NATA perspective on AS4760 and testing in Oral Fluid

FACTA Symposium
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Introduction

• Overview of Accreditation of Toxicology at NATA
  – Fields of NATA
  – Medical Testing Scope of Accreditation
  – Numbers of facilities accredited

• Laboratory issues AS 4760:2006 Sections 4 and 5

• On-site collection and screening issues AS 4760:2006 Sections 2 and 3
  – Collection and Personnel
  – Validation of devices
  – QA requirements

• Comments and questions from wider community
  • e.g. unions, employees, employers, regulators etc
Toxicology accreditation across NATA Fields

- Forensic Testing
- Chemical Testing
- Medical Testing

Important to ensure consistency across the fields.
- Medical Testing assesses to ISO 15189 & NPAAC STDs
  - (In-house IVDs – apply to confirmation testing GC & LC MS)
- TGA Framework for IVDs 2010 – Registration of IVDs
  - (Clinical Toxicology)

- Chemical and Forensic Testing to ISO 17025
- Technical advice offered by AACB Toxicology WP and ASCEPT
- Cross field technical group established to discuss accreditation and interpretation issues – (30 September 2010)
Toxicology Scope of Accreditation in Medical Testing

- 10.60 Chemical Pathology
- 10.61 General Chemistry

- **10.61.15 Drugs for toxicological purposes**
- Validated laboratory methods (commercial or in-house) but not to AS/NZS standard cut-offs or in compliance with toxicology standards
- Generally public and private pathology laboratories
  - can be any matrix
  - mainly clinical application – general toxicology (serum paracetamol, drugs of abuse OD)
  - Can be for WDT “Self proclaimed compliance with toxicology standards”
  - On-site screening devices

- **Urine specific**

- **10.61.16 Drugs for toxicological purposes to AS/NZS 4308:2001**
10.61.17 Drugs for toxicological purposes to AS/NZS 4308:2008

Section 2 Specimen Collection, storage, handling and dispatch
Section 2 (including appendix A) Specimen Collection, storage, handling, dispatch and on-site screening procedures
Section 3 General laboratory requirements
Section 4 Laboratory screening procedures
Section 5 Laboratory confirmatory procedures

Oral fluid specific

10.61.18 Drugs for toxicological purposes to AS 4760:2006

Section 2 Collection, storage, handling and dispatch
Section 3 On-site initial testing
Section 4 Laboratory initial testing
Section 5 Confirmatory testing procedures
Accreditation numbers to AS 4308

- **Forensic Testing**
  - 1 organisations accredited to Sections 2, 4 & 5
  - 3 organisations to Sections 4 & 5

- **Chemical Testing**
  - 1 organisation to Sections 4 & 5
  - 1 organisation to 4308:2001

- **Medical Testing**
  - 2 organisations to Sections 2 and Appendix A
  - 1 organisation to Sections 2 and 4
  - 7 organisations to Sections 2, 4 and 5
  - 3 organisations to Sections S, Appendix A, 4 and 5
  - 2 organisations to Sections 4 and 5
  - 1 organisation to 4308:2001
Accreditation to AS 4760

- Forensic Testing
  - 2 organisations accredited to Sections 4 & 5
  - 1 organisation to Section 5

- Chemical Testing
  - 1 organisation to Sections 4 & 5

- Medical Testing
  - 1 organisation to Sections 2 and 5
  - 3 organisations to Section 2

22 organisations accredited to parts of AS/NZS 4308

8 organisations accredited to parts AS 4760
Accreditation to AS 4760 vs 4308

Disappointing uptake of AS 4760:2006 standard compared to
– the (perceived) volume of Oral Fluid testing occurring in Australia
– and with uptake of AS/NZS 4308

Why?
– more urine testing being performed for longer
– to hard to achieve (QA requirements, validation of testing devices etc)
– to expensive (LCMS, QA requirements for on-site screening)
– fewer drivers / mandates for accreditation with standard

Note: As yet no organisation has been accredited to Section 3 - On-site Testing.
Issues for organisations seeking Laboratory Accreditation for Oral Fluid (Sections 4 & 5)

• Pre-diluted buffered samples vs neat oral samples received

• Many different types of collection/transport container
  – How simple mechanism of extracting samples from these

• May be unable to accurately determine the dilution factor required for pre-diluted samples
  – How exactly how much sample collected vs buffer
  – Final result difficult to determine
  – MU difficult to predict

• Drug recovery data in the transport containers is not consistently available
  – Where does the responsibility lie - requester / collector / laboratory?
• Reporting of final result - diluted result or extrapolated “neat” result

• Commercial QC not widely available in desired matrix

• Not aware of QAP which currently exists in Australia
  – Is sample exchange really appropriate or reference material available

• Should the laboratory run a “second” screen or proceed directly to confirmation upon receipt of an unconfirmed on-site initial test result

• General laboratory issues such as validation of methods etc,
  – Medical Testing organisations are subject to Requirements for In-house In Vitro Diagnostic Devices NPAAC (2007) document
Issues for clarification Sections 4 & 5
Initial screening and Confirmatory Testing Procedures

• Personnel

• 5.8.1 Day to day management - Toxicologist
  – Does this person need to be On-site at all times or part of the management structure? i.e. in a national corporate laboratory structure
  – NPAAC category “B” laboratory supervision visits

• Appropriate formal qualifications
  – What courses/qualifications have been recognised as appropriate or not appropriate?

• Experience with analysis of biological material for drugs
  – how much experience is deemed adequate
Issues for clarification Sections 4 & 5

Initial screening and Confirmatory Testing Procedures

- Personnel
- how many publications or court testimonies are deemed appropriate?
- Research concerning analytical toxicology
  - in what areas of toxicology (the drugs mentioned here or others)
  - is pharmacology training sufficient
  - how much input into the publications, when?
- Forensic cases the court determines who is an “expert”
- No requirement in Section 4 for experience or qualifications of personnel
e.g. screening analyst, access to a toxicologist
  - Some organisations may seek accreditation in Screening only
NATA training requirements

- Appropriately trained staff with demonstrated knowledge and experience in the relevant areas
- **Forensic Testing FAD:**
  - *Toxicologists* must be competent to perform qualitative and quantitative analyses for alcohol, drugs, metabolites and other toxic substances in biological materials. They must also be able to make a systematic search for such substances and apply appropriate extraction, separatory and identification procedures.
- Documented detailed training records
- Documented internal and external continuing education activities
  - Internal Journal reviews, case presentations, educational presentations
  - External Attendance at meetings conferences and workshops, membership of relevant professional societies
- Documented on-going competency assessments
Sections 2 and 3
Collection, storage, handling and dispatch and On-Site Testing

• Drug and Alcohol testing programs can be expensive for organisations (may be a tendency to go for a “cheap” option)

• Poor understanding by employers of the requirements in terms of
  – the standard
  – validation
  – QA activities
  – accreditation

• Collection and testing performed by
  – “stand alone” collection organisations
  – established laboratories
  – employers (OHS etc)
  – potentially hundreds of such organisations
Sections 2 and 3
Collection, storage, handling and dispatch
and On-Site Testing

• Wide range of collection and testing devices available
  – many with limited or no validation of devices
    or QA activities associated with testing
  – devices directed at incorrect analytes e.g. THC metabolite not THC
  – wide range in nominated cut-offs
  – Confusing for users who aren’t generally “laboratory” experienced

• Many organisations are self claiming ‘compliance with’ or ‘adherence to’ or “practices and/or devices which are consistent with” AS 4760

• Availability of AQTF recognised training courses for collectors
  – Some of those that are available are expensive
Issues for clarification – On-site initial testing

• **Validation of testing devices – the device must be “fit for purpose”**

• **What is “fit for purpose”**
  – Ability to detect drugs in Oral Fluid
  – That it can detect drugs at a level “some hours after common drug use”
  – Issues with “target” vs “nominated” cut-offs

• **No provision in 4760:2006 for a validation report on the on-site devices used but is required under ISO 15189 and ISO 17025 (and AS/NZS 4308:2008)**

• Acknowledged that the standard requires only a “nominated” cut-off to be met not the target cut-off – but is not recommended

• Use of different cut-offs is confusing for users of the service especially those who are familiar with the definitive cutoffs in AS/NZS 4308
On-site initial testing

- QA activities must be performed
- QC –
  - Negative QC is a drug free specimen
  - Positive QC is an oral fluid specimen …. at or within 50% of nominated cut-off (availability of commercial QC)
- No QAP currently available for Oral Fluid
- Send negative donor samples to laboratory (de-identified)
  - confirmatory cut-off probably be much lower than the on-site device nominated cut-off
  - and could return “positive” results
- What action would be required by the on-site testing agency
- Opens questions of agencies “missing” drug users and is the device “fit for purpose”
- Suggest only accept devices which can achieve the TARGET cut-off
Scope of accreditation – Medical Testing

- 10.61.18 Drugs for toxicological purposes to AS 4760:2006
  - Section 2 Collection, storage, handling and dispatch
  - Section 3 On-site initial testing
  - On-site screening performed on the ACB Cup testing device for cocaine and metabolites, opiates and amphetamines-type stimulants to AS4760:2006 target cut-offs
Further options for accreditation for consideration

- **10.61.15 Drugs for toxicological purposes**
  - On-site screening for Oral Fluid performed on the ACB Cup testing device for Δ⁹-tetrahydrocannabinol (THC) testing **not** to AS4760:2006 target cut-off

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**OR**

- Include all drug classes within AS 4760 Accreditation no matter what the nominated concentration as this is within the requirements of the standard
Requirements for this option

- Organisations would still be required to have validated testing devices but to the “nominated” cut-off
- Would still be required to run QA activities e.g. QC at or within 50% of nominated concentration
- Run a QAP when/if becomes available
  - will get different results for different nominated cut-offs depending at what level the QAP is set
- Send 1 and thereafter 1 of 20 subsequent donor negatives to a laboratory (Some results will be returned positive results depending on the nominated cut-off)
- Send every unconfirmed positive for confirmation
- Include a statement on report that the drug with the nominated concentration above the target cut of may not detect drug use due to the sensitivity of the assay?
Concerns with this approach

• But still comes back to “is the device fit for purpose”?
• What level of nominated cut-off will result in the device being so insensitive it is not worth performing the test as the capacity for detecting drug use is negated?
  – β-hCG assay which can’t measure accurately below 250 IU/L where cut-off for pregnancy is >25 IU/L
• Who makes the decision about what is an appropriate cut-off?
• Will it become a de-facto target cut-off
• Potentially undermine the standard
• Relieve pressure on device manufacturers to reach the target cut-off of AS 4760?
Summary

- Increasing pressure from employers and legislators to use accredited agencies but still in early stages
  - Collection
  - Screening
  - Laboratory testing
- Employers becoming more aware of the issues surrounding drug testing and benefits of using accredited testing organisations
- Number of inquiries regarding accreditation to both toxicology standards is growing rapidly
- Needs to be a driver to stimulate the uptake of the standard
- A number of issues identified which require careful consideration
  - QA, Validation of Devices and differences in cut-offs
- NATA working with the toxicology community to work on these issues
- Involve Standards Australia?
• Comments and questions?