

Dear Authorised Representative

### **NATA Accreditation for AS 4760:2006, Section 3**

NATA has received a number of enquiries and applications from facilities to have their accreditation extended to cover the above for on-site initial drug testing of oral fluid.

Following several assessments conducted, it has become apparent that a number of significant technical issues remain unable to be resolved. This is despite NATA attempting to seek independent feedback to clarify these from key professional bodies, for example RCPA and AACB, and from International Accreditation New Zealand (IANZ).

Accordingly, a decision has been made by NATA to withdraw the provision of accreditation for this testing. Until further notice NATA will no longer accept applications for accreditation in this area and any current applications will no longer be progressed.

Those organisations who have applications in progress should contact their NATA Client Coordinator to clarify the possibility of credit notes being issued for any NATA charges incurred covering arrangements for the accreditation activities performed to date in relation to this testing.

A summary of the issues identified in relation to this testing include:

- There are no clearly defined cut-offs concentrations for devices published in AS 4760:2006 as there are for urine devices in AS/NZS 4308:2008;
- Target values are only described as “nominated” target values and are very wide. The lowest concentration can be anything from the value described in Table 5.1 of AS 4760:2006 to a value above those described in Table 3.1;
- There is no definitive criteria for what constitutes “fit for purpose” as described in AS 4760:2006;
- There are no acceptance criteria for what constitutes a methodology or acceptance criteria for verification of devices as published in Appendix B of AS/NZS 4308:2008;
- There is no recognised expert technical group available for consultation for oral fluid drug testing e.g. the AACB Toxicology Working Party for urine toxicology;
- Due to the lack of a recognised technical expert group there has been inconsistency in the review of data collected at NATA assessments;
- The expertise of NATA technical assessors has been challenged in relation to this testing due to a lack of an expert technical group;

- There is concern as to the stability of some drug classes during the testing process, especially THC, which is compounded by the allowance of “nominated” targets;
- The allowance of a target screening concentrations at a level at or above the confirmatory concentration may impact on the ability of confirmatory laboratories to reproduce a non-negative screening result due to loss of drug during transport and handling.

The uncertainty created by the combination of the above points does not allow NATA to make a definitive decision with regard to the granting of accreditation and as such we are unable to provide a consistent and timely assessment of Section 3 of AS4760: 2006. This situation is not in the best interests of facilities seeking accreditation or their customers and NATA has resolved to remove the continued uncertainty around on site screening until such time as these issues can be resolved.

Should the above issues be resolved NATA will reconsider providing accreditation for Section 3 of AS 4760:2006.

The decision above does **NOT** affect the provision of accreditation for Sections 2, 4 or 5 of AS 4760:2006.

If you require any further information please contact Andrew Griffin, Deputy Sector Manager - Life Sciences at [Andrew.griffin@nata.com.au](mailto:Andrew.griffin@nata.com.au)

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