Guidelines for Legally Defensible Workplace Drug Testing

Specimen Collection Procedures

Version 2.0, valid from Oct 2011

1.0 Context

1.1 Legally defensible workplace drug testing is a three stage process. The specimen has to be collected, analysed and finally the analytical result has to be correctly interpreted. This all has to be done in the context of 'Chain of Custody'.

1.2 Chain of Custody is the system of controls which demonstrates that the specimen was freshly provided by an identified individual, and that the results reported relate beyond doubt to that specimen.

1.3 If any one of these three stages has flaws, then the whole process may be invalid:

Collection
Analysis
Interpretation of Results (Medical Review)

1.4 Where immediate test results are required Point of Collection Tests (POCT) can be utilised, but the principles and procedures for specimen collection outlined in these guidelines still apply.

2.0 Specimen Collection Guidelines

2.1 The collection of donor specimens involves some of the most difficult and sensitive areas of the workplace drug testing process. The Collecting Officer has to be aware that the donor may be nervous or unhappy or have understandable concerns about the test process.

2.2 These Guidelines for Specimen Collection Procedures therefore cover the general principles for Chain of Custody, the specific features for each specimen type (urine, oral fluid and hair), and the competency of the collecting officers.

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

3.0 General Principles

3.1 A collection should only involve one donor at a time, to prevent confusion between specimens and possible cross contamination.

3.1 The only people present should be the donor and the collecting officer. If the donor wants a third party present, to avoid distraction this third party should be a silent observer.

3.2 Specimens for legally defensible workplace drug testing need to be collected under circumstances which respect the dignity and confidentiality of the individual. They must guarantee the integrity of the specimen and ensure that it cannot be tampered with in any way.

3.3 Suitable records must be made to prove that the specimen collected and the specimen received by the laboratory are one and the same. The linking paperwork is referred to as the Chain of Custody Form, or Custody and Control Form.

3.4 The collecting officer is responsible for the secure handling and storage of the specimen(s) collected.

3.5 The collection process must be carried out by someone formally competence tested and authorised to perform the collection using the specific matrix / device agreed. A Standard Operating Procedure (SOP) must be written and followed precisely.

4.0 Procedures

4.1 The guidelines give the current best practice for the collection of specimens for laboratory analysis. Examples of typical specimen collection protocols for urine and oral fluid, including the use of POCT, are given in the Appendices.

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4.2 The procedures must cover the following aspects:

4.2.1 Privacy and security of the specimen collection site.

4.2.2 Identification of the individual giving the specimen.

4.2.3 Steps to protect against tampering and adulteration.

4.2.4 Evidence of the written informed consent of the individual to the analysis of the specimen.

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

4.3 Specimen Collection Site

4.3.1 The specimen collection site should be a dedicated room with clean and hygienic facilities, to guarantee privacy and security for the donor.

4.3.2 Access should be restricted to the collecting officer and the donor, but the donor may have a third party present. This person should be a 'silent witness' who should not interfere or question the procedures.

4.3.3 Facilities for personal hygiene should be available, and toilet facilities must be available for urine specimen collection .

4.4 Identification

4.4.1 The donor must provide evidence of identification (photo and signature).

4.4.2 If appropriate identification is not available then a supervisor or manager must sign to verify that the correct individual is being tested.

4.4.3 If the donor cannot be formally identified the collection should not start

4.5 Informed Consent

4.5.1 The donor must be aware of the reason for the test, must understand that it is to determine whether certain drugs have been used, and have an overview of what will happen to the specimen.

4.5.2 Where POC Tests are used, the donor must understand that a 'not negative' result from the on-site test device will require confirmatory analysis in a laboratory.

4.5.3 Provision of the specimen requested is taken as consent to the procedures. Formal written prior consent may also be obtained as additional confirmation.

4.5.4 The consent statement on the Chain of Custody form should provide consent for the sample to be analysed for drugs and their metabolites. It should also allow for the specimen to be checked for evidence of adulteration, substitution or other interference.

4.6 Medication

4.6.1 The donor should be invited to disclose recent medication (timescale will be dependent of sample type).

4.6.2 Should the donor refuse to do this, a note should be made that medication has been taken but not disclosed.

4.6.3 If the donor states that not medication has been taken within the specified period, this should be noted.

4.7 Specimen Collection Kits

4.7.1 Specimen Collection Kits must be suitable for the type of specimen being collected and should comprise the following components:

4.7.1.1 Sterile containers / devices for collecting the specimen:

4.7.1.1.1 collection cup with integral temperature measurement for urine

4.7.1.1.2 collection swab with indicator to show sample volume for oral fluid

4.7.1.1.3 sterile wipes for the scissors used to collect hair specimens

4.7.1.2 At least two specimen containers, demonstrably clean and unused.

4.7.1.3 Secure seal for each container, carrying the barcode link to the Chain of Custody Form

4.7.1.4 Packaging components that satisfy current mail and courier regulations.

4.8 Chain of Custody Form (Custody and Control Form)

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

4.8.1.1 Barcode identifier that links the form with the specimen containers

4.8.1.2 Identification of the donor (by name or code)

4.8.1.3 confirmation that the donor was formally identified as the person required to provide the specimen

4.8.1.4 Confirmation of sample integrity (will vary according to the type of specimen being collected)

4.8.1.5 Evidence that the donor was advised about medication (which can be recorded elsewhere)

4.8.1.6 Evidence that the donor has given consent for the specimen to be tested

4.8.1.7 Date and time of specimen collection

4.8.1.8 Signature of collecting officer

5 Collecting Officer Specification

5.1 Specimens must be collected by suitably trained, competence tested and authorised collection officers (CO's) who have a thorough understanding of the principles of chain of custody.

5.2 Collection officers must be trained, competence tested and authorised to collect process and transmit specimens according to the local SOP.

5.3 The training should include, at a minimum, instruction on

5.3.1 The concept and purpose of Chain of Custody

5.3.2 The principles of specimen collection (urine / oral fluid / hair)

5.3.3 Trouble shooting (e.g. shy bladder, dry mouth, shaven head)

5.3.4 Courtesy and consideration for the donor

5.3.5 Ethical issues

5.3.5.1 ownership of specimen

5.3.5.2 disclosure of POCT results

5.3.5.3 disclosure of medication

5.3.5.4 admission of illegal drug use

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6.0 Sample integrity – steps will vary according to the sample type

6.1 Urine collection must prevent any opportunity to substitute, dilute or adulterate or otherwise interfere with the specimen.

6.2 Oral fluid collection must establish that in the 10 minutes prior to the specimen being provided the donor has not taken anything by mouth, or held anything in the mouth eg chewing gum.

6.3 Hair collection must distinguish between the donor's head hair and real hair extensions or wigs

7.0 Other documents to consult include:

7.1 EWDTS Urine Guidelines

7.2 EWDTS Oral Fluid Guidelines

7.3 EWDTS Hair Guidelines