TD2023LDOC

Summary of Major Modifications

The *Technical Document* (*TD*) on Laboratory Documentation Packages, TD2023LDOC, has been revised to include the new Annex F regarding the production of an endocrine *ABP* Laboratory Documentation Package (LDP) or an endocrine *ABP* Laboratory Certificate of Analysis (CoA) by a Laboratory for the quantification of the *Markers* of the Endocrine Module of the *ABP*. In addition, other LDP requirements were updated.

Main Document

- Further clarification that *Athletes* (and/or representatives) may only request an LDP through the relevant *Testing* Authority (TA) or *Results Management* Authority (RMA). In addition, the Passport Custodian may request an *ABP* LDP or CoA.
- In section 3.3.1. Confirmation Procedure (CP) Data, the requirement for a "Summary table" is replaced with the need to provide Laboratory signed or initialized statements, traceable via hard copies or electronic records, that the results meet the applicable identification criteria (TD IDCR).
- The Laboratory is required to include a statement only if there is a deviation from the CP Standard Operating Procedure (SOP).
- In section 3.3.2 Additional Documentation for Non-Threshold Substances with a *Minimum Reporting Level* (*MRL*), there is further clarification that quantitation is not required for the target Analyte(s) of Non-Threshold Substances with an *MRL*, and that the *Sample* signal exceeding the 1.2 *MRL* is sufficient to confidently conclude that the *Sample* concentration is higher than the *MRL* and report an *Adverse Analytical Finding* (*AAF*).
- Clarification that establishing that the concentration of a Non-Threshold Substance with an *MRL* is higher than (>) the *MRL* is done during the "A" CP; however, only identification of the substance or its *Metabolite*(s) is necessary in the "B" *Sample*.
- If it is necessary to repeat a CP, then the LDP shall include a short explanation regarding the failed CP(s) (*e.g.,* date and/or analytical run number) including the reason(s) for why the CP was repeated.
- Re-ordered the Annexes for consistency.

Annex A - Laboratory Documentation Package for GC/C/IRMS Analysis

- Clarification that the GC-MS analysis mass spectrum shall be included for each relevant Target Compound (TC) and Endogenous Reference Compound (ERC) as per the TD IDCR.
- Removed the need to provide a Statement on Peak Purity.
- Clarification that the HPLC sequence injection is to be included in the documentation regarding the *Sample* preparation.
- Requirement to include a statement on the verification of retention time (RT) stability and completeness of fraction collection.

Annex B - Laboratory Documentation Package for Erythropoietin Receptor Agonists (ERA) Analysis by Electrophoretic Analytical Methods

- Regarding the Analysis for VAR-EPO on Blood *Samples*, the Laboratory shall include *WADA*'s written instructions on how to report the results for the *Sample* under investigation (based on the blood test results).
- Removed the need to provide the statement on quality control, instrument operation and other test validity data since this is clearly established with the data.
- Removed the option for Laboratories to provide Initial Testing Procedure data. The Laboratory is only required to provide the CP data in the LDP in order to be consistent with other Annexes.

Annex C - Laboratory Documentation Package for hGH Isoforms Differential Immunoassays and/or hGH Biomarkers Test Analysis

- Minor editorial updates.

Annex D - Hematological *ABP* Laboratory Documentation Package

- Clarifies that the *Sample*(s) selected for the compilation of an *ABP* LDP or CoA shall be conducted as described in Annex C of the ISRM and the TDAPMU.
- Requirement for a copy of the blood ABP Sample's temperature data logger report in hematological ABP Laboratory Documentation Packages.
- Removed the requirement to provide the time of submission of the results into ADAMS (the date of submission is sufficient).

Annex E - Steroidal ABP Laboratory Documentation Package

- Clarifies that the requirements are also relevant to blood (serum) *Samples* in support of the Steroidal Module of the Athlete Biological Passport (ABP) (*e.g.*, the Markers of the urinary or blood steroid profile).
- Clarifies that the Sample(s) selected for the compilation of an ABP Documentation Package or CoA shall be conducted as described in Annex C of the ISRM and the TDAPMU.
- Clarifies that the steroidal *ABP* LDP shall only include the CP analytical data whenever a CP for the *Markers* of the steroid profile has been performed on the *Sample*.
- Chain of Custody instructions removed with reference to chain of custody instructions in the Main Document.
- Includes a statement on whether the efficiency of hydrolysis and derivatization passed the Laboratory acceptance criteria for the *Sample*.
- Includes Laboratory acceptance criteria for the concentrations of each QC sample, and a statement on whether the QC test results passed those acceptance criteria.

Annex F - Endocrine *ABP* Laboratory Documentation Package

- New Annex included to clarify the requirements for an Endocrine *ABP* LDP and Endocrine *ABP* CoA.

The TD2023LDOC replaces the former TD2022LDOC and becomes effective on 1 September 2023.