

# **European Laboratory Guidelines for Legally Defensible Workplace Drug Testing**



## **1. Urine Drug Testing**



These guidelines for Legally Defensible Workplace Drug Testing have been prepared by the European Workplace Drug Testing Society (EWDTS). They are based on the UK Guidelines drawn up by a Steering Group representing the following UK analytical laboratories:

Cardiff BioAnalytical Services	Medscreen
Department of Forensic Medicine & Science, University of Glasgow	Newcastle Royal Infirmary Toxicology Department,
Forensic Science Service	OmniLabs
JMJ Laboratories	Scientifics
LGC	Tackler Analytical
London Toxicology Group	

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 detail within the appendices will therefore vary from country to country.

**The EWDTS is the owner of these Guidelines. They relate only to the collection of urine samples, their laboratory analysis, and subsequent interpretation of the results, and must be used in their entirety. Subsequent versions will be issued at the discretion of the EWDTS.**

#### **EWDTS Guidelines Committee**

L.J. Mostert, The Netherlands, Chair  
S. Suominen, Finland, Secretary  
O. Beck, Sweden  
L. Hadfield, representative of UK Steering Group  
C. Fernandez, Spain  
G. Kauert, Germany



## *Table of Contents*

<b>1</b>	<b>General</b>	<b>5</b>
1.1	Introduction	5
1.2	Objectives	5
1.3	Scope	5
1.4	Definitions	6
1.5	Service Provision	6
1.6	Drug Testing in Context	6
1.7	Outline of drug testing process	7
1.8	Laboratory Security	8
<b>2</b>	<b>Specimen collection</b>	<b>9</b>
2.1	Overview	9
2.2	Personnel	9
2.3	Procedures	9
2.4	Specimen Collection Kits	10
2.5	Chain of Custody Form	10
<b>3</b>	<b>Laboratory Organisation</b>	<b>11</b>
3.1	Personnel	11
3.2	Laboratory Head	11
3.3	Authorising Scientist	12
3.4	Laboratory Analyst	13
3.5	Toxicologist	13
3.6	Expert Witness	14
3.7	Other Personnel	14
3.8	Quality Manager	14
<b>4</b>	<b>Laboratory Analysis Procedures</b>	<b>15</b>
4.1	Summary	15
4.2	Chain of Custody	15
4.3	Receiving/Accessioning	15
4.4	Sample Processing	16



4.5 Urine validity testing	16
4.6 Screen Test	17
4.7 Standardisation of screen assays	18
4.8 Confirmation Test	18
4.9 Authorisation and reporting of Results	19
4.10 Long-Term Storage of Samples	19
4.11 Records	20
<b>5 Quality Assurance and Quality Control</b>	<b>21</b>
5.1 Quality assurance	21
5.2 Quality Control	21
5.3 Screen Tests	22
5.4 Confirmation tests	22
5.5 Quality assessment	23
5.6 Sub-contracting	24
<b>6 Challenges to Drug Test Results</b>	<b>25</b>
<b>7 Interpretation of Results</b>	<b>26</b>
7.2 Toxicology Review	26
<b>8 Definitions</b>	<b>27</b>
<b><i>Appendix A Urine Collection Procedures - an example of a typical protocol appropriate for [country]</i></b>	<b>30</b>
<b><i>Appendix B Example of a Donor's Statement of Informed Consent appropriate for [country]</i></b>	<b>34</b>
<b><i>Appendix C Some examples of flaws in the Chain of Custody</i></b>	<b>35</b>
<b><i>Appendix D Acceptable Screening Techniques</i></b>	<b>36</b>
<b><i>Appendix E Recommended maximum cut-off concentrations for Screening Tests appropriate for [country]</i></b>	<b>37</b>
<b><i>Appendix F Recommended cut-off concentrations for confirmation tests appropriate for [country]</i></b>	<b>38</b>
<b><i>Appendix G Medical Review</i></b>	<b>39</b>



## **General**

### **1.1 Introduction**

- 1.1.1 These Guidelines represent an overview of the best practice for laboratories providing workplace drug testing services within Europe. They are based on the general principles that have been established internationally. 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.
- 1.1.2 All laboratories that undertake legally defensible workplace drug testing within Europe should use these guidelines as a template for accreditation.
- 1.1.3 These Guidelines focus on urine, which is the usual specimen for analysis. However the same general principles should be applied for all specimen types.

### **1.2 Objectives**

- 1.2.1 The guidelines are designed to
  - 1.2.1.1 Provide a minimum set of criteria for the providers of workplace drug testing services within Europe.
  - 1.2.1.2 Ensure that the processes undertaken are capable of legal scrutiny.
  - 1.2.1.3 Provide safeguards to protect the specimen donors.
  - 1.2.1.4 Define for laboratories common quality assurance and quality control criteria that are capable of being accredited by an external body.

### **1.3 Scope**

- 1.3.1 These guidelines consider the three key stages of the workplace drug testing process.
  - 1.3.1.1 Obtaining the specimen from the donor (specimen collection).
  - 1.3.1.2 Analysis of the sample for the presence of drugs (laboratory analysis).
  - 1.3.1.3 Review and interpretation of the analytical results (interpretation).



## 1.4 Definitions

- 1.4.1 Within this document the following definitions apply:
- 1.4.1.1 **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 contracting with a laboratory.
  - 1.4.1.2 **Laboratory:** The facility providing the analytical services to detect drugs of abuse.
  - 1.4.1.3 **Customer:** The organisation requesting the drug testing service.
  - 1.4.1.4 **Donor:** The person providing the specimen for analysis.
- 1.4.2 Further definitions relating to elements of the services are provided in Section 8.

## 1.5 Service Provision

- 1.5.1 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.
- 1.5.2 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.
- 1.5.3 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.

## 1.6 Drug Testing in Context

- 1.6.1 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.



- 1.6.2 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.

## **1.7 Outline of drug testing process**

### **1.7.1 Collection**

- 1.7.2 The usual specimen collected for analysis is urine.
- 1.7.3 Urine specimens for legally defensible drug testing need to be collected under circumstances which respect the dignity of the individual whilst ensuring that the sample is freshly voided.
- 1.7.4 Suitable records must be made when the specimen is collected to prove that the specimen collected and the sample received by the laboratory is one and the same.
- 1.7.5 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.

### **1.7.6 Analysis**

- 1.7.7 When the sample is received at the laboratory, checks on the integrity of the sample are carried out. Providing the sample passes the integrity checks a portion of the sample is taken and screened for the presence of drugs. If the screen results are all negative no further analysis is necessary.
- 1.7.8 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 indicated by the screening test must be carried out on another portion of the sample.
- 1.7.9 When a negative result is obtained, either after the screen or confirmation test, it can be reported to the customer. Positive results may require interpretation.

### **1.7.10 Interpretation**



1.7.11 A laboratory positive result may be due to other reasons than intake of illicit drugs (i.e medication (prescribed or over-the-counter) or to dietary causes).

1.7.12 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.

### **1.7.13 Record Keeping**

1.7.14 Suitable records must be made during the analytical process to prove that the sample received by the laboratory and the sample, about which the final report is written, are one and the same.

1.7.15 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 to allow for any challenges to be made regarding the findings.

1.7.16 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.

## **1.8 Laboratory Security**

1.8.1 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.

1.8.2 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.

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

1.8.4 Sample bottles must be retained within the secure laboratory area until the disposal date agreed with the customer.





## 2 Specimen collection

### 2.1 Overview

- 2.1.1 Urine specimens for legally defensible drug testing need to be collected under circumstances which respect the dignity of the individual whilst ensuring that the sample is freshly voided and has not been tampered with in any way.
- 2.1.2 Suitable records must be made to prove that the specimen collected and the sample received by the laboratory are one and the same.
- 2.1.3 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 sample collected.
- 2.1.4 Where the customer takes responsibility for the collection process, the service provider has a duty of care to ensure that these guidelines are understood.

### 2.2 Personnel

- 2.2.1 Specimens must be collected by suitably trained personnel (Collecting Officers) who have a thorough understanding of the principles of chain of custody.
- 2.2.2 There are no specific qualifications, but collecting officers must be able to provide evidence of their training, and/or the instructions that they must follow during the collection process.

### 2.3 Procedures

- 2.3.1 The guidelines give the current best practice for the collection of urine specimens for analysis. An example of a typical specimen collection protocol is given in Appendix A.
- 2.3.2 The procedures must cover the following aspects:
  - 2.3.2.1 Privacy and security of the specimen collection site.
  - 2.3.2.2 Steps to ensure that the specimen is freshly voided.
  - 2.3.2.3 Steps to protect against tampering and adulteration.
  - 2.3.2.4 Identification of the individual giving the specimen.



2.3.2.5 Evidence of the written informed consent of the individual to the analysis of the specimen (an example is given in Appendix B).

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

## **2.4 Specimen Collection Kits**

2.4.1 The specimen collection kits should comprise the following components

2.4.1.1 Chain of Custody Form.

2.4.1.2 Barcode link between Chain of Custody Form and Sample Bottles.

2.4.1.3 Collection cup, demonstrably clean and unused.

2.4.1.4 Temperature measurement device.

2.4.1.5 At least two sample bottles, demonstrably clean and unused.

2.4.1.6 Secure seal for each bottle.

2.4.1.7 Packaging components that satisfy current mail and courier regulations.

## **2.5 Chain of Custody Form**

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

2.5.1.1 Information identifying the donor.

2.5.1.2 Date and time of collection.

2.5.1.3 Name of testing laboratory.

2.5.1.4 Names and signatures of all individuals who had custody of the sample during the collection process.



## 3 Laboratory Organisation

### 3.1 Personnel

- 3.1.1 The Laboratory must be staffed by suitably qualified personnel. The key roles, qualifications and responsibilities are outlined below. It is acceptable for individuals to perform more than one role.
- 3.1.2 The Laboratory must keep records that establish the individual's competency for the position(s) held. The individual's file must include a CV showing qualifications and previous employment experience, and training records for the current tasks performed.
- 3.1.3 All laboratory personnel must have received training in laboratory safety to ensure compliance with relevant legislation.

### 3.2 Laboratory Head

- 3.2.1 There must one person who has overall responsibility for the professional, organisational, educational, and administrative activities of the drug testing facility.
- 3.2.2 This person is responsible for the day-to-day management of the drug testing laboratory.
- 3.2.3 Some of the functions may be delegated to other appropriately qualified personnel but the overall responsibility for any delegated functions will remain with the designated Laboratory Head (typically the Laboratory Manager).
- 3.2.4 Qualifications:
  - 3.2.4.1 At least a degree or degree equivalent in, for example, the chemical or biological sciences or medical technology.
  - 3.2.4.2 Training, experience and a thorough understanding of chain of custody procedures, quality control practices, and the theory and practice of all analytical methods and procedures used in the laboratory.
- 3.2.5 Responsibilities:



- 3.2.5.1 Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug-testing laboratory.
- 3.2.5.2 Assure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.
- 3.2.5.3 Ensure that the laboratory has a manual of Standard Operating Procedures (SOPs), which is complete, up-to-date, and available for personnel performing tests, and followed by those personnel.
- 3.2.5.4 Maintain a quality control program to assure the proper performance and reporting of all test results in compliance with SOPs.
- 3.2.5.5 Maintain acceptable analytical performance for all controls and standards; for maintaining quality control testing.
- 3.2.5.6 Assure and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.
- 3.2.5.7 Ensure that all remedial actions necessary to maintain satisfactory operation and performance of the laboratory are taken (eg in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of external QA results), and that sample results are not reported until all appropriate corrective actions have been taken.
- 3.2.5.8 Ensure that the results provided are accurate and reliable.

### **3.3 Authorising Scientist**

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



3.3.2.1 At least a degree or degree equivalent in, for example, the chemical or biological sciences or medical technology.

3.3.2.2 Training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies.

3.3.3 Responsibilities:

3.3.3.1 Ensure that the results provided are accurate and reliable.

### **3.4 Laboratory Analyst**

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

3.4.2 Qualifications:

3.4.2.1 Appropriate training and experience in the theory and practice of the procedures used in the laboratory.

3.4.3 Responsibilities:

3.4.3.1 Maintenance of chain of custody.

3.4.3.2 Day-to-day analytical procedures following SOPs.

3.4.3.3 Remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

### **3.5 Toxicologist**

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

3.5.2 Qualifications:

3.5.2.1 At least a degree or degree equivalent in, for example, the chemical or biological sciences/medical technology and pharmacology/toxicology.



3.5.2.2 Training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual interprets. Thorough understanding of pharmacology and/or toxicology.

3.5.3 Responsibilities:

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

### **3.6 Expert Witness**

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

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

### **3.7 Other Personnel**

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

### **3.8 Quality Manager**

3.8.1 The person who assumes responsibility for quality assurance within the laboratory.

3.8.2 Qualifications:

3.8.2.1 Training and experience in auditing within an ISO or other relevant regulatory environment.

3.8.3 Responsibilities:

3.8.3.1 Monitoring the laboratory's quality control programme.

3.8.3.2 Auditing the laboratory operations in accordance with these guidelines.

3.8.3.3 Verify that all remedial actions necessary to maintain satisfactory operation and performance of the laboratory are taken.



## **4 Laboratory Analysis Procedures**

### **4.1 Summary**

- 4.1.1 When the sample is received at the laboratory, initial checks on the sample's chain of custody and appearance are carried out. If the sample passes these checks a portion of the sample is taken and goes through an initial screening test for the presence of drugs. Further testing of sample validity may also take place at this point.
- 4.1.2 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 pre-defined cut-off level) a confirmation test to prove or disprove the presence of the drug indicated by the screening test must be carried out on another portion of the sample.

### **4.2 Chain of Custody**

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

### **4.3 Receiving/Accessioning**

- 4.3.1 The laboratory should expect to receive at least two sealed sample bottles, and a chain of custody form, for every specimen collected.
- 4.3.2 At least one of these (referred to, in this document, as the "B" bottle) must be retained unopened and stored in conditions that reflect the storage of the sample under test (referred to, in this document, as the "A" bottle).
- 4.3.3 When a sample is received in the laboratory:
  - 4.3.3.1 Its packaging must be examined for evidence of tampering in transit.



- 4.3.3.2 The information on the sample bottles within the package must be compared with the information on the accompanying chain of custody form.
- 4.3.3.3 Any discrepancies must be noted and reported to the customer. Some minor discrepancies may be tolerated in the documentation without termination of the analysis. These must be agreed with the customer prior to analysis and should be documented.
- 4.3.3.4 Appendix C lists examples of flaws in the chain of custody and is given as guidance.

#### **4.4 Sample Processing**

- 4.4.1 Separate representative portions (aliquots) of the sample in bottle 'A' will be used for the screen and confirmation tests. Aliquots must be taken in such a manner that excludes the possibility of contamination.
- 4.4.2 The quality control requirements in section 5 must be satisfied when conducting either screen or confirmation tests, either on single samples, or samples grouped in batches.

#### **4.5 Urine validity testing**

- 4.5.1 The aim of validity testing is to demonstrate that the sample submitted for analysis is urine. The validity of the sample must be checked either before or during the screening process. Creatinine should always be analysed. The laboratory may also test for pH, nitrite or other adulterants.
- 4.5.2 Determination of the creatinine concentration
  - 4.5.2.1 If the creatinine concentration is less than or equal to 2.0 mmol/L (226 mg/l), the specific gravity must be determined. Acceptable values for specific gravity are 1.001 – 1.020.
  - 4.5.2.2 Samples with creatinine results within the range 0.5-2.0 mmol/l (56 -226 mg/l) and specific gravity results within range, should be reported as dilute.





4.5.2.3 Samples with creatinine results less than or equal to 0.5 mmol/l (56 mg/l) or specific gravity results out of range are unsuitable for testing and should be reported as eg “sample integrity failed”.

#### 4.5.3 Measurement of pH

4.5.3.1 Results within the range 4-9 are deemed to be within a normal range. Results less than 3 or greater than 11 should be considered to be adulterated. Samples falling outside this range should be reported as eg “sample integrity failed”.

#### 4.5.4 Nitrite test: If the nitrite concentration is determined:

4.5.4.1 A nitrite level equal to or above 500 µg/ml is conclusive proof of an adulterated sample. The result should be reported as eg “sample integrity failed”.

#### 4.5.5 Testing for other adulterants:

4.5.5.1 If other tests indicate that the sample has been adulterated, or is otherwise unsuitable for analysis then it should be reported as eg “sample integrity failed”

4.5.5.2 This remark is also reported when the sample does not fall under the criteria of pH, creatinine or nitrite above, yet is still not suitable for testing. This can be due to an unidentified interferant or poor sample quality such as turbidity.

### 4.6 Screen Test

4.6.1 The initial screening test must use an appropriate technique. Appendix D contains a list of currently agreed and accepted techniques. The assay, using the selected technique, must be validated prior to its use (see 5.2 Quality Control).

4.6.2 Recommended maximum screening calibration cut-off concentrations for workplace drug testing are given in Appendix E. These recommended cut-off concentrations may be subject to changes reflecting advances in technology.



- 4.6.3 Cut-off concentrations 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.
- 4.6.4 All screen test results must be reviewed with regard to the results of the validity tests performed.
- 4.6.5 Samples that test negative on all the initial screen tests and pass the validity tests must be reported as negative, and the samples can be disposed of.
- 4.6.6 Samples that test negative on all the initial screen tests but fail the validity tests may be further investigated to determine the reason why.
- 4.6.7 Samples which test positive for any drug on the initial screen test must have the presence of the drug confirmed (see 4.8 Confirmation Test)

#### **4.7 Standardisation of screen assays**

- 4.7.1 All assays must be calibrated against appropriate standards, following laboratory protocols based on the manufacturer's recommendations.
- 4.7.2 Where the assay has significant cross-reactivity to related compounds the assay must be calibrated against one named compound, and where necessary the sensitivity to other compounds must be determined.
- 4.7.3 The customer must be informed of the expected sensitivity to these compounds.

#### **4.8 Confirmation Test**

- 4.8.1 The presence of the drugs indicated by a positive screen result must be confirmed using a chromatographic technique in combination with mass spectrometry (e.g. GC/MS, LC/MS). All confirmations must be quantitative.
- 4.8.2 Recommended confirmation cut-off concentrations for workplace drug testing are given in Appendix F.



- 4.8.3 Confirmation cut off concentrations maybe subject to change as advances in technology or other considerations warrant identification of substances at other concentrations.
- 4.8.4 Confirmation cut-off levels for substances not indicated in Appendix F must be agreed with the customer taking into account the performance of the assays to be used.
- 4.8.5 Samples that are below the agreed cut off concentration must be reported negative. No further testing for drugs will be undertaken and the samples must be discarded.
- 4.8.6 Samples that contain drug or metabolite at concentrations greater than or equal to the agreed cut-off level must be reported positive.

#### **4.9 Authorisation and reporting of Results**

- 4.9.1 Before any laboratory test result is released, the results must be reviewed and certified as accurate by an Authorising Scientist.
- 4.9.2 At a minimum, the report must include the specimen identification number, the result (positive/negative) for each sample submitted and the cut-off which is used.
- 4.9.3 Only drugs which have been confirmed by a recognised confirmation test can be reported as positive.
- 4.9.4 Samples that fail integrity or validity tests must be identified to the customer on the report.
- 4.9.5 The laboratory must define and agree the meaning of all terms used in the report to the customer.
- 4.9.6 Results must be transmitted to the customer's designated representative in a manner that will ensure confidentiality of the information.
- 4.9.7 Laboratory results must not be provided verbally.

#### **4.10 Long-Term Storage of Samples**

- 4.10.1 Long-term frozen storage (-15°C or below) ensures that positive urine samples will remain suitable for any necessary retest.



- 4.10.2 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.
- 4.10.3 Within this one-year period the customer may request the laboratory to retain the sample for an additional period of time. If no such request is received, the laboratory may discard the sample after the end of 1 year, except that the laboratory shall be required to maintain any samples known to be under legal challenge for a further agreed period.

#### **4.11 Records**

- 4.11.1 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.
- 4.11.2 The required documentation must include
- 4.11.2.1 Training records on all individuals authorised to have access to samples.
  - 4.11.2.2 Chain of custody forms.
  - 4.11.2.3 Quality assurance/quality control records.
  - 4.11.2.4 Procedure manuals.
  - 4.11.2.5 All test data (including calibration curves and any calculations used in determining test results).
  - 4.11.2.6 Reports.
  - 4.11.2.7 Records of performance testing and computer-generated data.
- 4.11.3 The laboratory will be required to maintain documents for any sample under legal challenge for a further agreed period.
- 4.11.4 Records containing details of individuals will be dealt with in line with relevant Data Protection Legislation.



## **5 Quality Assurance and Quality Control**

### **5.1 Quality assurance**

- 5.1.1 Drug testing laboratories must have a quality system which encompasses all aspects of the testing process including but not limited to
  - 5.1.1.1 Sample receipt.
  - 5.1.1.2 Chain of custody.
  - 5.1.1.3 Security and reporting of results.
  - 5.1.1.4 Screen and confirmation testing.
  - 5.1.1.5 Certification of calibrators and controls.
  - 5.1.1.6 Validation of analytical procedures.
- 5.1.2 Quality assurance procedures shall be designed, implemented and reviewed to monitor the conduct of each step of the testing process.
- 5.1.3 The standard set by ISO 17025 must apply.
- 5.1.4 The laboratory must be accredited for Workplace Drug Testing by a recognised external accreditation body working to these European guidelines.

### **5.2 Quality Control**

- 5.2.1 Laboratory calibrators and controls shall be prepared using either certified drug reference materials or standard solutions obtained from commercial manufacturers.
- 5.2.2 The laboratory must retain records to demonstrate that all calibrators and controls are traceable back to primary standards (if available).
- 5.2.3 The calibrators and controls shall be properly labelled as to content and concentration.
- 5.2.4 All standards (eg pure reference materials, stock standard solutions, purchased standards) shall be labelled with the following dates:
  - 5.2.4.1 When received (if applicable).
  - 5.2.4.2 When prepared or opened.



5.2.4.3 When placed in service.

5.2.4.4 Expiration date.

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

### **5.3 Screen Tests**

5.3.1 These are the minimum requirements for the suitable control of all screen tests.

5.3.2 A system suitability check must be carried out prior to the analysis of samples.

5.3.3 Assays must be calibrated at least once per week.

5.3.4 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.

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

### **5.4 Confirmation tests**

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

5.4.2 A system suitability check must be carried out prior to the analysis of samples.

5.4.3 A calibration curve must include at least 3 calibration points and a blank. The calibration points must bracket the cut-off concentration.

5.4.4 Quantitative analysis must be carried using internal standardisation. The use of deuterated internal standards, when obtainable, is recommended.

5.4.5 An independently prepared control sample at a concentration of approximately the cut off concentration for each drug must be included in every batch of samples analysed.



- 5.4.6 Checks on assay drift and carry-over must be performed at intervals within each assay.
- 5.4.7 The retention time of a compound shall be within  $\pm 3$  seconds (or  $\pm 2\%$ , whichever is the lower) of the retention time of the calibration standard.
- 5.4.8 If using selected ion monitoring or its equivalent
  - 5.4.8.1 a minimum of three specific and significant ions shall be used.
  - 5.4.8.2 No ions less than  $m/z$  50 are to be used.
  - 5.4.8.3 The common low mass ions,  $m/z$  58, 86, 91, 105 shall not be considered as specific but may be included in addition to any other specific ion.
  - 5.4.8.4 The ratio of these ion intensities in the unknown shall be within 20% of corresponding ratios in the extracted reference material.
  - 5.4.8.5 If using deuterated internal standards, two specific and significant ions shall be used.
- 5.4.9 If using full scan to identify the compounds
  - 5.4.9.1 the scan range shall be from  $m/z$  50 to a value above that expected for the molecular weight of the compound or its derivative.
  - 5.4.9.2 All significant ions present in the calibration standard shall also be present in the sample.
  - 5.4.9.3 the ratio of the ion intensities of the significant ions in the sample must be within 30% of the corresponding ion intensities in the extracted calibration standard.
  - 5.4.9.4 The presence of significant ions in the spectrum of the unknown that are not in the spectrum of the calibration standard is acceptable provided that their presence can be explained and discounted.

## 5.5 Quality assessment

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



## **5.6 Sub-contracting**

- 5.6.1 Drug testing laboratories should perform all laboratory work with their own personnel and equipment. Interlaboratory transfer of samples is performed with strict adherence to chain of custody procedures. The sub-contracted laboratory must be accredited by a recognised external accrediting body and working to these guidelines.





## 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.

- 6.1.1 The B sample should be released for analysis to a drug-testing laboratory accredited by a recognised external accrediting body and working to these guidelines.
- 6.1.2 This release requires authorisation from the customer and the donor.
- 6.1.3 The release must be supported by a chain of custody that can withstand legal scrutiny and a copy of the quantitative result obtained on the corresponding A sample.
- 6.1.4 The original laboratory must retain the residue of the original sample and its containers, so that they can be compared with the B sample at a later date, if required.
- 6.1.5 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 B.
- 6.1.6 It is recommended that the laboratory that receives the B sample must perform a confirmation analysis only for those drugs identified to it, within 10 working days of receipt.
- 6.1.7 The final report on the B sample must say either that there was no drug found, or a named drug was found at a level that is either consistent or inconsistent with the level in the corresponding A sample.
- 6.1.8 The determinant as to whether a drug is found or not is the limit of quantitation quoted for the method used to confirm the presence of the drug.
- 6.1.9 Confirmation cut-off levels are not to be used as the determinant.
- 6.1.10 There must be no comment on the final report that states whether the sample is positive or negative.



## **7 Interpretation of Results**

- 7.1.1 An analytical positive result may be due to medication (prescribed or over-the-counter) or to dietary causes. An essential part of the drug testing process is the final review of positive analytical results.
- 7.1.2 The interpretation is best carried out by a qualified medical practitioner (Medical Review Officer - see Appendix G) who can consult with the laboratory toxicologist, the donor, and the donor's medical practitioner.

### **7.2 Toxicology Review**

- 7.2.1 A toxicologist must be available to advise the customer and/or Medical Review Officer regarding queries with results.
- 7.2.2 The toxicologist cannot issue a negative report for a positive analytical result even if the test result is likely to be due to the use of declared medication.



## 8 Definitions

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

<b>Adulteration</b>	See Tampering
<b>Aliquot</b>	A fractional part of a sample used for testing. It is taken as a sample representing the whole sample.
<b>Authorising Scientist</b>	A person who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports.
<b>Calibrator</b>	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 range of interest.
<b>Chain of Custody</b>	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 samples until disposal.
<b>Chain of Custody Form</b>	A form used to document the procedures from time of collection until receipt by the laboratory.
<b>Collecting officer</b>	A person trained to collect specimens from donors.
<b>Collection</b>	A place where individuals present themselves for



<b>Site</b>	the purpose of providing a specimen for analysis.
<b>Confirmation Test</b>	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 technique and chemical principle from that of the screen test in order to ensure reliability and accuracy.
<b>Cut-off</b>	A concentration level set to determine whether the sample is positive or negative for the presence of a drug.
<b>Donor</b>	The individual from whom a urine specimen is collected.
<b>Negative result</b>	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.
<b>Positive result</b>	A result reported by the laboratory as positive means that there is conclusive evidence that a drug is present in the sample tested at level greater than or equal to the confirmation cut off concentration.
<b>Quality control sample</b>	A sample used to evaluate whether or not an analytical procedure is operating within pre-defined tolerance limits.
<b>Medical Review Officer (MRO)</b>	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.
<b>Sample</b>	A representative portion of a specimen submitted to a laboratory for testing.

<b>Screen Test</b>	A test to eliminate negative samples from further consideration and to identify the presumptively
--------------------	---



	positive samples that require confirmation testing.
<b>Specimen</b>	The portion of (normally) urine that is collected from a donor.
<b>Standard (1)</b>	A reference material of known purity or a solution containing a reference material at a known concentration.
<b>Standard (2)</b>	An agreed protocol or procedure (eg ISO 17025)
<b>Standard Operating Procedure (SOP)</b>	A written document giving the detailed steps to be followed when undertaking a particular task (e.g. the analysis of a given drug in a urine sample).
<b>Tampering</b>	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.



## **Appendix A**

### ***Urine Collection Procedures - an example of a typical protocol appropriate for [country]***

#### ***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 drug testing and comply with all local health and safety requirements.

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

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

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

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

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

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

#### ***V) Privacy***

Procedures for collecting urine specimens shall allow individual privacy during urination.

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

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

- (a) To deter the dilution of specimens at the collection site, toilet water colouring agents should be placed in toilet tanks wherever accessible or in the toilet bowl, so the reservoir of water in the toilet bowl always remains coloured. Any other sources of water in the enclosure where urination occurs (e.g. taps, shower) will be secured prior to collection.
- (b) The collection officer will ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or



substances that could be used to tamper with or adulterate the donor's urine specimen. The collection officer will ensure that all personal belongings such as a purse or briefcase remain with the outer garments.

- (c) The donor will be instructed to wash and dry his or her hands prior to urination with inspection of the hands afterwards by the collection officer.
- (d) After washing hands, the donor will remain in the presence of the collection officer and will not have access to any unregulated source of water, soap dispenser, cleaning agent, or any other materials that could be used to adulterate the specimen.
- (e) The collection officer will give the donor a clean specimen container. The donor may provide his/her specimen in the privacy of a toilet cubicle or otherwise partitioned area that allows for individual privacy. The collection officer will remain outside the cubicle until the specimen is collected. The donor will be instructed not to flush the toilet until the specimen is handed to the collection officer.
- (f) The collection officer will note any unusual behaviour of the donor on the chain of custody form.
- (g) Upon receiving the specimen from the donor, the collection officer will:
  - Check the volume of urine in the specimen container and
  - Check the temperature of the urine specimen. (The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case should exceed 4 minutes).
  - Inspect the specimen to determine its colour and appearance for any signs of contaminants. Any unusual findings will be noted on the chain of custody form.

If the volume is approx. 30 millilitres (ml) or more and the temperature is within the acceptable range of 32° -38°C, the collection officer will proceed with step (h) below.

If the volume is less than 30 ml, the specimen will be discarded and a second specimen will be collected. The donor may be offered a reasonable amount of liquid to drink for this purpose (e.g., 250ml of water every 30 min, but not to exceed a maximum of 1 litre). In these circumstances a donor should normally be able to provide a 30 ml urine specimen within 2 to 3 hours. If the donor fails to provide a



specimen within this time period the collecting officer will contact the appropriate authority to obtain guidance on the action to be taken.

If the temperature of the urine specimen is outside the acceptable range of 32° -38°C, a second specimen will be collected (as above). A temperature outside of the range is a reason to be suspicious that the donor may have altered or substituted the specimen. If there is any reason to believe (temperature outside of range, visible contamination etc) that a donor may have adulterated, diluted, altered or substituted the specimen, another specimen will be obtained as soon as possible and both specimens will be forwarded to the laboratory for testing.

- (h) Both the donor and the collection officer will keep the specimen container /specimen bottles in view at all times prior to the urine specimen being sealed and labelled.
- (i) The specimen is split into a minimum of two specimen bottles. When the specimen is transferred from the specimen container to the specimen bottles, it will be poured and the collection officer will request the donor to observe the transfer of the specimen and the attachment of the tamper-evident seal/tape on the bottles. The tamper-evident seal ensures that any tampering with the specimen will be evident to laboratory personnel during the laboratory receipt.
- (j) Direct contact tests can only be carried out on the residue of the specimen after the sample has been split and sealed into specimen bottles.
- (k) A minimum of two sealed specimens together with the corresponding chain of custody documentation in a tamper evident container must be dispatched to the laboratory. One bottle will be used for the drug test while the second bottle will remain sealed at the analytical laboratory in case the donor wishes to challenge a positive result.
- (l) At an appropriate time after the urine specimen has been collected and sealed into the transport bottles the collection officer will invite the donor to wash his/her hands.
- (m) The specimen bottle will have an identification label that contains at a minimum the date, the donor's specimen number and the donor's signature/initials. The collection officer will enter all information on the chain of custody form to identify the origin of the specimen. Both specimen bottles and all pages of the chain of custody will be labelled at the time of collection with a unique identifier.
- (n) The collection officer will ask the donor questions relating to the drugs and medicines consumed within a minimum of 14 days prior to the provision of the urine specimen. These questions will be specific





and wide ranging covering areas such as medications prescribed or dispensed by a doctor, dentist or hospital department and over-the-counter preparations.

- (o) 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 B gives an example of a Donor's Statement of Informed Consent.
- (p) The collection officer will complete the specimen chain of custody form and package with the urine specimen ready for dispatch together to the analytical laboratory as soon as possible. If the specimen is not dispatched at once, the collection officer during storage prior to dispatch must give appropriate consideration to the temperature and security of the specimens, It is advised that the specimens should be stored at 4°C (do not freeze) when ever possible.
- (q) Other pages of the chain of custody form will be given/forwarded to the appropriate persons.
- (r) The collection officer and the donor will be present throughout the procedures outlined in the paragraphs of this section.

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

- (s) Collection officers will arrange to dispatch the collected specimens to the drug-testing laboratory. The specimens will be placed in containers designed to minimise the possibility of damage during shipment. Since specimens and the corresponding documents are sealed in packages that would indicate any tampering during transit to the laboratory by couriers, carriers, and postal services 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 Consent**  
**appropriate for [country]**

I confirm that I have provided a freshly voided urine specimen to the specimen collector. I have observed the specimen being placed and sealed in the specimen bottles 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 flaws in the Chain of Custody***

1. Barcode mismatch 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 any bottle
5. No seals
6. Only 1 sample received
7. Insufficient sample for complete analysis
8. Leaking sample



## ***Appendix D***

### ***Acceptable Screening Techniques***

1. Immunoassay
2. Gas Chromatography
3. High Pressure Liquid Chromatography
4. Enzyme-based assays
5. Any chromatographic technique hyphenated to mass spectrometry.



## **Appendix E**

### ***Recommended maximum cut-off concentrations for Screening Tests appropriate for [country]***

<b>Screen Test</b>	<b>Cut-Off Concentration (ng/ml)</b>
Amphetamine group	500
Benzodiazepines group	200
Cannabis metabolites	50
Cocaine metabolites	300
Opiates (total)	300
Methadone or metabolites	300
Barbiturates	200
Phencyclidine	25
Buprenorphine or metabolites	5
LSD or metabolites	1
Propoxyphene or metabolites	300
Methaqualone	300

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.

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.



## **Appendix F**

### ***Recommended cut-off concentrations for confirmation tests appropriate for [country]***

<b>Confirmation Test</b>	<b>Cut-Off Concentration (ng/ml) (Total)</b>
Amphetamines	
Amphetamine	200
Methylamphetamine	200
MDA	200
MDMA	200
MDEA	200
Other members of the amphetamine group	200
Benzodiazepines	
Temazepam	100
Oxazepam	100
Desmethyldiazepam	100
Others members of the benzodiazepine group by agreement with the customer.	
Opiates (total)	
Morphine	300
Codeine	300
Dihydrocodeine	300
6-Monoacetylmorphine	10
Cannabis metabolite (11-nor- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid.)	15
Cocaine metabolite (benzoylecgonine)	150
Methadone or metabolites	250
Barbiturates group	150
Phencyclidine	25
Buprenorphine or metabolites	5
LSD or metabolites	1
Propoxyphene or metabolites	300
Methaqualone	300



## ***Appendix G***

### ***Medical Review***

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