

## 1. Application

- 1.1. The provision of the services ("Services") by **E4Law Limited** trading as Lextox a company registered in England and Wales under number 7501682 of **The Maltings, East Tyndall Street Cardiff CF24 5EA** ("Supplier") to you ("Client") shall be subject to the terms of this service level agreement ("SLA"), the Supplier's quotation ("Quotation") and the Supplier's terms and conditions ("Terms and Conditions").

## 2. Sample Collection

- 2.1. The Supplier will provide a "Chain of Custody Sample Collection Kit" which stores the sample and provides chain of custody from collection to receipt at the Supplier's laboratory. It also identifies the donor, witness if applicable, and sample collector.
- 2.2. The Supplier can provide a sample collection service throughout England and Wales on request. The Supplier's collector ("Supplier Collector") will complete and sign the chain of custody form ("Chain of Custody") which shall be signed by the donor and collector and a witness if applicable. Normally two samples will be collected. Sample collection is not currently covered by our UKAS Schedule of Accreditation. The Chain of Custody sets out the terms on which the donor provides consent to the processing of their personal data in accordance with General Data Protection Regulation (EU) 2016/679 and related legislation.
- 2.3. All samples must have a fully completed Chain of Custody to ensure compliance with applicable laws. The Supplier shall provide detailed guidelines for scalp and body hair sample collection.
- 2.4. Samples may be returned to the laboratory in the prepaid envelope supplied, in person, by postal or courier service. They are logged and the integrity of the Chain of Custody checked immediately upon receipt at the Supplier's laboratory.
- 2.5. The Client is the Data Controller and is ultimately responsible for arranging the donor's consent via the Chain of Custody form

## 3. Non Routine Samples

- 3.1. If the Chain of Custody Sample Collection Kit is not completed or sealed correctly the Supplier will discuss the implications with the client and obtain their instruction before proceeding. For example;
  - if the pack is not signed by the donor;
  - if the sample seals are broken or
  - if there are discrepancies in the chain of custody information.This may delay the results being issued.
- 3.2. The Supplier recommends that each hair section should have a minimum weight of approximately 10mg to be analysed for drugs and approximately 20mg to be analysed for each of the alcohol markers. A section weighing less may be insufficient to allow detection of the requested compounds.
- 3.3. The Supplier may use the second hair sample from the Chain of Custody Sample Collection Kit with the first to obtain the recommended weight without prior authorisation from the client. This may result in there being insufficient 'B sample' to allow the result to be repeated by Lextox or another laboratory.
- 3.4. If the total weight of hair provided in the Chain of Custody Sample Collection Kit is not sufficient the Client will be informed and the following options offered:
  - the Supplier will continue with the analysis and report the findings or;
  - the collection of another hair sample can be arranged. In such circumstances, if the Supplier incurs further reasonable charges and delays in reporting results the Client will be liable for such additional charges.
- 3.5. If there is insufficient hair length to cover the time period requested by the Client (assuming the hair grows at a rate of one centimetre per month), if available, the second sample, the 'B Sample', will be opened to see if the sample is sufficient length for the requested analysis, this will be done without prior authorisation from the client. If the 'B Sample' is long enough then this sample will be used and the original 'A Sample' will be retained. If both samples have insufficient hair length, the available hair will be analysed and the client informed. The Client should notify the Supplier within 24 hours of being informed of the short hair length, if the Client wishes the Supplier to not report the analysis results. The Supplier's fees will be reduced accordingly.
- 3.6. In certain circumstances, a sample of hair may contain much older strands of hair than those that would normally be present, for example in dreadlocked hair. In such circumstances the client will be informed it may not be possible to determine the age of the sample and the period of time to which that sample relates. However, it may still be possible to determine the presence of a drug.

## 4. Analysis of Alcohol Markers

- 4.1. For consistency with the Society of Hair Testing (SoHT) Consensus on Chronic Excessive Alcohol Consumption, a 0-3cm or 0-6cm proximal section is recommended to be analysed. Shorter hair sections may be analysed but in such circumstances the results should be interpreted with caution as they will not be comparable to the cut-off levels recommended by the SoHT and detailed in the Consensus on Chronic Excessive Alcohol Consumption.
- 4.2. The SoHT Consensus can be found on the SoHT web site 'www.soht.org'.
- 4.3. The Supplier recommends that a 0-3cm proximal section, with a minimum hair weight of 20mg for each test, are analysed for both Ethyl Glucuronide (EtG) and Ethyl Palmitate (FAEE) for the most reliable interpretation.
- 4.4. The %UM and bias for the alcohol marker Ethyl Palmitate (FAEE) are 34.5% and -5.0% respectively refer to section 7.
- 4.5. The %UM and bias for the alcohol marker EtG are 30% and -7% respectively refer to section 7.

- 4.6. If the concentration is less than the reporting cut-off for Ethyl Glucuronide or Ethyl Palmitate (FAEE), then 'Not Detected' will be reported, otherwise the concentration in pg/mg for Ethyl Glucuronide and ng/mg for Ethyl Palmitate (FAEE) will be reported
- 4.7. This is summarised in the table below;

Compound	SoHT Cut-off	Lextox Reporting Cut-off
Ethyl Glucuronide	30.0pg/mg	30.0pg/mg
Ethyl Palmitate (FAEE) (0-3cm)	0.35ng/mg	0.35ng/mg
Ethyl Palmitate (FAEE) (0-6cm)	0.45ng/mg	0.45ng/mg

- 4.8. If scalp hair samples are received with lengths less than 3cm we will use a graduated reporting cut-off scheme to take into account the empirical findings that EtG levels generally increase in hair closer to the scalp, whereas Ethyl Palmitate (FAEE) levels generally decrease in hair closer to the scalp. For example, if 2cm of hair is supplied a cut-off of 45pg/mg will be applied for EtG, and a cut-off of 0.32ng/mg will be applied for Ethyl Palmitate (FAEE). For samples that measure between 3 and 6 cm in length a graduated scale for Ethyl Palmitate (FAEE) will also be applied.
- 4.9. Samples shorter than 1cm will not be analysed.
- 4.10. The use of cosmetic hair treatments such as hair dyes and bleaches can lead to a significant decrease in the level of EtG detected, whereas the use of products containing ethanol (ethyl alcohol) could elevate the level of Ethyl Palmitate (FAEE) detected.
- 4.11. The Supplier will analyse body hair samples for evidence of the alcohol markers EtG and Ethyl Palmitate (FAEE); however, we will only analyse samples collected from the chest, arm or leg. The Supplier recommends that a minimum hair weight of 20mg for each test is analysed for both Ethyl Glucuronide (EtG) and Ethyl Palmitate (FAEE). The cut-offs applied to all body hair samples, irrespective of their length, are 30pg/mg for EtG and 0.35ng/mg for Ethyl Palmitate (FAEE).

**5. Sample Testing**

- 5.1. All samples are analysed either by LC-MS/MS (Liquid Chromatography with Mass Spectrometry and Mass Spectrometry) or GC-MS/MS (Gas Chromatography with Mass Spectrometry and Mass Spectrometry) so as to provide a quantitative result.
- 5.2. The analysis result for each drug/metabolite is reported as 'Not Detected' if it is below the corresponding Reporting Cut Off as listed in Table 1. If the result is on or above the Reporting Cut Off and meets all other analytical and reporting criteria the quantity detected per milligram of hair is stated on the Certificate of Analysis or in the Expert Report.
- 5.3. Some compounds, which are not critical to the interpretation of the result, will not be reported if they fail any analytical or reporting criteria. All other compounds, critical to the interpretation, will be reported. All results will be reported as ng/mg apart from Ethyl Glucuronide which will be reported in pg/mg.
- 5.4. In the case of benzoylecgonine, as this metabolite is a hydrolysis product i.e. can be produced externally then a BZE/cocaine ratio of 5% will be applied. If the benzoylecgonine falls below the 5% ratio it will be reported as 'Not Detected'.
- 5.5. Donors who are aged 12 or under will be classified as a 'child' and the wash samples will be routinely analysed for the requested drugs and reported. The Reporting Cut Off levels will be applied and any drug/metabolite requested that is on or above the Reporting Cut Off level will be reported with a concentration value. Any drug/metabolite requested that falls below the Reporting Cut Off level but above the lowest calibrator for that run will be reported as 'Present'.

**6. Sample Reporting**

- 6.1. All individual sample results are reviewed by experienced scientific staff before results are reported. Any report from the Supplier will only contain the results of testing in respect of the drug or drug groups requested by the Client.
- 6.2. All reported results will receive either a Certificate of Analysis or an Expert Report. The Certificate of Analysis will be accompanied by a covering letter summarising the results. The Certificate of Analysis will include the following items:
- Donor Name, Date of Birth and Gender;
  - Unique Sample Number;
  - Collection Date;
  - Client Name and Address, Reference and/or Account Reference;
  - Sample Type;
  - Hair Section Length and Corresponding Approximate Time Period if applicable; and
  - Testing Method and Results.
- 6.3. The Supplier may, subject to an additional charge payable by the Client, provide a detailed Expert Report on the results for presentation to Court if requested by the Client.

- 6.4. The Supplier monitors its reporting times and endeavours to report all results within approximately five working days from satisfactory receipt of the sample at its laboratory. The Supplier's current delivery time for results and reports is 4 working days from satisfactory receipt of the sample at its laboratory. If the results are to be presented to Court, we recommend the Client ensures the sample is received by the Supplier at the laboratory at least 10 working days before the Court date.
- 6.5. Metabolites are produced by the body when a drug is ingested and metabolised (broken-down), and traces of the metabolites are deposited in the hair shaft in the same way as the parent drug. Drug use will only be stated in an Expert Report where there is the presence of metabolites, whereas the detection of the parent drug only allows a statement of positive association with the drug, which may include the use. This will be the case for delta-9-THC, cocaine, MDMA, heroin, diazepam, methadone and buprenorphine.
- 6.6. The Supplier will display all numerical values to three significant figures or the appropriate number of decimal places
- 6.7. Opinions and interpretations, and sample collections are not currently covered under the company's ISO 17025 Scope of Accreditation.

## 7. Uncertainty of Measurement (%UM) and Bias

- 7.1. The Supplier measures the Uncertainty of Measurement (%UM) and bias of analytical methods it uses. The %UM and bias indicate the variability of the analytical test and indicate the range of values within which the true value will be found. The Supplier estimates the Uncertainty of Measurement using a standard uncertainty multiplied by a coverage factor of K=2, resulting in a confidence level of 95%. Where possible the %UM will be calculated using an incurred sample as this will include variations due to extraction from the hair matrix. For some drugs the uncertainty associated with hair extraction is not possible to measure. In these cases a correction will be made based on the results of participation in external proficiency testing schemes. The levels of drugs, metabolites and alcohol markers reported are the actual values obtained and do not factor in the %UM.

## 8. Fitness for Purpose

- 8.1. All analytical methods are fully validated in-line with our ISO 17025 accredited quality management systems to accurately identify and quantify any target compound to a level of detection required to show evidence of drug use in hair samples.
- 8.2. There are a number of factors (pre-analytical and analytical) that can affect the results and sometimes their interpretation. Examples of pre-analytical factors that can affect the levels of drugs or metabolites detected in hair are:
  - Individual person to person variations in metabolism;
  - Hair collection timing and technique will affect estimated time ranges;
  - Use of chemical treatments such as dyes, bleaches and in some cases regular shampooing can reduce the level detected; or
  - The biology of the hair, i.e. the natural variations in hair growth.
- 8.3. Analytical factors may include:
  - Variables associated with reference standard manufacture; or
  - Laboratory measuring equipment and instruments.
- 8.4. Due to the pre-analytical factors, when a hair sample is sub-divided or a different hair sample is taken from the same donor covering the same time period, the Supplier cannot guarantee that the result obtained from the re-tested sample will be within the estimated uncertainty of measurement when compared with the original result.

## 9. Retention of Records and Samples

- 9.1. Processed hair extracts will be stored for up to one year after receipt. Due to previously mentioned pre-analytical factors and the unknown stability of the extracts, the Supplier cannot guarantee that results obtained from the re-analysis of extracts will not differ from original results.
- 9.2. Records pertaining to a sample will be retained for at least six years and maybe destroyed thereafter without further reference to the Client.
- 9.3. Any remaining hair samples will be retained for 30 days from issue of the analysis results after which they may be destroyed or anonymised and used for research.

## 10. Disclosure of Information to the Donor, other Parties and the Court

- 10.1. If a donor, opposing solicitor or any other parties, requests disclosure of their result, the Supplier will firstly contact the Client. If the Client does not agree (in writing) with the results being released then the Supplier will not release any information unless the donor submits a formal written Data Subject Access Request which the Suppliers will respond to in accordance with the General Data Protection Regulation (EU) 2016/679 and ICO Guidance.
- 10.2. In some cases, the analysis performed may identify multiple compounds including the unconfirmed presence of analytes not requested by the Client. These results will not be disclosed to the Client, but will be disclosed if requested by the Court and the corresponding fee charged for any additional work.
- 10.3. The table below details the assays available using either LC-MS/MS or GC-MS/MS, showing cut-offs, estimated uncertainty and bias measured using where possible incurred hair from external proficiency test schemes or in-house produced incurred samples.

Table 1 Drugs

Drug/metabolite	Method	Reporting Cut-Off Assuming 10mg of hair (ng/mg)	Estimated Uncertainty of Measurement ( $\pm$ %)	Experimental Bias Measurement
<b>Amphetamine Group</b>				
Amphetamine**	LC-MS/MS	0.2*	36.0%	+1.4%
<b>Methamphetamine Group</b>				
Methylenedioxyamphetamine (MDA)	LC-MS/MS	0.2*	-	-
Methylenedioxymethylamphetamine (MDMA)**	LC-MS/MS	0.2*	40.0%	+4.0%
Methamphetamine	LC-MS/MS	0.2*	-	-
<b>Benzodiazepine Group</b>				
Desmethyldiazepam**	LC-MS/MS	0.04	28.3%	+2.0%
Diazepam**	LC-MS/MS	0.04	28.6%	+3.3%
Oxazepam	LC-MS/MS	0.2	-	-
Temazepam	LC-MS/MS	0.2	-	-
Nitrazepam	LC-MS/MS	0.04	-	-
Flunitrazepam	LC-MS/MS	0.04	-	-
<b>Buprenorphine Group</b>				
Buprenorphine	LC-MS/MS	0.05	-	-
Norbuprenorphine	LC-MS/MS	0.05	-	-
<b>Cocaine Group</b>				
AEME	LC-MS/MS	0.2	-	-
Benzoylcegonine**	LC-MS/MS	0.05*	34.0%	-10.7%
Cocaethylene	LC-MS/MS	0.05*	-	-
Cocaine**	LC-MS/MS	0.5*	35.0%	-16.7%
Norcocaine	LC-MS/MS	0.05	-	-
<b>New Psychoactive Substances</b>				
Benzylpiperazine	LC-MS/MS	0.02	-	-
Hordenine	LC-MS/MS	0.02	-	-
Methylbenzylpiperazine	LC-MS/MS	0.02	-	-
Methcathinone	LC-MS/MS	0.02	-	-
Methiopropamine	LC-MS/MS	0.02	-	-
N-Methylphenethylamine	LC-MS/MS	0.02	-	-
2-Aminoindane	LC-MS/MS	0.02	-	-
Methylone	LC-MS/MS	0.02	-	-
1,4 Florophenyl piperazine	LC-MS/MS	0.02	-	-
Dimethylcathinone	LC-MS/MS	0.02	-	-
Ethylone	LC-MS/MS	0.02	-	-
4-Fluoroamphetamine	LC-MS/MS	0.02	-	-

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Drug/metabolite	Method	Reporting Cut-Off Assuming 10mg of hair (ng/mg)	Estimated Uncertainty of Measurement ( $\pm$ %)	Experimental Bias Measurement
5-APDB	LC-MS/MS	0.02	-	-
Buphedrone	LC-MS/MS	0.02	-	-
p-methoxyamphetamine (PMA)	LC-MS/MS	0.02	-	-
Butylone	LC-MS/MS	0.02	-	-
MDAT	LC-MS/MS	0.02	-	-
p-methoxymethamphetamine (PMMA)	LC-MS/MS	0.02	-	-
Dimethocaine	LC-MS/MS	0.02	-	-
MDPBP	LC-MS/MS	0.02	-	-
Methylethcathinone	LC-MS/MS	0.02	-	-
6-APB	LC-MS/MS	0.02	-	-
5-APB	LC-MS/MS	0.02	-	-
Pentylone	LC-MS/MS	0.02	-	-
ortho-Chlorophenylpiperazine	LC-MS/MS	0.02	-	-
Methoxetamine	LC-MS/MS	0.02	-	-
MPBP	LC-MS/MS	0.02	-	-
3,4-Dimethylmethcathinone	LC-MS/MS	0.02	-	-
Methylenedioxypropylvalerone (MDPV)	LC-MS/MS	0.02	-	-
5-MeO-DALT	LC-MS/MS	0.02	-	-
5-Iodo-2-aminoindane	LC-MS/MS	0.02	-	-
Trifluoromethylphenylpiperazine	LC-MS/MS	0.02	-	-
Camfetamine	LC-MS/MS	0.02	-	-
4-Methoxyphencyclidine	LC-MS/MS	0.02	-	-
Benzedrone	LC-MS/MS	0.02	-	-
2-Diphenylmethylpiperidine	LC-MS/MS	0.02	-	-
Naphyrone	LC-MS/MS	0.02	-	-
Diclofensine	LC-MS/MS	0.02	-	-
<b>Methadone Group</b>				
EDDP	LC-MS/MS	0.2	-	-
Methadone**	LC-MS/MS	0.2	30.4%	+8.7%
<b>Opiate Group</b>				
6-Monoacetylmorphine (6 MAM)**	LC-MS/MS	0.2*	35.0%	-14.7%
Codeine**	LC-MS/MS	0.2*	34.8%	+31.2%
Dihydrocodeine**	LC-MS/MS	0.2*	43.2%	+7.3%
Morphine**	LC-MS/MS	0.2*	35.0%	+11.3%

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Drug/metabolite	Method	Reporting Cut-Off Assuming 10mg of hair (ng/mg)	Estimated Uncertainty of Measurement (± %)	Experimental Bias Measurement
<b>Cannabis Group</b>				
Cannabinol	GC-MS/MS	0.01	-	-
Delta-9-tetrahydrocannabinol (THC)**	GC-MS/MS	0.01*	42.0 %	-8.8%
11-Hydroxy-delta-9-THC	GC-MS/MS	0.001	-	-
11-nor-9-carboxy-delta-9-THC	GC-MS/MS	0.001	-	-
<b>Antidepressant Group</b>				
Fluoxetine (Prozac)	LC-MS/MS	0.04	-	-
Trazodone	LC-MS/MS	0.04	-	-
Clozapine	LC-MS/MS	0.04	-	-
<b>Anti-Epileptic Group</b>				
Gabapentin	LC-MS/MS	0.2	-	-
Pregabalin	LC-MS/MS	0.2	-	-
<b>Spice Group</b>				
JWH-018	LC-MS/MS	0.02	-	-
JWH-019	LC-MS/MS	0.02	-	-
JWH-073	LC-MS/MS	0.02	-	-
JWH-081	LC-MS/MS	0.02	-	-
JWH-122	LC-MS/MS	0.02	-	-
JWH-200	LC-MS/MS	0.02	-	-
JWH-250	LC-MS/MS	0.02	-	-
RCS-4	LC-MS/MS	0.02	-	-
RCS-8	LC-MS/MS	0.02	-	-
<b>Single Compound Tests</b>				
LSD	LC-MS/MS	0.04	-	-
Cathinone**	LC-MS/MS	0.20	34.6%	+18.3%
Pethidine	LC-MS/MS	0.20	-	-
Phencyclidine (PCP)	LC-MS/MS	0.04	-	-
Ketamine**	LC-MS/MS	0.20	43.8%	+19.7%
Tramadol**	LC-MS/MS	0.20	31.2%	+13.8%
Mephedrone**	LC-MS/MS	0.04	38.0%	-10.0%
Zolpidem (hypnotic)	LC-MS/MS	0.04	-	-
Fentanyl	LC-MS/MS	0.02	-	-

\*: The cut-offs indicated comply with the SoHT consensus on hair analysis.

\*\* : The analytes indicated are UKAS accredited.