

EWDTs

European Workplace Drug Testing Society

European Guidelines for Workplace Drug Testing in **Urine and Oral fluid**

9th EWDTs Symposium in Lisbon

- Sanna Taskinen
- Michaela Neuhofer



- Current old versions of the guidelines:
 - Guidelines for Urine (2002)
 - Drug and Alcohol Testing in Hair, Collection and Analysis (2010)
 - Guidelines for Oral fluid (2011)
 - Specimen Collection Guidelines (2011)

- January 2014: chairs of the project were settled
 - Urine guideline (chair: Sanna Taskinen)
 - Oral fluid guideline (chair: Michaela Neuhofer)
 - Hair guideline (chair: Alberto Salomone)
 - Blood/blood spots (chair: Wim Schielen)
- The experts were chosen for the committee
- Meeting in Frankfurt 26th November, 2014
- Approval of the board: April, 2015

Beck, Olof (Sweden)
Bosch, Tessa (Netherlands)
Böttcher, Michael (Germany)
Carmichael, Duncan (UK)
Fucci, Nadia (Italy)
George, Claire (UK)
Neuhofer, Michaela (Austria)
Piper, Mark (UK)
Salomone, Alberto (Italy)
Schielen, Wim (Netherlands)
Steinmeyer, Stefan (Germany)
Taskinen, Sanna (Finland)
Weinmann, Wolfgang (Switzerland)

1. General
 2. Definitions
 3. Collection
 4. Laboratory Organisation
 5. Laboratory Analysis Procedures
 6. Analytical Methods and Validation
 7. Quality Assurance and Quality Control
 8. Interpretation of Results
 9. Challenges to Drug Test Results
- Appendix A: Collection Procedure
 - Appendix B: Donor's statement of Informed Consent
 - Appendix C: Fatal flaws in the Chain of Custody
 - Appendix D: Cut-off values for Screening Tests
 - Appendix E: Cut-off values for Confirmation Tests

Chapter 1: General	<ul style="list-style-type: none">• Requirement of accreditation (EN ISO/IEC 17025 and/or EN ISO 15189)• Guidelines are relevant to laboratory-based testing only
Chapter 2: Definitions	<ul style="list-style-type: none">• Identical to make the guidelines more comparable• Make sure that key-words are understandable for anybody
Chapter 4: Laboratory Organisation	<ul style="list-style-type: none">• All personnel should adhere to the requirements of EN ISO/IEC 17025 and/or EN ISO 15189• Minimum key functions for accreditation• Descriptions of key functions are shortened

<p>Chapter 6: Analytical Methods and Validation</p>	<p>6.1. Acceptable Screening Techniques Immunoassays ...chromatographic techniques</p> <p>6.2 Laboratory Screening Tests The initial screening test must use an appropriate technique – also chromatographic techniques.</p> <p>6.4 Confirmation Tests By chromatographic technique in combination with MS – quantitative If the first analysis is performed by a confirmation-level analysis (mass-spectrometry), the positive findings have to be confirmed and quantified by reanalysis with another portion of the sample.</p> <p>6.5 Validation Parameters for method validation are listed: precision, cut off verification, selectivity, limit of detection, limit of quantification, sensitivity, specificity, stability, measurement uncertainty, recovery of the collection device and matrix effects</p> <p>6.7 Long term frozen storage (-20 °C or below)</p>
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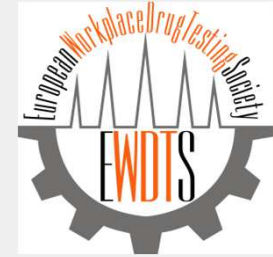
<p>Chapter 7: Quality Assurance and Quality Control</p>	<p>Quality controls Preparation, use and storage of calibrators and controls more in detail.</p> <p>Confirmation tests references:</p> <ul style="list-style-type: none"> - EC guidance of quality control and validation procedures for pesticide analyses (2013) - EC decision concerning the performance of analytical methods and the interpretation of results (2002) - Guideline of GTFCh <p>Requirements of identification for chromatography and mass spectrometry more in detail.</p>
<p>Chapter 8: Interpretation of Results</p>	<p>Toxicology Review: Toxicologists right to interpret results: if local legislation allows</p> <p>Medical Review: removed to this chapter from appendix.</p>

<p>Chapter 3: Collection</p>	<p>Urine: Well establish procedure. In Appendix A more about exceptional situations.</p>
<p>Appendix A Collection Procedure</p>	<p>Urine Collection Procedure</p> <ul style="list-style-type: none"> • Collection site requirements more in detail • Informing the donor about the test • Equal treatment of donors • Privacy (observed collection in certain circumstances) • Exceptional situations and instructions added
<p>Chapter 5: Laboratory Analysis Procedures</p>	<ul style="list-style-type: none"> • Chain of custody • Reporting of preliminary presumptive positive results as local legislation allows. • If the first analysis is performed by a confirmation-level analysis (mass spectrometry), the positive findings have to be retested with another portion of the sample. <p>Urine validity testing:</p> <ul style="list-style-type: none"> • Invalid samples: how to report negative/positive results more in detail

<p>Appendix B Example of a Donor's Statement of Informed Consent</p>	<p>Added: I confirm that I have received information about the meaning and content of the drug test.</p>
<p>Appendix C Some Examples of Fatal Flaws in the Chain of Custody</p>	<p>No changes</p>

Chapter 3: Collection	Oral fluid collection <ul style="list-style-type: none">• <i>Oral fluid collection kits:</i> more reliable oral fluid collection which enables quantification of drug. This means that accurate determination of collected OF is strongly recommended (gravimetric analysis or spectro-photometrically)• <i>Oral fluid collection procedure:</i> obligatory collection of identical sample A and sample B - must be carried out legal defensible and split sample in the presence of the donor or use two devices to generate two samples
Appendix A Collection Procedere	Oral Fluid Collection Procedere <ul style="list-style-type: none">• Note collection time• Check the volume of oral fluid on/in the specimen collection device.• Inspect the specimen to determine its colour and appearance of any signs of contaminants and adulteration.

<p>Chapter 5: Laboratory Analysis Procedures</p>	<p>5.3 Sample Receipt Laboratory should receive at least two sample container</p> <p>5.4 Sample Processing Container “A” for the screening and confirmation test Sample “B” retain unopened and stored in condition that reflect the storage of the sample under test</p> <p>5.5 Oral fluid validity testing: Laboratory has to expose adulteration and sample tampering</p> <p><i>Following data have to be coherent</i></p> <ul style="list-style-type: none">• Collection time• Dilution factor (gravimetric analysis or measured spectrophotometrically)• Sample volume• Endogenous biomarker (e.g. salivary Amylase, Cortisol,...)
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APPENDIX D SCREENING CUT OFF ON MONDAY MORNING ? What happend on Friday, last week or last month?

Blood

Under the influence
of drug
within 48 hours

Oral fluid

„Short“ detection
window
within 48 (72) hours

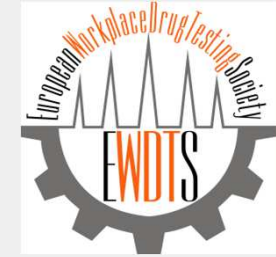
Urine

Intermediate
detection window
within 72 hours
(6 weeks)

Hair

Long detection
window
within months

APPENDIX D SCREENING CUT OFF ON MONDAY MORNING ?



What happen on Friday, last week or last month?

Oral fluid - **Short** detection window

Core Panel / Optional / Under investigation

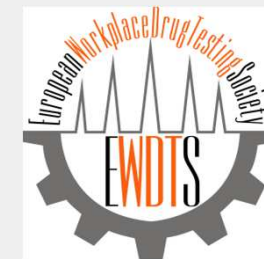
CORE PANEL	ng/mL
Amphetamine group	40
Cannabis (THC) + metabolites	10
Cocaine + metabolites	30
Opiates (Morphine)	40
6-AM	4
Methadone (I)	50
Benzodiazepines group	10

OPTIONAL	ng/mL
Buprenorphine	5
Propoxyphene or metabolites	40

Cut off under discussion e.g.

Pregabalin, Synthetic cannabinoids,
Synthetic cathinones (MDPV etc.),
Z-Drugs (Zopiclon, Zolpidem, Zaleplon)

APPENDIX D URINE SCREENING

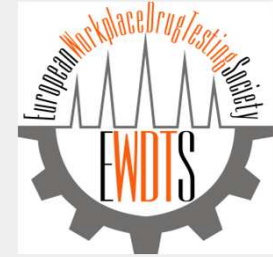


Urine Intermediate detection window

CORE PANEL	ng/mL
Amphetamine group	500
Benzodiazepines group	200
Cannabis metabolites	50
Cocaine metabolites	150
Opiates (total)	300
EDDP (or methadone)	100 (300)

OPTIONAL	ng/mL
Barbiturates	200
Buprenorphine	5
LSD or metabolites	1
Phencyclidine	25
Propoxyphene or metabolites	300

OTHER DRUGS Cut-off under investigation/discussion
Gammahydroxybuturate (GHB)
Ketamine
Other opioids (at least oxycodone, hydromorphone, tramadol, fentanyl, tilidine)
Pregabalin
Synthetic cannabinoids
Synthetic cathinones (MDPV etc.)
Z-Drugs (Zopiclon, Zolpidem, Zaleplon)



APPENDIX E CONFIRMATION CUT OFF ON MONDAY MORNING ? What happend on Friday, last week or last month?

Blood

Under the influence
of drug
within 48 hours

Oral fluid

„Short“ detection
window
within 48 (72) hours

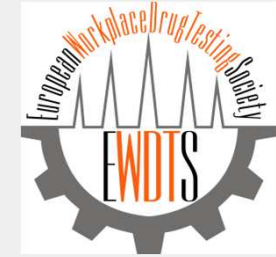
Urine

Intermediate
detection window
within 72 hours
(6 weeks)

Hair

Long detection
window
within months

APPENDIX E ORAL FLUID CONFIRMATION



AMPHETAMINE	ng/mL
Amphetamine (d+ l)	30
Methamphetamine	30
MDA	30
MDMA	30
Other members of the amphetamine group	

CANNABIS (THC)	2
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COCAINE	ng/mL
Cocaine metabolite (Benzoylecgonine)	8
Cocaine	8
Cocaethylene	

BENZODIAZEPINE	ng/mL
7-Amino-flunitrazepam	10
7-Amino-clonazepam	10
7-Amino-nitrazepam	10
Alprazolam	10
Bromazepam	10
Clonazepam	10
Desmethyldiazepam	10
Diazepam	10
Flunitrazepam	10
Flurazepam	10
Lorazepam	10
Lormetazepam	10
Midazolam	10
Nitrazepam	10
Nordiazepam	10
Oxazepam	10
Phenazepam	10
Temazepam	10

APPENDIX E ORAL FLUID CONFIRMATION



METHADONE	ng/mL
Methadone or metabolites (d+l)	20
EDDP	

OPIATES	ng/mL
Morphine	2
Codeine	2
Norcodeine	2
6-Acetylcodeine	2
Dihydrocodeine	2
6-Monoacetylmorphine	4

cut off under investigation / discussion:

Buprenorphine or metabolites
Propoxyphene or metabolites
Ketamine
LSD or metabolites
Opioids(at least Oxycodone, Hydromorphone, Tramadol, Buprenorphine, Fentanyl, Tilidine)
Phencyclidin (PCP)
Pregabalin
Synthetic cannabinoids
Synthetic cathinones (MDPV etc.)
Zaleplon
Zolpidem
Zopiclone

APPENDIX E URINE CONFIRMATION



AMPHETAMINES (should include but not limited to:)	ng/mL
Amphetamine (d+ l), Metamphetamine, MDA, MDMA	200
Other members of the amphetamine group	200
BENZODIAZEPINES (or metabolites) (should include but not limited to:)	ng/mL
Alprazolam, Bromazepam, Clonazepam, Diazepam, Flunitrzepam, Flurazepam, Lorazepam, Lormetazepam, Midazolam, Nitrazepam, Nordiazepam, Oxazepam, Phenazepam, Temazepam	100
OPIATES (should include but not limited to:)	ng/mL
Morphine, Codeine, dihydrocodeine	300
6-Monoacetylmorphine	10
CANNABIS	ng/mL
Cannabis metabolite (THC-COOH)	15
COCAINE	
Benzoyllecgonine	150
METHADONE	
Methadone (d+l)	250
EDDP	100

APPENDIX E URINE CONFIRMATION



OPTIONAL:	ng/mL
Barbiturates	250
Buprenorphine or metabolite	2
LSD or metabolites	1
Phencyclidine	25
Propoxyphene or metabolites	300

OTHER DRUGS

Cut-off under investigation/discussion

Gammahydroxybuturate (GHB)

Ketamine

Other opioids

(at least oxycodone, hydromorphone, tramadol, fentanyl, tilidine)

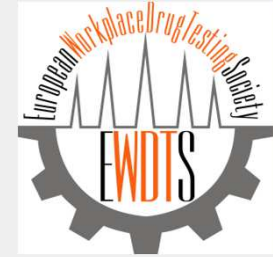
Pregabalin

Synthetic cannabinoids

Synthetic cathinones (MDPV etc.)

Z-Drugs (Zopiclon, Zolpidem, Zaleplon)

NEXT STEPS



- These guidelines are approved by the board.
- The guidelines will be now communicated within the members of EWDTTS for feedback
- Please give comments on three levels:
 1. It would be better if you change... including change in the language.
 2. I strongly recommend this/these changes...
 3. If you do not change this/these, I think the guidelines are unacceptable.



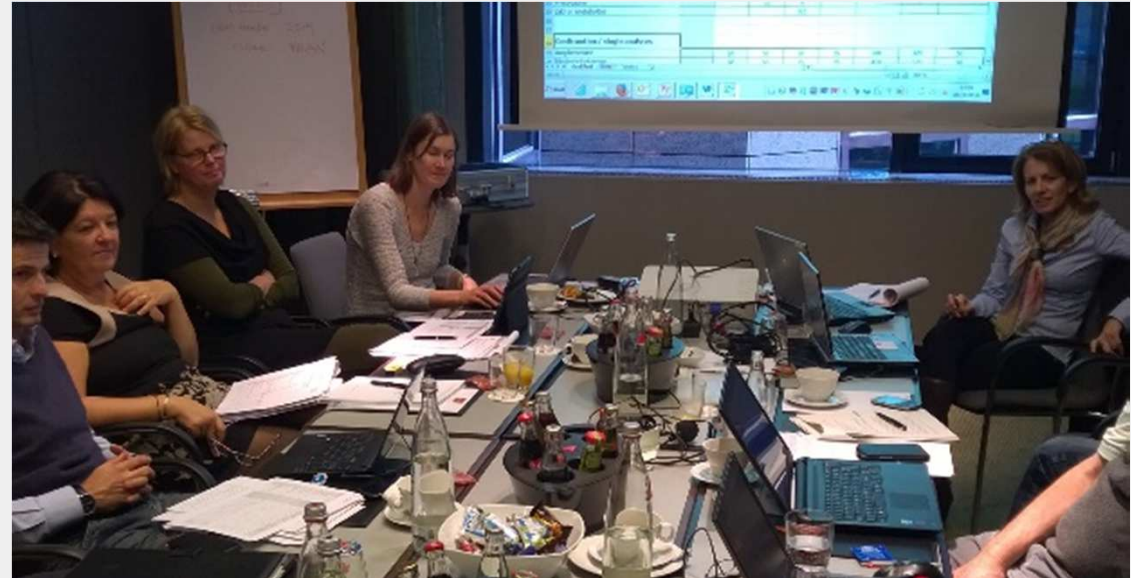
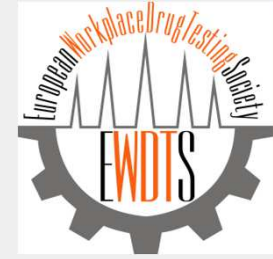
IN THE FUTURE



- The updating project will continue e.g.
 - Cut-off values
 - New substances
- New guidelines?
 - Guideline for alcohol?
 - Guideline for POC-testing?
 - Guideline for MRO?
 - Guideline for breath air?



Thank you for your attention!



Guidelines committee meeting in Frankfurt
26th November, 2014