



Drugs of Abuse – Regulatory Standards and Accreditation

A NATA Perspective on Lab Accreditation Results for Urine / Saliva

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Introduction

- Overview & Update of Accreditation of Drugs of Abuse Testing Facilities at NATA
 - Fields of NATA
 - Numbers of facilities accredited
 - Accreditation of collection & on-site screening facility
- Update on issues with accreditation for drugs of abuse testing facilities & outcome of the technical group discussion

DOA testing accreditation across NATA Fields

- Forensic Testing and Chemical Testing
 - Forensic Laboratories
 - Racing Laboratories
 - assess also against ISO/IEC 17025 and not subject to NPAAC

- Medical Testing
 - Pathology Laboratories
 - Stand-alone Facilities for Collection and On-site Screening
 - assesses also against ISO 15189 & relevant NPAAC requirements, e.g. supervision, record retention

Number of accreditations to urine testing (AS/NZS 4308) across all fields

- Section 2 Collection, storage, handling and dispatch
 - **24 Organisations**
- Appendix A On-site screening
 - **9 organisations (5 organisations as in April 2011)**
 - **4/9 are Stand-alone facilities for collection & on-site screening**
- Section 4 Laboratory screening
 - **23 organisations**
- Section 5 Confirmation
 - **18 organisations,**

Number of accreditations to oral fluid (AS 4760)

- **Section 2 Collection, storage, handling and dispatch**
 - 6 organisations (4 as in April 2011)
- **Section 3 On-site screening**
 - None
- **Section 4 Laboratory screening**
 - 4 organisations
- **Section 5 Confirmation**
 - 5 organisations
- NO organisation accredited for on-site screening in oral fluid

Accreditation for Laboratory for screening and confirmatory testing

follows AS/NZS 4308 and/or AS 4760 accreditation requirements
and the ISO 15189 or ISO/IEC 17025 framework

- includes specimen handling, CoC, screening and confirmation
- Validation of procedures/devices
- QC/QAP
- Reporting
- Staff training and expertise

Accreditation of Stand-alone Collection & On-site Testing Facility

follows AS/NZS 4308 and/or AS 4760 accreditation requirements
within the ISO 15189 framework

- apply the relevant **Management** and **Technical requirements** of the **ISO 15189** standard

Day 1 Visit to main office/ testing site

- Collection, on-site screening, storage and dispatch procedures
- CoC and records
- QC/QA results
- Training certificates and competency assessment of collectors
- Validation of devices
- Audits of collectors and sites by organisation
- Documentation & records of quality management system

Day 2 Site visit to review procedures

Different types of sites

- Dedicated collection sites controlled by facility
- Mobile units (camper vans) controlled by facility
- Dedicated client sites in workplaces, not under control of facility
 - Various levels of comfort and suitability
 - May have implications on the donors & integrity of sample
- Site-audit must be conducted by facility for each site & records kept
- Different sites may be selected for each assessment

Accreditation to AS/NZS 4308 vs AS 4760

- More facilities accredited to Urine testing (AS/NZS 4308) compared to Oral fluid testing (AS 4760)

Why?

- Urine testing has a longer history and more popular to customers?
- More facilities offer urine testing than oral fluid testing?
- Difficulty to achieve for oral fluid (QC/QAP requirements, validation of testing devices etc)

Accreditation to AS/NZS 4308 vs AS 4760

- Only a few facilities accredited to on-site screening
 - **9** organisations accredited for urine and **none** for oral fluid on-site screening
 - many organisations performing on-site screening, and
 - possibly many hundreds or thousands of tests performed daily
 - difficulty/cost to meet QC/QAP requirements, validation of testing devices etc

Issues with on site screening in urine

- Devices validated against Appendix B of AS/NZS 4308:2008 & QAP available since 2010
 - Performance in QAP varied significantly, e.g. at +25-50% cut-off level
 - Some collectors not run any QAP sample for a long period of time
 - Staff lack of knowledge & experience in review and action for unsatisfactory QAP results
 - Difficulty in assessing competency of the facility/staff based on QAP results

- Commercial QC materials available but expensive
 - QC not consistently run by each collector or at the client sites

Issues of on-site screening in oral fluid

- A limited QAP exists (unsure whether this is suitable for on-site testing)
- Not aware of any commercial QC which exists
- Wide range of “nominated” cut-offs with devices seen
- No validation data for on-site screening devices have been demonstrated
- Many different types of collection/ transport container pre-diluted or neat saliva

- ❖ **Cross field technical group** established to discuss accreditation and interpretation issues
 - Meetings held in Sept 2010 and April 2011
 - NATA News in June 2011 – Verification of on-site testing device & transport device for oral fluid
 - NATA Technical Circular (draft) for public comment in July 2011 – “Assurance that Collection Devices for Detection of Drugs in Oral Fluid are fit for purpose
 - Draft technical policy covering other issues under NATA internal review

Update on Technical Group Discussion for Issues in Drug of Abuse Accreditation Standards

- Facility performing on-site screening must have a formal arrangement with **expert toxicologists** for providing advice on toxicological issues as they may arise

- **An Expert Toxicologist** must
 - have comprehensive knowledge of qualitative and quantitative **analyses for drugs, metabolites** and other toxic substances in biological materials.
 - be able to make a systematic search for such substances and apply appropriate **extraction, separatory and identification procedures**.
 - Have relevant post graduate qualification with documented continuing **education activities**.
 - have appropriate **toxicology laboratory experience** and a sound knowledge of the scientific literature and procedures relevant to toxicology testing;
 - be able to **evaluate and interpret results of toxicological tests**;
 - be able to communicate orally the technical aspects of toxicological testing to a lay audience.

Update on Technical Group Discussion for Issues in Drug of Abuse Accreditation Standards

- Screening laboratory - personnel
 - A minimum of two qualified personnel must be present (i.e. being **in physical attendance**) in the screening laboratory, a screening analyst and laboratory supervisor, to ensure proper checking and cross-checking is performed prior to reporting of test results.
 - Where an **automated system** is used, the laboratory supervisor may attend the laboratory on his own.

- On-site creatinine test for urine
 - Performance of on-site creatinine test strip must be verified, e.g. by conducting correlation study with the confirmatory laboratory creatinine assay to ensure approximate comparability of results.
 - The semi-quantitative result obtained test must be recorded rather than 'Normal' or 'Abnormal' (which are Pathology terms).

Update on Technical Group Discussion for Issues in Drug of Abuse Accreditation Standards

- QC – on-site screening
 - 2 QC (Pos and Neg) must be run by **each** collector on the **first** collection site, and
 - At least 1 QC be run after each subsequent 25 specimens **provided** that the **transport conditions** of the test devices are monitored
 - Appropriate measures to ensure the lighting and other environmental conditions in collection sites are appropriate

- QAP – on-site screening
 - Enrol in QAP for the classes of drugs being detected. All different test device types must be **individually** enrolled.
 - Evidence of review and corrective action of QAP results by relevant personnel.
 - Review performance of the test device if unsatisfactory QAP results are obtained repeatedly.

Update on Technical Group Discussion for Issues in Drug of Abuse Accreditation Standards

- Oral fluid on-site screening device
 - To be “Fit for Intended Use”, the nominated concentration must be **at or within $\pm 25\%$** of the on-site initial test **target concentrations** specified in the Standard.
 - Oral fluid test devices must be **validated** according to principle of AS 4308 Appendix B
 - Against the on-site initial test **target concentrations** as per AS 4760

- Oral fluid transport device
 - The **drug recovery rate** of the collection and/or transport device must be verified and should be determined in consultation with the laboratory performing the confirmatory test.

Update on Technical Group Discussion for Issues in Drug of Abuse Accreditation Standards

- Pre-diluted / buffered oral fluid
 - Where a pre-diluted and/or buffered oral fluid sample is used for confirmatory testing, **a comment** should be included in the report to indicate that **the test results are based on the sample as delivered to the laboratory** and any dilution factor is not taken into consideration for the calculation of the concentration and the reported results.

Summary

- Employers becoming more aware of the benefits of using accredited testing organisations
- Number of inquiries and applications for accreditation to both toxicology standards is growing
- A number of issues identified which require careful consideration
- NATA working with the toxicology community to work on these issues
- Increase communication with Standards Australia ?



- Thank the experts of the technical group!
- Comments and questions?