

WADA Technical Document – TD2021LCOC

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Written by:	WADA Science	Approved by:	WADA Executive Committee
Reviewed by:	WADA <u>Laboratory Expert Group</u>		
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LABORATORY INTERNAL CHAIN OF CUSTODY

1.0 Introduction

The purpose of this *Technical Document (TD)* is to harmonize the approaches used by Laboratories and ABP Laboratories to maintain Fit-for-purpose Laboratory Internal Chain of Custody, which ensures that the results generated by the Laboratory or ABP Laboratory can be unequivocally linked to the *Sample* and thereby to the *Athlete* that provided the *Sample*.

There are two (2) parts involved in the chain of custody for an individual *Sample*:

- The external chain of custody initiated at the collection site to record *Sample's* custody from collection to the delivery to the Laboratory or ABP Laboratory; and
- The Laboratory Internal Chain of Custody from *Sample* receipt to disposal.

2.0 Laboratory Internal Chain of Custody

The Laboratory Internal Chain of Custody documentation records the chronological traceability of custody (by authorized *Person(s)* or upon storage) and the actions performed on the *Sample* and any Aliquot of the *Sample* taken for Analytical Testing.

The Laboratory Internal Chain of Custody is documentation (worksheets, logbooks, forms, electronic records, etc.) that record the custody of *Samples* and Aliquots. A Laboratory Internal Chain of Custody does not require a separate dedicated form. Within the Laboratory or ABP Laboratory, the Laboratory Internal Chain of Custody shall be a continuous record of individuals and storage locations in regard to the custody of the *Samples* or Aliquots.

[Comment: Laboratory Internal Chain of Custody is documented by a written or electronic record which includes the date, location, action(s) taken, and the Person(s) performing an action with a Sample or Aliquot.]

Any deviations from the chain of custody shall be documented as part of the *Sample* record and include an impact statement.

Forensic corrections shall be conducted in accordance with ISO/IEC 17025.

2.1. Maintaining Chain of Custody

The Laboratory or ABP Laboratory shall implement Fit-for-purpose Laboratory Internal Chain of Custody standard operating procedures (SOP) compliant with this TD2021LCOC and maintain, as part of its Analytical Testing records, the external chain of custody documentation that accompanies the *Samples* as well as the Laboratory Internal Chain of Custody.

All entries into the Laboratory Internal Chain of Custody shall be completed by the authorized staff involved at the time that any change of custody occurs (from *Person* to *Person* or to/from storage devices). Time

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references do not need to be recorded in the Laboratory Internal Chain of Custody, with the exception of the time of *Sample* receipt by the Laboratory or ABP Laboratory.

A Laboratory Internal Chain of Custody is required for both “A” and “B” *Sample* containers and every Aliquot prepared for an Analytical Testing Procedure.

i. Samples are considered to be under custody when they are:

- In the physical possession of authorized Laboratory staff or authorized *Person(s)*; or
[Comment: Authorized Person(s) may be used and shall be trained, approved by the Laboratory and incorporated within the Laboratory’s Management System for the reception and transfer of unopened Samples delivered to the Laboratory, for example: facility security personnel.]
- Within the control zone of the Laboratory and in view (line of sight) of authorized Laboratory or ABP Laboratory staff, after being in his/her physical possession; or
- Stored in a secured, restricted and defined storage location.

ii. Aliquots are considered to be under custody when they are:

- In the physical possession of authorized Laboratory staff; or
- Kept in the Laboratory controlled zone, with access restricted to authorized Laboratory or ABP Laboratory staff only; or
- Stored in a secured, restricted and defined storage location.

iii. The Sample or Aliquot, when in an uncontrolled or unsecured zone of the Laboratory or ABP Laboratory, shall be in the possession of authorized Laboratory or ABP Laboratory staff.

2.2. Recording Chain of Custody during Analytical Testing

i. Samples

In the case of *Samples*, the Laboratory Internal Chain of Custody shall record all custody from their receipt in the Laboratory or ABP Laboratory, through storage and handling, to *Sample* disposal.

- *Sample Reception*

The transfer of the *Samples* from the courier or other delivery *Person* shall be recorded including:

- The date of receipt;
- The time of receipt;
- The initials or (electronic) signature of the authorized Laboratory representative receiving the *Samples*; and

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- The courier company tracking number, if available.
- *Sample Handling*
The transfer of the *Samples* during Analytical Testing shall be recorded including:
 - The date;
 - The reason/task for the change in the custody of the Sample;
 - The Laboratory or ABP Laboratory Sample identification code;
 - The identity of the individual or storage location the *Sample* is taken/transferred from; and
 - The individual or storage location receiving the *Sample*, including the unique equipment identifier of each storage unit (freezer or refrigerator identification) used to store the *Sample(s)*.

ii. Aliquots

The Laboratory Internal Chain of Custody shall record all Aliquot custody from Aliquot preparation to disposal including:

- The date;
- The Analytical Testing Procedure(s) for which the Aliquot was taken;
- The Laboratory or ABP Laboratory Aliquot identification code;
- The identity of the authorized individual preparing/transferring the Aliquot(s); and
- The authorized individual or storage location receiving the Aliquot(s), including the unique equipment identifier of each storage unit used to store the Aliquot(s).

When multiple *Samples* are aliquotted, a batch Aliquot Laboratory Internal Chain of Custody document for Initial Testing Procedure(s) (ITP) and/or Confirmation Procedure(s) (CP) may be used in lieu of an individual Aliquot Laboratory Internal Chain of Custody.

If all or part of the Laboratory Internal Chain of Custody is recorded using a data and information management system (e.g. a Laboratory Information Management System, LIMS), then the software shall have the capability to securely and uniquely identify the authorized *Persons* recording the chain of custody at the time that any change of custody occurs. In addition, the software shall have the capability to produce a hard copy summary of the *Sample* and Aliquot chain of custody, as described above, for a Laboratory Documentation Package.

2.3. Recording Chain of Custody for *Sample* Transfers

Laboratories and ABP Laboratories shall incorporate Laboratory Internal Chain of Custody procedures and forms to record the transfer of *Samples* to another entity (e.g. another Laboratory, WADA-approved laboratory, an external long-term storage facility). The Laboratory Internal Chain of Custody shall record the removal of the *Sample* “A” and/or “B” containers from storage in compliance with Article 2.2.i (*Sample*

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Handling) of this *TD* including the packaging of *Samples* and the transfer of custody from the Laboratory or ABP Laboratory to a courier or other responsible shipping body. A copy of the above Laboratory Internal Chain of Custody should also be included in the shipment and shall be signed by the recipient.