent together to the testing facility.

An example oral fluid collection protocol is detailed in appendix B.

## 3 Laboratory Analysis Procedures

### 3.1 Introduction

When samples are received at the laboratory, initial checks on the sample's chain of custody and appearance are carried out. If the sample passes these checks a portion of the sample is taken and goes through initial screening tests for the presence of drugs.

If the screening results are all negative no further analyses are necessary. However if the screening tests carried out indicate the possible presence of a drug (above a pre-defined cut-off level) a confirmation test to prove or disprove the presence of the drug indicated by the screening test must be carried out on another portion of the sample. A SCREEN-ONLY PRESUMPTIVE POSITIVE TEST IS NOT CONSIDERED TO BE LEGALLY DEFENSIBLE.

### 3.2 Sample Receipt (Accessioning)

The laboratory should receive at least two sealed sample containers and a corresponding chain of



## Guidelines for Oral Fluid

Version 001, March 2011

custody form.

At least one of these (referred to, in this document, as the "B" container) must be retained unopened and stored in conditions that reflect the storage of the sample under test (referred to, in this document, as the "A" container).

When a sample is received in the laboratory:

- Its packaging must be examined for evidence of tampering in transit.
- The information on the sample containers within the package must be compared with the information on the accompanying chain of custody form.
- Any discrepancies must be noted and, where appropriate, reported to the customer. Some minor discrepancies may be tolerated in the documentation without termination of the analysis. These must be agreed with the customer prior to analysis.
- Appendix D lists examples of fatal flaws in the chain of custody and is provided for guidance. Flaws of this nature would normally result in the sample not being tested.

### 3.3 Sample Processing

Separate representative portions (aliquots) of the sample in container 'A' will be used for the screening and confirmation tests. Aliquots must be taken in such a manner that excludes the possibility of contamination.

**Short-term storage:** samples that are not currently undergoing analysis must be refrigerated.

**Long-term storage:** once analyses are complete, samples MUST be frozen.

The A and the B samples must be stored under identical conditions.

The quality control requirements in section 4 must be satisfied when conducting either screening or confirmation tests, either on single samples, or samples grouped in batches.

### 3.4 Oral Fluid Validity Testing

The minimum validity test that must be completed for oral fluid is the visual inspection of the sample(s). The laboratory may also test for other adulterants.

A sample should be reported as e.g. "Sample unsuitable for analysis" in the following situations:

- Interference occurs on immunoassay drug tests on two separate aliquots (i.e. valid



## Guidelines for Oral Fluid

Version 001, March 2011

- immunoassay drug test results cannot be obtained);
- Interference with the drug confirmatory assay occurs on at least two separate aliquots of the sample and the laboratory is unable to identify the interfering substance(s);
- The physical appearance of the sample is such that testing the sample may damage the laboratory's instruments

### 3.5 Testing for Other Adulterants

Additional validity tests should be considered when the following conditions are observed:

- Abnormal physical characteristics (e.g., unusual colour or texture, unusual odour, semi-solid characteristics);
- Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or possible unidentified interfering substance or adulterant.

### 3.6 Laboratory Screening Tests

The initial screening test must use an appropriate technique. Appendix E contains a list of currently agreed and accepted techniques. The assay, using the selected technique, must be validated prior to its use.

Recommended maximum screening calibration cut-off concentrations for workplace drug testing are listed in Appendix F. These recommended cut-off concentrations may be subject to changes reflecting advances in technology and knowledge.

Cut-off concentrations for substances not indicated in Appendix F will need to be agreed with the customer taking into account the performance of the assays to be used and the pharmacokinetics of the drugs involved.

All screening test results must be reviewed with regard to the results of the validity tests performed.

Samples that test negative on all the initial screening tests and pass the validity tests must be reported as negative, and the samples can be disposed of as agreed with the customer.

Samples that test negative on all the initial screening tests but fail the validity tests may be further investigated to determine the reason why.

Samples which test positive for any drug following the initial screening test must have the



## **Guidelines for Oral Fluid**

Version 001, March 2011

presence of the drug confirmed (refer to section 3.8 Confirmation Tests).

### **3.7 Standardisation of Laboratory Screening Assays**

All assays must be calibrated against appropriate standards and by following laboratory protocols based on the manufacturer's recommendations or validated alternatives.

The assay must be calibrated against one named compound, and the cross-reactivity to other related compounds must be determined.

The customer must be informed of the expected cross-reactivity to these compounds.

All commercial assay systems should be CE marked.

### **3.8 Confirmation Tests**

The presence of the drugs indicated by a positive screening result must be confirmed using a chromatographic technique in combination with mass spectrometry (e.g. GC-MS or LC-MS). All confirmations must be quantitative. The confirmation method must be materially different to the screening technique (e.g. where GC or LC is used for screening).

Recommended confirmation cut-off concentrations for workplace drug testing are given in Appendix G.

Confirmation cut off concentrations may be subject to change as advances in technology or other considerations warrant identification of substances at other concentrations.

Confirmation cut-off levels for substances not indicated in Appendix G must be agreed with the customer taking into account the performance of the assays to be used and the pharmacokinetics of the drugs involved.

Samples that are below the agreed cut-off concentration must be reported negative. Normally no further testing for drugs will be undertaken and the samples may be discarded as per the customer agreed timetable.

Samples that contain drugs and/or metabolites at concentrations greater than or equal to the agreed cut-off level must be reported positive.

Laboratories must adhere to national and international guidelines that specify additional criteria for chromatographic and mass spectral acceptability.

### **3.9 Authorisation and Reporting of Results**

Before any laboratory test result is released, the results must be reviewed and certified as accurate



## Guidelines for Oral Fluid

Version 001, March 2011

by a competent member of staff.

At a minimum, the report must include the specimen identification number and the test result (positive/negative) for each sample submitted.

Only drugs that have been confirmed by a recognized confirmation test can be reported as positive.

Samples that fail integrity or validity tests must be identified to the customer on the report.

The laboratory must define and agree the meaning of all terms used in the report to the customer.

Laboratory results should not be provided verbally.

Written or electronic results must be transmitted to the customer's designated representative in a manner that will ensure confidentiality of the information.

### 3.10 Long-Term Storage of Samples

Currently long-term deep frozen storage (-15°C or below) indicates that most positive samples will remain suitable for any necessary retest.

Unless otherwise authorised in writing by the customer, drug testing laboratories must retain all samples confirmed positive in properly secured long-term frozen storage for a minimum of 1 year.

Within this one-year period the customer may request the laboratory to retain the sample for an additional period of time. If no such request is received, the laboratory may discard the sample after the end of 1 year, except that the laboratory shall be required to maintain any samples known to be under legal challenge for a further agreed period.

Samples must be retained within the secure laboratory area until the disposal date agreed with the customer.

### 3.11 Records

The laboratory must maintain and make available for an agreed period, documentation of all aspects of the testing process involved in the generation of a positive result.

The required documentation must include:

- Training and competency records for all individuals authorised to have access to samples and sample data.
- Chain of custody forms.
- Quality assessment/quality control records.
- Standard operating procedures



## **Guidelines for Oral Fluid**

Version 001, March 2011

- All test data (including calibration curves and calculations for determining test results)
- Reports
- Records of proficiency testing and computer generated data

The laboratory will be required to maintain documents for any sample under legal challenge for a further agreed period.

Document control must be managed in accordance with ISO/IEC 17025 requirements and records containing details of individuals should be dealt with in line with European Data Protection Legislation.

### **4 Quality Assurance and Quality Control**

#### **4.1 Quality Assurance**

Drug testing laboratories must have a quality management system which encompasses all aspects of the testing process including but not limited to:

- Sample receipt
- Chain of custody
- Security and reporting of results
- Screening and confirmation testing
- Certification of calibrators and controls
- Validation of analytical procedures

Quality assurance procedures shall be designed, implemented and reviewed to monitor the conduct of each step of the testing process.

The laboratory must be accredited to ISO/IEC 17025 for Workplace Drug Testing in Oral Fluid by a recognised external accreditation body.

#### **4.2 Quality Control**

Calibrators and controls shall be prepared using either certified drug reference materials or certified standard solutions obtained from where possible two commercial manufacturers and should be appropriate to the matrix. If two manufacturers are not feasible then the controls should be taken from separate lots from the same manufacturer.

The calibrators and controls shall be properly labelled as to content, concentration and expiry date. All standards (e.g. pure reference materials, stock standard solutions, purchased standards) shall



## Guidelines for Oral Fluid

Version 001, March 2011

be labelled with the following:

- Date received (if applicable).
- Date prepared or opened.
- Date placed in service.
- Expiration date.

All data acquired on control samples must be recorded in such a way as to facilitate interpretation of control results and trends.

### 4.3 Laboratory Screening Tests

These are the minimum requirements for the suitable control of all laboratory screening tests.

Assays must be calibrated weekly or when quality control samples indicate poor performance.

Control samples at concentrations of approximately 50% below and above the cut-off concentration for each drug group must be included in every batch of samples. These must be sourced independently from calibrators.

Quality control samples must comprise at least 5% of the total number of samples in each batch being analysed.

### 4.4 Laboratory Confirmation tests

These are the minimum requirements for the suitable control of all laboratory confirmation tests:

- A system suitability check must be carried out prior to the analysis of samples.
- A calibration curve must include at least 3 calibration points and a blank. The calibration points must bracket the cut-off concentration.
- Quantitative analysis must be carried out using internal standardisation. The use of deuterated internal standards, when obtainable, is recommended.
- An independently prepared control sample at a concentration of approximately the cut-off concentration for each drug must be included in every batch of samples analysed.
- Checks on assay drift and carry-over must be carried out at appropriate intervals within each batch run.

### 4.5 External Quality Assessment

The laboratory must take part in appropriate external quality assessment schemes. Performance outside the criteria laid down by the scheme must be rectified.



## **Guidelines for Oral Fluid**

Version 001, March 2011

### **4.6 Sub-contracting**

Drug testing laboratories should carry out all laboratory work with their own personnel and equipment. If it is necessary to sub-contract, then the sub-contracted laboratory must be accredited by a recognised external accrediting body and compliant with these guidelines.

Analyses undertaken by sub-contracted laboratories must be identified on the test report to the customer.

## **5 Interpretation of Results**

A confirmed analytical positive result may be due to medication (prescribed or over-the-counter) or to dietary causes. An essential part of the drug testing process is the final review of analytical results.

The interpretation is best carried out by a suitably qualified medical practitioner (Medical Review Officer - see Appendix H) who can consult with the laboratory toxicologist, the donor, and the donor's medical practitioner.

### **5.1 Toxicology Review**

A toxicologist must be available to advise the customer and/or Medical Review Officer regarding queries with test results.

The toxicologist cannot issue a negative report for a positive analytical result even if the test result can be explained by e.g.: declared medication, diet, medical condition.

## **6 Challenges to Drug Test Results**

In situations where there is a challenge to the results of a positive drug test result, the following guidelines must be used.

It is recommended that the B sample only be released for analysis to a drug testing laboratory that is capable of carrying out the analysis of the identified drug or adulterant, has been accredited by a recognised external accrediting body and is compliant with these guidelines.

This release requires authorisation from both the customer and the donor.

The release must be supported by chain of custody procedures that can withstand legal scrutiny



## Guidelines for Oral Fluid

Version 001, March 2011

and include information about the findings of the original test and the cut-offs used for the test.

The original laboratory must retain the residue of the original sample, so that it can be compared with the B sample at a later date, if required.

All laboratories that undertake B sample testing must be able to demonstrate that they can accurately determine the concentration of a drug or metabolite at 50% of the recommended confirmation cut-off concentration listed in Appendix G (or the cut-off used for the original test, whichever is the lower).

On receipt in the testing laboratory, the B sample should follow chain of custody procedures as outlined in sections 3.2 and 3.3. It is recommended that the laboratory should carry out validity checks outlined in section 3.4 prior to carrying out the confirmation analysis. Only those drugs identified for confirmation testing should be looked for and reported on within 10 working days from receipt.

The final report on the B sample must say either that there was no drug found, or a named drug was found at a level that is either consistent or inconsistent with the level in the corresponding A sample.

The determinant as to whether a drug is found or not is the limit of quantification (LOQ) quoted for the method used to confirm the presence of the drug.

Confirmation cut-off levels are not to be used as the determinant. There must be no comment on the final report that states whether the sample is positive or negative.



## Guidelines for Oral Fluid

Version 001, March 2011

### ***Appendix A Laboratory Organisation***

#### **Laboratory Head**

There must be one person who has overall responsibility for the professional, organisational, educational, and administrative activities of the drug testing facility.

This person is responsible for the day-to-day management of the drug testing laboratory.

Some of the functions may be delegated to other appropriately qualified personnel but the overall responsibility for any delegated functions will remain with the designated Laboratory Head (typically the Laboratory Manager).

#### Qualifications:

- At least a degree or degree equivalent in, for example, the chemical or biological sciences or medical technology.
- Training, experience and a thorough understanding of chain of custody procedures, quality control and assessment practices, and the theory and practice of all analytical methods and procedures used in the laboratory.

#### Responsibilities:

- Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug-testing laboratory.
- Assure the continued competency of laboratory personnel by documenting their in-service training and competence testing, and reviewing their work performance.
- Ensure that the laboratory has a manual of Standard Operating Procedures (SOP's), which is complete, up-to-date, and available for personnel performing tests, and followed by those personnel.
- Maintain a quality control program to assure the proper performance and reporting of all test results in compliance with SOP's.
- Ensure successful participation in an appropriate External Quality Assessment Scheme (EQAS).
- Maintain acceptable analytical performance for all controls and standards; for maintaining quality control testing.
- Assure and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.
- Ensure that all remedial actions necessary to maintain satisfactory operation and



## Guidelines for Oral Fluid

Version 001, March 2011

performance of the laboratory are taken (e.g. in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of EQAS results), and that sample results are not reported until all appropriate corrective actions have been taken.

- Ensure that the results provided are accurate and reliable.

### Authorising Scientist

A person responsible for the review and certification of pertinent data and quality control results, prior to release of analytical results.

#### Qualifications:

- At least a degree or degree equivalent in, for example, the chemical or biological sciences or medical technology.
- Training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, including EQA, and analytical procedures relevant to the results that the individual certifies.
- Ensure that the results provided are accurate and reliable.

### Laboratory Analyst

A person responsible for undertaking the day-to-day analytical procedures.

#### Qualifications:

- Appropriate training, competence testing and experience in the theory and practice of the procedures used in the laboratory.

#### Responsibilities:

- Maintenance of chain of custody.
- Day-to-day analytical procedures following SOP's.
- Remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

### Toxicologist

A person responsible for interpreting an analytical result for the customer or the customer's designated Medical Review Officer.



## Guidelines for Oral Fluid

Version 001, March 2011

### Qualifications:

- At least a degree or degree equivalent in, for example, the chemical or biological sciences or medical technology.
- Training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual interprets.

### Responsibilities:

- The interpretation of drug test results to the customer or the customer's designated medical representative.

### **Expert Witness**

A person to present evidence to administrative or disciplinary proceedings that are based on analytical results reported by the laboratory.

The qualifications and experience of this individual must be acceptable to the court or enquiry.

### **Other Personnel**

Other technical or non-technical staff must have the necessary training and skills for the tasks assigned.

### **Quality Manager**

The person who has responsibility for quality assurance within the laboratory.

### Qualifications:

- Training and experience in auditing in accordance with ISO/IEC 17025 or an equivalent standard.

### Responsibilities:

- Monitoring the laboratory's quality control programme, quality assessment and quality manual.
- Auditing the laboratory operations in accordance with these guidelines.
- Verify that all remedial actions necessary to maintain satisfactory operation and performance of the laboratory are taken.



## **Guidelines for Oral Fluid**

Version 001, March 2011

### ***Appendix B Oral Fluid Collection Protocol***

*(Note: Only formally competence tested and authorised persons may act as collection officers. Medical qualification are NOT required for collection officers.)*

#### **I) Collection Site**

Procedures shall provide for a designated collection site to be secure. During the collection process the collection site must be dedicated solely to sample collection and comply with all local health and safety requirements.

#### **II) Chain of Custody**

During the collection process chain of custody forms will be completed fully by the collection officer and donor.

#### **III) Access to Authorised Personnel Only**

Only authorised personnel shall be permitted in any part of the designated collection site when oral fluid samples are being collected or stored.

#### **IV) Identification of the donor.**

When a donor arrives at the collection site, the collection officer will request that the donor presents photographic identification. If the donor does not have acceptable photographic identification, the collection officer will obtain a positive identification of the donor by an authorised supervisor or manager within the parent organisation. If the donor's identity cannot be established, the collection officer will not proceed with the collection.

#### **V) Privacy**

Procedures for collecting oral fluid specimens shall allow, where possible, for donor privacy during sample collection.

#### **VI) Integrity of the Specimen**

The collection officer must adopt procedures to minimise the risk of adulteration of the specimen during collection. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:



## Guidelines for Oral Fluid

Version 001, March 2011

- a) Throughout the collection process, the collection officer will note any unusual behaviour of the donor on the chain of custody form.
- b) The collector will ask the donor to remove any articles from the mouth e.g. chewing gum.
- c) The collector will wait for 10 minutes to observe that the donor has nothing in their mouth.
- d) Oral fluid samples will then be collected from the donor in strict accordance with the standard operating procedure and the manufacturer's instructions for the collection system being used.
- e) Upon receiving the specimen from the donor, the collection officer will:
  - Check the volume of oral fluid on/in the specimen collection device.
  - Inspect the specimen to determine its colour and appearance for any signs of contaminants.
- f) Any unusual findings will be noted on the chain of custody form.
- g) If the volume is less than that required by the laboratory, the specimen will be discarded and a second specimen will be collected.
- h) If the donor is unable to provide a suitable volume of oral fluid for analysis then the collection process is stopped and advice should be sought.
- i) Both the donor and the collection officer will keep the specimen container(s) in view at all times prior to the oral fluid specimen(s) being sealed and labelled.
- j) The collection officer will request the donor to observe the transfer of the specimen to two sample containers and the attachment of the tamper-evident seal to the containers. The tamper-evident seal ensures that any tampering with the specimen will be evident to laboratory personnel during the laboratory receipt.
- k) The specimen container(s) will have an identification label that contains at a minimum; the date, the donor's specimen number and the donor's signature/initials. The collection officer will enter all information on the chain of custody form to identify the origin of the specimen. Both specimen containers and all pages of the chain of custody will be labelled at the time of collection with a unique identifier.
- l) The collection officer will explain the significance relating to the drugs and medicines consumed within a minimum of 7 days prior to the provision of the oral fluid specimen. The donor will be given the opportunity to declare any medication used.
- m) The donor will be asked to read and sign a statement on the chain of custody form certifying that the specimen identified on the form was in fact the specimen provided by



## **Guidelines for Oral Fluid**

Version 001, March 2011

the donor and giving informed consent for the work to be undertaken. Appendix C gives an example of a Donor's Statement of Informed Consent.

- n) The collection officer will complete the specimen chain of custody form and package with the oral fluid specimen ready for dispatch together to the analytical laboratory. If the specimen is not dispatched at once, the collection officer during storage prior to dispatch, must give appropriate consideration to the temperature and security of the specimens. It is advised that the specimens should be refrigerated whenever possible (do not freeze).
- o) Other pages of the chain of custody form will be given or forwarded to the appropriate persons.
- p) The collection officer and the donor will be present throughout the procedures outlined in the paragraphs of this section.

### **VII) Transportation to Laboratory**

Collection officers will arrange to dispatch the collected specimens to the drug-testing laboratory. The specimens will be placed in containers designed to minimise the possibility of damage during shipment. Since specimens and the corresponding documents are sealed in packages that would indicate any tampering during transit to the laboratory by couriers, carriers, and postal services, usually there is no requirement for documented chain of custody procedures for the transport of the package.



## Guidelines for Oral Fluid

Version 001, March 2011

### ***Appendix C Example of a Donor's Statement of Informed Consent***

I confirm that I have provided a sample of my oral fluid to the specimen collector. I have observed the specimen being placed and sealed in the specimen containers and I confirm that the information on this form and on the specimen labels is correct. I hereby give permission for a minimum of two sealed specimen containers to be sent to the laboratory and I consent that they be tested for evidence of drug use and for tests to be carried out to confirm the validity of the sample. Furthermore, I understand that the results will be communicated confidentially to the employer or a designated representative.

I consent to the above.

Donor's Name (Block Capitals):

Donor's Signature:

Date:

Donor's identifier on the specimen labels (if different from above):



## **Guidelines for Oral Fluid**

Version 001, March 2011

### ***Appendix D Some Examples of Fatal Flaws in the Chain of Custody***

1. Barcode mismatches or absent
2. No documentation received with the sample
3. No written consent to test from the donor
4. Seals broken or tampered with on the sample container/transport container
5. No seals
6. Only 1 sample received (if two samples are required)
7. Insufficient sample for complete analysis
8. Leaking sample



## **Guidelines for Oral Fluid**

Version 001, March 2011

### ***Appendix E Acceptable Screening Techniques***

1. Immunoassays
2. Gas Chromatography
3. High Performance Liquid Chromatography
4. All chromatographic techniques hyphenated to mass spectrometry.
5. Capillary Zone Electrophoresis



## Guidelines for Oral Fluid

Version 001, March 2011

### ***Appendix F Recommended Maximum Cut-Off Concentrations for Screening Tests***

#### Laboratory Screen Test Cut-Off Concentration in neat oral fluid (ng/ml)

Amphetamine group	40
Benzodiazepines group	10
Cannabis (THC)	10
Cocaine metabolites	30
Opiates (Morphine)	40
6-AM	4
Methadone or metabolites	50
Barbiturates	60
Buprenorphine or metabolites	5
Propoxyphene or metabolites	40

#### **Note:**

1. These recommended cut-off values may be subject to changes as advances in technology or other considerations warrant identification of these substances at other concentrations.
2. Cut-off levels for substances not indicated in Appendix F will need to be agreed with the customer taking into account the performance of the assays to be used.
3. Dilution of the sample has to be corrected for when the screen results are interpreted.



## Guidelines for Oral Fluid

Version 001, March 2011

### ***Appendix G Recommended Cut-Off Concentrations for Confirmation Tests***

#### Confirmation Test Cut-Off Concentration in Neat Oral Fluid (ng/ml) (Total)

Amphetamines	
Amphetamine	30
Methamphetamine	30
MDMA	30
Other members of the amphetamine group	30
Benzodiazepines	
Temazepam	10
Oxazepam	10
Desmethyldiazepam	10
Other members of the benzodiazepine group by agreement with the customer.	
Opiates	
Morphine	40
Codeine	40
Dihydrocodeine	40
6-Monoacetylmorphine	4
Cannabis (THC)	2
Cocaine metabolite	8
Methadone or metabolites	20
Buprenorphine or metabolites	5
Propoxyphene or metabolites	40

#### **Note:**

1. These recommended cut-off values may be subject to changes as advances in technology or other considerations warrant identification of these substances at other concentrations.
2. Cut-off levels for substances not indicated in Appendix G will need to be agreed with the customer taking into account the performance of the assays to be used.
3. Dilution of the sample has to be corrected for, when results are interpreted unless the cut-offs agreed with the customer reflect the concentration in the diluted sample.
4. The Limit of Quantification (LOQ) for each drug has to be no more than 1/5 of the confirmation cut off level.



## Guidelines for Oral Fluid

Version 001, March 2011

### ***Appendix H Medical Review***

- (a) The Medical Review Officer (MRO) is a medical physician with responsibility for interpreting laboratory results.
- (b) A medical physician will have greater access to medical records than a toxicologist and may therefore be in a better position to provide interpretation of positive analytical results.
- (c) The MRO must have specialist knowledge of and training in oral fluid
- Specimen collection procedures.
  - Analytical procedures.
  - Chain of Custody.
  - Alternative explanations for positive and negative analytical results in oral fluid.
- (d) The MRO can issue a negative report for a positive analytical result if the test result is likely to be due to the use of declared medication, or a valid alternative explanation has been found.
- (e) The service provider may provide access to an independent medical review service.