TD2027USM
Summary of Major Modifications

This document summarizes the modifications to the Technical Document (TD) on Analytical and Reporting Requirements for the Urinary Markers of the Steroidal Module of the Athlete Biological Passport (ABP). The TD2027USM replaces the current TD2021EAAS and has been revised to better reflect the analytical processes in the Laboratories when measuring the Markers of the Steroidal Module in urine Samples as well as to improve the harmonization of reporting in ADAMS.

The main modifications include (ordered by section of the TD):

1.0 Introduction

1.1 Procedure for Analysis of the Urinary Steroid Markers

Description of the “steroid profile” (Article 1.1 in TD2021EAAS) has been removed, and this term is not used anymore across the document.

The Initial Testing Procedure and Confirmation Procedure steps have been more detailed and reference to TD VAL has been added.

Table 1 listing the urine Markers has been updated to clarify that the T/E ratio will be reported by the Laboratories based on T and E concentrations. The A/T ratio has been removed from the list of Markers even though the graph will remain available in ADAMS as supportive information.

The list of factors impacting the urinary steroid Markers (Article 1.3 in TD2021EAAS) has been removed from the introduction and is now included in article 2.1.2 as “Factors impacting the urinary steroid Markers” (see below).

2.0 Analytical Testing Procedure Requirements

2.1.1 ITP Validation Requirements

Enzymatic hydrolysis and derivatization have been removed from the validation requirements.

2.1.2 ITP Analysis Requirements

Quantitative Procedure section includes information related to Sample, calibration and quality controls.

Description of the enzyme required for the hydrolysis has been updated.

Determination of the T/E ratio from the ratios of chromatographic peak areas or peak heights after correction against a calibrator or a calibration curve has been removed. T/E ratio will be reported by the Laboratories based on T and E concentrations.

The list of factors impacting the urinary steroid Markers has been amended to keep only three factors: microbial contamination, ethanol glucuronide (EtG) and 5α-reductase inhibitors.

2.1.3 Reporting Initial Testing Procedure Results for the Urinary Steroid Markers

d) MRPLs for Carboxy-finasteride, 4-hydroxy- and/or 6-hydroxy-dutasteride are indicated in the comment to Article 2.1.3 d)

Table 2 is an updated version of the previous table 3 (in TD2021EAAS) and conditions for reporting T and E concentrations have been modified. When T or E are below their respective LOQ/LOD, the Laboratories shall report "-1" instead of "-2".

2.2.2 Confirmation Procedure

a) Laboratories shall include the analysis of EtG in all CPs while 5α-reductase inhibitors shall be confirmed only upon specific request from the TA or WADA.

Figure 1 has been added to illustrate the steps for the GC-MS^n Confirmation Procedure and GC/C/IRMS analysis of the urinary steroid Markers.

CP Validation and analytical requirements that are different from ITP are now listed in Articles 2.2.2.1 and 2.2.2.2, respectively.

Section "Quantitative Procedure" of Article 2.2.2.2 provides more details about the total and free fractions of the steroids that shall be quantified in a CP.

2.2.3 Reporting Confirmation Procedure Results for the Urinary Steroid Markers

b) clarifies that Laboratories shall report the total concentrations of the urinary steroid Markers (i.e., the combination of the free steroid fraction released after hydrolysis of its glucuronide-conjugated phase-II Metabolite and the unconjugated free steroid) in ADAMS. The comment of this article clarifies how to report urinary steroid Markers when they are lower than the limit of quantification or when the identification criteria are not met.

d) indicates that Laboratories shall report the concentrations of 5αAND, 5βAND, and T in the free fraction (Tfree) and then the ratios 5αAND/A, 5βAND/Etio and T_{free}/T_{total} are automatically calculated in ADAMS.

3.0 References

References to WADA International Standards and Technical Documents have been updated while references to peer-reviewed articles have been removed.