European Guidelines for Workplace Drug Testing in Blood and Blood Spots

9th EWDTS Symposium in Lisbon

• Wim Schielen
Updating project

• 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)
Updating project

- 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, except for Blood/Blood Spots
The Guidelines Committee for Blood and Blood Spots

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)
Wilhelm, Lars (Germany)
The Guidelines Committee for **Blood and Blood Spots**

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
• Appendix F: Pre-analytical work up of whole-blood, plasma, serum and whole-blood blood spots
# Blood and Blood Spots

## Chapter 1: General
- Requirement of accreditation (EN ISO/IEC 17025 and/or EN ISO 15189)
- Guidelines are relevant to laboratory-based testing only

## Chapter 2: Definitions
- As much as possible Identical to make the guidelines more comparable. Extra definitions for blood-related issues.

## Chapter 4: Laboratory Organisation
- 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
| Chapter 6: Analytical Methods and Validation | Validation chapter added  
Long term frozen storage (-20 °C or below). |
| Chapter 7: Quality Assurance and Quality Control | Confirmation tests: New more detailed chapter about minimum requirements  
References: |
| Chapter 8: Interpretation of Results | Toxicology Review: Toxicologists right to interpret results: if local legislation allows  
Medical Review: removed to this chapter from appendix. |
# Blood and Blood Spots

## Chapter 3: Collection

**Blood:** Well establish procedure. In Appendix A more about exceptional situations.

## Appendix A

**Blood Collection Procedure**

- Collection site requirements more in detail
- Informing the donor about the test
- Privacy: equal treatment of donors, observed collection in certain circumstances
- Exceptional situations and instructions added

## Chapter 5: Laboratory Analysis Procedures

- Chain of custody must be secured for all matrices
- 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.

**Blood validity testing:**

- Unvalid samples: how to report negative/positive results more in detail
### Main content in Appendices

<table>
<thead>
<tr>
<th>Appendix B</th>
<th>Example of a Donor’s Statement of Informed Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Added: I confirm that I have received information about the meaning and content of the drug test.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appendix C</th>
<th>Some Examples of Fatal Flaws in the Chain of Custody</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No changes</td>
</tr>
</tbody>
</table>
Appendix F
Pre-analytical work up of whole-blood, plasma, serum and whole-blood blood spots

<table>
<thead>
<tr>
<th>Suggested procedures for the work up of</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1, whole-blood samples, fresh and frozen</td>
</tr>
<tr>
<td>F2, plasma, fresh and frozen</td>
</tr>
<tr>
<td>F3, serum, fresh and frozen</td>
</tr>
<tr>
<td>F4, whole-blood spots</td>
</tr>
</tbody>
</table>
APPENDIX D  SCREENING
CUT OFF ON MONDAY?
What was used Today/Yesterday, on Friday, last week, or last month?

**Blood**
Under the influence of drugs - **Short** detection window

**Oral fluid**
**Short** detection window

**Urine**
**Intermediate** detection window

**Hair**
**Long** detection window

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APPENDIX D BLOOD SCREENING
CUT OFF VALUES?
What was used Today/Yesterday

**Blood** - **Short** detection window, Core Panel / Optional / Under investigation

<table>
<thead>
<tr>
<th>CORE PANEL</th>
<th>ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine group</td>
<td>20-60</td>
</tr>
<tr>
<td>Cannabis (THC) + metabolites</td>
<td>10</td>
</tr>
<tr>
<td>Cocaine + metabolites</td>
<td>25-35</td>
</tr>
<tr>
<td>Opiates (Morphine)</td>
<td>10</td>
</tr>
<tr>
<td>6-AM</td>
<td>5</td>
</tr>
<tr>
<td>Methadone (I)</td>
<td>10-50</td>
</tr>
<tr>
<td>Benzodiazepines group</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPTIONAL</th>
<th>ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>1-5</td>
</tr>
<tr>
<td>Propoxyphene or metabolites</td>
<td>20-40</td>
</tr>
</tbody>
</table>

**Cut off under discussion e.g.**
- Pregabalin, Synthetic cannabinoids,
- Synthetic cathinones (MDPV etc.),
- Z-Drugs (Zopiclon, Zolpidem, Zaleplon)

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APPENDIX E CONFIRMATION
CUT OFF VALUES?
What was used Today/Yesterday

Blood
Under the influence of drugs - **Short** detection window

**Oral fluid**
**Short** detection window

Urine
**Intermediate** detection window

Hair
**Long** detection window

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### APPENDIX E BLOOD CONFIRMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration Range (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AMPHETAMINES</strong> (should include but not limited to:)</td>
<td></td>
</tr>
<tr>
<td>Amphetamine (d+ l), Metamphetamine, MDA, MDMA</td>
<td>20-60</td>
</tr>
<tr>
<td>Other members of the amphetamine group</td>
<td>20-60</td>
</tr>
<tr>
<td><strong>BENZODIAZEPINES (or metabolites)</strong> (should include but not limited to:)</td>
<td></td>
</tr>
<tr>
<td>Alprazolam, Bromazepam, Clonazepam, Diazepam, Flunitrzepam, Flurazepam, Lorazepam, Lormetazepam, Midazolam, Nitrazepam, Nordiazepam, Oxazepam, Phenazepam, Temazepam</td>
<td>10-20</td>
</tr>
<tr>
<td><strong>OPIATES</strong> (should include but not limited to:)</td>
<td></td>
</tr>
<tr>
<td>Morphine, Codeine</td>
<td>10</td>
</tr>
<tr>
<td>6-Monoacetylmorphine</td>
<td>5</td>
</tr>
<tr>
<td><strong>CANNABIS</strong></td>
<td></td>
</tr>
<tr>
<td>Cannabis metabolite (THC-COOH)</td>
<td>1-5</td>
</tr>
<tr>
<td><strong>COCAINE</strong></td>
<td></td>
</tr>
<tr>
<td>Benzoylecgonine</td>
<td>50</td>
</tr>
<tr>
<td><strong>METHADONE</strong></td>
<td></td>
</tr>
<tr>
<td>Methadone (d+I)</td>
<td>20</td>
</tr>
<tr>
<td>EDDP</td>
<td>-</td>
</tr>
</tbody>
</table>
NEXT STEPS

DRAFT Version Guidelines Blood/Blood Spots due in Q3 2015, for experts

preFINAL Version Guidelines Blood/Blood Spots due in Q4 2015, for EWDTS Board

EWDTS Board approval in Q1 2016

• The guidelines will then be communicated within the members of EWDTS 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
IN THE FUTURE

- The updating project will continue e.g.
  - Cut-off values
  - New substances

- New guidelines?
  - Guidelines for alcohol?
  - Guidelines for breath air?
  - Guidelines for MRO’s?
  - Guidelines for POC-testing?
Thank you for your attention!

Guidelines committee meeting in Frankfurt
26th November, 2014

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