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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 *TD*s, 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.

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Annex A: Urine Steroidal Module of the *ABP*

Article 2.0 Urine *ABP* Laboratory Documentation Package Requirements

Article 2.3 GC-MS^n Confirmation Procedure (CP) data

- Comment included to clarify that the GC-MS^n 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-MS^n 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-MS^n CP and requiring the following:
    - The confirmed SG of the "B" *Sample*;
    - The Laboratory shall include the results of the "B" GC-MS^n confirmation of the steroid profile (as described for the "A" *Sample*) if the CP of the steroid profile by GC-MS^n 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-MS^n analysis of the *Sample*'s steroid profile

- Clarification that for the ITP GC-MS^n, 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_c 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.