TD2021LDOC

Summary of Major Modifications

The Technical Document on Laboratory Documentation Packages, TD2021LDOC, has been aligned with the 2021 World Anti-Doping Code (Code) and the recently approved 2021 International Standard for Laboratories (ISL); and, the other International Standards, which are set to come into force on 1 January 2021.

The main changes in the TD2021LDOC include:

Main Document

Article Article 1.0 Introduction

- Clarification that a Laboratory is not required to produce a Laboratory Documentation Package for a Negative Finding unless requested by a hearing body or disciplinary panel as part of Results Management procedure.

Article 2.0 Formatting Requirements

- Requirement that any adjustment to records shall be conducted as forensic corrections.

Article 3.2 Chain of Custody

- Comment included to clarify that the List with the complete signatures/initials/names of Laboratory staff be provided to assist with interpretation of the chain of custody documents.

Article 3.3.2 Additional Documentation for Quantitative Confirmation Procedure (CP) Methods

- Comment included to clarify the relevant TDs, Laboratory Guidelines and TD LDOC Annexes for the reporting requirements of exogenous and endogenous Threshold Substances.
- Clarification that Laboratories shall provide their results for Threshold as the mean value (units) from triplicate determinations;
- Clarification that Laboratories shall provide the confirmed Specific Gravity (SG) and the adjusted DL if the SG is greater than 1.018.

Article 3.4 Laboratory Test Report(s)

- Comment included to clarify that the ADAMS Test Report shall include details in compliance with the TD DL or applicable TD or Laboratory Guidelines for quantitative CPs.
Annex A: Urine Steroidal Module of the ABP

Article 2.0 Urine ABP Laboratory Documentation Package Requirements

Article 2.3 GC-MSn Confirmation Procedure (CP) data

- Comment included to clarify that the GC-MSn confirmatory identification of the steroid Markers need only be performed once by the Laboratory and that the identification of the target steroid Markers is required prior to reporting an AAF or an ATF based on GC/C/IRMS results. Further clarification provided that the confirmatory identification of the Markers during the initial confirmation by GC-MSn becomes relevant for an Adverse Passport Finding (APF) based on the altered values (concentrations, ratios) of the Markers in the absence of a positive GC/C/IRMS result).

- Instructions are included for the “B” Sample GC-MSn CP and requiring the following:
  - The confirmed SG of the “B” Sample;
  - The Laboratory shall include the results of the “B” GC-MSn confirmation of the steroid profile (as described for the “A” Sample) if the CP of the steroid profile by GC-MSn has been requested for the “B” Sample although the “A” Sample has not been reported as an AAF for the Marker(s) of the steroid profile based on the results of the GC/C/IRMS analysis.

Article 3.0 Urine ABP Laboratory Certificate of Analysis Requirements

Article 3.2 ITP GC-MSn analysis of the Sample’s steroid profile

- Clarification that for the ITP GC-MSn, the following additional information shall be provided:
  - SG of the “A” Sample;
  - Clarification that a chromatographic printout shall be provided for all Markers of the steroid profile;
  - The measured values of the Markers of the steroid profile;
  - The associated $u_e$ expressed in units;
  - The presence of absence of substances that may alter the steroid profile.

Annex B: GC/C/IRMS

Article 2.0 Laboratory Documentation

- Clarification that if an adjustment is necessary based on a SG > 1.018, then the SG of the Sample and the resulting adjusted concentration of the Target Compound(s) shall be provided;
- Clarification that for the GC-MS analysis, the following additional information shall be provided:
  - A summary table with relative abundances (RAs) of diagnostic ions, retention time (RT) data and relevant calculation results;
  - The applicable criteria utilized to identify the target Analyte(s);
A summary table shall include signed/initialed (or electronic signature/validated LIMS record) statements that the results meet the applicable criteria.
A statement on the criteria that were fulfilled, as per the TD IRMS to report an AAF.

Annex C: ERA

- A comment is provided to clarify that Erythropoietin Receptor Agonists (ERAs), as defined in the Prohibited List, include erythropoietin and its analogs and mimetics (previously known by the name of Erythropoiesis Stimulating Agents (ESA)).

Articles 2.2.1. Initial Testing Procedure (ITP) (if provided) and 2.2.2. Confirmation Procedure (CP)

- The test description is updated with a comment clarifying that the method used for ERA immunopurification shall be described.
- The test sensitivity controls should be included if used by the Laboratory.

Annex D: hGH

Article 2.2. CP Analytical Data

- The scheme/sequence of key analysis steps shall be described in the summary test description.

Annex E: Blood ABP

Article 2.0 Blood ABP Laboratory Documentation Package Requirements

- The ABP blood Sample and XN-checks (levels 1, 2 and 3) quality control (QC) results summary table is required to include the acceptance criteria.

Article 7.0 References

- References have been updated.

In addition:

- Formatting as well as updating of terms and definitions, where relevant;
- Footnotes have been inserted as comments where relevant in the text and Annexes.

The TD2021LDOC replaces the former TD2019LDOC and becomes effective on 1 April 2021.