DOF

Drugs in Oral Fluid Scheme

Scheme Description

LGC
Proficiency Testing
1 Chamberhall Business Park
Chamberhall Green
Bury
Lancashire
BL9 0AP
United Kingdom

Telephone: +44 (0) 161 762 2500
Email: axiopt@lgcgroup.com
Website: www.lgcstandards.com

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Record of issue status and modifications

ISSUE	ISSUE DATE	DETAILS	AUTHORISED BY
3	July 2013	Change of scheme year.	K Morgan
4	Feb 2014	Clarification of traceability of Assigned values and screening groups. Addition of 'Methods' section.	K Morgan
5	Dec 2014	Addition to sample description and Appendix clarification. Inclusion of subcontracting information in 'Test Materials' section.	K Morgan
6	Jan 2016	Update to EWDTS Reporting thresholds Removed Hard copy report information	K Morgan A McCarthy
7	July 2016	Update to include details regarding SDPA used for the analysis of quantitative data (page 4)	K Morgan
8	Jan 2017	Expansion to description of Test Material description	K Morgan
9	Dec 2018	Website information added to page 3 EWDTS threshold reference added, minor edit in Appendix B	A McCarthy B Whetton
10	Nov 2019	Removed 'Standards' from page 1 SAMHSA reporting thresholds added to scheme.	A McCarthy K Morgan
11	Sep 2020	Removed fax number and hard copy report info	A McCarthy
12	July 2021	Updated email address and UKAS logo Update to scheme year	A Collins R Forsyth
13	August 22	Minor clarifications in reporting threshold table	K Morgan

Notes:
Where this document has been translated, the English version shall remain the definitive version.

Scheme Aims and Organisation

The primary aim of the Drugs in Oral Fluid proficiency testing scheme (DOF) is to enable laboratories, performing the analysis of oral fluid samples for various drugs of abuse, to monitor their performance and compare it with that of their peers. The DOF scheme also aims to provide information to participants on technical issues and methodologies relating to these analyses.

The DOF scheme year operates from January to December. Further information about DOF, including test material availability, round despatch dates and reporting deadlines, are available on the current DOF application form and on the website www.lgcstandards.com.

The operation of all schemes is supported by an Advisory Group consisting of members of the professional bodies, scheme participants, and others experienced in the field. The scheme reports on the performance of relevant U.K. participants to the National Quality Assurance Advisory Panels for Chemical Pathology.

Test Materials

Details of test materials available in DOF are given in Appendix B. The test parameters are continually reviewed to ensure they meet the needs of current laboratory testing and regulatory requirements.

The oral fluid is supplied from donors, patients and known drug addicts.

Note: All test materials provided are intended for use as proficiency testing materials only and are not to be used for any other purpose

Test materials are formulated to contain analytes at concentrations covering both the sub- and supra-threshold concentrations. Analytes other than those covered by reporting thresholds may be included if they are deemed to be of interest by the independent Advisory Group. In addition, analytes that are under investigation/discussion by the EWDTS (European Workplace Drug Testing Society) may also be included. (e.g. Ketamine, Oxycodone, Tramadol, Pregabalin, Synthetic cannabinoids, Zaleplon).

Some aspects of the scheme, such as test material production, homogeneity testing and stability assessment, can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and LGC is responsible for this work. The planning of the scheme, the evaluation of performance and the authorisation of the final report will never be subcontracted.

Statistical Analysis

Information on the statistics used in DOF can be found in the General Protocol and in the Scheme Report. Methods for determining assigned values and the values for SDPA used for individual samples are given in Appendix A.

Methods

Methods are listed in PORTAL. Please select the most appropriate method from the list. If none of the methods are appropriate, then please report your method as 'Other' and record a brief description in the Comments Section in PORTAL.

Results and Reports

DOF results are returned through our electronic reporting software, PORTAL, full instructions for which are provided by email.

Participants will create their own individual screening profile detailing the analyses undertaken from a choice on PORTAL. Results are required to be entered for each analyte specified in the screening profile.

Participants submit their results relative to the threshold concentrations recommended by the European Workplace Drug Testing Society or SAMHSA. The thresholds are tabulated on the following page.

Participants will have a choice of methodologies and the AV and Qual Form will be detected/not detected. Participants may enter quantitative data if they so wish but this is not mandatory. Units will be µg/L and two decimal places. This data is processed with the AV being the RMean and the SDPA being RobustSD.

A performance summary is issued detailing performance with respect to the analyses which have a reporting threshold both for the current round and the four previous rounds (inclusive of the current round).

DOF reports will be available on the website within 10 working days of round closure. Participants will be emailed a link to the report when it is available.

Screening tests	EWDTS µg/L	SAMHSA µg/L	Single analytes (total)	EWDTS µg/L	SAMHSA µg/L
Amfetamines screen	**40**		Amfetamine Methyl-amfetamine MDMA / MDA / MDEA Other members of the amphetamine group	**15** **15** **15**	
Amfetamine/Methamphetamine MDMA/MDA		**50** **50**	Amfetamine Methamphetamine MDMA MDA		**25** **25** **25** **25**
Barbiturates* screen	**60**	**-**	Specific barbiturate*	**10**	
Benzodiazepines screen	**10**	**-**	Specific benzodiazepines: 7-aminoflunitrazepam 7-amino-clonazepam 7-amino-nitrazepam Alprazolam Bromazepam Clonazepam Desmethyldiazepam (Nordiazepam) Diazepam Flunitrazepam Flurazepam Lorazepam Lormetazepam Midazolam Nitrazepam Oxazepam Phenazepam Temazepam	 **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **3** **10**	**-**
Cannabinoid screen (THC)	**10**	**4**	Delta-9-THC	**2**	**2**
Cocaine and metabolites screen	**30**	**15**	Benzoylecgonine Cocaine Cocaethylene	**8** **8** **-**	**8** **8** **-**
Methadone screen EDDP screen	**50**	**-**	Methadone EDDP	**20** **-**	**-** **-**
Propoxyphene and metabolites screen	**40**	**-**	Propoxyphene or metabolite	**5**	**-**
Opiates screen	**40**		Morphine Codeine Norcodeine 6-Monoacetylcodeine Dihydrocodeine	**15** **15** **2** **2** **15**	

Codeine/Morphine Hydrocodone/Hydromorphone Oxycodone/Oxymorphone		**30** **30** **30**	Codeine Morphine Hydrocodone Hydromorphone Oxycodone Oxymorphone		**15** **15** **15** **15** **15** **15**
6-Monoacetylmorphine screen	**4**	**4**	6-Monoacetylmorphine	**2**	**2**
Buprenorphine and metabolites screen	**5**	**-**	Buprenorphine or metabolites	**1**	**-**
Phencyclidine* screen	**10**	**10**	Phencyclidine*	**10**	**10**
LSD and metabolites* screen	**1**	**-**	LSD or metabolites*	**1**	**-**

Table: The European Workplace Drug Testing Society thresholds (2015-11-02 Version 2.0).

Analytes marked with an asterisk (*) have values suggested by the scheme.

Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Rule, Federal Register, Vol 84, No.207, October 25, 2019; 57554-57600

APPENDIX A - Description of abbreviations used

Assigned Value (AV)

The assigned value may be derived in the following ways:

- From the robust mean (RMean). This is the median of participant results after the removal of test results that are inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors. Generally, the assigned value will be set using results from all methods, unless the measurement is considered method-dependant, in which case the assigned value will be set by method as illustrated in the report tables.
  For some analytes, where there is a recognised reference method for that type of measurement, this may be used as the assigned value for a particular analyte i.e. it would be applied to results obtained by any method.

  Traceability: Assigned values which are derived from the participant results, or a sub-set of the results are not traceable to an international measurement standard. The uncertainty of assigned values derived in this way is estimated from the participant results, according to ISO 13528.

- From a formulation value (Formulation). This denotes the use of an assigned value derived from sample preparation details, where known and exact quantities of analyte have been used to prepare the sample.

  Traceability: Assigned values calculated from the formulation of the test sample are traceable, via an unbroken metrological traceability chain, to an international measurement standard. The measurement uncertainty of the assigned value is calculated using the contributions from each calibration in the traceability chain.

- From a qualitative formulation (Qual Form). This applies to qualitative tests where the assigned value is simply based on the presence/absence of the analyte in the test material.

Traceability: Assigned values calculated from the qualitative formulation of the test sample are traceable to a certified reference standard or a microbiological reference strain.

- From expert labs (Expert). The assigned value for the analyte is provided by an 'expert' laboratory.

  Traceability: Assigned values provided by an 'expert' laboratory may be traceable to an international measurement standard, according to the laboratory and the method used. The uncertainty of measurement for an assigned value produced in this way will be provided by the laboratory undertaking the analysis. Details of traceability and the associated uncertainty will be provided in the report for the scheme/round.

Range
This indicates the concentration range at which the analyte may be present in the test material.

SDPA
SDPA represents the 'standard deviation for proficiency assessment' which is used to assess participant performance for the measurement of each analyte.

Units
This indicates the units used for the assessment of data. These are the units in which participants should report their results. For some analytes in some schemes participants may have a choice of which units to report their results, however, the units stipulated in this scheme description are the default units to which any results reported using allowable alternative results will be converted to.

DP
This indicates the number of decimal places to which participants should report their measurement results.

APPENDIX B: Test Material Description

Sample: PT-DO-01, PT-DO-02 and PT-DO-03

Participants will receive: 3 x 1.7ml oral fluid obtained from volunteers and known drug users, issued at quarterly intervals.

The pools of oral fluid are heated at 60°C for 1.5hr prior to sample production and may be spiked with additional analytes. The samples are preserved by the addition of 0.1 g/L gentamicin and 0.1 g/L penicillin. No buffer or commercial additives are normally used, however the samples obtained from known drug users may contain a small amount of the buffers encountered in oral fluid kits and occasionally a small amount (0.25%) of the non-ionic surfactant Tritox X-100 may be used to stabilise the sample. The samples regularly contain mixtures of drugs with their metabolites from 6 major classes:-

Amfetamines & stimulants	Benzodiazepines
Cannabinoids	Opiates
Cocaine & metabolites	Non-opiate narcotics

Other, current drugs and/or metabolites may also be included (e.g. Ketamine, LSD, Pregabalin, Tramadol, etc.). In addition, occasionally zero spikes may be issued.