Laboratory Guidelines 2021

Summary of Major Modifications

Several WADA Laboratory Guidelines (LGs) have been revised to align with the 2021 World Anti-Doping Code (Code); the recently approved 2021 International Standard for Laboratories (ISL); and, the other International Standards that are set to come into force on 1 January 2021.

All LGs have undergone formatting as well as updating of terms and definitions, where relevant.

In addition:

1. **Conducting and Reporting Subcontracted Analysis and Further Analysis for Doping Control**

   In this new version 3.0, the relevant articles have been updated to the ISL 2021. In addition, Laboratories and Testing Authorities (TA) as Sample custodians for Sample storage, including for long-term storage, have been introduced.

   This Laboratory Guideline becomes effective on 29 January 2021.

2. **TUE Enquiries**

   In this new version 4.0, the relevant articles have been updated to the ISL 2021. The Laboratory Guidelines and its Appendix A: TUE Enquiry Form have been updated to also include human Chorionic Gonadotrophin (hCG), human Growth Hormone (hGH; Biomarkers Test), amphetamine and methylphenidate as Presumptive Adverse Analytical Findings (PAAFs) for which Laboratories may contact the TA (or Results Management Authority, if different) to enquire about the existence of a TUE and instructions on whether the Laboratory shall proceed or not with the confirmation based on an approved TUE.

   This Laboratory Guideline becomes effective on 29 January 2021.

3. **Human Growth Hormone (hGH) Biomarkers Test**

   In this new version 3.0, the relevant articles have been updated to the ISL 2021 and the related Technical Document TD2021GH. The main changes include:

   - Assay Requirements: This article has been subdivided into Method Validation and Method Accreditation Requirements;
   - Assay Pre-Analytical Procedure: It has been clarified that “A” Sample serum fractions obtained from Samples received as whole blood (in SST™-II tubes or SST™-II Plus Advance tubes or SST™ tubes) and not used for the Initial Testing Procedure may be stored frozen in the Sample collection tube according to the tube manufacturer’s instructions until analysis.
• Interpretation and Reporting of Test Results: Following recent studies, a small modification has been introduced in the **GH-2000 function for males** to have a better correction of the GH-2000 scores for age. This does not imply any change in the decision limits.

In addition, the requirement to report the expanded Measurement Uncertainty ($U_{95\%}$) for the analytical value of the GH-2000 score has been eliminated, in line with the changes established for the reporting of other Threshold Substances in the TD DL. The reporting of the GH-2000 score at levels higher than the **Decision Limit (DL)**, and of a compliant combined standard Measurement Uncertainty ($u_c$) at values close to the **DL**, as determined by the Laboratory during Test Method validation, are sufficient for reporting an **Adverse Analytical Finding (AAF)**.

• Footnotes have been inserted as Comments where relevant in the main text.

These **Laboratory Guidelines** becomes effective on 29 January 2021.