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TD2021IRMS

Summary of Major Modifications

The *Technical Document* on Detection of Synthetic Forms of *Prohibited Substances* by GC/C/IRMS, TD2021IRMS, 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 TD2021IRMS include:

- The adjustment of the title to better reflect the revised scope of this *TD*, which has been expanded towards the analysis of other prohibited substances in addition to endogenous anabolic androgenic steroids (EAAS).

Articles 1.1.2 GC/C/IRMS Analysis as a CP for the administration of Synthetic Forms of Other *Prohibited Substances* and **2.0 GC/C/IRMS Analysis**

- Addition of new target compounds (TC): 6α-hydroxy-androstenedione (6α-OH-AD), epiandrosterone sulfate (EpiA-S), prednisone (PS) and prednisolone (PSL), including the conditions that would trigger GC/C/IRMS analysis for these TCs.

Article 2.0 GC/C/IRMS Analysis

- The addition of a new endogenous reference compound (ERC): pregnanetriol (PT);
- The calculation of absolute $\Delta\delta^{13}C$ values.

Article 2.1.1 GC/C/IRMS Test Method Validation Requirements

- Definition of GC/C/IRMS validation requirements, including a better description of several validation parameters (e.g. linearity of the ion source and the instrument, Limit of Quantification in urine); revision of u_{c_Max} requirements for TCs and ERCs; as well as revised criteria for reference population data and validation of ERCs and TCs.

Article 2.1.2 GC/C/IRMS Analysis Requirements

- Definition of GC/C/IRMS analysis requirements, including a better description of system calibration; the possibility of using Fit-for-Purpose *Sample* preparation techniques other than HPLC; the monitoring of $\delta^{13}C$ determinations of Certified Reference Materials (CRM) / Reference Materials (RM) through the use of RM control charts; the negative and positive QC samples; and the use of ERCs and TCs during the GC/C/IRMS analysis. In this Article, it has been also clarified, as a comment, that GC/C/IRMS analyses for Epitestosterone may also be performed at concentrations lower than the established cut-offs, at the Laboratory's discretion, and that this does not invalidate an *AAF* or *ATF* resulting from the GC/C/IRMS analysis.

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Article 2.2 Identification of TC(s) and ERC(s) prior to reporting an *AAF* or *ATF*

- It has been clarified that the same *Sample* Aliquot(s) that were subjected to GC/C/IRMS analysis shall be analyzed by GC-MS under similar chromatographic conditions to ensure the identity of the peaks of the relevant TC(s) and ERC(s).

Article 2.3.2 Interpretation of GC/C/IRMS Positive Results

- The criteria to consider a GC/C/IRMS result as positive have been updated, including criteria for new ERC-TC combinations and the revision of decision rules in consideration of the new requirement to obtain positive results with two different ERCs for reporting an *AAF*. In addition, it has been clarified, as a comment, that the criterion for the ERC-A and ERC-Etio pairs shall not be applied alone if T, 5αAdiol and 5βAdiol are measurable in the *Sample*.

Article 2.4 Conclusion of GC/C/IRMS Findings

- Clear guidance is provided, including examples, on the interpretation of GC/C/IRMS results to conclude a Negative Finding, *AAF*, or *ATF*. This has been further explained schematically in an updated figure in Annex A.

Article 3.0 Reporting GC/C/IRMS Results

- Concise guidance is provided on the reporting of GC/C/IRMS findings.

Annex A Selection and Use of ERCs

- The figure has been updated to reflect the revised procedure, including the use of two ERCs to conclude an *AAF*, or a third ERC when PD is not measurable in the *Sample* or if its $\delta^{13}C$ value is not consistent with an endogenous origin.

Annex B Decision Rules for GC/C/IRMS Positive Test

- The table has been updated to reflect the revised decision rules.

In addition:

- Terms and definitions have been updated where relevant;
- Footnotes have been inserted as Comments where relevant in the main text.

The TD2021IRMS replaces the former TD2019IRMS and becomes effective on 1 May 2021.