WORLD ANTI-DOPING AGENCY

TD2018EAAS

Summary of Major Modifications

The Technical Document on Measuring and Reporting of Endogenous Anabolic Androgenic Steroids has undergone a revision by *WADA*'s Laboratory Expert Group (LabEG).

The new version of the document, TD2018EAAS, includes the following main modifications:

1.0 Introduction

It has been clarified that the Confirmation Procedure for the "steroid profile" may also be performed upon request from the Athlete Passport Management Unit (APMU), the Testing Authority or *WADA*.

1.1 The "Steroid Profile"

The administration of aromatase inhibitors and anti-estrogens was added to the list of substances (confounding factors) that may alter the urinary "steroid profile".

2.1 Method Characteristics

Footnote 3 was modified to clarify that the Limit of Quantification (LOQ) shall be determined during the method validation as the lowest concentration that can be measured with a u_c (%) of 30%.

Footnote 4 was added to emphasize that direct enzymatic hydrolysis of urine *Samples* may increase the effects of microbial contamination.

2.2 Reporting the "steroid profile" from the Initial Testing Procedure

- It was specified that the "steroid profile" for each *Sample* analyzed shall be reported in *ADAMS*.
- The requirement for the Laboratory to report the validity of the *Sample* was removed, since the validity of the *Sample* is automatically determined in *ADAMS* as per section 2.2.1.
- Footnotes 5 and 6 were created from statements previously included in the main text body of the document. These footnotes provide further clarifications regarding the reporting of the "steroid profile" following the performance of the Initial Testing Procedure
- Footnote 7 was included to clarify that the Specific Gravity reported in *ADAMS* shall be the one measured by the Laboratory using, for example, a refractometer.

- Prior footnote 5 and footnote 8, were merged into footnote 9, and were modified to clarify that if, the *Marker* of the "steroid profile" cannot be quantified, the concentration of the *Marker* shall be reported as "-1". If, otherwise, the chromatographic peak signal for a *Marker* cannot be detected (*i.e.* is below the detection capability of the assay), the concentration of the *Marker* shall be reported as "-2". Table 1 was modified accordingly.
- Footnote 10 was added to detail that the Laboratory may also provide information on other steroidal parameters such as dehydroepiandrosterone (DHEA) and 6α-hydroxy-androstenedione at the request of the Testing Authority, Results Management Authority or the APMU.
- A few paragraphs were added at the end of the section to detail the steps to follow when there are suspicions of sample manipulation or tampering.

2.2.1 Validity of (the "steroid profile" of) the *Sample*

The text was reorganized to further clarify how to report the concentrations of T and E, as well as the T/E ratio, depending on the concentration levels of T and E in the *Sample*.

Footnote 13 was added to specify that, following the reporting of the "steroid profile" in *ADAMS* by the Laboratory, the *Sample* may still be deemed as "invalid" by the APMU upon review of the "steroid profile" data in consideration, for example, of the presence in the *Sample* of substances that may alter the "steroid profile".

3.0 Confirmation Procedures

A paragraph was added to clarify that the Laboratory shall confirm the presence or absence of the confounding factors of the "steroid profile" in the *Sample*.

3.1 "*Atypical Passport Finding* Confirmation Procedure Request (*ATPF*-CPR)"

A sentence was added to explain how the *Sample*'s "steroid profile" is included automatically in the *Athlete*'s steroidal Passport in *ADAMS*.

The conditions for the application of the Confirmation Procedures for an "*ATPF*-CPR" were clarified.

A paragraph was added to detail when APMUs may advise in writing to the Laboratories not to confirm the "steroid profile" for an *ATPF* (*e.g.* in case of a Passport linked to a pattern of alcohol abuse or when there are other *AAF* reported for the *Sample*).

It was specified that the GC/C/IRMS Confirmation Procedure for an *ATPF* is not mandatory when the GC-MS or GC-MS/MS quantitative analysis does not confirm the abnormally high T/E ratio of the *Sample.*

3.3 Confirmation Procedure Requests from the APMU, the Testing Authority or *WADA*

A new section was added to clarify that the APMU, Testing Authority or *WADA* may request the performance of Confirmation Procedures for the 'steroid profile".

3.4 GC-MS or GC-MS/MS quantification Confirmation Procedure

It was clarified that all the *Markers* of the "Steroid Profile" for a *Sample* with an *ATPF* or a SSP finding shall be confirmed quantitatively before proceeding with the GC/C/IRMS analysis.

3.4.1 Method Characteristics for the GC-MS or GC-MS/MS quantification Confirmation Procedure

It was added that a Solid Phase Extraction (SPE) shall be performed prior to the enzymatic hydrolysis of the *Sample.*

3.5 GC/C/IRMS Confirmation Procedure

This new section was added to detail the cases when a GC/C/IRMS Confirmation Procedure may not be necessary.

3.6 Reporting Results from the Confirmation Procedures

It was specified that the SG shall be determined from a new Aliquot of the "A" or "B" *Sample*, as applicable.

4.0 References

Reference 5 was added, which describes some of the analytical criteria to determine that a *Sample* may not be consistent with human urine:

J D Cook, Caplan YH, LoDico CP and Bush DM. The Characterization of Human Urine for Specimen Validity Determination in Workplace Drug Testing: A Review. *J Anal Toxicol* **24**: 579-588, 2000