WORLD ANTI-DOPING AGENCY
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TD2021NA

Summary of Major Modifications

The *Technical Document* on Harmonization of Analysis and Reporting of 19-Norsteroids Related to Nandrolone, TD2021NA, 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 TD2021CG/LH include:

Article 1.0 Introduction

- A better clarification is provided (as a comment) on the possible endogenous origins of urinary 19-NA.

Article 2.0 Initial *Testing* Procedure (ITP)

- It's been clarified that the internal standard may be labelled with isotopic labels other that deuterium.

Article 3.0 Confirmation Procedures (CP)

- It's been clarified that the CP may also target the analysis of another *Metabolite* of 19-norsteroids (19-NE), in addition to 19-NA

Article 3.1 Identification and Estimation of Concentration

- A clarification is provided (as a comment) that the CP of 19-NA does not require quantification, but only to confirm the estimated concentration.

Article 3.2.1 Conducting GC/C/IRMS Analysis

- Includes a better description of the conditions that shall trigger GC/C/IRMS analysis of 19-NA;
- Instructions on GC/C/IRMS analysis when there are indications of 5α-reductase inhibitor activity in the *Sample*;
- Guidance to discriminate between oral consumption of natural sources of 19-NA and injection of norsteroid preparations based on the pharmacokinetics of 19-NA excretion, as well as on detection of 19-norsteroid preparations with a pseudo-endogenous carbon isotopic signature (which lead to negative GC/C/IRMS results);

Article 3.2.2 GC/C/IRMS Test Method Validation Requirements

- Guidance is provided on method validation requirements when applied to 19-NA, including the validation the use of at least two (2) endogenous reference compounds (ERCs).

Article 3.2.3 GC/C/IRMS Analysis Requirements

- A better description of negative and positive quality control samples, as well as the requirement to inject a blank urine sample before the *Sample* under GC/C/IRMS confirmation to avoid any potential contamination;

Article 3.2.4 Interpretation of GC/C/IRMS Results

- Criteria for interpretation of GC/C/IRMS results for 19-NA have been updated in accordance with the TD2021IRMS, including the mandatory use of two endogenous reference compounds (ERC) for reporting an *Adverse Analytical Finding* (*AAF*).

Article 3.3.1 Test for Norethisterone and Pregnancy

- The order of additional tests on *Samples* from female *Athletes* has been clarified, with the test for the presence of the main *Metabolite* of norethisterone (oral contraceptive) being done before the test for pregnancy;
- It has been clarified that Laboratories shall target the detection of the 3α,5β isomer of tetrahydronorethisterone (THNE);
- It has been clarified that for the Laboratory to conclude that the 19-NA detected in the *Sample* resulted from the permitted use of norethisterone-containing oral contraceptives, THNE should be detected at peak signals which are compatible with the 19-NA level.

Article 3.3.2 Test for Demethylation

- It has been clarified that the potential formation of 19-NA by *in-situ* 19-demethylation of androsterone (A) shall be verified by GC/C/IRMS analysis.

Article 4.0 Reporting

- A better guidance is provided for results interpretation and reporting in a tabulated form.
- The flowchart in Annex A has been updated

Article 5.0 References

- The list of scientific publications and *WADA* laboratory standards references has been updated

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 TD2021NA replaces the former TD2019NA and becomes effective on 1 April 2021.