Specific Accreditation Guidance

Legal

Workplace Drug Testing - a guide to industry

January 2018

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Background

No one likes the idea of having to be involved in workplace drug testing - employers or employees.

Unfortunately it is a fact of life in many safety sensitive workplaces that testing may have to be undertaken. Safety has to be the first concern in any working environment.

So if you are involved in workplace drug testing, either as an employer or employee, there is only one thing that really counts.

A correct answer is the only good answer. Correct answers lead to reliable decisions.

A test result saying a person does not have drugs in their system when they really do – a false negative - may lead to serious outcomes for the individual and all those around him or her.

But a false positive result may also have serious consequences -

- for a worker, being unfairly penalised and/or stigmatised;
- for the employer, having to shut down or delay work causing inconvenience to many and loss of productivity.

Hence everyone needs to have confidence in workplace drug testing services and know that they are competent to deliver the correct answers.

What criteria are used?

In workplace drug testing, two Australian standards are often used as the basis for workplace testing:

AS/NZS 4308:2008 *Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine*

AS 4760:2006 *Procedures for specimen collection and the detection and quantitation of drugs of abuse in oral fluid*

What is actually covered?

The steps in a drug testing process are:

- sample collection;
- screening test;
- confirmatory testing.

The reliability of the result may be compromised by any of these steps not being performed properly. For example, a well performed test will never compensate for a poorly acquired or badly managed sample.

Where does NATA fit in?

NATA accreditation is a means of providing everyone with confidence in the competence of drug testing services through its third-party, peer assessment processes.

For oral fluid testing under AS 4760, NATA does not currently offer accreditation for Section 3: On-site Initial Testing. See Technical Annex 1 for further information.

Should there be changes made to Section 3 by Standards Australia in the future, NATA will review this policy.

Accreditation is available for other sections of AS 4760 as follows:

Section 2 - Specimen collection, storage, handling and dispatch;

Section 4 - Laboratory screening procedures; and

Section 5 - Laboratory confirmatory procedures.

NATA currently offers accreditation under AS/NZS 4308 dealing with urine testing for the following:

Section 2 - Specimen collection, storage, handling and dispatch;

Section 4 - Laboratory screening procedures;

Section 5 - Laboratory confirmatory procedures; and

Appendix A - On-site screening procedure.

Where can it go wrong?

Samples need to be taken at the right time and placed in appropriate containers that will not result in contamination. They need to be correctly labelled with all the relevant information. If samples are to be stored for any time, or transported for testing, they need to be kept in appropriate conditions and with adequate security. Extended delays may compromise the sample and, hence, the test result.

Screening tests performed using test kits may be relatively simple to undertake but still need to be performed by competent personnel in an environment that will not cause contamination. The kits themselves may be compromised if they are not kept at the correct temperature including when they are transported, since screening tests are not usually performed in a nice air-conditioned laboratory. This also means that personnel need to undertake periodic checks on the kits - called quality control or QC - to ensure they are working as expected.

So it is clear that all of the processes in a laboratory - from sample receipt and registration through to the issuing of a test report - have to be managed competently and be under complete control.

In short, a failure to perform correctly any of these steps in the process has the potential to deliver incorrect results resulting in incorrect decision making. In safety sensitive activities in the transport industry, this is clearly a critical issue.

Why NATA?

For employers operating their workplace drug and alcohol management plans, NATA accreditation is one of the tools you can use to provide confidence in the integrity of a testing system.

For those that may be the subject of drug testing, NATA accreditation is a means of having confidence that your sample will be obtained, transported, stored and tested by a service that has the competence and capability to deliver a reliable result.

For government agencies and regulators, NATA accreditation facilitates the policy objective of providing a safe industry.

The key to confidence in any test result must lie in the collective competence of all those involved in:

- managing the collection of the sample;
- transporting the sample securely under appropriate conditions;
- undertaking the testing; and
- reporting the result.

It is in the practical demonstration of this competence where NATA accreditation proves its value.

NATA Accreditation - what is it?

So what is NATA Accreditation? Everything seems to be accredited these days so does it actually mean anything?

It's nothing new. NATA has been around assessing the competence of testing services for well over sixty years. Indeed, it has been around that long because it has been delivering confidence in testing services provided to industry, business and the public.

A NATA accredited drug testing facility has subjected itself to a third-party on-site assessment by technical experts - NATA calls it peer assessment - of its competence and capability to deliver reliable test results. Facilities are reassessed at regular intervals to ensure their ongoing competence and capability.

NATA accreditation is for specific activities and tests. It is not a blanket "tick" for everything a facility does. So those using the accredited drug testing service can be assured that an assessment team has looked specifically at all facets of the drug testing activities in detail and not just some generic aspects of laboratory practice.

What are the criteria for accreditation?

There are two levels of published standards that are applied at a NATA assessment.

Firstly, there are the standards that describe sound laboratory practices; that is, the need to have things like:

- competent and trained staff;
- appropriate equipment and instruments;
- proper management and storage of test kits and reagents;
- secure and controlled storage and management of samples;
- comprehensive record keeping; and
- clear and precise reporting.

These things, and much more, are described in international standards used in accreditation around the world.

The second level of standards used in NATA assessments describe the specific technical requirements for the sampling and testing being accredited. In workplace drug testing, the standards are AS/NZS 4308 (urine) and AS 4760 (oral fluid).

It is stressed that NATA does not write standards used in accreditation as it would be a conflict of interest.

A last word on standards. It is a convention in national and international standards writing bodies that standards should:

- meet the needs of as many stakeholders as possible; and
- state the minimum requirements needed to comply with what the standard is trying to achieve, not something gold plated.

For those with an interest in some of the technical issues associated with NATA's accreditation of workplace drug testing facilities, refer to the Technical Annexes to this Guide.

Who can be accredited?

NATA accreditation is available to any third-party, second-party and in-house service providers that are competent and capable of delivering reliable test results. For larger organisations, the costs of engaging third-party providers may make the in-house option more cost effective.

In-house and second party providers are, of course, required to demonstrate management and operational separation from the areas where personnel are subject to drug and alcohol testing.

Fees for NATA accreditation vary depending upon the location of the service provider and the scope of the accreditation being sought - sample collection and/or on-site testing and/or laboratory testing.

From application to the granting of accreditation, fee-for-service applies. Once accreditation is granted, reassessments and surveillance activities are covered by an annual fee.

The non-fee costs of accreditation for a service provider that has established processes reflecting sound laboratory practice are primarily confined to the time associated with the assessment process.

Please contact NATA for more information.

Practical tips for the industry

- Looking for a NATA accredited facility

  Employers seeking a service provider can start with the search engine on the NATA website www.nata.com.au . Each service provider will have a “scope of accreditation” which will contain a specific reference to AS/NZS 4308 and/or AS 4760 together with the particular parts covered by the accreditation - sampling, screening and/or laboratory testing.

  Indeed, employees that find themselves the subject of a drug test might be wise to seek to have all steps in the process undertaken by accredited facilities so should also check the accreditation status of the provider on the NATA website.

  Alternatively, NATA may be contacted directly for advice on which facilities have accreditation and for what. (Contact details are provided on the back page.)

- What to ask for from the service provider

  The best way of making sure that you get what you need from a NATA accredited service provider is to ask that the results be provided on a “NATA endorsed report”. This will have the NATA logo and statement of the accreditation held and provide the end user with assurance that the testing has been performed in accordance with the NATA accreditation criteria.

  If a facility is accredited yet they state that they cannot provide an endorsed report, there may be an issue so it is advisable to contact NATA.

- Turn-around-times

  Employers do not want to have staff and equipment assets sitting around doing nothing. Employees don’t want to be in limbo waiting for a test result. So when ordering services, make sure your provider knows your deadlines and seek their assurance that they will provide acceptable turn-around-times.

- Reality check

  NATA accreditation offers confidence but it is still advisable for service users to do their own checks.

  - Verify that information such as date of test, location, sample ID and NATA-endorsement all included in the test report?
  - Depending on one’s budget, consider having a laboratory test (confirmation) on a negative screening result every now and then or have two laboratories do the confirmation test.
  - Check the service provider’s accreditation every few months as they come and go out of the NATA system and scopes of accreditation change.

- If in doubt, seek advice from NATA

  Problems with service providers should be sorted directly if possible. But if you do not feel an accredited facility is not doing what you have asked of them, or you have evidence of incorrect results, contact NATA. Depending on the nature of the issue, NATA may provide some practical advice or, if it constitutes a complaint, investigate the matter with the accredited facility.

More about NATA

Established in 1947, NATA was the world's first comprehensive laboratory accreditation body, and continues as one of the largest. NATA's authority stems from its 60+ years of accreditation history and formal recognition by the Australian Government through a Memorandum of Understanding.

The core of NATA accreditation is the third party, objective, peer review process at a scientific/technical level that provides confidence that the accredited facility has the competence and capability to produce reliable outputs.

NATA's ability to provide confidence in the technical competence and capability of a broad range of measurement, testing and inspection activities is achieved through the services provided by over three thousand voluntary peer assessors – people who have specific understanding and technical expertise of the activities performed by the laboratory or inspection body – supported by NATA's staff of lead assessors.

NATA regularly engages with its stakeholders to ensure that accreditation processes are relevant and the level of rigour in the peer assessment is fit-for-purpose – delivering the required level of confidence in the right aspects of the work at a cost that is manageable for the accredited facilities and their clients.

Whilst being a not for profit private sector organisation, NATA is overseen by a Council consisting of government, professional and industry representatives.

Further assistance

Workplace drug testing enquiries should be directed to:

Sector Manager, Legal and Clinical Services

1st Floor, 2-6 Railway Parade, CAMBERWELL VIC 3124
Ph: 03 9274 8200 or Email: Andrew.Griffin@nata.com.au

Technical Annex 1
AS 4760 Section 3 On-site Initial Testing

Having conducted several assessments, it has become apparent that there are a number of significant issues with Section 3 of AS 4760:2006 which remain unable to be resolved. This is despite NATA seeking independent feedback to clarify these issues from key professional bodies including the Royal College of Pathologists of Australasia (RCPA), the Australasian Association of Clinical Biochemists (AACB) and from our counterpart organisation in New Zealand, International Accreditation New Zealand (IANZ).

Accordingly, NATA has not granted accreditation to any facility for AS 4760, Section 3 and a decision has now been made to withdraw the provision of accreditation for this testing. A communication to this effect was sent to NATA's stakeholders in July 2013.

Until further notice NATA will no longer accept applications for accreditation in this area and any current applications will no longer be progressed.

The issues identified in relation to this testing include the following.

- There are no prescribed cut-off concentrations for screening devices or set quality control limits as there are for urine screening devices as detailed in Appendix A of AS/NZS 4308:2008.
- The target concentrations for screening devices in Table 3.1 are described as "nominated" in Section 1.5. This section also states that "there is yet to be an accepted cut-off concentration" and that "concentrations higher than the initial testing target concentrations may sometimes be used if sensitivity is the limiting factor but this reduces the ability to detect drug use".

  Accordingly, a facility may nominate its own targets (but not lower than those in Table 5.1 used for confirmatory testing). Where the nominated targets are set higher than those in Table 3.1 by the facility due to the insensitivity of a screening device, false negative results may result, despite compliance with the Standard. This would be a key concern for both drug screening programs and the public.
- The ability to test for drugs with known instability in saliva post collection, especially tetrahydrocannabinol (THC), is compounded by the allowance of "nominated" targets. The allowance of nominated screening concentrations at levels at or above the confirmatory concentrations may impact on the ability of confirmatory testing to reproduce a non-negative screening result due to loss of drug during transport and handling.
- There are no acceptance criteria for what constitutes acceptable verification of screening devices as there are for urine screening devices as detailed published in Appendix B of AS/NZS 4308:2008.
- The Standard requires quality control (QC) to be run. However, it is noted that the negative QC is defined as a drug free specimen. Such a specimen does not test the sensitivity of a device to identify donor samples which contain drugs at a concentration below the nominated target cut-offs. This is inconsistent with Appendix A of AS/NZS 4308:2008 which requires the below cut-off QC to be at a concentration between 25% and 50% below the cut-off concentration.

  The positive control is at or within 50% above the nominated concentrations. This is also inconsistent with AS/NZS 4308:2008 which requires the positive control to be between 25% and 50% above the cut-off concentrations (in Table 1).

Whilst NATA will not consider granting accreditation for testing to AS 4760:2006, Section 3, agencies are still testing and claiming compliance with the Standard. It is NATA's view that this poses a significant risk to health and safety given the deficiencies as noted above.

Technical Annex 2
Quality Control

Quality Control – Why

There is some confusion relating to NATA's criteria for quality control – QC - for on-site screening tests. Indeed, there seems to be a perception that QC is:

- a huge cost – well not really when you take into account the purpose and the need to get the correct result.
- time consuming – a few minutes.
- unnecessary – it's the testing equivalent to a pre-flight check pilots do before taking off for the day. If the pre-checks fail, you don't go anywhere.

QC is what gives confidence that the test kit will actually work, and hence, that a test is worth conducting. It is anything but an optional extra.

Quality Control – How

A few facts about NATA's standards based accreditation criteria for QC for on-site screening.

1. A collection agency accredited to AS/NZS 4308 Appendix A must ensure that each collector runs 'High' and 'Low' QC in accordance with the Standard at the beginning of the day's testing.
2. They are then expected to perform one QC at each 25th donor, again in accordance with the Standard.
3. If at any point in the day the QC fails, all tests since the previous successful QC must be disregarded and corrective action undertaken.

It is not expected the collection agency performs QC before each "test" or each time they set up in a new customer site as long as they perform QC at each 25th subsequent sample and can demonstrate the devices have been stored securely and transported within manufacturer's specification in relation to temperature.

In practice, a day of screening tests might look like the following.

- An agency performs High and Low QC at site 1, prior to the first donor.
- If the QC result is satisfactory, donor testing continues until 25 have been completed at which point another single QC (high or low) is performed. If only 20 donor tests have been performed at site 1, no further QC is required.
- The collector moves to site 2 ensuring that the test devices have been transported in accordance with the manufacturer's recommendations.
- At site 2, donor testing continues (counting from the number of tests since the last QC at site 1) until the 25th donor has been tested at which point, another single QC is performed. Again, if the QC is satisfactory, testing will continue.
- If the QC is not satisfactory, testing will be suspended until corrective action is taken. Additionally, all tests conducted since the previous QC will need to be reviewed and possibly invalidated.
- This sequence would continue until testing ceases for that day.

Quality Control - More about cost

Service providers operate in a competitive environment so sample collection and testing charges reflect the usual commercial reality.

Is QC a cost? Any step in the process takes time and resources so QC does cost. But since it is an integral part of the test itself, it is not an area to look for cost savings.

Where is the cost incurred in undertaking QC?

- QC material - is a urine sample with known amounts of the drugs of interest. There would be a “high” and “low” QC providing a check of the test kit near its upper and lower detection limits.
- Refrigeration of QC material - liquid QC material is refrigerated or frozen upon receipt. Keeping the material in accordance with the manufacturer’s specifications prolongs its shelf life.
- Test kits - each QC does require the use of a test kit.
- Time - QC can be done in a few minutes. There is a need to maintain records and to review the QC periodically.
- Sample integrity - while not part of QC, it should be remembered even QC checks performed in accordance with these requirements cannot compensate for degraded samples. Hence, there is cost associated with urine samples being securely stored and transported. AS/NZS 4308 also requires refrigeration of samples prior to transport.

Overall, the importance to the entire testing regime means that quality control should really be viewed as an investment, not a cost.

AMENDMENTS

The table below provides a summary of changes made to the document with this issue.

Section	Amendment
New Document	This document replaces the former Information Paper 10.