USING e-ANNOTATION TOOLS FOR ELECTRONIC PROOF CORRECTION

Required software to e-Annotate PDFs: Adobe Acrobat Professional or Adobe Reader (version 8.0 or above). (Note that this document uses screenshots from Adobe Reader DC.)
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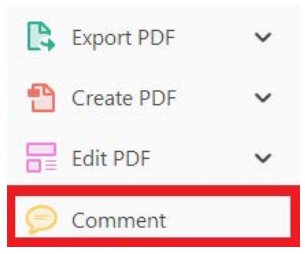
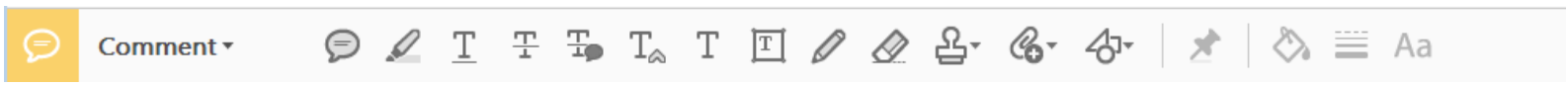
Once you have Acrobat Reader open on your computer, click on the Comment tab (right-hand panel or under the Tools menu).



This will open up a ribbon panel at the top of the document. Using a tool will place a comment in the right-hand panel. The tools you will use for annotating your proof are shown below:

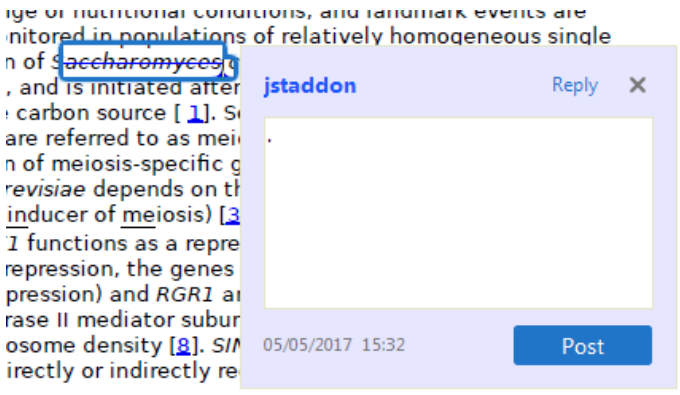


1. Replace (Ins) Tool – for replacing text.

Strikes a line through text and opens up a text box where replacement text can be entered.

How to use it:

- Highlight a word or sentence.
- Click on .
- Type the replacement text into the blue box that appears.

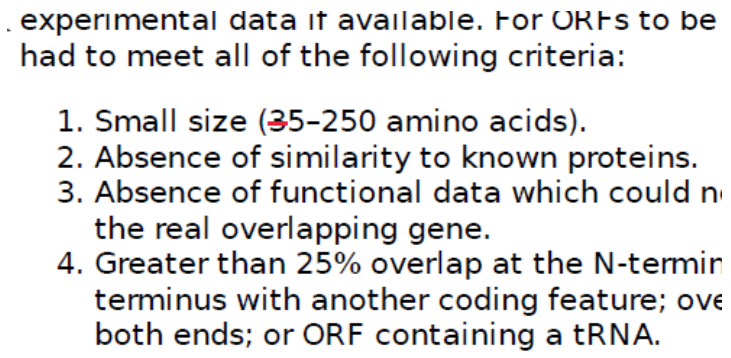


2. Strikethrough (Del) Tool – for deleting text.

Strikes a red line through text that is to be deleted.

How to use it:

- Highlight a word or sentence.
- Click on .
- The text will be struck out in red.

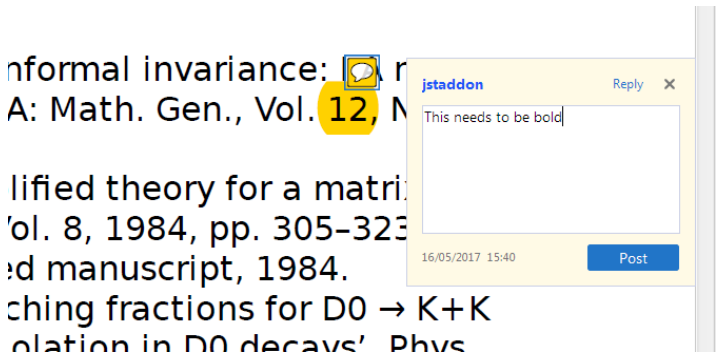


3. Commenting Tool – for highlighting a section to be changed to bold or italic or for general comments.

Use these 2 tools to highlight the text where a comment is then made.

How to use it:

- Click on .
- Click and drag over the text you need to highlight for the comment you will add.
- Click on .
- Click close to the text you just highlighted.
- Type any instructions regarding the text to be altered into the box that appears.

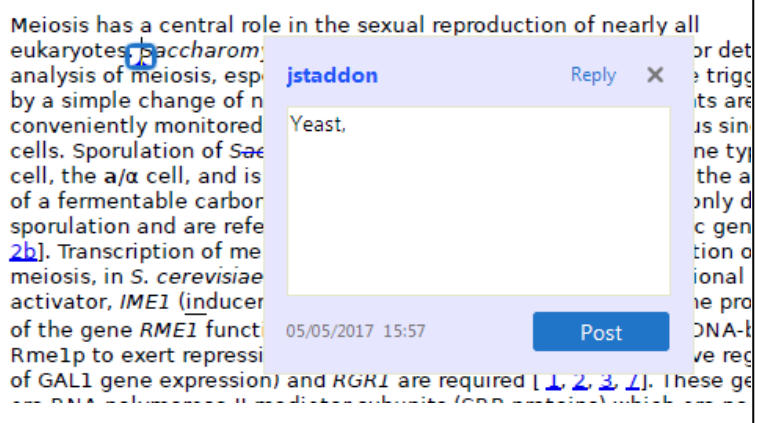


4. Insert Tool – for inserting missing text at specific points in the text.

Marks an insertion point in the text and opens up a text box where comments can be entered.

How to use it:

- Click on .
- Click at the point in the proof where the comment should be inserted.
- Type the comment into the box that appears.



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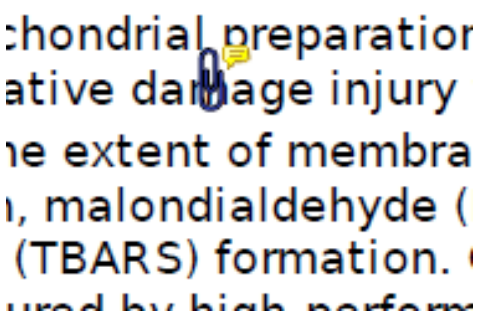
5. Attach File Tool – for inserting large amounts of text or replacement figures.

Inserts an icon linking to the attached file in the appropriate place in the text.

How to use it:

- Click on  .
- Click on the proof to where you'd like the attached file to be linked.
- Select the file to be attached from your computer or network.
- Select the colour and type of icon that will appear in the proof. Click OK.

  The attachment appears in the right-hand panel.

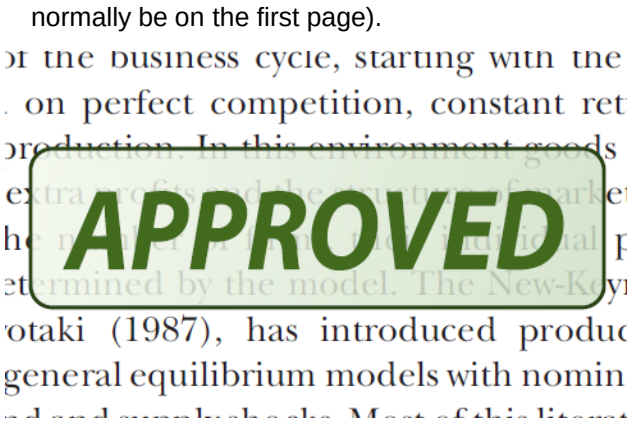


6. Add stamp Tool – for approving a proof if no corrections are required.

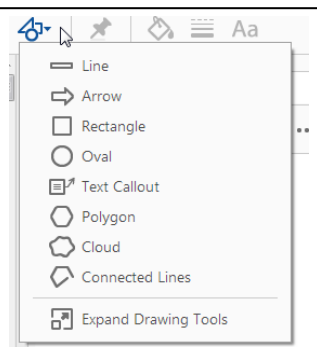
Inserts a selected stamp onto an appropriate place in the proof.

How to use it:

- Click on  .
- Select the stamp you want to use. (The Approved stamp is usually available directly in the menu that appears. Others are shown under *Dynamic*, *Sign Here*, *Standard Business*).
- Fill in any details and then click on the proof where you'd like the stamp to appear. (Where a proof is to be approved as it is, this would normally be on the first page).



Drawing tools available on comment ribbon

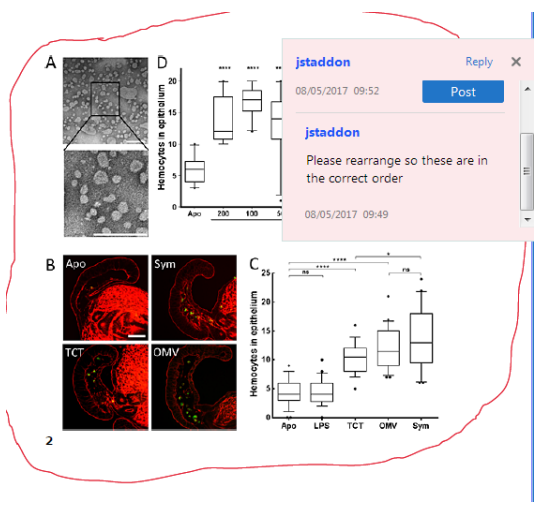


7. Drawing Markups Tools – for drawing shapes, lines, and freeform annotations on proofs and commenting on these marks.

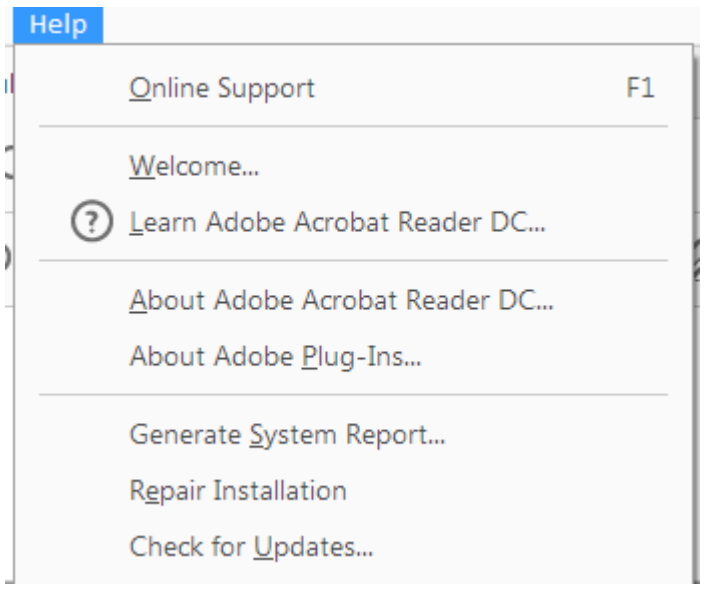
Allows shapes, lines, and freeform annotations to be drawn on proofs and for comments to be made on these marks.

How to use it:

- Click on one of the shapes in the Drawing Markups section.
- Click on the proof at the relevant point and draw the selected shape with the cursor.
- To add a comment to the drawn shape, right-click on shape and select *Open Pop-up Note.*
- Type any text in the red box that appears.



For further information on how to annotate proofs, click on the Help menu to reveal a list of further options:



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RESEARCH ARTICLE

European guidelines for workplace drug testing in oral fluid

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These guidelines for Legally Defensible Workplace Drug Testing have been prepared and updated by the European Workplace Drug Testing Society (EWDTS). The European Guidelines are designed to establish best practice procedures whilst allowing individual countries to operate within the requirements of national customs and legislation. The EWDTS recommends that all European laboratories that undertake legally defensible workplace drug testing should use these guidelines as a template for accreditation. These guidelines are relevant to laboratory-based testing only. These guidelines follow current best practices and are constantly under review.

KEYWORDS

EWDTS, guidelines, oral fluid, workplace drug testing

1 | GENERAL

1.1 | Introduction

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

The updated oral fluid guidelines have been communicated within the members of EWDTS and experts from different countries, and accepted by the board.

In the age of globalisation, the legal basis for workplace drug and alcohol testing has a complex structure consisting of international, European, and national laws, acts, and regulations from different levels.[1] Since 1988, the European Workplace Drug Testing Society (EWDTS) has offered a pan-European platform to allow all sectors involved in workplace drug testing (WDT) share best practices.

In 2010, the first guidelines were published as a handbook for specimen collection, specimen analysis, and interpretation of the results. Since that time there have been goals and specific directives which have impacted the WDT sector. This will continue with the impact of further data protection and human rights legislation; for example, GDPRs (General Data Protection Regulations). GDPR EU-2016/679 is a regulation by which the European Parliament, the Council of the European Union, and the European Commission intend

to strengthen and unify data protection for all individuals within the European Union (EU). In many European countries, there is no legal mandate to test, and conversely there is no legislation to prevent a test programme.

Most countries have implemented a testing regime in safety-critical workplace sectors, for example, nuclear, transportation, and refinery operations. Testing programmes within the military and prison systems are also prevalent in many countries.

Most European countries have no specific legislation on WDT. In Belgium, Greece, Slovenia, Sweden, and Luxembourg further acts like the *Law on Safety and Health at the Workplace*, *Public Employment Act*, *Code for Civil Servants*, and others permit pre-employment testing or occupational physicians are authorised to make examinations when required for specific jobs.

In the Czech Republic, Estonia, Ireland, Lithuania, and Slovakia, WDT is regulated in the *Labour Law* or *Safety, Health, and Welfare at Work Acts* or similar acts. In Italy, since 2007, WDT is established and prescribed in the *Decree on Health and Safety at Work (81/08)* for jobs which pose safety hazards to others.[2] The *Act on Workplace Drug Testing* permits WDT in Finland. By contrast, there is no legislation and only alcohol testing can be done in Hungary: "The Act on Labour Safety (No. 93/1993) does not authorise the labour safety controllers to make drug tests." In Austria, the *Employee Protection Act* defines that the "employee is obliged not to be in a state caused by the use of alcohol, medicines and drugs that endanger themselves or others." In Portugal and Germany, the responsibility for workers' safety and health is part of the employers' duties. This "duty of care" requirement is common in many countries, and in turn can be used to initiate a testing protocol.

Regarding the hierarchy of jurisprudence and all the different national laws, it is necessary to set up additional recommendations and to bring WDT procedures, which were already common in practice, in line. Otherwise, companies and institutions may not be able to implement the same procedure in all their offices, whether or not the headquarters are based in Europe. EWDTS attempts to ensure that WDT in Europe is performed to a defined quality standard and in a legally secured way. The three main points of all EWDTS guidelines are specimen collection, specimen analysis, and interpretation of results. Some chapters handle general aspects like "Laboratory Organisation" and "Quality Assurance and Quality Control", and these parts are identical in both the urine and oral fluid guidelines.

In the oral fluid guidelines, collection devices, collection procedures, chain of custody, and validity testing are reported. As there are different kits on the market – the focus is on oral fluid collection devices, the components of the whole collection kit, and the process of oral fluid collection. There should be a guarantee that all oral fluid collection devices fulfil the requirement for exact determination of known volume. There is demand for precise determination of the oral fluid amount in the collected sample to ensure accurate calculation of drug concentrations. The use of "two sample containers, demonstrably clean and unused" as well a "tamper-evident seal for each container" are further requests. In the subchapter "Oral Fluid Collection Procedures", the demand for A and B samples is described. The measurement of endogenous biomarker in accordance with reference values, an accurate known dilution factor, and sample volume are strongly recommended to verify the collected sample. Any use of adulterants or efforts to tamper with samples by the donors must be uncovered forcefully. In summary, the updated version of the European Guidelines for Workplace Drug Testing in Oral Fluid are geared towards bringing together different methods of operation and ensuring best practice procedures.

2 | OBJECTIVES

- Provide a common framework for European providers of oral fluid workplace drug testing services.
- Promote standards by providing guidelines which are accepted at a European level.
- Ensure that the processes undertaken are capable of legal scrutiny.
- Provide safeguards to protect the dignity of the specimen donors and the validity of the specimen.
- Define for laboratories common quality assurance and quality control criteria that are capable of being accredited by an external body.
- Ensure that the entire drug testing process is conducted to give accurate and reliable information about drug use of the donor.

3 | SCOPE

These guidelines consider the three key stages of the workplace drug testing process.

- Specimen collection: obtaining the oral fluid specimen from the donor
- Laboratory analysis: analysing the sample for the presence of drugs
- Interpretation: reviewing and interpreting the analytical results

4 | SERVICE PROVISION

Where a service provider is contracted to deliver all the stages, they must ensure that the minimum criteria in this document are met in all the key areas. In those instances where a customer may undertake some stages of the process within their own organisation (eg, specimen collection or interpretation), the service provider has a 'duty of care' to ensure that the customer understands the full implications of the drug testing process. The service provider does not have the authority to make decisions regarding the fitness for work of any individual being tested. It is recommended that any issues related to fitness for work be referred to the company's medical representative.

5 | DRUG TESTING IN CONTEXT

It should be explained to any purchaser of a laboratory drug testing service that drug testing should form part of an overall drug policy,

which the purchaser has agreed with their employees and should have in place before testing is initiated. The service provider should have an effective company drugs policy in place. The policy may include drug testing of the staff involved in the analysis and reporting of workplace drug testing results.

6 | OUTLINE OF DRUG TESTING PROCESS

6.1 | Specimen collection

Oral fluid specimens for legally defensible drug testing need to be collected under circumstances which respect the dignity of the individual whilst ensuring that the specimen is freshly collected Suitable records must be made when the specimen is collected to document that the specimen collected and the specimen received by the laboratory are one and the same. This is the first link in the chain of custody process which, when reconstructed at a later date, can be used to document that the final result belongs to the specimen collected.

6.2 | Analysis

When the specimen is received at the laboratory, checks on the integrity of the specimen are carried out. Providing the specimen passes the integrity checks, a portion of the specimen is taken and screened for the presence of drugs and sample validity. If the screen results are all negative, no further analysis is necessary. However, if the screen tests carried out indicate the possible presence of a drug (above a predefined cut-off level), a confirmation test to prove or disprove the presence of the drug or drug metabolite indicated by the screening test must be carried out on another portion of the specimen. When a negative result is obtained, either after the screen or the confirmation test, it can be reported to the customer. Positive results may require interpretation.

6.3 | Interpretation

A laboratory positive result may be due to other reasons than intake of illicit drugs (ie, prescribed, over-the-counter medication or dietary causes). It requires interpretation that is best carried out by the laboratory toxicologist in conjunction with a qualified medical practitioner who can consult both with the donor and the donor's medical practitioner.

6.4 | Record keeping

Suitable records must be made during the analytical process to document that the specimen received by the laboratory and the specimen about which the final report is written, are one and the same. All samples which prove positive for the presence of drugs, and all records of the analytical process, must be kept for an agreed period of time or according to national legislation to allow for any challenges to be made regarding the findings. If the customer requires an independent toxicological review, the laboratory must make available, if requested, the analytical data upon which it based its final report. The definitions T1 adopted for these guidelines are reported in Table 1.

7 | ORAL FLUID COLLECTION

7.1 | 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 supervised.
- Steps to protect against tampering and adulteration.
- Identification of the donor giving the specimen.
- Evidence of the written informed consent of the individual to the analysis of the specimen (an example is given in Appendix B).
- Disclosure of recent medication, or evidence that the individual was advised of the significance of recent medication.
- Confidentiality of all information received. Q14

All specimens for legally defensible drug testing must be collected under circumstances that respect the dignity of the individual whilst ensuring that the specimen is freshly generated and has not been tampered with in any way. The collection site must be secure and the absence of potential interfering substances must be guaranteed. The validity of the specimen must be guaranteed.

Suitable records must be made when the specimen is collected to prove that the specimen collected and the specimen received by the laboratory are one and the same. Where the customer takes responsibility for the collection process, the service provider has a duty of care Q15 to ensure that these guidelines are understood.

7.2 | Personnel

Specimens must be collected by suitably trained personnel (Collecting Officers). Although no healthcare professional education is required, documented training, which includes a demonstration of competence, must be undertaken before collections are performed.

The training must include, at a minimum, instructions on the following:

- Collection process.
- Storage and transport conditions of samples.
- Chain-of-custody process.
- Troubleshooting (ie, how to deal with issues like refusal of the test, insufficient sample, suspicion of tampering of the sample, dry mouth)
- Responsibility of the Collecting Officer for maintaining donor privacy, confidentiality of information, and specimen integrity.
- Ethical issues, especially regarding the declaration by the donor of the present use of prescribed medications.

TABLE 1 For purposes of these guidelines the following definitions have been adopted

Adulteration	See Tampering
Aliquot	A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.
Authorising Scientist	A person who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports.
Calibrator	A solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test sample/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a concentration range of interest.
Chain of Custody	Procedures to account for each specimen by tracking its handling and storage from point of collection to final disposal. These procedures require that the donor identity is confirmed and that a chain of custody form is used from time of collection to receipt by the laboratory. Within the laboratory appropriate chain of custody records must account for the specimen until disposal.
Chain of Custody Form	A form used to document the procedures from time of collection until receipt by the laboratory.
Collecting Officer	A person trained to collect specimens from donors.
Collection Site	A place where individuals present themselves to providing a specimen for analysis.
Confirmation Test	An analytical procedure to identify and quantify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different aliquot technique and chemical principle from that of the screen test in order to ensure reliability and accuracy.
Customer	The organisation requesting the drug testing service.
Cut-off	A concentration level set to determine whether the sample is positive or negative for the presence of a drug.
Donor	The individual from whom an oral fluid specimen is collected.
Derivative drugs/ metabolites	Drugs and metabolites that requires chemical modification for GC–MS analysis, ice, benzoylecgonine, temazepam
Laboratory	The facility providing the analytical services to detect drugs of abuse.
Negative result	A result reported by laboratory that indicates that either no drug is present in the sample or that any drug present is below the cut-off.
Observed Collection	A donor gives the specimen under the direct observation of the collecting officer.
Positive result	A result reported by the laboratory as positive means that there is conclusive evidence that a drug or drug metabolite is present in the specimen tested at a level greater than or equal to the confirmation cut-off concentration.
Quality control sample	A sample used to evaluate if an analytical procedure is operating within pre-defined tolerance limits.
Medical Review Officer (MRO)	A medical physician responsible for receiving laboratory results from the drug-testing laboratory who has knowledge of substance abuse and has appropriate training or experience to interpret and evaluate an individual's positive test result, in light of declared information.
Sample	A representative portion of a specimen used by a laboratory for testing.
Screening Test	A test to eliminate negative specimen from further consideration and to identify the presumptive positive specimen that require confirmation testing.
Service Provider	The organisation contracted to provide the drug testing service. This may be a laboratory, or a third party providing other elements of the service, and sub-contracting the tests to another laboratory.
Specimen	The portion of oral fluid that is collected from a donor.
Standard (1)	A reference material of known purity or a solution containing a reference material at a known concentration.
Standard (2)	An agreed protocol or procedure (eg, EN ISO/IEC 17025 and EN ISO 15189)
Standard Operating Procedure (SOP)	A written document giving the detailed steps to be followed when undertaking a particular task (eg, the analysis of a given drug or drug metabolite in an oral fluid specimen).
Tampering	Any process by which an individual knowingly interferes with (or attempts to interfere with) the processes of specimen collection, transport, or analysis with the intention of avoiding a legitimate test result. The actions undertaken can include (but are not limited to) the addition of water or foreign substances to the specimen, specimen substitution, damaging bottle seals or packaging and the deliberate consumption of interfering substances or copious volumes of water prior to specimen collection.
Toxicologist	A person responsible for interpreting a toxicological analytical result for the customer or the customer's designated Medical Review Officer.

On successful completion of collector training, a person may begin performing collections.

7.3 | Oral fluid collection kits

The laboratory and the manufacturer 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. It is recommended that the device used to collect the oral fluid sample collects a known volume. This may be achieved through spectrophotometrical determination or through an integrated volume indicator. In case of uncertainty, gravimetric analysis is strongly recommended. Scientific data which demonstrate the accuracy of the volume of any buffer (if used) and the collected sample must be available. The laboratory should be able to clearly identify which collection device has been used to collect the sample.

The collection kit should comprise the following components:

- Specimen collection device(s).
- Chain of custody donor 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.

7.4 | 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 label or code number assigned to the sample).
- Information uniquely identifying the donor.
- Evidence that donor identity has been confirmed.
- Evidence that the donor has given informed consent for the specimen to be tested.
- Date, time, and place 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.
- Copies for donor, employer, and laboratory.

7.5 | 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.

It is acknowledged that currently some oral fluid collection devices cannot mechanically collect and generate two separate samples from the single collection procedure. In this case, two devices may be used to generate two samples. As these samples are discrete and not homogeneous, the aliquots could be mixed and then divided into two aliquots (A and B). The sequential collection should be done within 5 minutes of each other. In addition, the exact times of the generation of the samples must be noted on the donor consent documentation. The two samples are then sent to the testing facility. Regardless of which type of device is used, there must be a "volume adequacy indicator" on the device to show the collector that an adequate minimum volume has been collected, if two separate collection procedures are used to generate two samples. The receiving laboratory must gravimetrically or spectrophotometrically determine a more precise quantity of collected oral fluid present in the container. When gravimetrical determination is used to measure collected oral fluid, it is recommended to determine the average net weight of unused collection devices for each batch. This known amount of oral fluid is very important in the subsequent calculation of drug concentrations. Individual manufacturer's tolerances must be known and confirmed. In all cases, the testing laboratory should receive two samples, labelled "A" and "B". An example oral fluid collection protocol is detailed in Appendix A.

8 | LABORATORY ORGANISATION

A Quality Management System of the organisation/laboratory is required via accreditation according to EN ISO/IEC 17025 and/or EN ISO 15189 in fields of forensic toxicology and/or WDT analysis.

All personnel must have contracts with the institution (Laboratory Organisation) which they work for and every person must have agreed to the "confidentiality policy" of the institution (in written form).

8.1 | Personnel

All personnel should adhere to the requirements of EN ISO/IEC 17025 and/or EN ISO 15189 International Standards and as such, only staff who are suitably qualified and whose competence has been formally assessed can work within the laboratory. The laboratory must maintain accurate job descriptions for managerial, technical, and key support personnel involved in the analytical tests.

The laboratory must keep records that establish the individual's qualifications/competency for all functions performed. The individual's file must include an up-to-date curriculum vitae listing educational qualifications and previous employment experience, training, and competency assessment records for the current tasks performed. Personnel performing specific tasks shall be qualified based on appropriate education, training, experience, and/or demonstrated skills, as required. 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.

The key functions outlined in the following sections are identified as the minimum requirement for a laboratory to maintain EN ISO 17025 and/or EN ISO 15189 accreditation for the provision of workplace drug testing services and/or forensic toxicology. It is acceptable for individuals to have responsibility to carry out more than one role. By virtue of the laboratory's accreditation, it can be accepted that the appropriate qualifications for each role are in place. Role titles may vary between organisations, but the responsibilities will remain the same.

8.1.1 | 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, as mentioned in EN ISO 17025 and/or EN ISO 15189. 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 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. Sample containers must be retained within the secure laboratory area until the disposal date.

8.1.2 | Laboratory director

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 director (typically the laboratory supervisor).

8.1.3 | Authorising scientist

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

8.1.4 | Laboratory analyst

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

8.1.5 | Toxicologist

A person responsible for interpreting a toxicological analytical result for the customer or the customer's designated Medical Review Officer (MRO).

8.1.6 | Expert witness

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

8.1.7 | Quality manager

A person responsible for quality assurance within the laboratory organisation.

8.1.8 | Other personnel

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

9 | LABORATORY ANALYSIS PROCEDURES

9.1 | Process

When specimens are received at the laboratory, initial checks of the sample's chain of custody and appearance are carried out. If the specimen passes these checks, a portion of the specimen in container A is taken and goes through initial screening tests for the presence of drugs. Further testing of sample validity may also take place at this point. If the screening results are all negative (below a pre-defined cut-off level), 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 or drug metabolite indicated by the screening test must be carried out on another portion of the specimen.

The screen-only presumptive positive test is not considered to be legally defensible, but may report preliminary presumptive positive results to the clients as local legislation allows. In the report, it must be mentioned that preliminary presumptive positive results need confirmation. If the first analysis is performed by a confirmation-level analysis (mass spectrometry), the positive findings must be retested with another portion of the sample.

9.1.1 | Chain of custody

Laboratories must use chain of custody procedures to maintain control and accountability of specimens and aliquots from receipt through completion of testing, reporting of results, during storage, and continuing until final disposal of specimens and aliquots. Chain of custody records must be maintained on paper or in computerised form.

9.1.2 | Sample receipt

The laboratory should receive at least two sealed sample containers and a corresponding chain of custody form. At least one of these (referred to in this document as container B) must be retained unopened and stored in conditions that reflect the storage of the sample under test (referred to in this document as container A).

When a sample is received in the laboratory:

- Incoming orders and samples must be registered by the laboratory.
- Incoming samples are immediately checked regarding completeness, intactness, and suitability for testing.
- 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 immediately 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 and should be documented.
- Appendix C 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.

9.1.3 | Sample processing

Separate representative portions (aliquots) of the sample in container A will be used for screening and confirmation tests. The sample preparation should follow the SOP and the manufacturer's instructions for the collection system being used. 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 at 2–8°C. Stability must be investigated and appropriate measures undertaken to ensure the sample is valid for the analysis. The long-term storage conditions are device dependent and the conditions should be as recommended by the device manufacturer. The A and the B samples must be stored under identical conditions.

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

9.2 | Oral fluid validity testing

The aim of validity testing is to demonstrate that the sample submitted for analysis is oral fluid. The validity of the sample must be checked either before or during the screening process. The minimum validity test that must be completed for oral fluid is the visual inspection of the sample(s), measurement of oral fluid volume and testing on matrix authenticity through measurement of endogenous biomarkers (eg, salivary amylase, cortisol …). The laboratory may also test for adulterants and sample tampering.

The following data must be coherent:

- Collection time
- Dilution factor (gravimetrical analysis or measured spectrophotometry)
- Sample volume
- Endogenous biomarker in accordance with reference values (eg, salivary Amylase, Cortisol…)

9.2.1 | Testing for adulterants

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

- Abnormal physical characteristics (eg, unusual colour or texture for the specific used device through bleeding, unusual odour, missing "pads" …)
- Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (eg, non-recovery of internal standards, unusual response); or possible unidentified interfering substance or adulterant.

A sample should be reported as, for example, "Sample cannot be used for screening and/or confirmation analysis" in the following situations:

- A valid immunoassay drug test result cannot be obtained on two separate aliquots (eg, a reasonable suspicion on interference occurred).
- A valid drug test result cannot be obtained on two separate aliquots with drug confirmatory assay (a reasonable suspicion on interference occurred – eg, components in the buffer which might interfere or cause ion suppression).
- The physical appearance of the sample is such that testing the sample may damage the laboratory's instruments.
- Gravimetrical analysis exposes unexplainable deviation of weight (ie, less weight caused by "sucked pads", higher weight through water in the mouth.)
- Spectrophotometrical analysis and measurement of endogenous biomarker indicates a dilution of the sample with water.

10 | ANALYTICAL METHODS AND VALIDATION

10.1 | Acceptable screening techniques

The following methods are accepted:

- Immunoassays
- Gas chromatography
- Liquid chromatography as ultra-performance liquid chromatography (UPLC)/ultra-fast liquid chromatography (UFLC)
- All chromatographic techniques coupled to mass spectrometry
- Capillary zone electrophoresis

10.2 | Laboratory screening tests

The initial screening test must use an appropriate technique. 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 Table 2. These recommended cut-off concentrations may be subject to change reflecting advances in technology and knowledge. Cut-off concentrations for substances not indicated in Table 2 will need to be agreed with the customer, considering the performance of the assays to be used and the pharmacokinetics of the drugs involved. T2

All screening test results must be reviewed regarding 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.

The presumptive presence for any drug following the initial preliminary screen must have the presence of the drug or drug metabolite confirmed (Section 10.4). If the first analysis is performed by a confirmation-level analysis (mass spectrometry), the positive findings must be confirmed and quantified by reanalysis with another portion of the sample.

10.3 | Standardisation of laboratory screening assays

All assays must be calibrated against appropriate standards 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 limitations of the tests.

10.4 | 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 (eg, gas chromatography–mass spectrometry (GC-–MS) or liquid chromatography–mass spectrometry (LC–MS)). If the first analysis is performed by a confirmation-level analysis (mass

TABLE 2 Recommended substances and maximum cut-off concentrations for screening tests in oral fluid. Laboratory screen test cut-off concentration in neat oral fluid (ng/mL)

	ng/mL
Amphetamines group	40
Cannabis (THC)	10
Cocaine + metabolites	30
Opiates (Morphine)	40
6-AM	4
Methadone (l)	50
Benzodiazepines group	10
Buprenorphines	5
Propoxyphene or metabolites	40
Cut-off under investigation / discussion:	
Barbiturate	-
Ketamine	-
LSD or metabolites	-
Other opioids (e.g. Oxycodone, Hydromorphone, Tramadol, Buprenorphine, Tilidine, Fentanyl)	-
Phencyclidine	-
Pregabalin	-
Synthetic cannabinoids (JWH-018, JWH-073)	-
Synthetic cathinones (MDPV etc.)	-
Z-Drugs (Zopiclone, Zolpidem, Zaleplon)	-

Note:

[1]The laboratory has to take into account country-specific differences in the drug-panel they are using.

[2]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.

[3]Cut-off levels for substances not indicated in Appendix D will need to be agreed with the customer taking into account the performance of the assays to be used. The toxicologist/laboratory must explain the meaning to the customer.

[4]Dilution of the sample must be corrected for when the screen results are interpreted.

[5]When using immunological analyses, the differences in cross-reactivity of different substances must be noted and factored into laboratory reports.

[6]The laboratory is responsible for remaining up to date with local drug trends and has a responsibility to use this knowledge to advise the customer of the most appropriate substances to be included in the drug testing panel.

spectrometry), the positive findings must be confirmed and quantified by reanalysis with another portion of the sample.

All confirmations must be quantitative. The customer must be informed of the compounds detected in the confirmation tests. Recommended maximum confirmation cut-off concentrations for workplace drug testing are given in Table 3. The cut-off concentrations are a result of modern instrumentation techniques and the relatively short detection time window in oral fluid matrices. These cut-offs are the maximum recommended cut-offs for workplace drug testing purposes. 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 concentration for substances not indicated in Table 3 must be agreed with the customer, considering 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. No further testing 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.

TABLE 3 Recommended substances and maximum cut-off concentrations for confirmation tests in oral fluid. Confirmation test cut-off concentration in neat oral fluid (ng/mL)

	ng/mL
Amphetamine	
Amphetamine (d + l)	15
Methamphetamine	15
MDA	15
MDMA	15
Other members of the amphetamine group	
Benzodiazepine	
7-Amino-flunitrazepam	3
7-Amino-clonazepam	3
7-Amino-nitrazepam	3
Alprazolam	3
Bromazepam	3
Clonazepam	3
Desmethyldiazepam	3
Diazepam	3
Flunitrazepam	3
Flurazepam	3
Lorazepam	3
Lormetazepam	3
Midazolam	3
Nitrazepam	3
Nordiazepam	3
Oxazepam	3
Phenazepam	3
Temazepam	10
Opiates	
Morphine	15
Codeine	15
Norcodeine	2
Dihydrocodeine	15
6-Monoacetylmorphine	2
Cannabis (THC)	2
Cocaine	
Cocaine metabolite (Benzoylecgonine)	8
Cocaine	8
Cocaethylene	-

11 | VALIDATION

All methods must be validated and their suitability for intended purpose must be evaluated in accordance with EN ISO/IEC 17025.

Laboratories accredited according to EN ISO 15189 should produce evidence of adequate method validation and certificate of participation to Proficiency Test and External Quality Assessment.

The following parameters must be determined at least for quantitative confirmation analyses and whenever possible, for screening analyses: precision, cut-off verification, selectivity, limit of detection, limit of quantification, sensitivity, specificity, stability, measurement uncertainty, recovery of the collection device, and matrix effects.

12 | AUTHORISATION AND REPORTING OF RESULTS

Before any laboratory test result is released, the results must be reviewed and certified as accurate by a competent member of staff (analytical validation). At a minimum, the report must include the specimen identification number and the test result (positive/negative) for each sample submitted. Reporting must be managed in accordance with EN ISO/IEC 17025 and/or EN ISO 15189 requirements. In addition, the cut-off used for the test should be included. Only drugs that have been confirmed by a recognised 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. Results must be transmitted to the customer's designated representative in a manner that will ensure confidentiality of the information. 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.

13 | LONG-TERM STORAGE OF SAMPLES

The laboratory must demonstrate that the long-term storage conditions of samples are adequate to ensure that analytes are stable over the time period required for any re-test. Currently long-term deep-frozen storage (−20°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 1-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. 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. Negative samples (A + B) samples may be discarded as per the laboratory and customer agreed timetable.

14 | 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.
- All test data (including method validation, calibration curves and calculations for determining test results).
- Maintenance and instrument calibration records.
- 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 EN ISO/IEC 17025 and/or EN ISO 15189 requirements and records containing details of individuals should be dealt with in line with European Data Protection Legislation.

15 | QUALITY ASSURANCE AND QUALITY CONTROL

15.1 | 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 testing laboratory and all screening and confirmation tests used in workplace drug testing must be fully validated and accredited by a recognised external accreditation body. When an unaccredited method is used the customer should be informed accordingly.

15.2 | Quality control

Calibrators and controls shall be prepared using either certified drug reference materials or certified standard solutions obtained, where possible, from 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 laboratory must retain records to demonstrate that all calibrators and controls are traceable back to primary standards (if available). The calibrators and controls shall be properly labelled as to

content, concentration, data placed in service and expiry date. All standards (eg, pure reference materials, stock standard solutions, purchased standards) shall be labelled with the following:

- Date received (if applicable)
- Date prepared or opened or placed in service
- Expiration date
- Initials of the technicians who has prepared the (in house) calibrator, etc

All data acquired on control samples as well as lot number of drug reference materials must be recorded in such a way as to facilitate interpretation of control results and trends.

16 | LABORATORY SCREENING TESTS

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

system suitability check must be carried out prior to the analysis of samples. Screening tests are carried out using reagents and calibrators directly provided by the manufacturers provided the analysis is carried out according to the indications and the value of the cut-off defined by the manufacturer. Since the negative outcome of a screening analysis is generally accepted as valid, it is essential to verify that the method can minimise false negative results.

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.

17 | CONFIRMATION TESTS

These are the minimum requirements for identification of analytes and confirmation of results.

17.1 | Identification

17.1.1 | Mass spectrometry coupled to chromatography

a. Mass spectrometry coupled to a chromatographic separation method is a very powerful combination for identification of an analyte in the sample extract. It simultaneously provides retention time, ion/charge ratios and relative abundance (intensity) data.

Requirements for chromatography

a. The minimum acceptable retention time for the analytes under examination should be at least twice the retention time corresponding to the void volume of the column. The retention time of the analytes in the extract should correspond to that of the calibration standard (may need to be matrix-matched) with a tolerance of ±1%, for both gas chromatography and liquid chromatography.

Tolerance 1% means (with rt: retention time):

$$\frac{rt_{analyte\ in\ sample} - rt_{analyte\ in\ calibrator}}{rt_{analyte\ in\ calibrator}} \leq 0.01$$

Requirements for mass spectrometry (MS)

a. Reference spectra for the analytes should be generated using the same instruments and techniques used for analysis of the samples. If major differences are evident between a published spectrum and the spectrum generated within the laboratory, the latter must be shown to be valid.
b. Identification relies on proper selection of diagnostic (characteristic) ions. The (quasi) molecular ion is a diagnostic ion that should be included in the measurement and identification procedure whenever possible. In general, and especially in single-stage MS, high *m/z* ions are more specific than low *m/z* ions (eg, *m/z* < 100).
c. Extracted ion chromatograms of sample extracts should have peaks (exceeding S/N 3:1 of similar retention time, peak shape, and response ratio to those obtained from a calibration standard analysed at comparable concentration in the same batch. Shift in retention time should not exceed 1% compared to calibration standard. Chromatographic peaks from different selective ions for the same analytes must overlap with each other. Where an ion chromatogram shows evidence of significant chromatographic interference, it must not be relied upon to quantify or identify residues. The ion that shows the best signal-to-noise ratio and no evidence of significant chromatographic interference should be used for quantification.
d. In case of full-scan measurement, careful subtraction of background spectra, either manual or automatic, by deconvolution or other algorithms, may be required to ensure that the resultant spectrum of the chromatographic peak is representative. Whenever background correction is used, this must be applied uniformly throughout the batch and should be clearly indicated.
e. Different types and modes of mass spectrometric detectors provide different degrees of selectivity and specificity, which relates to the confidence in identification. General requirements for identification by MS methods have been published and should be regarded as guidance criteria for identification, not as absolute criteria to prove presence or absence of a compound.
f. The relative intensities or ratios of selective ions (full-scan MS or SIM) or product ions (MS/MS), expressed as a ratio relative to the most intense (product) ion, should correspond to those of the calibration standard at comparable concentrations and measured under the same conditions. Matrix-matched calibration solutions may need to be used. Table 4 indicates the maximum tolerances for ion ratios.[3] T4
g. The variability of ion ratios should preferably be determined from calibration standards during initial method validation and

TABLE 4 Recommended maximum tolerances for ion ratios using different MS techniques

Ion ratio (least/most intense ion)	Maximum tolerance (relative) for GC–EI–MS	Maximum tolerance (relative) for GC–CI–MS, GC–MS^n, LC–MS, LC–MS^n**
>50%	20%	20%
>20%–50%	20%	25%
>10%–20%	25%	30%
≤10%	50%	50%

subsequently during routine analysis. Diagnostic ions should have an ion ratio of >0.05 (least/most intense ion).

h. At higher deviation of the relative abundance of a qualifier ion, analysis needs to be repeated. If tolerances remain beyond acceptance criteria, further investigation of influences of matrix effects or disturbing compound are recommended – such as standard addition experiments or chance of chromatographic system – to verify or to exclude the presence of a compound. In these cases, complementary interpretation by an experienced analyst is recommended.

i. For more confidence in identification, further evidence may be achieved from additional mass spectrometric information. For example, evaluation of full-scan spectra, isotope pattern, adduct ions, additional accurate mass fragment ions, additional product ions (in MS/MS), or accurate mass product ions. For high resolution mass spectrometry (HRMS) the mass resolution shall typically be greater than 10 000 for the entire mass range at 10% valley (which equates to resolving power of 20 000 FWHM (full width at half maximum). For accurate mass measurements (AMM) the instrument mass error in routine mass measurements must be less than 2 mDa and resolution shall typically be greater than 5000 FWHM.

For combination of LC with high-resolution quadrupole time-of-flight tandem mass spectrometry (HR–QToF–MS/MS) or other mass spectrometric technique with HR–MS/MS the following settings are recommended for mass spectral identification based on a mass spectral library (commercial or home-made):

For HR-QToF-MS/MS analysis, a mass resolution of >10 000 amu with a mass accuracy of <5 ppm and an isotope ratio comparability of better than 80% should be used in routine analysis. If comparison to a library is performed with MS/MS spectra, a fit value of >70% should be used as a threshold, for identification of compounds. Additionally, 1% tolerance of LC-retention time is required (Point e).

a. The chromatographic profile of the isomers of an analyte or any relevant metabolites may also provide evidence. Additional evidence may be sought using a different chromatographic separation system and/or a different MS-ionisation technique.

18 | CONFIRMATION OF RESULTS.

If the initial analysis does not provide unambiguous identification or does not meet the requirements for quantitative analysis, a confirmatory analysis of sample A is required. This may involve reanalysis of the extract or the sample. In cases where a detection threshold for a drug is exceeded, a confirmatory analysis of a portion of sample B may be required by the authorities. For unusual analyte/matrix combinations, a confirmatory analysis is also recommended.

The use of different determination techniques and/or confirmation of qualitative and/or quantitative results by an independent expert laboratory will provide further supporting evidence.

18.1 | External quality assessment

The laboratory must take part in appropriate external quality assessment schemes. When the scheme is not available, the laboratory must conduct appropriate inter-laboratory testing to ensure appropriate assay performance.

18.2 | Sub-contracting

Drug testing laboratories should carry out all laboratory work with their own personnel and equipment. If it is necessary to sub-contract, inter-laboratory transfer of samples is performed with strict adherence to chain of custody procedures. The sub-contracted laboratory and its methods 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.

18.3 | Interpretation of results

A confirmed analytical positive result may be due to medication (prescribed or over-the-counter) or due 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 qualified medical professional (eg, MRO) or a Forensic Toxicologist (depending on the country-specific situation).

18.4 | Toxicology review

It is mandatory that a toxicologist is available to advise the customer and/or MRO regarding queries with test results.

18.5 | Medical review

The MRO is a medical physician with responsibility for interpreting laboratory results together with a toxicologist. Depending on the country-specific situation a medical physician usually has greater access to medical records than a toxicologist and may therefore be in a better position to provide interpretation of positive analytical results.

The MRO must have specialist knowledge of and training in

- specimen collection procedures,
- analytical procedures,
- chain of custody, and
- alternative explanations for positive analytical results.

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 medical explanation has been found.

The service provider may provide access to an independent medical review service.

18.6 | 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. Sample" should be released for analysis to a drug testing laboratory accredited by a recognised external accrediting body and working to these guidelines. This release requires authorisation from both the customer/MRO and the donor.

The release must be supported by chain of custody procedures that can withstand legal scrutiny and include information about the findings of the original test (corresponding sample A) and the cut-offs used for the test. The original laboratory must retain the residue of the original sample and its containers so that it can be compared with sample B later 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 E (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. It is recommended that the laboratory should carry out validity checks outlined prior to carrying out the confirmation analysis. Only those drugs identified for confirmation testing should be looked for. 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 sample A. 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.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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APPENDIX A

Oral fluid collection procedure

(Note: Only formally competence tested and authorised persons may act as Collecting Officers. Medical qualification is NOT required for Collecting 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. **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.

III. **Chain of custody**

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

IV. **Identification of the donor**

When a donor arrives at the collection site, the Collecting Officer will request that the donor presents photographic identification. If the donor does not have acceptable photographic identification, the Collecting 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 Collecting Officer will not proceed with the collection.

V. **Informing the donor about the test**

The donor must be informed about the purpose and the content of the test.

VI. **Consent of the donor**

The donor gives their consent for oral fluid collection and analysis of drugs by signature. If the donor refuses to give a sample, a note to this effect should be recorded on the form designated for that purpose. Appendix 2 gives an example of a Donor's Statement of Informed Consent.

VII. **Privacy**

Procedures for collecting oral fluid specimens shall allow, where possible, for donor privacy during sample collection. Donors must be treated equally regardless of gender and any physical impairment. The process should avoid embarrassment but should also be rugged enough to satisfy challenge of the sample integrity. If there is a strong suspicion of sample adulteration and/or the previous sample was adulterated, the sample can be collected under the supervision of the Collecting Officer.

VIII. **Integrity of the specimen**

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

a. Throughout the collection process, the Collecting Officer will note any unusual behaviour of the donor on the chain of custody form.
b. The Collecting Officer will ask the donor to remove any articles from the mouth, for example chewing gum.
c. The Collecting Officer 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 and prepared for analysis 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 Collecting Officer will:
   - Note collection time.
   - Check the volume of oral fluid on/in the specimen collection device.
   - Inspect the specimen to determine its colour and appearance of any signs of contaminants and adulteration.
f. Any unusual findings will be noted on the chain of custody form.
g. If the volume is less than that required by recommendation/order of 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, the collection process is stopped and advice should be sought.
i. Both the donor and the Collecting 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 Collecting 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 same is requested if split samples are obtained by two devices. 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 Collecting 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 Collecting 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 the donor and giving informed consent for the work to be undertaken. Appendix 2 gives an example of a Donor's Statement of Informed Consent.
n. The Collecting 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, during storage prior to dispatch the Collecting Officer 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 Collecting Officer and the donor will be present throughout the procedures outlined in the paragraphs of this section.

IX. **Exceptional situations**

a. The donor wants to give the sample later
   The Collecting Officer must not allow the donor to leave the collection site and come back later to give a sample. The Collecting Officer will contact the appropriate authority to obtain guidance on the action to be taken.
b. Admission of illegal drug use
   If the donor admits illegal drug use, this should be noted on the chain of custody form.

X. **Transportation to laboratory**

Collecting 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 and packed properly to comply with local/international mail and courier regulations for biological specimens. 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.

APPENDIX B

Example of a Donor's Statement of Informed ConsentI confirm that I have received information about the meaning and content of the drug test. 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):_____

APPENDIX C

Some examples of fatal flaws in the chain of custody

1. A unique identifier (eg, barcode) is mismatched 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.
7. Insufficient sample for complete analysis.
8. Leaking sample.

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