WORLD ANTI-DOPING AGENCY
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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), amfetamine 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.