

WADA Technical Document – TD2003LDOC

Document Number:	TD2003LDOC	Version Number:	1.3
Written by:	WADA Project Team	Approved by:	
Date:	June 5, 2003	Effective Date:	January 1, 2004

LABORATORY DOCUMENTATION PACKAGES

The required Documentation Packages shall be provided by the Laboratory whenever required by the *International Standard for Laboratories* or in support of an *Adverse Analytical Finding* challenged by an *Athlete*. The package will be comprised of the information listed below. Each page of the package shall be numbered sequentially and the package certified to be a true copy of the original data and forms. The items listed below do not constitute a list of required flow charts, forms or documents, but instead a list of information necessary to support the analytical result. Laboratory working documents, computer printouts, and similar documents may be in the native language of the laboratory personnel. Table of contents and any flowcharts explaining the sequence of steps in the process and any other explanatory portions of the Documentation Packages should be provided in English or French, if requested.

The items listed below shall be the only information the Laboratory is required to include in the Documentation Package. Therefore, the Laboratory is not required to support an *Adverse Analytical Finding* by producing standard operating procedures, general quality management documents (e.g., ISO compliance documents) or any other documents not specifically required below.

All Documentation Packages provided shall contain the following information:

- Table of Contents
- List of Laboratory Staff involved in the test, including signatures and/or initials and position title(s)
- *Sample* Collection Control Form (external chain of custody form)
- Documentation of shipping and receipt of intact *Sample*
- Documentation linking *Sample* Identification Number to Laboratory Identification Number
- "A" *Sample* Bottle Laboratory Internal Chain of Custody
- Urine Integrity test results (if completed)

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- Screening Test Data
 - Screening Test Description
 - Screening Aliquot Laboratory Internal Chain of Custody documentation
 - Screening Test Results on negative, positive and athlete Aliquot
 - Documentation of any deviations from the written screening procedures, if any
 - Data run in the same analytical run or used to verify instrument performance or operation during that run.
[For example, tuning data for the mass spectrometer; chromatographic performance verification samples, if any; and/or quality control data, if any. This does not refer to data generated at other times (e.g., validation data for the method)]
- "A" Sample Confirmation Procedure Data
 - Confirmation Procedure Description
 - Confirmation Aliquot Laboratory Internal Chain of Custody documentation
 - Confirmation Procedure Data on negative, positive and all *Athlete Aliquot(s)*
 - Quantitative Data or ratio data and uncertainty estimation, if applicable
 - Documentation of any deviations from the written confirmation procedures, if any *[For example, a change in the split ratio or a dilution of the derivatized sample due to sample overload in the GC/MS; application of an additional cleanup step; or an explanation for the re-analysis of the sample with a new aliquot.]*
 - Data run in the same analytical run or used to verify instrument performance or operation during that run.
[For example, tuning data for the mass spectrometer; chromatographic performance verification samples, if any; and/or

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quality control data, if any. This does not refer to data generated at other times (e.g., validation data for the method)]

- "A" *Sample* Certificate of Analysis or certified Test Report
- Documentation of identity of "B" *Sample* with information on opening procedure and signature of athlete, representative, or surrogate present at opening
- "B" *Sample* Bottle Laboratory Internal Chain of Custody
- "B" *Sample* Confirmation Procedure Data
 - Confirmation Procedure Description
 - Confirmation Aliquot Laboratory Internal Chain of Custody documentation
 - Confirmation Procedure Data on negative, positive and all *Athlete Aliquot(s)*
 - Data run in the same analytical run or used to verify instrument performance or operation during that run. *[For examples, see "A" sample section]*
 - Quantitative Data or ratio data and uncertainty estimation, if applicable
 - Documentation of any deviations from the written confirmation procedures, if any *[For examples, see "A" sample section]*
 - "B" *Sample* Certificate of Analysis or certified Test Report