DAU

Drugs of Abuse in Urine Proficiency Testing Scheme

Scheme Description

LGC Standards
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Record of issue status and modifications

<table>
<thead>
<tr>
<th>ISSUE</th>
<th>ISSUE DATE</th>
<th>DETAILS</th>
<th>AUTHORISED BY</th>
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<tr>
<td>1</td>
<td>Feb 2012</td>
<td>Version 1 created.</td>
<td>K. Morgan</td>
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<tr>
<td>2</td>
<td>Aug 2012</td>
<td>UKAS logo added to first page.</td>
<td>N. Stephenson</td>
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<tr>
<td>3</td>
<td>Jan 2013</td>
<td>Updated clinical reporting thresholds, report turnaround time and analytes.</td>
<td>K. Morgan</td>
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<tr>
<td>5</td>
<td>Dec 2014</td>
<td>Minor formatting changes. Email and website address update on page 1. Inclusion of subcontracting information in ‘Test Materials’ section. Inclusion of ethyl glucuronide and ethyl sulfate and clarification of Appendix A and B.</td>
<td>K Morgan</td>
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<tr>
<td>6</td>
<td>Jan 2016</td>
<td>Update of reporting thresholds for workplace members. Removed Hard copy report information</td>
<td>K Morgan A McCarthy</td>
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<tr>
<td>7</td>
<td>July 2016</td>
<td>Clarification of SDPA used for the analysis of the quantitative data.</td>
<td>K Morgan</td>
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<td>8</td>
<td>Jan 2018</td>
<td>Inclusion of SAMHSA reporting thresholds</td>
<td>K Morgan</td>
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<tr>
<td>9</td>
<td>Dec 2018</td>
<td>Website information added to page 3 Reference for EWDTS and SAMHSA thresholds, minor edit in Appendix B</td>
<td>A McCarthy B Whetton</td>
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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 of Abuse in Urine proficiency testing scheme (DAU) is to enable laboratories, performing the analysis of urine samples for various drugs of abuse, to monitor their performance and compare it with that of their peers. The DAU scheme also aims to provide information to participants on technical issues and methodologies relating to these analyses.

The DAU scheme year operates from April to March. Further information about DAU, including test material availability, round despatch dates and reporting deadlines, is available on the current DAU application form and on the LGC website www.lgcstandards.com.

The operation of the scheme 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 U.K. participants to the National Quality Assurance Advisory Panels for Chemical Pathology.

Test materials are formulated to contain analytes at concentrations covering both the sub- and supra-threshold concentrations of both ranges. Analytes other than those covered by reporting thresholds may be included if they are deemed to be of interest by the independent Advisory Group.

Participation levels

Participants have the choice of two levels of participation:
1. Screening only - This is designed for participants who report using immunoassay type techniques and POCT (point of care testing).
2. Full - Participants will be able to report for the screening only analytes using immunoassay type techniques and individual analytes by chromatography techniques. Approximately 210 individual analytes are available and are managed by your PORTAL online screening profile.

Reporting thresholds

Prior to submitting your results you will be asked to configure your screening profile (applicable to both screening and full participation), we recommend that you only select the analytes that you are routinely screening for; any drugs that are detected which you are not routinely screening should be added/removed from your screening profile on a round by round basis.

When configuring the screening profile it’s essential that you choose the analyte with the reporting threshold that is most appropriate to your laboratory, this will either be the clinical threshold or EWDTS threshold. The reporting thresholds for SAMHSA have also been included. The Analyte is present and the relevant reporting threshold stated.

E.g. Amfetamine (Clinical threshold 1000 µg/L) or Amfetamine (EWDTS threshold 200 µg/L)

Note: Failure to choose the most appropriate threshold to your laboratory could result in your laboratory being incorrectly assessed.

Please see table overleaf detailing the thresholds relating to the relevant participation level (screening only or full).
## DAU Scheme Description

### Screening tests

<table>
<thead>
<tr>
<th></th>
<th>Clinical μg/L</th>
<th>EWDTS μg/L</th>
<th>SAMHSA μg/L</th>
<th>Individual analytes</th>
<th>Clinical μg/L</th>
<th>EWDTS μg/L</th>
<th>SAMHSA μg/L</th>
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<tr>
<td>Amfetamines Screen</td>
<td>1000</td>
<td>500</td>
<td>500</td>
<td>Amfetamine</td>
<td>1000</td>
<td>200</td>
<td>250</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Methyl-amfetamine</td>
<td>1000</td>
<td>200</td>
<td>250</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MDMA / MDA / MDEA</td>
<td>1000</td>
<td>200</td>
<td>250</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Other amfetamine</td>
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<td>200</td>
<td>-</td>
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<tr>
<td>Barbiturates Screen</td>
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<td>200</td>
<td>-</td>
<td>Specific barbiturate</td>
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<td>150</td>
<td>-</td>
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<tr>
<td>Cannabinoid Screen</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>Delta-9-THC-COOH</td>
<td>15</td>
<td>15</td>
<td>15</td>
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<tr>
<td>Cocaine and Metabolite Screen</td>
<td>300</td>
<td>150</td>
<td>150 (Benzoylcegonine)</td>
<td>Benzoylcegonine</td>
<td>300</td>
<td>100</td>
<td>100</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Cocaine</td>
<td>3000</td>
<td>-</td>
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<tr>
<td>Benzodiazepine Screen</td>
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<td>200</td>
<td>-</td>
<td>Specific benzodiazepine (Alprazolam, Bromazepam, Clonazepam, Diazepam, Flunitrazepam, Flurazepam, Lorazepam, Lormetzazepam, Midazolam, Nitrazepam, Nordiazepam, Oxazepam, Phenazepam, Temazepam)</td>
<td>300</td>
<td>100</td>
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<td>Methadone Screen</td>
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<td>Methadone</td>
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<td>75</td>
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<td>Propoxyphene and Metabolite Screen</td>
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<td>300</td>
<td>-</td>
<td>Propoxyphene or metabolites</td>
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<td>300</td>
<td>-</td>
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<td>Opiates Screen (total)</td>
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<td>300</td>
<td>Codeine/Morphine 2000 (Morphine)</td>
<td>Morphine (total)</td>
<td>300</td>
<td>2000</td>
<td>2000</td>
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<td></td>
<td>Codeine (total)</td>
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<td>2000</td>
<td>2000</td>
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<td>Dihydromorphine (total)</td>
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<td>6-Monoacetylmorphine</td>
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<td>Buprenorphine and Metabolite Screen</td>
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<td>-</td>
<td>LSD or metabolites</td>
<td>1</td>
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</table>

*European Guidelines for Workplace Drug Testing in Urine 2015-11-01 Version 2.0

### Test Materials

Details of test materials available in DAU 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 urine 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 purposes.

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 DAU 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**
DAU results are returned through our electronic reporting software, PORTAL, full instructions for which are provided by email. However, participants may request result submission forms on which to report and return results if they are unable to report through electronic means. This will incur an additional charge.

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.

DAU reports will be available on the website within 15 working days of round closure. Participants will be emailed a link to the report when it is available.

Separate reports are issued depending upon level of participation and reporting thresholds. Quantitative data is shared between the different reporting threshold participants.
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

Samples: All participation levels

Participants will receive: 3 x 15ml lyophilized human urine from volunteers, patients or known addicts.

The pools of urine are heated at 60°C for 1.5hr prior to lyophilisation and may be spiked with additional analytes. They regularly contain mixtures of drugs with their metabolites from 6 major classes:

- Amphetamines & stimulants
- Cannabinoids
- Cocaine & metabolites
- GHB
- Minor tranquillizers
- Opiates
- Non-opiate narcotics
- Ethyl glucuronide

Other, current drugs and/or metabolites may also be included (e.g. ketamine, GHB, oxycodone, tramadol, synthetic cannabinoids, synthetic cathinones). Ethyl glucuronide and ethyl sulfate will also be included, on occasions throughout the scheme year.

Screening only participants who report drug groups will have a choice of screening methodologies and the AV and Qual Form will be present/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.

Full participants will have access to screening and confirmatory methodologies. The AV and Qual Form will be present/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.

All 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.

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).