

WADA Technical Document – TD2009LDOC

Document Number:	TD2009LDOC	Version Number:	1.0
Written by:	WADA Laboratory Committee	Approved by:	WADA Executive Committee
Date:	September 20, 2008	Effective Date:	January 01, 2009

LABORATORY DOCUMENTATION PACKAGES

The required Documentation Packages shall be provided by the Laboratory as required by the *International Standard for Laboratories (ISL)* or in support of an *Adverse Analytical Finding* challenged by an *Athlete*. The package will be comprised of the information listed below. 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 shall 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 providing standard operating procedures, general quality management documents (e.g., ISO compliance documents) or any other data or documents, in hardcopy or electronic format, not specifically required below. Deviations from this technical document shall not invalidate the *Adverse Analytical Finding(s)*.

1. All Documentation Packages generated by the Laboratories should meet the following formatting requirements:

- A cover page and a signed statement by the Laboratory Director or authorized delegate certifying that the documentation package contains authentic copies of original data and forms;
- Sequentially numbered pages of the documentation package;
- Table of Contents;
- Presentation in a format that will allow proper review by relevant stakeholders;
- Data, charts, graphs, etc be described.
[Descriptions may be provided in the Table of Contents, page headers, titles, etc].

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2. All Documentation Packages provided shall contain the following information:

- List of Laboratory staff involved in the test, including signatures and/or initials and position title(s) (Each individual's complete signature/name can assist in interpreting the Laboratory Internal Chain of Custody);
- *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 (if available);
- "A" *Sample* Bottle Laboratory Internal Chain of Custody;
- Urine analysis results for adulteration or manipulation as per ISL 5.2.4.1, if completed (not applicable for blood).
- **Initial Testing Procedure Data**
 - Initial Testing Procedure description;
 - Initial Aliquot Laboratory Internal Chain of Custody documentation;
 - Initial Testing Procedure results on negative control(s), positive control(s) and all *Athlete Aliquot*(s) related to the *Adverse Analytical Finding*;
 - Documentation of any deviations from the written Initial Testing Procedures, if any;

Instrument performance data from the same analytical run used to verify instrument performance or operation during that run. Data utilized for this purpose include instrument performance report(s) and quality control sample data.

[For example, tune report from a mass spectrometer or other instrument report; flow cytometer performance data; 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)].

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- **Confirmation Procedure Data**

- Confirmation Procedure description;
- Confirmation Aliquot Laboratory Internal Chain of Custody documentation;
- Confirmation Procedure data on negative control(s), positive control(s) and all *Athlete Aliquot(s)* related to the *Adverse Analytical Finding*;
- Identification data and/or quantitative data and uncertainty estimation, if applicable;
[A summary table is to be provided that compiles the necessary data and applicable criteria utilized to identify and/or quantitate the target substance(s) to report an *Adverse Analytical Finding* or *Atypical Finding*.]
- 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];
- Instrument performance data from the same analytical run used to verify instrument performance or operation during that run. Data utilized for this purpose is to include instrument performance report(s) and quality control sample data;
[For example, tune report from a mass spectrometer or other instrument report; flow cytometer performance data; 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)];
- Laboratory Test Report.