Specific Accreditation Criteria

Legal ISO/IEC 17025 and ISO 15189 Annex

Assurance that collection devices for the detection of drugs in oral fluid are fit for purpose

January 2018

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1. Introduction

This annex is applicable to accredited facilities and those seeking accreditation for the collection, storage, handling and dispatch of oral fluid for the detection of drugs in accordance with the requirements of Australian Standard (AS) 4760:2006, Section 2.

This annex also applies to accredited or applicant facilities performing laboratory testing on oral fluid samples in accordance with the requirements of AS 4760:2006 Sections 4 and 5.

NATA will not, however, offer accreditation to facilities for on-site initial testing to AS 4760:2006 Section 3. This decision remains in force until further notice.

2. Background

NATA accredits facilities for drug collection and/or testing to either ISO/IEC 17025 or ISO 15189.

AS 4760:2006, Section 2 is considered to be a specific procedure i.e. method, to enable assessment against the requirements of ISO/IEC 17025 and ISO 15189.

In accordance with ISO/IEC 17025 or ISO 15189, facilities must confirm that they can properly operate methods before introducing them, ensure that the methods are appropriate for their intended use and that they meet the needs of customers.

Accordingly, facilities must demonstrate the appropriateness of collection devices, prior to their use.

3. Policy

AS 4760:2006 Section 2.4.3 a) states that “the manufacturer’s recommended procedure to ensure maximum efficiency of transfer of drugs to the testing device and minimise degradation shall be followed at the point of collection as well as during storage and transportation”.

Where a manufacturer has conducted studies (i.e. validation) in relation to the performance of drug collection devices, collection facilities must ensure that the study results can be replicated i.e. verified, in the environment in which the collection devices shall be used.

As such, quantitative drug recovery rates for all drug classes to be tested, over a range of concentrations, must be performed. The concentration ranges must consider the targets defined in Table 3.1 AS 4760:2006. For example:

- low concentrations above but close to the target concentration;
- a medium concentration up to 50% above the target concentration; and
- a high concentration greater than 50% above the target concentration.

Note: Drug quantitation is able to be performed by a laboratory accredited for confirmatory drug testing by mass spectrometry.

The outcome on results caused by delays in testing (from the time of specimen collection) together with temperature storage conditions must also be considered as part of the verification studies.

Where a manufacturer does not provide performance data for collection devices with regard to drug recovery rates, the collection facility shall then perform validation studies. As detailed in AS 4760:2006, the storage and transport conditions identified in manufacturer's literature must be followed. Where verification (or validation) studies identify limitations with regard to drug recovery, for example specimens needing to be stored at specific temperatures prior to testing, these shall be defined in a documented policy/procedure and communicated to interested parties e.g. customers of the facility and the initial or confirmatory testing laboratories (where relevant). These conditions shall also be monitored and recorded for specimens collected and testing laboratories informed. Records of verification (or validation) studies must be kept.

4. Reporting of results

Where facilities receive oral fluid for laboratory initial testing (AS 4760:2006 Section 4) and/or confirmatory testing procedures (AS 4760:2006 Section 5) an evaluation of the integrity of the specimen must be made. This includes establishing and evaluating the effect, if any, of the time between testing and collection and whether the specimen was received in accordance with the transport and storage requirements, particularly in relation to temperature, as per the manufacturer instructions for the collection device. Such an evaluation must be made against the drug stability data for the specimen collection device used.

Records of the evaluations made in relation to sample integrity must be maintained.

Where there is doubt about the integrity of the specimen due to a delay in receipt or testing from time of collection or transport/storage conditions have not been met, an appropriate comment must be included on the test report advising that the integrity of the specimen is in doubt and the result needs to be interpreted with caution.

Similarly, where the testing facility is unable to make an evaluation as to the integrity of the specimen due to a lack of available information, an appropriate comment must be included on the test report advising that the integrity of the specimen could not be established and the result needs to be interpreted with caution.

5. Further information

Any questions regarding this Annex may be directed to Andrew Griffin, Sector Manager – Legal and Clinical Services in the NATA Melbourne office on (03) 9274 8200, or by email at Andrew.Griffin@nata.com.au

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 Technical Circular 18.