TD2014IRMS

Summary of Major Modifications

The Technical Document on Detection of Synthetic Forms of Endogenous Anabolic Androgenic Steroids by GC-C-IRMS, TD2014IRMS, replaces the existing Guidelines on GC-C-IRMS analyses and complements the Technical Document on Measuring and Reporting of Endogenous Anabolic Androgenic Steroids, TD2014EAAS v2.0. The TD2014IRMS incorporates guidance to the analytical requirements, interpretation and reporting of GC-C-IRMS results as a confirmation procedure for the exogenous administration of EAAS.

1.0 Introduction

- This section briefly describes the scope of the document.

1.1 *Application of GC-C-IRMS*

- It is specified that GC-C-IRMS analyses shall be conducted as a Confirmation Procedure when the laboratory receives an "Atypical Passport Finding (ATPF) Confirmation Procedure Request" or a "Suspicious Steroid Profile Confirmation Procedure Request" notification through ADAMS, in accordance with the provisions of the TD2014EAAS v2.0.
- In addition, flexibility is provided on the performance of GC-C-IRMS analyses on any sample upon request by the Testing Authority, the Athlete Passport Management Unit (APMU) or WADA, as well as on the capacity of the laboratory to advice on the performance of the test.

1.1.1 GC-C-IRMS analysis for formestane, boldenone or boldenone metabolite(s)

- Instructions are provided on the conditions that would trigger the GC-C-IRMS confirmation analyses for formestane, boldenone or boldenone metabolite(s) findings, as well as on those conditions that can be evaluated and reported without the need for GC-C-IRMS confirmation.

1.1.2 B Sample Confirmation Procedure

- It is specified that GC-C-IRMS-based Adverse Analytical Findings for the markers of the "steroid profile" or for formestane, boldenone or boldenone metabolite(s) require the repetition of the GC-C-IRMS analysis during the B sample Confirmation Procedure.

2.0 GC-C-IRMS analysis

2.1 *GC-C-IRMS Method Characteristics*

- In this section, GC-C-IRMS method performance characteristics are specified with the objective of harmonizing assay performance across WADA-accredited laboratories. Specifications are given on system calibration, use of controls and reference materials, sample preparation procedures, definition of target compounds (TCs) and endogenous reference compounds (ERCs), maximum allowed uncertainty values, determination of laboratory's reference ranges, etc.

2.2 *Identification of urinary metabolites prior to reporting an Adverse Analytical Finding*

- Requirements are established for the identification of the TC(s) and ERC.

2.3 *Interpretation of GC-C-IRMS results*

- In this section, the criteria for interpreting the results of GC-C-IRMS analyses as positive, inconclusive or negative are specified.
- The criteria for concluding that an GC-C-IRMS result is positive, *i.e.* that the finding is consistent with an exogenous origin of the TC(s), involves 3 considerations which account for the laboratory's specific conditions as well as differences between target compounds:
    1. The laboratory reference ranges (*i.e.* the $\Delta\delta$ value of the diagnostic ERC-TC pair in the sample shall be greater than the laboratory's reference mean $\Delta\delta$ + 3SD value), and
    2. TC-specific criteria (*i.e.* reporting limits established for particular diagnostic ERC-TC pairs, as specified in points i – vii of the section and in the table on Appendix 1), and
    3. Use of combined criteria for more than one diagnostic ERC-TC pair (*e.g.* for determination of a positive finding, a $\Delta\delta$ value for the ERC-T greater than 3 $^{o}/_{oo}$ is not sufficient; the $\Delta\delta$ value for at least one of the ERC-Adiol pairs must also be greater than 3 $^{o}/_{oo}$).

3.0 Reporting GC-C-IRMS Results

- Instructions are provided for reporting of GC-C-IRMS results as Adverse Analytical Findings (for positive results), Atypical Findings (for inconclusive results) or No Prohibited Substance(s) or Metabolite(s) or Marker(s) of a Prohibited Method(s) on the test menu were detected (for negative results).
- It is recommended that laboratories seek a second opinion before reporting an Adverse Analytical Finding based on the results of GC-C-IRMS analysis.

4.0 Interpretation

- Clarifications are provided on the complementary information provided by GC-C-IRMS analyses and the determination of the steroid profile, and how it could be applied for the interpretation of results.

4.0 Appendix 1

- A table summarizes the interpretation criteria for concluding that a GC-C-IRMS result is positive.