



European Guidelines for Workplace Drug Testing in Exhaled Breath

2022-10 Version 1.0 FINAL

Foreword

These guidelines for Legally Defensible Workplace Drug Testing have been prepared by the European Workplace Drug Testing Society (EWDTS)¹.

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.

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1. General

1.1. Introduction

These guidelines represent an overview of the best practice for European laboratories providing Exhaled breath workplace drug testing services to maintain the legal defensibility of a drug test when tested by either an employment tribunal or a court of law. 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. The detection of alcohol in exhaled breath will be addressed in a separate guideline.



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1.2. Objectives

- To provide a common framework for European providers of exhaled breath workplace drug testing services.
- To promote best practice standards by providing guidelines accepted throughout Europe.
- 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, a common quality assurance and quality control criteria which have the potential of accreditation by an external body.
- To ensure that the entire drug testing process is conducted to give accurate and reliable information about a donor's drug use.

1.3. Scope

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

- Specimen collection: Obtaining the exhaled breath specimen from the donor
- Laboratory analysis: Analysis of the sample for the presence of drugs
- Interpretation: Review and interpretation of the analytical results

1.4. 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 (e.g. 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



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individual being tested. It is recommended that any issues related to fitness for work be referred to the company's medical representative.

1.5. 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 his 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.

1.6. Outline of drug testing process

Specimen collection

Exhaled breath specimens for legally defensible drug testing should be collected under circumstances which respect the dignity of the donor while ensuring that the specimen is correctly 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.

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 or a sub-sample (if applicable) 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 or a sub-sample (if applicable) of the specimen. When a negative



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result is obtained, either after the screen or confirmation test, it can be reported to the customer. Positive results may require interpretation.

Interpretation

A laboratory positive result may be due to other reasons than intake of illicit drugs (i.e. 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.

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.



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2. Definitions

For purposes of these guidelines the following definitions have been adopted:

Adulteration See Tampering

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 for the purpose of 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 portion or sub-sample, technique and chemical principle (if applicable) from that of the screen test in order to ensure reliability and accuracy. Screening and confirmation can be done using the same technique, as long as they detect the analyte by mass spectrometry.



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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 a breath specimen is collected.

Laboratory The facility providing the analytical services to detect drugs of abuse.

Negative result A result reported by the laboratory that indicates that either no drug or drug metabolite is present in the specimen or that any drug or drug metabolite 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 whether or not 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.



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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 exhaled breath 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 (e.g. 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 (e.g. the analysis of a given drug or drug metabolite in an breath specimen).

Sub-sample A fractional part of a specimen used for testing. It is taken as a sample representing the whole 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



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3. Exhaled Breath Collection

3.1. 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. It may be lawful in certain countries to take a photograph of the donor if necessary to evidence identification.
- 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
- All information is considered as confidential.

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 has to 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.



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Where the customer takes responsibility for the collection process, the service provider has a duty of care to ensure that these guidelines are understood.

3.2. 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:

- The collection process
- The storage and transport conditions of samples
- The chain-of-custody process
- Troubleshooting (i.e. refusal to test, individuals who report problems with supplying an exhaled breath sample (restricted air flow))
- The 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.

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

3.3. Exhaled Breath Collection Kits

The laboratory and 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 exhaled breath sample collects a known volume. This is commonly achieved by measuring the exhaled volume of air. The laboratory should be able to clearly identify which collection device has been used to collect the sample.



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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 sub-samples must be collected (if the collection device allows the collection of at least two sub-samples). Otherwise, a minimum of two samples must be collected.
- Tamper-evident seal for the container(s).
- Packaging components that satisfy current postal and courier regulations.

3.4. 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. It may be lawful in certain countries to take a photograph of the donor if necessary to evidence identification.
- Evidence that the 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.



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3.5. Exhaled Breath Collection Procedures

One or two samples (depending on the collection device used) are collected so that sub-samples A and B are created. In the case where two samples are collected, the time between collections shouldn't exceed five minutes.

It is acknowledged that currently some exhaled breath 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 first aliquot must be labelled A, and the second labelled B. In addition, the exact times of the generation of the samples must be noted in the donor consent documentation.

The collected samples are then sent to the testing facility.

In all cases the testing laboratory should receive enough sample so that sub-samples A and B exist.

An example exhaled breath collection protocol is detailed in Appendix A.

4. Laboratory Organisation

A Quality Management System of the organization / laboratory is required via accreditation according to EN ISO/IEC 17025 and/or EN ISO 15189 in fields of forensic toxicology and/or workplace drug testing 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).

4.1. 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.



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The laboratory must keep records that establish the individual's qualifications / competency for all functions performed. The individual's file must include a current curriculum vitae listing educational qualifications, previous employment experience, training, and competency assessment records for the current tasks performed. Personnel performing specific tasks shall be qualified on the basis of 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 national legislation. The key functions outlined below 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.

NOTE: Role titles may vary between organisations, but the responsibilities will remain the same.

4.2. 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.



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4.3. 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 Supervisor).

4.4. 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.

4.5. Laboratory Analyst

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

4.6. Toxicologist

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

4.7. Expert Witness

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

4.8. Quality Manager

A person responsible for quality assurance within the laboratory organisation.

4.9. Other Personnel

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



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5. Laboratory Analysis Procedures

5.1. Process

When specimens are received at the laboratory, initial checks on the sample's chain of custody and appearance are carried out. If the specimen passes these checks the specimen in subsample "A" is taken and goes through initial screening tests (if available) 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 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 subsample.

The screen-only presumptive positive test is not considered to be legally defensible, but preliminary presumptive positive results may be reported to the clients as local legislation allows. In such cases, the report it has to 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 are considered definitive and legally defensible, hence no further testing will be required.

5.2. 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 sub-samples.

Chain of custody records must be maintained on paper or in computerised form.

5.3. Sample Receipt

The laboratory should receive at least two sub-samples, inside a sealed tamper proof evidence bag and a corresponding chain of custody form.



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

5.4. Sample Processing

Separate representative portions or sub-samples of the sample will be used for the screening and confirmation tests. The sample preparation should follow the standard operating procedure and the manufacturer's instructions for the collection system being used. Sub-samples must be taken in such a manner that it excludes the possibility of contamination.

Short-term storage: samples that are not currently undergoing analysis must be stored in a freezer. Stability has to be investigated and appropriate measures undertaken to ensure the sample is valid for the analysis.

All specimen portions or sub-samples must be stored under identical conditions.



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The quality control requirements in section 7 must be satisfied when conducting either screening or confirmation tests, either on single samples or samples grouped in batches.

5.5. Exhaled Breath Validity Testing

The aim of validity testing is to demonstrate that the sample submitted for analysis is exhaled breath.

The validity of the sample must be checked either before or during the analyses process. The minimum validity test that must be completed for exhaled breath is the collection of the minimum volume of exhaled breath, as prescribed by the collection device manufacturer, by the collector. The laboratory may also test for lung-fluid specific components, such as the lung fluid characteristic lipid DPPC (dipalmitoylphosphatidylcholine).



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6. Analytical Methods and Validation

6.1. Acceptable Screening Techniques

Following methods are accepted e.g.:

- Immunoassays
- Gas Chromatography
- High Performance Liquid Chromatography
- All chromatographic techniques coupled to mass spectrometry
- Capillary Zone Electrophoresis

6.2. 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 Appendix D. These recommended cut-off concentrations may be subject to change reflecting advances in technology and knowledge.

Cut-off concentrations 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 and the pharmacokinetics of the drugs involved.

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.

The presumptive presence for any drug following the initial preliminary screen must have the presence of the drug or drug metabolite confirmed (refer to section 6.4 Confirmation Tests). If the first analysis is performed by a confirmation-level analysis (mass-spectrometry), the positive findings are considered definitive and legally defensible, hence no further testing will be required.



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6.3. 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 customer must be informed of the limitations of the tests.

6.4. 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 (e.g. GC-MS or LC-MS).

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 Appendix E.

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 E 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 should 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.



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6.5. 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 (if available) and External Quality Assessment.

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

6.6. 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 should 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.



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6.7. 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 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. 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.

6.8. 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



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- 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.

7. Quality Assurance and Quality Control

7.1. 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 should be fully validated and accredited by a recognised external accreditation body.

When an unaccredited method is used, the customer should be informed accordingly.



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7.2. 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 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 (e.g. 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 lot number of drug reference materials must be recorded in such a way as to facilitate interpretation of control results and trends.

7.3. 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.

Assays must be calibrated with every batch or when quality control samples indicate poor performance.

If immunoassays are used for screening, control samples at concentrations of approximately 25% 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.



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7.4. Confirmation tests

These are the minimum requirements for identification of analytes and confirmation of results².

² Standard Practices for Method Validation in Forensic Toxicology, ANSI/ASB Standard 036, 1st Ed. 2019. Available at <https://www.aafs.org/asb-standard/standard-practices-method-validation-forensic-toxicology>

8. 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 (e.g. Medical Review Officer) or a Toxicologist (depending on the country-specific situation) (See chapter 4).

8.1. Toxicology Review

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

8.2. Medical Review

The Medical Review Officer (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.



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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.

9. 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.

The remaining sub-sample(s) 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 sub-sample) and the cut-offs used for the test.

All laboratories that undertake the testing of the remaining sub-sample 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 remaining sub-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 remaining sub-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 first reported result. 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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Appendix A

Exhaled Breath 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 exhaled breath 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. It may be lawful in certain countries to take a photograph of the donor if necessary to evidence identification.

V. Informing the donor about the test

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



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The donor gives his/her consent for exhaled breath 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 B gives an example of a Donor's Statement of Informed Consent.

VI. Privacy

Procedures for collecting exhaled breath specimens shall allow, where possible, for donor privacy during sample collection. Donors have to 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 closer supervision of collecting officer.

VII. 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 e.g. chewing gum.
- c) Exhaled breath 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.
- d) Upon receiving the specimen from the donor, the collecting officer will:
 - Note collection time
- e) Any unusual findings will be noted on the chain of custody form.



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- f) If the donor is unable to provide a suitable volume of exhaled breath for analysis then the collection process is stopped and advice should be sought.
- g) Both the donor and the collecting officer will keep the specimen container(s) in view at all times prior to the exhaled breath specimen(s) being sealed and labelled.
- h) 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. The specimen containers and all pages of the chain of custody will be labelled at the time of collection with a unique identifier.
- i) 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 breath specimen. The donor will be given the opportunity to declare any medication used.
- j) 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 C gives an example of a Donor's Statement of Informed Consent.
- k) The collecting officer will complete the specimen chain of custody form and package with the breath collection device ready for dispatch together to the analytical laboratory. If the specimen is not dispatched at once, the collecting 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).
- l) Other pages of the chain of custody form will be given or forwarded to the appropriate persons.
- m) The collecting officer and the donor will be present throughout the procedures outlined in the paragraphs of this section.



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VIII. 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.

IX. 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.



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11. Appendix B

Example of a Donor's Statement of Informed Consent

I 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 exhaled breath to the specimen collector.

I have observed the collection device containing the specimen being placed and sealed in the tamper proof evidence bag and I confirm that the information on this form and on the specimen labels is correct.

I hereby give permission for collection device(s) 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):



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12. Appendix C

Some Examples of Fatal Flaws in the Chain of Custody

1. A unique identifier (e.g. 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 collection device/transport container
5. No seals
6. Only 1 sample (or sub-sample) received



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13. Appendix D

Recommended Substances and Maximum Cut-Off Concentrations for Screening (if available)

Tests in Exhaled Breath

Cut-off concentrations and analytes below are a result of modern instrumentation techniques and the relatively short detection time window in exhaled breath. These cut-offs are the maximum recommended cut-offs for workplace drug testing purposes.

Laboratory Screen Test Cut-Off Concentration in exhaled breath is 0.4 pg/L of exhaled breath.

The list below comprises recommended analytes.

Primary Substances	pg/L
Amphetamines group	0.4
Benzodiazepines group	0.4
Cannabis and metabolites	0.4
Cocaine and metabolites	0.4
Methadone and EDDP	0.4
Opiates group	0.4

Secondary Substances	pg/L
Buprenorphine	0.4
Gabapentin	0.4
Pregabalin	0.4
Ketamine	0.4
Opioids (e.g. Oxycodone, Hydromorphone)	0.4
Synthetic Cathinones	0.4
Tramadol	0.4
Z-Drugs (e.g. Zopiclone, Zolpidem, Zaleplon)	10



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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 has to explain the meaning to the customer.
4. When using immunological analyses the differences in cross-reactivity of different substances must be noted and factored into laboratory reports.
5. 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.



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14. Appendix E

Recommended Substances and Maximum Cut-Off Concentrations for Confirmation Tests in Exhaled Breath

Cut-off concentrations below are a result of modern instrumentation techniques and the relatively short detection time window in exhaled breath.

These cut-offs are the maximum recommended cut-offs for workplace drug testing purposes.

Confirmation Test Cut-Off Concentration in exhaled breath samples is 0.4 pg/L of exhaled breath.

The list below includes, but it is not limited to, the recommended target analytes.

Maximum confirmation test cut-off concentrations in breath (pg/sample):

In the list below, where the value is given, this is the recommended maximum cut-off value.

Primary Substances	pg/L
Amphetamines	
Amphetamine (d + l)	0.4
Methamphetamine	0.4
MDMA	0.4
Other amphetamines	0.4
Benzodiazepines	
*Individual benzodiazepines	0.4
Cannabinoids	
CBD	0.4
THC	0.4
11-OH- Δ -9-THC	0.4
11-nor- Δ -THC-COOH	0.4
Cocaine	

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Cocaine	0.4
Benzoylcegonine (cocaine metabolite)	0.4
Methadone	
Methadone (d + l)	0.4
EDDP (methadone metabolite)	0.4
Opiates	
6-Acetylmorphine	0.4
Codeine	0.4
Morphine	0.4

Secondary Substances	pg/L
Opioids	
Buprenorphine	0.4
Hydromorphone	0.4
Oxycodone	0.4
Tramadol	0.4
Other drugs	
Ephedrine	0.4
Gabapentin	0.4
Ketamine	0.4
Methylphenidate	0.4
Synthetic cathinones	
4-FA	0.4
4-FMA	0.4
3-MMC	0.4
4-MMC (mephedrone)	0.4
Z-drugs	



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Zolpidem	0.4
Zopiclone	0.4

*The laboratory should take into account the specific benzodiazepines to test for in their particular country.

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 E will need to be agreed with the customer taking into account the performance of the assays to be used. The toxicologist/laboratory has to explain the relevance of the cut-offs to the customer.
4. The laboratory is responsible for keeping abreast of local drug trends and advising the customer regarding relevant drugs for inclusion in the drug testing panel.
5. The Limit of Quantification (LOQ) for each drug has to be no more than 50 % of the confirmation cut-off level.
6. The laboratory has to be able to determine d- and l-amphetamines, if required.