TABLE 1

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

Adulteration	See Tampering
Aliquot	A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.
Authorising Scientist	A person who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports.
Calibrator	A solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test sample/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a concentration range of interest.
Chain of Custody	Procedures to account for each specimen by tracking its handling and storage from point of collection to final disposal. These procedures require that the donor identity is confirmed and that a chain of custody form is used from time of collection to receipt by the laboratory. Within the laboratory appropriate chain of custody records must account for the specimen until disposal.
Chain of Custody Form	A form used to document the procedures from time of collection until receipt by the laboratory.
Collecting Officer	A person trained to collect specimens from donors.
Collection Site	A place where individuals present themselves 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 aliquot technique and chemical principle from that of the screen test in order to ensure reliability and accuracy.
Customer	The organisation requesting the drug testing service.
Cut-off	A concentration level set to determine whether the sample is positive or negative for the presence of a drug.
Donor	The individual from whom an oral fluid specimen is collected.
Derivative drugs/metabolites	Drugs and metabolites that requires chemical modification for GC/MS analysis i.e benzoylecgonine, temazepam
Laboratory	The facility providing the analytical services to detect drugs of abuse.
Negative result	A result reported by laboratory that indicates that either no drug is present in the sample or that any drug present is below the cut-off.

Observed Collection	A donor gives the specimen under the direct observation of the collecting officer.
Positive result	A result reported by the laboratory as positive means that there is conclusive evidence that a drug or drug metabolite is present in the specimen tested at a level greater than or equal to the confirmation cut-off concentration.
Quality control sample	A sample used to evaluate 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.
Service Provider	The organisation contracted to provide the drug testing service. This may be a laboratory, or a third party providing other elements of the service, and sub-contracting the tests to another laboratory.
Specimen	The portion of oral fluid that is collected from a donor.
Standard (1)	A reference material of known purity or a solution containing a reference material at a known concentration.
Standard (2)	An agreed protocol or procedure (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 oral fluid specimen).
Tampering	Any process by which an individual knowingly interferes with (or attempts to interfere with) the processes of specimen collection, transport or analysis with the intention of avoiding a legitimate test result. The actions undertaken can include (but are not limited to) the addition of water or foreign substances to the specimen, specimen substitution, damaging bottle seals or packaging and the deliberate consumption of interfering substances or copious volumes of water prior to specimen collection.
Toxicologist	A person responsible for interpreting a toxicological analytical result for the customer or the customer’s designated Medical Review Officer

TABLE 2

Recommended Substances and Maximum Cut-Off Concentrations for Screening Tests in Oral Fluid . Laboratory Screen Test Cut-Off Concentration in neat oral fluid (ng/mL)

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

Note:

1. *The laboratory has to take into account country-specific differences in the drug-panel they are using.*
2. *These recommended cut-off values may be subject to changes as advances in technology or other considerations warrant identification of these substances at other concentrations.*
3. *Cut-off levels for substances not indicated in Appendix D will need to be agreed with the customer taking into account the performance of the assays to be used. The toxicologist/laboratory has to explain the meaning to the customer.*
4. *Dilution of the sample has to be corrected for when the screen results are interpreted.*
5. *When using immunological analyses the differences in cross-reactivity of different substances must be noted and factored into laboratory reports.*
6. *The laboratory is responsible for remaining up to date with local drug trends and has a responsibility to use this knowledge to advise the customer of the most appropriate substances to be included in the drug testing panel.*

TABLE 3

Recommended Substances and Maximum Cut-Off Concentrations for Confirmation Tests in Oral Fluid . Confirmation Test Cut-Off Concentration in neat oral fluid (ng/mL).

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

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

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