

TD2021GH

Summary of Major Modifications

The *Technical Document* on Human Growth Hormone (hGH) Isoform Differential Immunoassays for *Doping Control Analyses*, TD2021GH, 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 TD2021GH include:

Article 2.0 Assay Requirements

- The section on assay technical requirements has been split into two articles: **2.1 Test Method Validation Requirements** and **2.2 Test Method Accreditation Requirements**.

Article 2.3 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.

Article 3.2 Reporting of Test Results

- The requirement to report the expanded Measurement Uncertainty ($U_{95\%}$) for the analytical value of the recGH/pitGH ratio has been eliminated, in line with the changes established for the reporting of other Threshold Substances in the TD DL. The reporting of the recGH / pitGH ratio at levels higher than the *Decision Limit* (*DL*), and of a compliant relative 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*).

Article 4.0 Measurement Uncertainty

- It has been clarified that, in equations 1 and 2, the u_c shall be the relative u_c , expressed in %.

In addition:

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

The TD2021GH replaces the former TD2019GH and becomes effective on 1 April 2021.