WORLD ANTI-DOPING AGENCY
play true

Athlete Biological Passport

Operating Guidelines

& Compilation of Required Elements

Version 5.0

October 2014

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Part One: Introduction, Objective and Scope

1.0 Introduction to the *Athlete Biological Passport*

The term "athlete biological passport" was first proposed in the early 2000s by the scientific community when monitoring of select haematological variables (*Markers* of blood doping) was identified as a means to define an individual's haematological profile.

In conjunction with several stakeholders and medical experts, the World Anti-Doping Agency *(WADA)* began to further develop, harmonize and validate this concept. The result was a formal operating guideline and mandatory standards known as the *Athlete Biological Passport* (*ABP*), first published in 2009.

The *ABP* Program is administered through *WADA's Anti-Doping Administration and Management System (ADAMS),* a secure online database management tool for data entry, storage, sharing, and reporting, designed to assist stakeholders and *WADA* in their anti-doping operations.

The *ABP* intends to establish that an *Athlete* is manipulating his/her physiological variables, without necessarily relying on the detection of a particular *Prohibited Substance* or *Prohibited Method*.

This approach has proven effective in establishing anti-doping rule violations (ADRVs), without having to rely on traditional analytical approaches and *Target Testing* those likely to be doping. The *ABP* does not replace traditional *Testing* methods, but rather complements analytical methods to further refine and strengthen overall anti-doping strategies.

Although there has already been some longitudinal profiling of *Markers* of steroid doping, the *ABP* now introduces a standardized approach to determine steroid abuse through urine sampling. Consequently, *ADAMS* now provides a harmonized process for both the Haematological Module and the Steroidal Module of the *ABP*, following nearly identical administrative procedures.

1.1 Objective

The objective of integrating the *ABP* into the larger framework of a robust anti-doping program remains the following:

1. To identify *Athletes* for specific analytical *Target Testing* through intelligent, timely interpretation of *Passport* data.
    i) For the Haematological Module, this could be for Erythropoiesis- Stimulating Agents (ESAs) or homologous blood transfusion (HBT).

ii) For the Steroidal Module, this could be the use of Gas Chromatography-Combustion-Isotope Ratio Mass Spectrometry (GC-C-IRMS) to detect exogenous steroids.

2. In the absence of a positive analytical test (*Adverse Analytical Finding*, or *AAF*), a *Passport* may still be used to pursue an ADRV in accordance with World Anti-Doping Code (*Code*) Article 2.2.

The framework proposed in these Operating Guidelines builds on existing anti-doping infrastructure to promote harmonization in *ABP* Programs, facilitate exchange of information and mutual recognition of data and, consequently, to enhance efficiencies in the operation of Anti-Doping Activities.

As with all Guidelines under the *Code*, this document is subject to ongoing review and assessment to ensure it continues to reflect best practice moving forward. *WADA* encourages feedback on this document and recommends stakeholders consult *WADA's* Web site, http://www.wada-ama.org for the latest version.

1.2 Scope

The *ABP* is presented to equip *Anti-Doping Organizations* (*ADOs)* with a robust, viable framework in which to:

a. Use biological data for intelligent *Target Testing* and

b. Pursue ADRVs in accordance with *Code* Article 2.2 *(Use)*.

The processes and framework outlined in these Operating Guidelines are intended to support both the *ABP* Haematological and Steroidal Modules.

This document is divided into three parts.

Part One provides background and context for the creation of the *ABP*, introduces the Haemotological and Steroidal Modules of the *Passport* and explains the role of the *ABP* Operating Guidelines in supporting *ADOs*.

Part Two explains the principles behind the *ABP* and how an *ADO* should implement the *ABP* Program within the context of their ongoing activities. These Guidelines foster consistency and uniformity in application, without mandating specific administrative or procedural elements.

Part Three is a series of Appendices of Technical Documents (TDs) which are mandatory protocols to be followed by the *ADOs* choosing to apply the *ABP* Program. The sharing and mutual recognition of information between programs is only possible through this standardization of procedure.

These TDs set out the minimum requirements for *Sample* collection, *Sample* transport, *Sample* analysis, and results management.

Included as appendices for ease of reference, they should be considered International Standard for Testing and Investigations *(*ISTI*)* and International Standard for Laboratories (ISL) TDs. Some TDs are intended for a more specific audience, e.g. the TD2014EAAS for Laboratory personnel.

These mandatory protocols have been established to harmonize the results of monitored biological *Markers* within the *ABP* to ensure both legal fortitude and scientific certainty.

Each *ADO* remains free to adapt the recommended process suggested herein to reflect its own resources and context, but to operate an *ABP* Program as defined in this document, the attached protocols provided herein as Appendices must be rigorously observed. Only programs that fully adhere to these TDs herein and fully utilize *ADAMS* can be considered *ABP* Programs.

Part Three also includes a template agreement developed by *WADA* for the sharing of *Passport* information between multiple *ADOs* (supported by *ADAMS*), which is included herein as Appendix F.

1.3 Definitions

This document includes defined terms from the *Code*, and these *International Standards* (*IS*): ISTI, ISL and International Standard for the Protection of Privacy and Personal Information (ISPPPI). *Code* terms are written in italics. *IS* terms are underlined.

Definitions are provided in Guidelines Section 5.0.

Part Two: Modules, Management and Administration

2.0 *ABP* Haematological and Steroidal Modules

The Haematological Module collects information on *Markers* of blood doping. The Module aims to identify the *Use* of *Prohibited Substances* and/or *Prohibited Methods* for the enhancement of oxygen transport or delivery, including the *Use* of ESAs and any form of blood transfusion or manipulation.

In addition to identifying the use of ESAs included under Class 2 of the *Prohibited List* (Peptide Hormones, Growth Factors, Related Substances and Mimetics), the Haematological Module also seeks to identify the *Use of Prohibited Methods* categorized under Section M1 of the *Prohibited List* (Manipulation of Blood and Blood Components).

2.1 Haematological *Markers*

The following *Markers* are considered within the *ABP* Haematological Module:

HCT: Haematocrit

HGB: Haemoglobin

RBC: Red blood cell (erythrocyte) count

RET%: Reticulocytes percentage

RET#: Reticulocyte count

MCV: Mean corpuscular volume

MCH: Mean corpuscular haemoglobin

MCHC: Mean corpuscular haemoglobin concentration

RDW-SD: Red cell distribution width (standard deviation)

IRF: Immature reticulocyte fraction

Further calculated *Markers* specific to the Haematological Module include OFF-hr Score (OFFS), which is a combination of HGB and RET%[1], and Abnormal Blood Profile Score (ABPS), which is a combination of HCT, HGB, RBC, RET%, MCV, MCH, and MCHC[2].

2.2 Steroidal *Markers*

The Steroidal Module collects information on *Markers* of steroid doping. The Module aims to identify endogenous anabolic androgenic steroids (EAAS) when administered exogenously and other anabolic agents, such as selective androgen receptor modulators (SARMS) categorized under Section S1.2 of the *Prohibited List*.

The following *Markers* are considered within the *ABP* Steroidal Module (the "steroid profile"), as detailed in TD2014EAAS (Appendix D):

T/E: Testosterone/Epitestosterone ratio

T: Testosterone

E : Epitestosterone

[1] Gore C, Parisotto R, Ashenden M, Stray-Gundersen, J, Sharpe K, Hopkins W, Emslie K, Howe C, Trout G, Kazlauskas R, Hahn A. Second-generation blood tests to detect erythropoietin abuse by athletes. Haematologica 2003; 88: 333-43.

[2] Sottas PE, Robinson N, Giraud S, Taroni F, Kamber M, Mangin P, Saugy M. Statistical Classification of Abnormal Blood Profiles in Athletes. The International Journal of Biostatistics 2006; 2(1):3.

A: Androsterone

Etio: Etiocholanolone

5αAdiol: 5α-androstane-3α,17β-diol

5βAdiol: 5β-androstane-3α,17β-diol

Together with the specific gravity of the urine *Sample*, further urinary ratios of steroid *Metabolites* to be considered include A/T, A/Etio, 5αAdiol/5βAdiol and 5αAdiol/E.

2.3 *Testing* and Defining the Target Population

An *ABP Testing* Program must follow the ISTI and applicable TDs specific to the *ABP*.

Targeted tests that follow the recommendations of the *Athlete Passport* Management Unit (APMU) should be privileged over Random Selection *Testing* to improve the sensitivity of the *ABP*. In general, the sensitivity of the *ABP* to detect doping is improved where both *In-* and *Out-of Competition Testing* and No Advance Notice *Testing* are distributed throughout the year.

[2.3 Comment: For the Haematological Module, data points are most statistically independent when Samples have been collected at least 5 days apart. This does not preclude Testing an Athlete twice in less than 5 days when a specific doping scheme is suspected.]

The criteria listed below may be considered in determining the target population for the *ABP* in the context of an *ADO*'s overall Test Distribution Plan (TDP), keeping in mind that every urine *Sample* will be subjected to analysis for the steroidal variables:

- Nature of the sport: sports and/or disciplines within the jurisdiction of the *ADO* with an aerobic or endurance component (risk of blood doping) or with a power/strength component (risk of *Use* of androgenic anabolic steroids).
- Possible risk for doping practice warrants inclusion of *Athlete* in such a program.
- Age of *Athlete* and their prospects for long-term, elite-level participation.
- Whether any *Athlete(s)* under an *ADO's* jurisdiction are already subject to the *ABP* program of another *ADO*.
- Inclusion of the *Athlete* in the *ADO's Registered Testing Pool* (*RTP*) to support intelligent *Testing* and provide supporting information for Expert interpretation.
- *Athlete* is currently screened by other methods or programs.

2.4 *Athlete* Information

Given that additional information is required from *Athletes* beyond what is collected in traditional anti-doping documentation pursuant to the ISTI, supplemental or revised documentation may be required. Therefore, *ABP* documentation should ensure that the required information is collected by various means, both prior to and after *Testing*, for Laboratory information and *ADO* assessment as required.

In addition to the mandatory information set out in ISTI Article 7.4.5, which must be recorded as a part of all *Sample* Collection Sessions, the following minimum information should be included on the *Doping Control* form and/or on associated *Sample* collection paperwork, such as a Chain of Custody form or other required (Haematological Module) supplementary reports:

- Location of *Testing*.
- *Event* (if relevant).
- Blood loss or gain, due to pathology or transfusion (with estimated volume), in the 3 months preceding each *Sample* collection.
- Information on the *Use* of simulated hypoxic conditions in the prior 2 weeks. The type of device and the manner in which it was used (frequency, duration, simulated altitude) shall be recorded.
- Information on exposure to a high altitude (>1500 meters) in the prior 2 weeks, including estimated altitude and duration.
- Information on most recent training or physical activity, as applicable.
- Information on recent exposure to extreme heat conditions.
- Information whether the *Sample* was collected immediately following at least 3 consecutive days of an intensive endurance *Competition*, such as a stage race in cycling.

3.0 *ABP* Partner Roles and Responsibilities

3.1 Objective

To protect the rights of the *Athlete* and implement a credible and viable *ABP* Program, a reasonable distinction between the roles and responsibilities of the various partners should be established. These responsibilities include test planning, profile interpretation and results management.

3.2 Resources

The following resources are required to adopt and implement the *ABP*:

- Access to a network of *Doping Control* Officers (DCOs) and Blood Collection Officers (BCOs) where necessary, operating in locations where target *Athletes* will be present.
- An effective whereabouts management system to facilitate *Athlete* location (i.e. *ADAMS*).
- Access to *ADAMS*, which contains the Adaptive Model.
- A manager with relevant expertise and availability for "real-time" management of *ABP* processes, or an arrangement with an external APMU.
- An Expert Panel with interpretive and consultative skills, ideally accessed via an APMU.

[3.2 Comments: Convenient access is provided in this link to the ADAMS Athlete Biological Passport (ABP) Module Guide available on WADA's Web site. If an ADO chooses not to establish an APMU in advance of Testing, either because of resource limitations or because insufficient Testing is conducted to warrant such arrangements, the ADO must liaise with the analyzing Laboratory or WADA-Approved Laboratory for the ABP for guidance when a steroidal Atypical Finding (ATF) has been identified.]

3.3 Specific Partner Responsibilities

The purpose of the *ABP* Program is to use biological *Markers* of doping to establish the possible *Use* of a *Prohibited Substance* or *Prohibited Method* and to apply traditional *Testing* methods and/or *Target Testing* more intelligently. Distinguishing the various roles and responsibilities in the *ABP* process clarifies the precise functions of all partners, establishing accountability, consistency, and credibility.

3.3.1 *Anti-Doping Organization*

The *ADO* is responsible for:

- Adopting, implementing and administrating an *ABP* in accordance with these Guidelines, including compliance with the ISTI.
- Ensuring that recommendations received from the APMU are converted into effective, targeted, timely and appropriate follow-up *Testing*.
- Sharing of relevant information with other *ADOs* (when appropriate).
- Following up on *Adverse Passport Findings* (*APFs*) in accordance with TD2015RMR (Appendix E) and *Code* Article 7.5. This presumes that the *ADO* is the *Passport* Custodian.

3.3.2 *Athlete Passport* Management Unit

The APMU is responsible for:

- Providing recommendations that can be converted into effective, targeted, timely and appropriate follow-up *Testing* by the *ADO* (*Passport* Custodian).
- Real-time administrative management of the *Passports*, and liaising with Expert Panels as required.
- Compiling all necessary information to establish an *ABP* Documentation Package.
- Issuing all *APFs* to the *ADO* (*Passport* Custodian) and *WADA*.

3.3.3 Laboratory

The *WADA*-accredited Laboratory or *WADA*-Approved Laboratory for the *ABP* is responsible for:

- Complying with the TD2015BAR for the analysis of blood *Samples* (Appendix C) and participating succesfully in the *WADA* External Quality Assessment Scheme (EQAS) Program for the Haematological Module of the *ABP* to ensure that robust, standardized, and credible biological data is incorporated into an *Athlete's Passport*.
- Complying with the TD2014EAAS (Appendix D) for the measurement and reporting of EAAS in urine and participate succesfully in the appropriate *WADA* EQAS.
- Generating a Certificate of Analysis or Laboratory Documentation Package as applicable.

3.3.4 Expert Panel

The Expert Panel is responsible for:

- Reviewing *Passport* data and results from the Adaptive Model provided by the APMU to identify any possible pathological or confounding conditions that may have impacted an *Athlete*'s analytical results.
- Recommending any follow-up *Testing* or suggesting possible clinical *Testing* that may be required to a) confirm the assessment or b) collect further evidence to support or confirm possible pathologies.
- Reviewing any explanations given by the *Athlete* and providing an opinion on whether the *Atypical Passport Finding* (*ATPF*) was highly probable, given that a *Prohibited Substance* or *Prohibited Method* had been used.

- Working with the relevant APMU as required, and providing evidentiary support as necessary throughout the results management process.

3.3.5 World Anti-Doping Agency

WADA is responsible for:

- Providing access to the *ABP* Module(s) via *ADAMS* to the aforementioned partners to support a coordinated and secure exchange of information.
- Carrying out its monitoring, appeal rights and responsibilities as set forth in *Code* Article 20.7.
- Providing ongoing support to *ADOs* operating *ABP* Programs, as required.
- Continuing to enhance and develop the *ABP* for all stakeholders.

4.0 *ABP* Administration

4.1 Objective

Although the administrative organization of the *ABP* may be adapted to best suit the relevant *ADO*, these Operating Guidelines seek to foster harmonization in the interests of mutual recognition of *Athletes' Passports*, standardized practice and to ensure efficiency in overall program application.

The majority of administrative standardization is achieved by following all steps and Processing all data in *ADAMS*. This ensures that all mandatory requirements are met, and that the *Athlete Passports* are shared and stored securely, and in accordance with the ISPPPI. Furthermore, *ADAMS* will facilitate prompt exchange of information between *ADOs*, APMUs, *WADA*-accredited Laboratories and/or *WADA*-Approved Laboratories for the *ABP*, *Sample* Collection Personnel, and *WADA*.

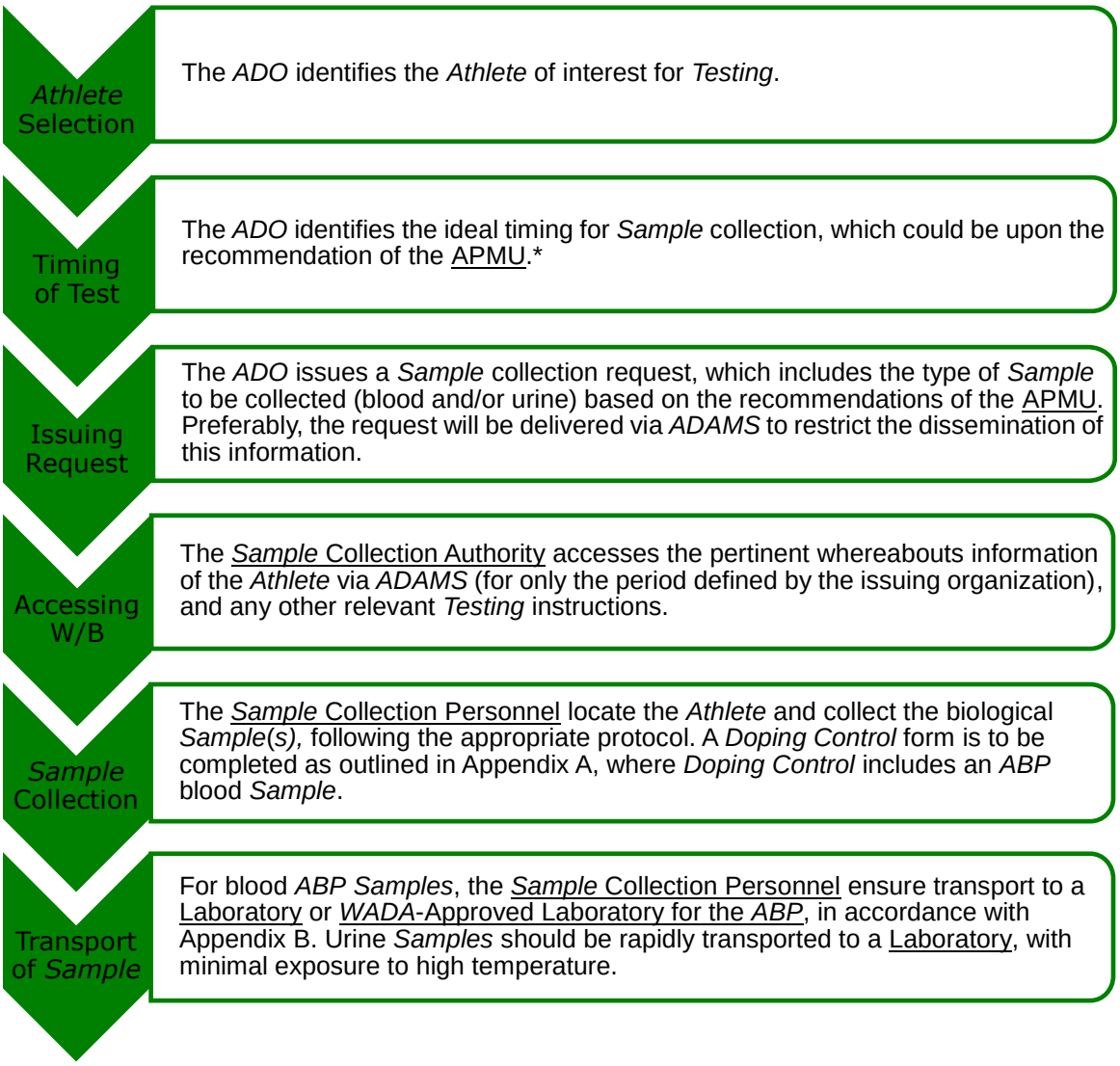
4.2 Recommended Administrative Sequence

The following outlines the suggested sequence of interactions between the *Athlete, Sample* Collection Personnel*, ADOs,* Laboratory(ies)*, ADAMS,* APMUs, and Expert Panels to establish an individual *Athlete*'s *Passport* in an effective and efficient manner*.*

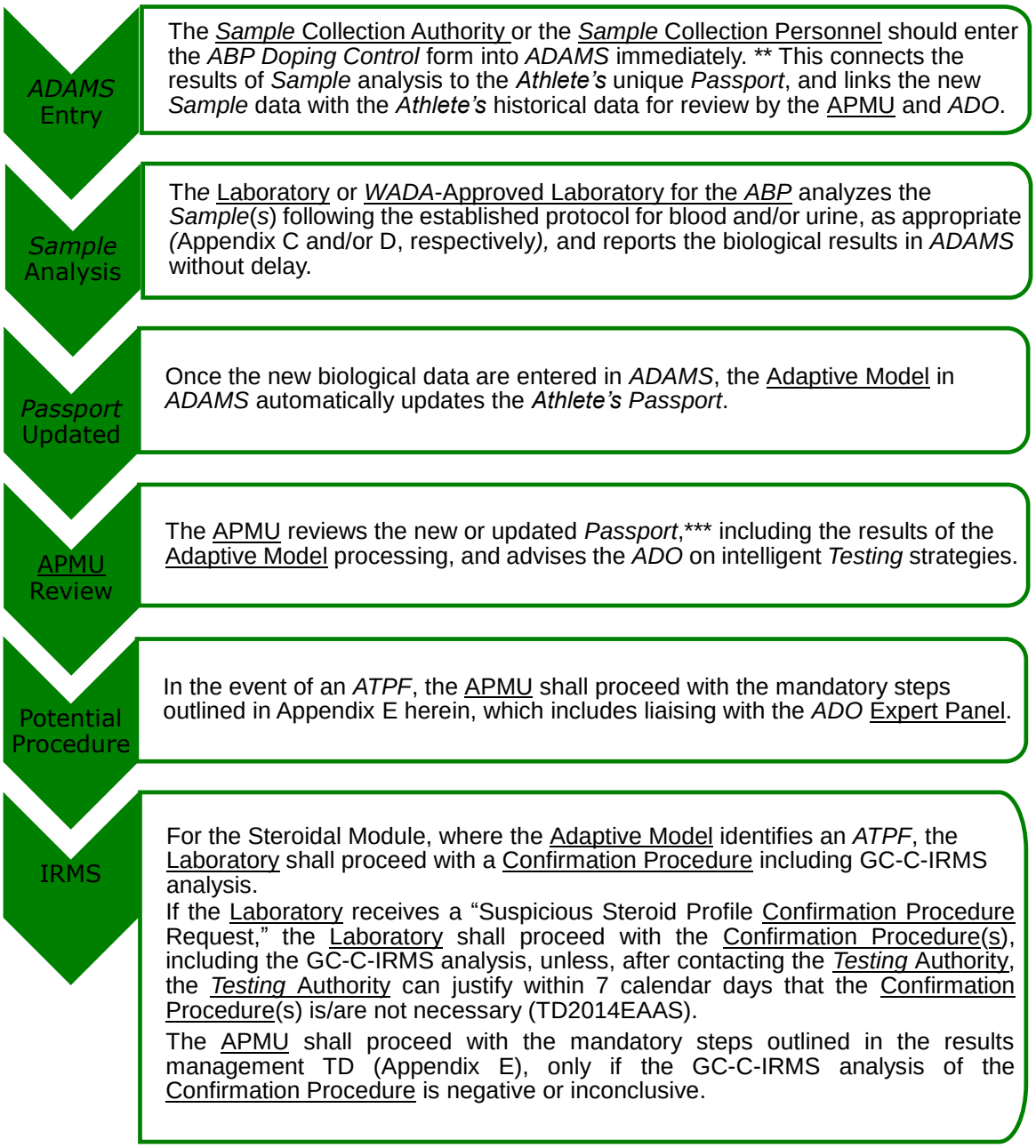
The recommended sequence outlined below may be modified or adapted to merge with existing anti-doping infrastructure, procedures and mechanisms as required. However these Guidelines suggest *ADOs* establish a process that ensures transparency and, ideally, independence between the planning, interpretation and results management aspects of an *ABP*.

To create a framework for such independence, the sequence set out herein includes the incorporation of an APMU that would be the central hub connecting Laboratory- or *WADA*-Approved Laboratories for the *ABP*-generated biological data with active test planning advice and intelligence. This APMU may be associated with a Laboratory's operations, or be managed under the responsibility of an *ADO.* The key element of an APMU is that it requires a *Person* or *Persons* to manage the *Passport*, including requesting further *Testing*, seeking Expert input and coordinating communication.

4.3 *ABP* Administrative Sequence Graphic



ABP Administrative Sequence Graphic, *cont.*



* When an *ABP* blood *Sample* is collected, the *ADO* must consider whether the collection of concominant urine or blood *Sample*s is warranted, under the circumstances, to perform traditional analysis. It is suggested that *Out-of-Competition ABP* blood tests include concomitant *Samples* and that, in all instances, an effective process be in place to carry out prompt, *Target Testing* when the APMU makes such a recommendation.

** *ADOs* should make all efforts to ensure that *Doping Control* forms are entered into *ADAMS* without delay. The use of paperless *Doping Control* procedures will expedite this process.

*** To provide Experts with a more balanced view of the longitudinal profiles of the *Athlete* population, the APMU should regularly provide a random set of profiles to the Experts, and not solely those deemed atypical by the Adaptive Model.

4.4 *Passport* Custodianship and Sharing

For any individual *Athlete,* only one *Passport* should be established. By adopting standardized protocols and procedures, and using *ADAMS* for the management of *Passport* information, *ADOs* can enhance efficiencies and program effectiveness through exchange of information and mutual recognition of program outcomes. Such coordination and reciprocal agreement reduces unnecessary duplication in resource expenditure and fosters enhanced confidence among *ADO*s and *Athletes* alike.

Within the framework provided by the ISPPPI*, ADOs* are encouraged to coordinate their activities where multiple *ADOs* have *Testing* jurisdiction over a single *Athlete* and multiple *ADO*s may wish to perform *Passport Testing*. In the interests of a "one *Athlete* – one *Passport*" principle, *ADOs* are encouraged to work cooperatively to see that *Testing* is coordinated appropriately with all results collated in a unique *Athlete*'s *Passport*. Any individual *Athlete* shall have a *Passport* Custodian that ensures that all *ADOs* that have *Testing* jurisdiction over the *Athlete* do not work in isolation.

The *Passport* Custodian is responsible for sharing *Passport* information with other *ADOs* to ensure proper coordination and best use of resource expenditure. *WADA* has developed a template agreement for the sharing of *Passport* information between multiple *ADOs* (supported by *ADAMS*), which is included herein as Appendix F.

In the case of an *ATPF*, the *Passport* Custodian is responsible for results management in compliance with Appendix E, regardless of whether another *ADO* was the *Testing* Authority of the test that triggered the *ATPF*.

In *ADAMS*, *Passport* custodianship is attributed to the *Testing* Authority that first tests the *Athlete*, independently of whether it is an *ABP* haematological or steroid test or both.* This process ensures that the custodianship will most likely automatically be assigned to the organization that has a real interest in the *Athlete*.** *Passport* custody can be transferred to another *ADO* with *Testing* jurisdiction over the *Athlete*.***

* Custodianships existing before August 2014 remain unaffected, to preserve existing sharing arrangements between *ADOs*.

** When the *Athlete* is first tested by a *Major Event Organizer* (*MEO*), *Passport* custody is attributed to the IF. When a *NADO* first tests an *Athlete* with a different sport nationality, *Passport* custody is attributed to the IF. This can later be reassigned to another *NADO* if appropriate.

*** If no agreement can be found on the *Passport* custodianship, *WADA* shall determine which *ADO* is the *Athlete's Passport* Custodian. *WADA* shall not rule on this without consulting the *ADOs* involved.

5.0 Definitions

5.1 2015 *Code* Defined Terms

***ADAMS*:** The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-Doping operations in conjunction with data protection legislation.

***Administration*:** Providing, supplying, supervising, facilitating, or otherwise participating in the *Use* or *Attempted Use* by another *Person* of a *Prohibited Substance* or *Prohibited Method*. However, this definition shall not include the actions of bona fide medical personnel involving a *Prohibited Substance* or *Prohibited Method* used for genuine and legal therapeutic purposes or other acceptable justification and shall not include actions involving *Prohibited Substances* which are not prohibited in *Out-of-Competition Testing* unless the circumstances as a whole demonstrate that such *Prohibited Substances* are not intended for genuine and legal therapeutic purposes or are intended to enhance sport performance.

***Adverse Analytical Finding* (*AAF*):** A report from a *WADA*-accredited laboratory or other *WADA*-approved laboratory that, consistent with the International Standard for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use* of a *Prohibited Method*.

***Adverse Passport Finding* (*APF*):** A report identified as an *Adverse Passport Finding* as described in the applicable *International Standards*.

***Anti-Doping Organization* (*ADO*):** A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations.*

***Athlete*:** Any *Person* who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization).* An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "Athlete." In relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or

national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment to Athlete: This definition makes it clear that all International- and National-Level Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond International- or National-Level Athletes to competitors at lower levels of Competition or to individuals who engage in fitness activities but do not compete at all. Thus, a National Anti-Doping Organization could, for example, elect to test recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2). The decision on whether Consequences apply to recreational-level Athletes who engage in fitness activities but never compete is left to the National Anti-Doping Organization. In the same manner, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not analyze Samples for the full menu of Prohibited Substances. Competitors at all levels of Competition should receive the benefit of anti-doping information and education.]

***Athlete Biological Passport* (*ABP*):** The program and methods of gathering and collating data as described in the International Standard for Testing and Investigations and International Standard for Laboratories.

***Atypical Finding* (*ATF*):** A report from a *WADA*-accredited laboratory or other *WADA*-approved laboratory which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding.*

***Atypical Passport Finding* (*ATPF*):** A report described as an *Atypical Passport Finding* as described in the applicable *International Standards*.

***CAS*:** The Court of Arbitration for Sport.

***Code*:** The World Anti-Doping Code.

***Competition*:** A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

***Consequences of Anti-Doping Rule Violations* (*Consequences*):** An *Athlete's* or other *Person's* violation of an anti-doping rule may result in one or more of the following: (a) *Disqualification* means the *Athlete's* results in a particular *Competition* or *Event* are invalidated, with all resulting *Consequences* including forfeiture of any medals, points and prizes; (b) *Ineligibility* means the *Athlete* or other *Person* is barred on account of an anti-doping rule violation for a specified period of time from participating in any *Competition* or other activity or funding as provided in Article 10.12.1; (c) *Provisional Suspension* means the *Athlete* or other *Person* is barred temporarily from participating in any *Competition* or activity prior to the final decision at a hearing conducted under Article 8; (d) *Financial Consequences* means a financial sanction imposed for an anti-doping rule violation or to recover costs associated with an anti-doping rule violation; and (e) *Public Disclosure* or *Public Reporting* means the dissemination or distribution of information to the general public or *Persons* beyond those *Persons* entitled to earlier notification in accordance with Article 14. Teams in *Team Sports* may also be subject to *Consequences* as provided in Article 11.

***Doping Control*:** All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, *TUEs*, results management and hearings.

***Event*:** A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

***In-Competition*:** Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "*In-Competition"* means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

[Comment to In-Competition: An International Federation or ruling body for an Event may establish an "In-Competition" period that is different than the Event Period.]

***International Event*:** An *Event* or *Competition* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization,* or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event.*

***International-Level Athlete*:** *Athletes* who compete in sport at the international level, as defined by each International Federation, consistent with the International Standard for Testing and Investigations.

[Comment to International-Level Athlete: Consistent with the International Standard for Testing and Investigations, the International Federation is free to determine the criteria it will use to classify Athletes as International-Level Athletes, e.g., by ranking, by participation in particular International Events, by type of license, etc. However, it

must publish those criteria in clear and concise form, so that Athletes are able to ascertain quickly and easily when they will become classified as International-Level Athletes. For example, if the criteria include participation in certain International Events, then the International Federation must publish a list of those International Events.]

***International Standard*:** A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard.*

***Major Event Organizations* (*MEOs*):** The continental associations of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.

***Marker*:** A compound, group of compounds or biological variable(s) that indicates the *Use* of a *Prohibited Substance* or *Prohibited Method.*

***Metabolite*:** Any substance produced by a biotransformation process.

***National Anti-Doping Organization* (*NADO*):** The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Sample*s, the management of test results, and the conduct of hearings at the national level. If this designation has not been made by the competent public authority(ies), the entity shall be the country's *National Olympic Committee* or its designee.

***National Event*:** A sport *Event* or *Competition* involving *International-* or *National-Level Athletes* that is not an *International Event*.

***National-Level Athlete*:** *Athletes* who compete in sport at the national level, as defined by each *National Anti-Doping Organization*, consistent with the International Standard for Testing and Investigations.

***National Olympic Committee* (*NOC*):** The organization recognized by the International Olympic Committee. The term *National Olympic Committee* shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical *National Olympic Committee* responsibilities in the anti-doping area.

***Out-of-Competition*:** Any period which is not *In-Competition*.

***Person*:** A natural *Person* or an organization or other entity.

***Prohibited List*:** The List identifying the *Prohibited Substances* and *Prohibited Methods*.

***Prohibited Method*:** Any method so described on the *Prohibited List*.

***Prohibited Substance*:** Any substance, or class of substances, so described on the *Prohibited List*.

***Registered Testing Pool* (*RTP*):** The pool of highest-priority *Athletes* established separately at the international level by International Federations and at the national level by *National Anti-Doping Organizations,* who are subject to focused *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or *National Anti-Doping Organization*'s test distribution plan and therefore are required to provide whereabouts information as provided in Article 5.6 and the International Standard for Testing and Investigations.

***Sample or Specimen*:** Any biological material collected for the purposes of *Doping Control*.

[Comment to Sample or Specimen: It has sometimes been claimed that the collection of blood Samples violates the tenets of certain religious or cultural groups. It has been determined that there is no basis for any such claim.]

***Tampering*:** Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures from occurring.

***Target Testing*:** Selection of specific *Athletes* for *Testing* based on criteria set forth in the International Standard for Testing and Investigations.

***Testing*:** The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

***Use*:** The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

***WADA*:** The World Anti-Doping Agency.

5.2 ISTI Defined Terms

Blood Collection Officer (BCO): An official who is qualified to and has been authorized by the *Sample* Collection Authority to collect a Blood *Sample* from an *Athlete*.

Chain of Custody: The sequence of individuals or organizations who have responsibility for the custody of a *Sample* from the provision of the *Sample* until the *Sample* has been delivered to the laboratory for analysis.

***Doping Control* Officer (DCO):** An official who has been trained and authorized by the *Sample* Collection Authority to carry out the responsibilities given to DCOs in the International Standard for Testing and Investigations.

***Doping Control* Station:** The location where the *Sample* Collection Session will be conducted.

No Advance Notice *Testing*: *Sample* collection that takes place with no advance warning to the *Athlete* and where the *Athlete* is continuously chaperoned from the moment of notification through *Sample* provision.

Random Selection: Selection of *Athletes* for *Testing* which is not *Target Testing*.

***Sample* Collection Authority:** The organisation that is responsible for the collection of *Samples* in compliance with the requirements of the International Standard for Testing and Investigations, whether (1) the *Testing* Authority itself; or (2) another organization (for example, a third party contractor) to whom the *Testing* Authority has delegated or sub-contracted such responsibility (provided that the *Testing* Authority always remains ultimately responsible under the *Code* for compliance with the requirements of the International Standard for Testing and Investigations relating to collection of *Samples*).

***Sample* Collection Equipment:** Containers or apparatus used to collect or hold the *Sample* at any time during the *Sample* Collection Session. *Sample* Collection Equipment shall, as a minimum, consist of:

- For urine *Sample* collection:
  - Collection vessels for collecting the *Sample* as it leaves the *Athlete's* body;
  - Suitable kit for storing partial *Samples* securely until the *Athlete* is able to provide more urine; and
  - Sealable and tamper-evident bottles and lids for storing and transporting the complete *Sample* securely.
- For blood *Sample* collection:
  - Needles for collecting the *Sample*;
  - Blood tubes with sealable and tamper-evident devices for storing and transporting the *Sample* securely.

***Sample* Collection Personnel:** A collective term for qualified officials authorized by the *Sample* Collection Authority to carry out or assist with duties during the *Sample* Collection Session.

***Sample* Collection Session:** All of the sequential activities that directly involve the *Athlete* from the point that initial contact is made until the *Athlete* leaves the *Doping Control* Station after having provided his/her *Sample(s)*.

Test Distribution Plan (TDP): A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has *Testing* Authority, in accordance with

the requirements of Article 4 of the International Standard for Testing and Investigations.

***Testing* Authority:** The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, *WADA*, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).

5.3 *ABP* Operating Guidelines and Related TDs Defined Terms

***Athlete Biological Passport* Documentation Package:** The material produced by the Laboratory and *Athlete Passport* Management Unit to support an *Adverse Passport Finding* such as, but not limited to, analytical data, Expert Panel comments, evidence of confounding factors as well as other relevant supporting information.

Expert Panel: The Experts, with knowledge in the concerned field, chosen by the *Anti-Doping Organization* and/or *Athlete Passport* Management Unit, who are responsible for providing an evaluation of the *Passport*. For the Haematological Module, Experts should have knowledge in one or more of the fields of clinical haematology (diagnosis of blood pathological conditions), sports medicine or exercise physiology. For the Steroidal Module, the Experts should have knowledge in Laboratory analysis, steroid doping and/or endocrinology.

The Panel may include a pool of appointed Experts and any additional ad hoc Expert(s) who may be required upon request of any of the appointed Experts or by the *Athlete Passport* Management Unit of the *Anti-Doping Organization.*

***Passport*:** A collation of all relevant data unique to an individual *Athlete* that may include longitudinal profiles of *Markers*, heterogeneous factors unique to that particular *Athlete* and other relevant information that may help in the evaluation of *Markers*.

***Passport* Custodian**: The *Anti-Doping Organization* responsible for result management of that *Athlete*'s *Passport* and for sharing any relevant information associated to that *Athlete*'s *Passport* with other *Anti-Doping Organization(s)*.

Results Management: Pre-hearing administration of potential anti-doping rule violations.

5.4 ISL Defined Terms

Adaptive Model: A mathematical model that was designed to identify unusual longitudinal results from *Athletes*. The model calculates the probability of a longitudinal profile of *Marker* values assuming that the *Athlete* has a normal physiological condition.

Aliquot: A portion of the *Sample* of biological fluid or tissue (e.g. urine, blood) obtained from the *Athlete* used in the analytical process.

***Athlete Passport* Management Unit (APMU):** A unit composed of a *Person* or *Persons*, designated by the *Anti-Doping Organization*, responsible for the administrative management of the *Passports* advising the *Anti-Doping Organization* for intelligent, *Targeted Testing* liaising with the Expert Panel compiling and authorizing an *Athlete Biological Passport* Documentation Package and reporting *Adverse Passport Findings*.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or to measure the concentration/ratio of one or more specific *Prohibited Substances*, *Metabolite*(*s*) of a *Prohibited Substance*, or *Marker*(*s*) of the *Use* of a *Prohibited Substance* or *Method* in a *Sample*.

[Comment: A Confirmation Procedure for a threshold substance shall also indicate a concentration/ratio of the Prohibited Substance greater than the applicable Decision Limit (as noted in the TD DL).]

Initial *Testing* Procedure: An analytical test procedure whose purpose is to identify those *Samples* which may contain a *Prohibited Substance*, *Metabolite*(*s*) of a *Prohibited Substance*, or *Marker*(*s*) of the *Use* of a *Prohibited Substance* or *Prohibited Method* or the quantity of a *Prohibited Substance*, *Metabolite*(*s*) of a *Prohibited Substance*, or *Marker*(*s*) of the *Use* of a *Prohibited Substance* or *Prohibited Method*.

International Standard for Laboratories (ISL): The International Standard applicable to Laboratories as set forth herein.

Laboratory(ies): *WADA*-accredited laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of *Prohibited Substances*, *Methods* or *Markers* on the *Prohibited List* and, if applicable, quantification of a Threshold Substance in *Samples* of urine and other biological matrices in the context of anti-doping activities.

Laboratory Documentation Packages: The material produced by the Laboratory to support an analytical result such as an *Adverse Analytical Finding* as set forth in the *WADA* Technical Document for Laboratory Documentation Packages.

***WADA*-Approved Laboratory for the *ABP*:** Laboratory(ies) not otherwise accredited by *WADA*; applying test methods and processes in support of an *Athlete*

Biological Passport program and in accordance with the criteria for approval of non-accredited laboratories for the *Athlete Biological Passport*.

5.5 ISPPPI Defined Terms

Anti-Doping Activities: Activities specified by the *Code* and the *International Standards* to be carried out by *Anti-Doping Organizations*, and their Third-Party Agents, for the purpose of establishing whether anti-doping rule violations took place, including collecting whereabouts information; conducting *Testing*; performing results management; determining whether an *Athlete's Use* of a *Prohibited Substance* or *Prohibited Method* is strictly limited to legitimate and documented therapeutic purposes; educating *Participants* on their rights and responsibilities; conducting investigations into anti-doping rule violations; and initiating legal proceedings against those who are alleged to have committed such a violation.

Personal Information: Information, including without limitation Sensitive Personal Information, relating to an identified or identifiable *Participant* or relating to other *Persons* whose information is Processed solely in the context of an *Anti-Doping Organization's* Anti-Doping Activities.

[3.2 Comment: It is understood that Personal Information includes, but is not limited to, information relating to an Athlete's name, date of birth, contact details and sporting affiliations, whereabouts, designated therapeutic use exemptions (if any), anti-doping test results, and results management (including disciplinary hearings, appeals and sanctions). Personal Information also includes personal details and contact information relating to other Persons, such as medical professionals and other Persons working with, treating or assisting an Athlete in the context of Anti-Doping Activities. Such information remains Personal Information and is regulated by this Standard for the entire duration of its Processing, irrespective of whether the relevant individual remains involved in organized sport.]

Processing (and its cognates, Process and Processed): Collecting, retaining, storing, disclosing, transferring, transmitting, amending, deleting or otherwise making use of Personal Information.

Security Breach: Any unauthorized and/or unlawful Processing of, including access to, Personal Information whether in electronic or hard-copy or other form, or interference with an information system, that compromises the privacy, security, confidentiality or integrity of Personal Information.

Third Party: Any natural *Person* or legal entity other than the natural *Person* to whom the relevant Personal Information relates, *Anti-Doping Organizations* and Third-Party Agents.

Part Three: Technical Documents Appendices

ISTI and ISL *Passport* Operation Requirements

Adoption of the following Technical Documents (TDs, level-two documents) is mandatory to comply with *ABP* requirements.

All TDs identified herein are found in the relevant *International Standards* documentation, but are included in these Appendices for ease of reference. The requirements of these Appendices are applicable to the *ABP* only, and are not applicable to blood collected for any other *Doping Control* purpose.

APPENDIX A: Blood *Sample* Collection Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2015BSCR

Document Number:	TD2015BSCR	Version Number:	1.0
Written by:	*WADA*	Approved by:	*WADA* Executive Committee
Date:	20 September 2014	Effective Date:	01 January 2015

1. Objective

These requirements are intended to assist in the collection of blood *Samples* for the measurement of individual *Athlete* haematological *Markers* within the framework of the *Athlete Biological Passport* (*ABP*).

2. Scope

The International Standard for Testing and Investigations (ISTI) is applicable to the collection of blood *Samples* carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the *ABP*. This Appendix describes additional requirements for blood storage and transport related to the *ABP*. *WADA's* Blood *Sample* Collection Guidelines should also be considered for best practices moving forward. In the case of any discrepancy between the requirements set out in this Appendix and those set out in the ISTI or Blood *Sample* Collection Guidelines, this Appendix shall prevail for *Sample* collection related to the *ABP*.

3. Timing of *Sample* Collection

If collection occurs after training or *Competition*, test planning shall consider the *Athlete*'s whereabouts information to ensure *Testing* does not occur within two hours of such activity. If the *Athlete* has trained or competed less than two hours before the time the *Athlete* has been notified of his/her selection, the DCO, BCO or other *Sample* Collection Personnel shall chaperone the *Athlete* until this two-hour period has elapsed. If for some reason, the *Sample* was taken within two hours of training or *Competition*, the nature, duration and intensity of the exertion shall be recorded by the DCO to make this information available to the APMU and subsequently, to Experts.

4. Commencement of the *Sample* Collection Session and 10-Minute Time-out

Following notification to the *Athlete* that he/she has been selected for *Doping Control*, and following the DCO/BCO's explanation of the *Athlete's* rights and responsibilities in the *Doping Control* process, the DCO/BCO shall ask the *Athlete* to remain in a normal seated position with feet on the floor for at least 10 minutes prior to providing a blood *Sample*.

[Comment: the Athlete shall not stand up at any time during the 10 minutes prior to Sample collection. To have the Athlete seated during 10 minutes in a waiting room and then to call the Athlete out in a blood test room is not acceptable.]

5. *Doping Control* Documentation

The DCO/BCO shall use the *Doping Control* form specific to the *ABP*, if such a form is available. If an *ABP*-specific *Doping Control* form is unavailable, the DCO/BCO shall use a regular *Doping Control* form but he/she shall collect and record the following additional information on a related form or supplementary report to be signed by the *Athlete* and the DCO/BCO:

- Confirm that there was no training or *Competition* in two hours prior to the blood test.
- Did the *Athlete* train, compete or reside at an altitude greater than 1,500 meters within the prior two weeks? If so, or if in doubt, the name and location of the place where the *Athlete* had been and the duration of his/her stay shall be recorded. The estimated altitude shall be entered, if known.
- Did the *Athlete* use any form of altitude simulation such as a hypoxic tent, mask, etc. during the prior two weeks? If so, as much information as possible on the type of device and the manner in which it was used (e.g. frequency, duration, intensity) should be recorded.
- Did the *Athlete* receive any blood transfusion(s) during the prior three months? Was there any blood loss due to accident, pathology or donation in the prior three months? What was the estimated volume?
- The DCO/BCO should record in the *Doping Control* form any extreme environmental conditions the *Athlete* was exposed to during the last two hours prior to blood collection, including any sessions in any artificial heat environment, such as a sauna.
- Was the *Sample* collected immediately following at least three consecutive days of an intensive endurance *Competition*, such as a stage race in cycling?

6. *Sample* Collection Equipment

The DCO/BCO instructs the *Athlete* to select the *Sample* Collection Equipment in accordance with ISTI Article E.4.6. Vaccutainer®(s) shall be labelled with a unique *Sample* code number by the DCO/BCO prior to the blood being drawn, if they are not pre-labelled, and the *Athlete* shall check that the code numbers match.

[Comment: WADA Blood Sample Collection Guidelines have been updated to reflect these requirements, and include practical information on the integration of ABP Testing into "traditional" Testing activities. In these Guidelines, a table has been included that identifies which particular equipment is appropriate when combining particular test types (i.e. ABP + hGH; ABP + HBT, etc.).

Although the ABP requires only a single tube of blood, the Blood Sample Collection Guidelines outline how the ABP may be coordinated with other blood analyses that may be performed at the same time.]

7. The *Sample* Collection Procedure

The *Sample* collection procedure for the collection of blood for the purposes of the *ABP* is consistent with the procedure set out in ISTI Articles E.4.1 through E.4.15, with the following additional elements:

- The BCO ensures that the 10-minute (or more) time-out period has elapsed prior to performing venipuncture and drawing blood; and
- The BCO ensures that the vacuum tubes were filled appropriately; and
- After the blood flow into the tube ceases, the BCO removes the tube from the holder and gently homogenizes the blood in the tube manually by inverting the tube gently at least three times.

8. Post-Venipuncture Procedure

- The *Athlete* and the DCO/BCO sign the blood collection form(s).
- The blood *Sample* is deposited and sealed in the *Sample* collection container in accordance with the ISTI.

APPENDIX B: Blood *Sample* Transport Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2015BSTR

Document Number:	TD2015BSTR	Version Number:	1.0
Written by:	*WADA*	Approved by:	*WADA* Executive Committee
Date:	20 September 2014	Effective Date:	01 January 2015

1. Objective

This Technical Document (TD) is intended to assist the storage and transport of blood *Samples* collected for the measurement of individual *Athlete* blood variables within the framework of the *Athlete Biological Passport* (*ABP)*.

2. Scope

This protocol covers the storage and transport of blood *Samples* both *In-Competition* and *Out-of-Competition*.

3. Responsibility

The International Standard for Testing and Investigations (ISTI) is applicable to the storage and transport of blood *Samples* carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the *ABP*. This protocol describes certain specificities of blood storage and transport related to the *ABP*.

4. Storage

Once a blood *Sample* has been collected in accordance with *ABP* blood *Sample* collection requirements, it shall be stored in accordance with ISTI Article 9.3 and the present protocol.

Storage procedure is the DCO's responsibility.

5. Type of Storage Devices

The DCO shall place the blood *Sample* in a storage device, which may be the following:

- Refrigerator.
- Insulated cool box.
- Isotherm bag.
- Any other device that possesses the capabilities mentioned below.

6. Capabilities of the Storage Device

The storage and transport device shall be capable of maintaining blood *Samples* at a cool temperature during storage. Whole blood *Samples* shall not be allowed to freeze. A temperature data logger shall be used to record the temperature during transport. In choosing the storage device, the DCO shall take into account the time of storage, the number of *Samples* to be stored in the device and the prevailing environmental conditions (hot or cold temperatures).

6.1 Security of the Storage Device

The storage device shall be located in the blood *Doping Control* Station and shall be kept secured appropriately in accordance with the ISTI.

7. Transport Procedure

Blood *Samples* shall be transported in accordance with ISTI Article 9, consistent with the practices of *WADA's* Blood *Sample* Collection Guidelines, and in conjunction with this protocol. Blood *Samples* shall be transported in a device that maintains the integrity of *Samples* over time, due to changes in external temperature.

The transport procedure is the DCO's responsibility.

7.1 Security of the Transport Device

The transport device shall be transported by secure means using an *ADO*-authorized transport method.

7.2 Remarks Concerning the Storage and Transport Procedure

Blood *Samples* shall be transported as rapidly as possible to a Laboratory or *WADA*-Approved Laboratory for the *ABP* located close to the *Sample* collection site, and be delivered no later than 36 hours following *Sample* collection.

[Comment: WADA's Blood Sample Collection Guidelines reflect these protocols and include practical information on the integration of ABP Testing into "traditional"

Testing activities. A table has been included that identifies which particular timelines for delivery are appropriate when combining particular test types (i.e. ABP + hGH, ABP + HBT, etc.), and which types of Samples may be suited for simultaneous transport.]

APPENDIX C: Blood Analytical Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2015BAR

Document Number:	TD2015BAR	Version Number:	1.0
Written by:	*WADA*	Approved by:	*WADA* Executive Committee
Date:	20 September 2014	Effective Date:	01 January 2015

1. Introduction

This Technical Document (TD) has been established to harmonize the analysis of blood *Sample*s collected, both *In-Competition* and *Out-of-Competition*, for the measurement of individual *Athlete* blood variables within the framework of the *Athlete Biological Passport* (*ABP*).

The International Standard for Laboratories (ISL) is applicable to the analysis of blood *Sample*s carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the *ABP*. This TD describes certain specificities of blood analysis related to the *ABP*.

Blood *Sample*s shall be analyzed in a Laboratory or *WADA*-Approved Laboratory for the *ABP*. If not reasonably possible for technical and/or geographical reasons, blood *Sample*s can be analyzed at a satellite facility of a Laboratory or using mobile units operated under applicable ISO accreditation by a Laboratory.

The blood *Sample* shall be analyzed within 48 hours of *Sample* collection. If the Laboratory or *WADA*-Approved Laboratory for the *ABP* has taken delivery of the *Sample* after 48 hours from the time of *Sample* collection, the Laboratory shall analyze the *Sample* as soon as possible. However, the APMU and *Testing* Authority shall be advised of such delay and departure from the requirement. The APMU will coordinate with the appropriate *ADOs*, Laboratory and haematological Experts to ensure the validity of any result in the time elapsed between the *Sample* collection and the analysis; the temperature of the *Sample* during that period; or any other deviation from collection or transportation requirements.

2. Timing

The Blood *Sample* should be analyzed as soon as possible upon reception, within 48 hours of *Sample* collection. In cases when the Laboratory or *WADA*-Approved Laboratory for the *ABP* is unable to analyze the *Sample* upon its immediate reception, the Laboratory or *WADA*-Approved Laboratory for the *ABP* is responsible for maintaining the *Sample* at a cool temperature (approximately 4°C) between its reception and the start of the analytical procedure.

If there is a deviation from the aforementioned procedure, the APMU will coordinate with the appropriate Laboratories and haematological Experts to assess the validity of any result in terms of the time elapsed between the collection and the analysis, and of the temperature of the *Sample* during that period.

To standardize analytical results in the *ABP* framework, it is important to have blood *Sample*s analyzed in an appropriate dedicated network of Laboratories (i.e. *WADA*-accredited or *WADA*-Approved Laboratories for the *ABP*), using analyzers with comparable technical characteristics. The instrumentation must be validated, to provide comparable results prior to analysis of *Doping Control Sample*s.

3. Instrument Check

Before performing any blood analyses, all reagents must be verified to ensure that they are within their expiration dates, and that they comply with the reagent manufacturer's recommendations. Operational parameters of the instrument must be properly controlled (background level, temperature of the incubation chambers, pressure, etc.), and fall within the manufacturer's specifications.

All internal quality controls shall be analyzed twice following the specifications provided by the manufacturer. These internal quality controls shall be furnished exclusively by the manufacturer of the instrument and handled in strict accordance with the specifications provided by the manufacturer (e.g. expiration dates, storage conditions). All results shall be in agreement with reference value ranges provided by the manufacturer.

On a regular basis (as determined by the head of the Laboratory or *WADA*-Approved Laboratory for the *ABP*), one fresh blood *Sample* shall be homogenized for a minimum period of 15 minutes on an appropriate mixer (e.g. roller mixer) and then analyzed seven consecutive times. Coefficients of variation shall be below 1.5% for Haemoglobin (HGB) and Haematocrit (HCT), and below 15% for percentage Reticulocyte (RET%) count to confirm the appropriate precision of the instrument.

At least one internal quality control from the manufacturer (either level 1, 2 or 3) shall be conducted after every 30 to 50 blood *Sample* analyses. Once a day, and after all blood *Sample* analyses are completed, one internal quality control (either level 1, 2 or

3) shall be analyzed once again to demonstrate continuous stability of the instrument and the quality of the analyses done.

4. External Quality Assessment Scheme

The Laboratories (or as otherwise approved by *WADA*) shall take part in and meet the requirements of *WADA's* External Quality Assessment Scheme (EQAS) for blood variables. The external quality controls shall be analyzed seven times consecutively, and then the mean results of the following blood variables (full blood count) shall be returned:

Red Blood Cell (Erythrocyte) Count	RBC
Mean Corpuscular Volume	MCV
Haematocrit	HCT
Haemoglobin	HGB
Mean Corpuscular Haemoglobin	MCH
Mean Corpuscular Haemoglobin Concentration	MCHC
White Blood Cell (Leukocyte) Count	WBC
Platelet (Thrombocyte) Count	PLT
Reticulocytes Percentage	RET%

Laboratories (or as otherwise approved by *WADA*) may also participate in ring tests between Laboratories (hospitals, clinics, etc.) using the same technology and the same procedure.

5. Analysis of Blood *Samples*

All blood *Sample*s shall be homogenized for a minimum period of 15 minutes using an appropriate mixer (e.g. roller mixer) prior to analysis. Each blood *Sample* shall be analyzed twice consecutively.

Absolute differences between the results of the two analyses shall be equal or less than the following for the relevant analyses to be accepted:

- 0.1g/dL for HGB analysis;
- 0.15 absolute difference for RET% analysis (if first measurement lower or equal to 1.00%); and
- 0.25 absolute difference for RET% analysis (if first measurement higher than 1.00%).

The data from the second injection is used to confirm the first injection data. Therefore, if the absolute differences between the results of the analyses are within the criteria above, then only the first injection data is reported. If absolute differences between the results of the two analyses are greater than those defined above for a specific *Sample*, the analysis shall be started again in accordance with this section 5. The reason for repetition shall be documented.

The requirements for an Initial *Testing* Procedure, an A *Sample* Confirmation Procedure and a B *Sample* Confirmation Procedure, as defined in the ISL, shall not be applicable to blood *Samples* analyzed for the purposes of the *ABP*.

6. Reporting

The results of the Laboratory or *WADA*-Approved Laboratory for the *ABP* analysis shall be reported promptly in *ADAMS*.

APPENDIX D: Endogenous Anabolic Androgenic Steroids Measurement and Reporting

WADA Technical Document – TD2016EAAS

Document Number:	TD2016EAAS	Version Number:	1.0
Written by:	*WADA* Laboratory Expert Group	Approved by:	*WADA* Executive Committee
Date:	16 September 2015	Effective Date:	1 January 2016

1.0 Introduction

The purpose of this Technical Document (TD) is to harmonize the approaches to the measurement and reporting of Endogenous Anabolic Androgenic Steroids (EAAS) in urine, including data in support of the steroidal module of the *Athlete* Biological Passport (ABP) or "steroid profile".

EAAS concentrations and their ratios form the urinary "steroid profile", which may be altered following the administration of synthetic forms of EAAS, in particular testosterone (T), its precursors [for example androstenediol, androstenedione and prasterone (dehydroepiandrosterone or DHEA)], or its active metabolite [dihydrotestosterone (DHT)], as well as epitestosterone (E).

The steroid module of the ABP uses the Adaptive Model to identify an *Atypical Passport Finding* (*ATPF*), which triggers the performance of Confirmation Procedures. It is also used to apply intelligent longitudinal target *Testing* of the *Athlete*. Furthermore, an abnormal "steroid profile" (obtained from a single urine *Sample*) or an atypical "longitudinal steroid profile" (including values obtained from a series of "steroid profiles" collected over a period of time), may be a means to pursue an anti-doping rule violation (ADRV).

EAAS *Testing* and reporting follows a two-step procedure. An Initial Testing Procedure is conducted to estimate the "steroid profile" of the *Athlete's Sample*. A subsequent Confirmation Procedure is performed when the estimated "steroid profile" constitutes an *ATPF*, as determined by the Adaptive Model, or represents a "suspicious steroid profile" (SSP) finding.

The Confirmation Procedure includes the quantification of the *Markers* of the "steroid profile" as described in this TD as well as Gas Chromatography – Combustion - Isotope Ratio Mass Spectrometry (GC-C-IRMS) analysis, which is considered in a separate TD (TDIRMS) [1].

1.1 The "Steroid Profile"

Each urine *Sample* shall be analyzed to determine its "steroid profile".

For the purposes of this TD, the "steroid profile" is composed of the following *Markers* (as free steroid content obtained from the free steroid fraction plus those released from the conjugated fraction after hydrolysis with β-glucuronidase from *E. coli*):

- androsterone (A);
- etiocholanolone (Etio);
- 5α-androstane-3α,17β-diol (5αAdiol);
- 5β-androstane-3α,17β-diol (5βAdiol);
- testosterone (T);
- epitestosterone (E).

and the following ratios:

- testosterone to epitestosterone (T/E) ;
- androsterone to testosterone (A/T);
- androsterone to etiocholanolone (A/Etio);
- 5α-androstane-3α,17β-diol to 5β-androstane-3α,17β-diol (5αAdiol/5βAdiol); and
- 5α-androstane-3α,17β-diol to epitestosterone (5αAdiol/E).

The administration of EAAS can alter one or more of the *Markers* and/or ratios of the urinary "steroid profile", resulting in increase or decrease of concentrations and/or ratios of specific pairs of steroid *Metabolites* [2-4].

Additionally, alteration of the urinary "steroid profile" can occur for a number of reasons including, but not limited to:

- the administration of other anabolic steroids (*e.g.* stanozolol);
- the administration of human chorionic gonadotrophin (hCG) in males;
- the administration of inhibitors of 5α-reductase (*e.g.* finasteride);
- a large intake of alcohol (ethanol);
- the administration of ketoconazole or other similar compounds;the use of masking agents (*e.g.* probenecid) and diuretics; or
- microbial growth.

2.0 Initial Testing Procedure

The Laboratory shall use a validated Initial Testing Procedure that is fit-for-purpose to estimate the *Markers* of the urinary "steroid profile" in the range of values determined in males and females.

The Initial Testing Procedure is conducted on a single Aliquot.

2.1 Method Characteristics

- Gas chromatography combined with mass spectrometry (GC-MS or GC-MS/MS) of TMS derivatives (keto and hydroxyl groups) is required.
- Calibration standard(s) or a calibration curve should be included in each sequence of analysis.
- At least two urine quality control (QC) samples containing low and high representative concentrations of the *Markers* of the "steroid profile" should be included in each sequence of analysis.
- The enzymatic hydrolysis shall be carried out with purified β-glucuronidase from *E. coli* (*H. pomatia* mixtures are not acceptable).
- The completeness of hydrolysis of the glucuroconjugated urinary steroids shall be controlled with isotopically labeled A-glucuronide (or an equivalent scientifically recognized alternative).
- The completeness of the derivatization shall be controlled through the monitoring of mono-O-TMS vs. di-O-TMS derivative of A.
- When needed, the volume [1] of the *Sample* Aliquot may be adjusted as a function of its specific gravity (SG) and of the sex of the *Athlete*.
- The T/E ratios shall be determined from the ratios of the corrected chromatographic peak areas or peak heights [2].

[1] Much smaller concentrations of T and E are generally present in *Samples* from females and in those *Samples* with low SG; therefore, larger Aliquot volumes may be required for a reliable measurement.

[2] Ratios of T and E peak heights or peak areas corrected against a calibrator or a calibration curve (same mass or same ion transition screened for both steroids).

- The linearity of the method, established during method validation, shall cover the ranges of *Marker* concentrations normally found in males and females - the limit of quantification (LOQ) for T and E shall not be greater than 2 ng/mL [3].
- The relative standard combined Measurement Uncertainty [u_c (%)] for the determination of A, Etio, 5αAdiol, 5βAdiol, T and E, as estimated during method validation of the Initial Testing Procedure, shall be not greater than 30% at the respective LOQ;
    - For concentrations at five times the LOQ, the u_c (%) shall be not greater than 20% for A and Etio or 25% for the Adiols;
    - The u_c (%) for determinations of T and E shall not exceed 20% when the steroid concentrations are greater than 5 ng/mL;
    - The u_c (%) for determinations of T/E ratios calculated from the corrected chromatographic peak areas or heights shall not exceed 15% when the concentrations of T and E are both greater than 5 ng/mL; for smaller concentrations of T or E, the u_c (%) for the T/E determinations shall not exceed 30%.
- Evidence of microbial degradation [*e.g.* presence of 5α- androstanedione (5αAND) and 5β-androstanedione (5βAND)] and the presence of 5α-reductase inhibitors (*e.g.* finasteride), ethanol *Metabolite(s)* and ketoconazole (and similar substances) shall be monitored.

[3] The LOQ shall be determined as the smallest concentration that can be measured with the uncertainty criterion established for the given *Marker* of the "steroid profile" when applying the Initial Testing Procedure.

The LOQ for T, E, A, Etio, 5αAdiol and 5βAdiol shall be recorded in *ADAMS* by the Laboratory. The LOQ values shall be updated in *ADAMS* whenever a significant change is made to the analytical method.

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

Following the performance of the Initial Testing Procedure, the Laboratory shall report the "steroid profile" of the *Sample* in *ADAMS*, including:

- the SG of the *Sample*;
- the concentrations of T, E (see Table 1), A, Etio, 5αAdiol and 5βAdiol (without adjustment for the SG of the *Sample*) [4, 5];
- the T/E ratio (see Table 1) [6];
- the results of screening for signs of microbial contamination (*e.g.* ratio of 5α-androstanedione to androsterone - 5αAND/A; ratio of 5β-androstanedione to etiocholanolone - 5βAND/Etio)[7];
- the presence or absence in the *Sample* of substance(s) that may alter the "steroid profile" [7]; and
- the validity of the "steroid profile" of the *Sample* as "Yes" or "No".

[4] When reporting the "steroid profile" in *ADAMS*, the Laboratory shall report the values of concentrations for T, E, A, Etio, 5αAdiol and 5βAdiol, and the T/E ratio (without adjustment for the urine SG or correction to a specific number of significant figures). An automatic correction of reported values to 2 significant figures will be made in *ADAMS* upon application of the Adaptive Model of the ABP to the "longitudinal steroid profile" of the *Athlete*.

[5] Any concentration measurement which is below the LOQ of the assay shall be reported as "-1" by the Laboratory. When the chromatographic peak signal for E cannot be detected (*i.e.* below the detection capability of the assay), the concentration of E shall be reported as "-2" (see Table 1).

[6] In *ADAMS*, the values of the other four ratios (A/T, A/Etio, 5αAdiol/5βAdiol and 5αAdiol/E) are automatically computed after the reporting of the "steroid profile" by the Laboratory.

[7] A *Sample* showing signs of microbial degradation or containing any of the substances that may cause an alteration of the "steroid profile" may not be suitable for inclusion in the "longitudinal steroid profile". These findings are to be considered by the *Athlete* Passport Management Unit (APMU) during the results management process when evaluating the analytical data for the *Sample* and assessing the possible pathological or confounding conditions that may have impacted an *Athlete's* analytical results.

In cases when the Laboratory analyzes two (2) or more *Samples*, which are linked to a single *Sample* collection session from the same *Athlete*, the Laboratory shall report the "steroid profile" for each of the *Samples* analyzed.

If, as determined during the Initial Testing Procedure, no *Prohibited Substance* or *Method* is detected in the *Sample*, the Laboratory shall report the "steroid profile" of the *Sample* in *ADAMS*, while reporting the test results as "No *Prohibited Substance(s)* or *Metabolite(s)* or *Marker(s)* of a *Prohibited Method(s)* on the test menu were detected".

If, on the other hand, the Laboratory confirms the presence of a *Prohibited Substance* or *Method*, the Laboratory shall still report the "steroid profile" of the *Sample* in *ADAMS* as determined during the Initial Testing Procedure, while reporting the *Sample* as an *Adverse Analytical Finding* (or *Atypical Finding*, as applicable) for the *Prohibited Substance* or *Method* detected.

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

The validity of the *Sample* shall be reported in ADAMS as "Yes" or "No".

The Laboratory shall report the validity of the *Sample* as:

a) **"No"**: **only when the *Sample* shows signs of extensive degradation**, as determined by:

- 5αAND/A ≥ 0.1 and/or 5βAND/Etio ≥ 0.1.

b) "**Yes"**: **in all other situations**, including:

- When the concentration of either T and/or E is below the Laboratory's LOQ, but its chromatographic peak signal is still measurable and the T/E ratio can be determined from the corrected chromatographic peak areas or peak heights [2]. The calculated value of the T/E ratio shall be reported in *ADAMS* whereas the concentration of T and/or E, as applicable, shall be reported as "-1" (Table 1) [5].
- When the T/E ratio cannot be determined from the ratios of the corrected chromatographic peak areas or peak heights [2] because the chromatographic peak signal for T and/or E is not detectable *(i.e.* it is below the Limit of Detection – LOD - of the assay) [8]:

[8] When the measurement of a *Marker* of the "steroid profile" is not possible due to, for example, dilution, unusual matrix interferences, inhibition of the enzymatic hydrolysis or incomplete derivatization, the Laboratory should repeat the analysis with an alternative, validated *Sample* preparation procedure (*e.g.* solid phase extraction, extraction with a different solvent or other equivalent procedure).

- If the chromatographic peak signal for T cannot be detected, the concentration of T and the T/E value shall be reported as "-1" (Table 1). A comment shall be included in the Test Report in *ADAMS* stating that the T/E ratio could not be measured because the concentration of T was below the detection capability of the assay;
- If the chromatographic peak signal for E cannot be detected, the concentration of E shall be reported as "-2" and the T/E ratio shall be calculated on the basis of the Laboratory's LOQ value for E (*e.g.* if T concentration is 6 ng/mL while E cannot be detected, and the Laboratory's LOQ for E is 1.5 ng/mL, the T/E shall be reported as 4.0) (Table 1). A comment shall be included in the Test Report in *ADAMS* stating that the T/E ratio could not be measured accurately because the concentration of E was below the detection capability of the assay;
- If the chromatographic peak signals for both T and E cannot be detected, the concentration of T and the T/E value shall be reported as "-1", whereas the concentration of E shall be reported as "-2" (Table 1). A comment shall be included in the Test Report in *ADAMS* stating that the T/E ratio could not be measured because the concentrations of T and E were below the detection capability of the assay.

- When other *Marker*(s) of the "steroid profile" cannot be measured accurately (*i.e.* concentrations below the LOQ of the assay) [8]. In such cases, the concentration of the negatively impacted *Marker*(s) shall be reported as "-1" [5] while the validity of the *Sample* shall be reported as "Yes".
- Less extensive microbial contamination shall be reported in *ADAMS*, while the validity of the *Sample* shall be reported as "Yes" [7]:
  - 5αAND/A ratio and/or between 0.05 and 0.1,
  - 5βAND/Etio ratio between 0.05 and 0.1.
- When the Laboratory reports an *Adverse Analytical Finding* or an *Atypical Finding* for a *Prohibited Substance* that may alter the "steroid profile" (*e.g.* an anabolic steroid, hCG in males, a diuretic or masking agent)[7].
- When the Laboratory detects the presence in the *Sample* of other substances that may cause an alteration of the "steroid profile" [7, 9] .

[9] It is mandatory that the Laboratory tests at least for the presence of conjugated *Metabolite(s)* of ethanol [*e.g.* ethanol glucuronide (EtG)], inhibitors of 5α-reductase and ketoconazole during the Initial Testing Procedure and report the estimated concentration of EtG if above 5 µg/mL (without the need to report the Measurement Uncertainty). Furthermore, the analysis of these substances shall also be included in the Confirmation Procedure of atypical or suspicious "steroid profile" findings.

Table 1. Summary of conditions for reporting T and E concentrations and T/E ratio.

Concentration of T	Concentration of E	T/E ratio
Chromatographic peak signal of T measured at or above the LOQ. $[T] \geq LOQ_{(T)}$ **Report T as measured**	Chromatographic peak signal of E measured at or above LOQ. $[E] \geq LOQ_{(E)}$ **Report E as measured**.	**Report T/E as determined** from corrected peak heights/areas
	Chromatographic peak signal of E detected, but below LOQ. $LOD_{(E)} \leq [E] < LOQ_{(E)}$ **Report E as "-1"**	
	Chromatographic peak signal of E not detected. $[E] < LOD_{(E)}$ **Report E as "-2"**	**Report T/E as T/$LOQ_{(E)}$** *Comment in Test Report*: T/E ratio could not be measured accurately because the concentration of E was below the detection capability of the assay
Chromatographic peak signal of T detected, but below the LOQ. $LOD_{(T)} \leq [T] < LOQ_{(T)}$ **Report T as "-1"**	Chromatographic peak signal of E measured at or above LOQ. $[E] \geq LOQ_{(E)}$ **Report E as measured**	**Report T/E as measured** from corrected peak heights/areas
	Chromatographic peak signal of E detected, but below LOQ. $LOD_{(E)} \leq [E] < LOQ_{(E)}$ **Report E as "-1"**	
	Chromatographic peak signal of E not detected. $[E] < LOD_{(E)}$ **Report E as "-2"**	**Report T/E as "-1"** *Comment in Test Report*: T/E ratio could not be measured accurately because the concentrations of T and E could not be measured
Chromatographic peak signal of T not detected. $[T] < LOD_{(T)}$ **Report T as "-1"**	Chromatographic peak signal of E measured at or above LOQ. $[E] \geq LOQ_{(E)}$ **Report E as measured**	**Report T/E as "-1"** *Comment in Test Report*: T/E ratio could not be measured accurately because the concentration of T was below the detection capability of the assay
	Chromatographic peak signal of E detected but below LOQ. $LOD_{(E)} \leq [E] < LOQ_{(E)}$ **Report E as "-1"**	**Report T/E as "-1"** *Comment in Test Report*: T/E ratio could not be measured accurately because the concentrations of T and E could not be measured
	Chromatographic peak signal of E not detected. $[E] < LOD_{(E)}$ **Report E as "-2"**	**Report T/E as "-1"** *Comment in Test Report*: T/E ratio could not be measured accurately because the concentrations of T and E were below the detection capability of the assay

3.0 Confirmation Procedures

Confirmation Procedures for the exogenous administration of EAAS include the GC-MS or GC-MS/MS quantification and GC-C-IRMS analysis of the relevant *Marker(s)* of the "steroid profile". GC-C-IRMS analysis is considered in a separate Technical Document, the TDIRMS [1].

"*ATPF* Confirmation Procedure Request"

Following the reporting by the Laboratory of the *Sample's* "steroid profile" in *ADAMS*, the Adaptive Model will generate an "*ATPF* Confirmation Procedure Request" notification when the following criteria are met:

1) The *Sample* is matched with a Doping Control Form (DCF) in *ADAMS*, allowing the automatic inclusion of the *Sample's* "steroid profile" in the *Athlete's* steroidal passport,
2) There is an existing "longitudinal steroid profile" of the *Athlete* in *ADAMS*,
3) The *Sample's* T/E ratio is abnormal, as determined by the Adaptive Model, when compared with the previous longitudinal T/E values of the *Athlete*.
   - Upon reception of the "*ATPF* Confirmation Procedure Request" notification for an abnormal T/E ratio through *ADAMS*, the Laboratory shall confirm T, E [10] and the T/E ratio by GC-MS or GC-MS/MS and analyze the *Markers* of the "steroid profile" by GC-C-IRMS (refer to the TD IRMS [1]).
   - The Adaptive Model will also determine abnormal values of the other ratios of the "steroid profile" (A/T, A/Etio, 5αAdiol/5βAdiol, 5αAdiol/E). However, in such cases the Laboratory will not receive an automatic "*ATPF* Confirmation Procedure Request" notification through *ADAMS*. Instead, the *Athlete* Passport Management Unit (APMU) will advise the *Testing* Authority on whether the *Sample* shall be subjected to Confirmation Procedures. Therefore, in these cases the Laboratory shall receive a request from the *Testing* Authority before proceeding with the Confirmation Procedure(s) [11].

[10] For T/E values, only T needs to be confirmed if the concentration levels of E or the volume of the *Sample* are not sufficient.

[11] Or as covered by agreement between the Laboratory and the *Testing* Authority.

"Suspicious Steroid Profile Confirmation Procedure Request"

The Laboratory will receive a "Suspicious Steroid Profile Confirmation Procedure Request" notification through *ADAMS* if:

1) The *Sample* is matched with a DCF in *ADAMS*, but there is no existing "longitudinal steroid profile" of the *Athlete* in *ADAMS* (*i.e.* this is the first *Sample* in the *Athlete's* steroidal passport), or

   The *Sample* cannot be matched with a DCF in *ADAMS* within fourteen (14) calendar days after the reception date of the *Sample* by the Laboratory, and therefore the "steroid profile" of the *Sample* cannot be processed by the Adaptive Model in *ADAMS*,

   and

2) The *Sample's* "steroid profile" meets **any** of the following criteria:
   - T/E ratio (calculated from the corrected chromatographic peak areas or heights) greater than 4.0;
   - A/T ratio less than 20;
   - 5αAdiol/5βAdiol ratio greater than 2.4;
   - concentration of T or E (adjusted for the SG [12]) greater than 200 ng/mL in males or greater than 50 ng/mL in females;
   - concentration of A or Etio (adjusted for the SG[12]) greater than 10,000 ng/mL;
   - concentration of 5αAdiol (adjusted for the SG[12]) greater than 250 ng/mL in males or greater than 150 ng/mL in females, combined with a 5αAdiol/E ratio greater than 10 in either sex.

- Upon receipt of the "Suspicious Steroid Profile Confirmation Procedure Request" notification, the Laboratory shall proceed with the Confirmation Procedure(s) unless, after contacting the *Testing* Authority, the *Testing* Authority can justify in writing within seven (7) calendar days that the Confirmation Procedure(s) is not necessary. Justification for not proceeding with the Confirmation Procedure may include, for example, a naturally elevated T/E ratio confirmed by previous *Testing*, or a T/E ratio between 4.0 and 6.0 for the first test on the *Athlete*.

[12] The concentrations are adjusted to a urine SG of 1.020 based on the following equation (free and hydrolyzed glucuroconjugated steroids).

$$\mathbf{Conc_{corr} = Conc_{measured} * (1.020 - 1)/(SG - 1)}$$

- If the *Testing* Authority justifies that confirmation is not necessary, the Laboratory shall update the *ADAMS* report for the *Sample* with a comment stating that the *Testing* Authority considered that the Confirmation Procedure(s) was not necessary and the explanation provided by the *Testing* Authority. If the *Testing* Authority cannot justify that confirmation is not necessary, the Laboratory shall proceed with the confirmation analyses.
- In cases when the Laboratory receives "*ATPF* Confirmation Procedure Requests" or "Suspicious Steroid Profile Confirmation Procedure Requests" for two (2) or more *Samples*, which are linked to a single *Sample* collection session from the same *Athlete*, the Laboratory, in consultation with the *Testing* Authority, shall prioritize the confirmation of the *Sample* with the highest concentration levels of the *Markers* of the "steroid profile".
- When the Laboratory receives an "*ATPF* Confirmation Procedure Request" or a "Suspicious Steroid Profile Confirmation Procedure Request" for a *Sample* for which *Adverse Analytical Finding(s)* have been reported for other *Prohibited Substance(s)* or *Method(s)*, the Laboratory should consult the *Testing* Authority about the need to conduct the Confirmation Procedures for the *Markers* of the "steroid profile".
- A Laboratory may have a contractual agreement in place with the *Testing* Authority to conduct the Confirmation Procedures when a *Sample* meets any of the analytical criteria of a "suspicious steroid profile" or at the Laboratory's discretion based on its expertise.

  Under such circumstances, the Laboratory may proceed to the confirmation of the "suspicious steroid profile" immediately without waiting for an "*ATPF* Confirmation Procedure Request" or a "Suspicious Steroid Profile Confirmation Procedure" request from *ADAMS.* Following the performance of the Confirmation Procedure(s), the Laboratory shall report in *ADAMS* the "steroid profile" of the *Sample* as determined during the Initial Testing Procedure as well as the confirmed values of the *Markers* of the "steroid profile" and the GC-C-IRMS test results. Furthermore, the Laboratory shall report the *Sample* test result in *ADAMS* (as *Adverse Analytical Finding*, *Atypical Finding*, or "No *Prohibited Substance*(s) or *Metabolite*(s) or *Marker*(s) of a *Prohibited Method*(s) on the test menu were detected") based on the results of the GC-C-IRMS Confirmation Procedure in accordance with the TDIRMS [1].

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

The Laboratory shall identify (in compliance with the TDIDCR [5]) and quantify the relevant *Markers* of an *ATPF* or a SSP finding in one additional *Sample* Aliquot by a validated fit-for-purpose GC-MS or GC-MS/MS quantification method.

- The Laboratory shall confirm the abnormal *Markers* (concentrations, T/E*)* of the "steroid profile" that triggered the *ATPF* or SSP finding before proceeding with the GC-C-IRMS analysis [10, 13].
- If a GC-C-IRMS analysis is to be performed on a *Sample* with a normal "steroid profile" upon request from the *Testing* Authority, the *Athlete* Passport Management Unit (APMU), or *WADA*, the Laboratory shall consult with the relevant authority to determine which *Marker(s)* of the "steroid profile" require quantification.

During the Confirmation Procedure, the presence of conjugated *Metabolite(s)* of ethanol (*e.g* EtG), inhibitors of 5α-reductase (*e.g.* finasteride), ketoconazole as well as the signs of microbial degradation including, for example, the presence of the free forms of T, 5αAND or 5βAND, shall be determined.

3.1.1 Method Characteristics for GC-MS or GC-MS/MS quantification Confirmation Procedure

The same analytical requirements presented in 2.1 apply, with the following modifications:

- Calibration standards and urine QC samples containing representative levels of the *Markers* of the "steroid profile" shall be included.
- The u_c (%) shall be not greater than 15% for determinations of A, Etio, 5αAdiol and 5βAdiol at concentrations representing five times the respective LOQ.
- For determinations of T, E and T/E ratios, the u_c (%) shall be not greater than 15% when the concentrations of T and E are greater than 5 ng/mL.

[13] Upon reception of the immediate "*ATPF* Confirmation Procedure Request" notification for an abnormal T/E ratio through *ADAMS*, the Laboratory shall confirm the concentrations of T and E [10], and the T/E ratio.

- In cases of abnormal findings for other ratios of the "steroid profile", the Laboratory shall confirm the relevant concentrations of the *Markers* of the "steroid profile" upon request from the *Testing* Authority [11].

In cases of "Suspicious Steroid Profile Confirmation Procedure Requests", the Laboratory shall confirm the relevant concentrations of the *Markers* of the "steroid profile", which produced the suspicious finding, and the T/E ratio, if applicable (T/E > 4.0), in consultation with the *Testing* Authority.

3.2 Reporting Results from the Confirmation Procedures

Following the performance of the Confirmation Procedure(s) on the "A" or the "B" *Sample* [14], the Laboratory shall report in *ADAMS*:

- the SG of the *Sample;*
- the confirmed values (*e.g.* concentrations, T/E ratio) of the *Markers* of the "steroid profile", without adjustment for the SG of the *Sample* (Table 1)[5, 6];
- the associated u_c expressed in units;
- the GC-C-IRMS confirmation results (refer to TD IRMS [1]) [14];
- the confirmed results for signs of microbial contamination (*e.g.* 5αAND/A, 5βAND/Etio, T_{free} / T_{total} [15]);
- the validity of the *Sample* (as per section 2.2.1 above)[15, 16];
- the confirmed presence of conjugated *Metabolite(s)* of ethanol, inhibitors of 5α-reductase (*e.g.* finasteride), ketoconazole or any other substances that might have altered the "steroid profile", if applicable. The Laboratory shall report the confirmed estimated levels of EtG if above 5 μg/mL (without the need to report the Measurement Uncertainty for this determination).

Following the confirmation of an *ATPF* or SSP, the Laboratory shall update the *ADAMS* test result record for the *Sample* (as *Adverse Analytical Finding*, *Atypical Finding*, or No *Prohibited Substance*(s) or *Metabolite*(s) or *Marker*(s) of a *Prohibited Method*(s) on the test menu were detected) based on the results of the GC-C-IRMS Confirmation Procedure in accordance with the TDIRMS [1]).

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[14] When an *Adverse Analytical Finding* is reported for the *Marker(s)* of the "steroid profile" based on the results of a GC/C/IRMS analysis performed on the "A" *Sample*, only the GC/C/IRMS analysis shall be repeated during the "B" *Sample* Confirmation Procedure, if applicable. Refer to the TDIRMS [1].

[15] In addition to the determination of the 5αAND/A and 5βAND/Etio ratios as signs of microbial contamination, as described in section 2.2.1 for the Initial Testing Procedure, the determination during the Confirmation Procedure of an elevated ratio of free Testosterone to total Testosterone (T_{free} / T_{total} > 0.05) shall also invalidate (the "steroid profile" of) the *Sample*.

[16] The reporting of the validity of the *Sample* shall not be based on the results of the GC-C-IRMS confirmation analysis.

3.3 Additional Analyses: Steroid Ester(s) and DNA

When matched blood *Samples* have been collected during the same *Sample* Collection Session as urine *Samples* identified with an atypical or suspicious "steroid profile", Laboratories, in consultation with the *Testing* Authority, should consider conducting analysis to detect the presence of steroid ester(s) in serum/plasma.

It is recommended that confirmation analyses for steroid ester(s) serum/plasma be conducted prior to the performance of the GC-C-IRMS analysis in urine. The detection of steroid ester(s) in serum/plasma also constitutes an unequivocal demonstration of the exogenous origin of the steroid(s). On the other hand, the absence of detectable steroid ester(s) in serum/plasma does not invalidate a GC-C-IRMS positive result in urine.

The performance of DNA analyses may also be considered to establish, in conjunction with the *Athlete's* "longitudinal steroid profile", the individual origin of the *Sample*(s).

4.0 References

1. *WADA* Technical Document TDIRMS (current version): Detection of synthetic forms of Endogenous Anabolic Androgenic Steroids by GC-C-IRMS.

https://www.wada-ama.org/en/resources/search?f[0]=field_resource_collections%3A30

2. Mareck U, Geyer H, Opfermann G, Thevis M, Schänzer W. Factors influencing the steroid profile in doping control analysis. *J Mass Spectrom*. **43**(7):877-91, 2008.

3. Ayotte C. Detecting the administration of endogenous anabolic androgenic steroids. *Handb Exp Pharmacol.* **195**:77-98, 2010.

4. Kuuranne T, Saugy M, Baume N. Confounding factors and genetic polymorphism in the evaluation of individual steroid profiling. *Br J Sports Med*. **48**(10):848-55, 2014.

5. *WADA* Technical Document TDIDCR (current version): Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for Doping Control Purposes.

https://www.wada-ama.org/en/resources/search?f[0]=field_resource_collections%3A30

APPENDIX E: Results Management Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2016RMR

Document Number:	TD2016RMR	Version Number:	1.0
Written by:	*WADA*	Approved by:	*WADA* Executive Committee
Date:	17 November 2015	Effective Date:	01 January 2016

1. Administrative Management

The *Anti-Doping Organization* (*ADO*) referred to throughout this document on Results Management is the *Passport* Custodian.

These processes shall be administered and managed by an *Athlete Passport* Management Unit (APMU) on behalf of or within the *ADO*. The APMU will initially review profiles to facilitate targeting recommendations to the *ADO* when appropriate, or refer to the Expert Panel as appropriate. Management and communication of the biological data, APMU reporting and Expert reviews shall be conducted in *ADAMS* and be shared by the *Passport* Custodian with other *ADO(s)* with *Testing* jurisdiction over the *Athlete* to coordinate further *Passport Testing*

This Appendix describes a step-wise approach to the review of an *Athlete's Passport*:

- The review begins with the creation of a longitudinal profile and application of the Adaptive Model.
- In case of an *Atypical Passport Finding* (*ATPF*), an Expert conducts an initial screening and returns an evaluation based on the information available at that time.
- The process may culminate in the creation of an *ABP* Documentation Package and Expert Panel opinion following the reception of all information, including any explanation from the *Athlete*.

Laboratories or *WADA*-Approved Laboratories for the *ABP* are presumed to have conducted the *Sample* analysis and custodial procedures in accordance with the *International Standard* for Laboratories (ISL) and Technical Documents (TDs). The *Athlete* or other *Person* may rebut this presumption by establishing that a departure from the ISL and/or TDs occurred, which could reasonably have significantly modified the result. In such cases, the *ADO* shall have the burden to establish why such a departure does not invalidate the result.

2. Review by the Adaptive Model

An *Atypical Passport Finding* (*ATPF*) is generated by the Adaptive Model and identifies either a single *Marker* value or a longitudinal profile of *Marker* values as being outside the *Athlete*'s intra-individual range, assuming a normal physiological condition. An *Atypical* Passport *Finding* requires further attention and review. The Adaptive Model predicts for an individual an expected range within which a series of *Marker* values falls assuming a normal physiological condition. Outliers correspond to those values out of the 99%-range (0.5 - 99.5 percentiles).

For the Haematological Module, an *ATPF* is generated when the haemoglobin concentration (HGB) and/or stimulation index OFF-score (OFFS) value of the last test falls outside the expected intra-individual ranges. Furthermore, the longitudinal profile composed of (up to) the last 20 valid HGB and/or OFFS values is considered as atypical when deviating from the expected ranges, as determined by the Adaptive Model. An *ATPF* is only generated by the Adaptive Model on values of the primary *Markers* HGB and OFFS.

For the Steroidal Module, an *ATPF* is generated when at least one value of the ratios T/E, A/T, A/Etio, 5αAdiol/5βAdiol or 5αAdiol/E of the last test falls outside the expected intra-individual ranges. In addition, the "longitudinal steroid profile" composed of (up to) the last 20 valid values of one of these five ratios is considered as atypical when deviating from the expected ranges, as determined by the Adaptive Model.

A specificity of 99% is used to identify both haematological and steroidal *ATPFs* that warrant further investigation and/or results management. In the case of a "longitudinal steroidal profile," an *ATPF* caused by an atypically high T/E value will trigger an *ATPF* Confirmation Procedure Request notification through *ADAMS* as established in the TD2016EAAS. When the Adaptive Model determines an *ATPF* for any of the other ratios of the "steroid profile" (A/T, A/Etio, 5αAdiol/5βAdiol, 5αAdiol/E), the APMU should advise the *Testing* Authority in the APMU report on whether the *Sample* shall be subjected to Confirmation Procedures.

If an athlete is tested only once or the sample is unmatched and the sample fulfills the criteria for a Suspicious Steroid Profile Finding, then the Adaptive Model can not be applied. See the TD2016EAAS for full details on the procedure to be taken in these situations.

[Comment: If there is a departure from WADA ABP requirements for collection, transport and analysis of Samples, the corresponding result should not be considered in the Adaptive Model calculations. However, the non-conforming biological result should remain in the Athlete's Passport and may be used for reference and Target Testing purposes. Any non-conforming result (e.g. a blood result analyzed after 48 hours) may be included in the Expert Panel assessment of a profile provided, if the

Expert Panel's attention is drawn to this particular result. The APMU will coordinate with the appropriate Laboratory or WADA-Approved Laboratory for the ABP and Expert Panel to ensure the validity of any non-conforming result.]

3. The Initial Expert Review

For the Steroidal Module, if a result rendered by a Laboratory represents an *ATPF* caused by an atypically high T/E value, the *Sample* will undergo Confirmation Procedures, including GC-C-IRMS analysis. If the Laboratory result represents an *ATPF* for any of the other ratios of the "steroid profile" (A/T, A/Etio, 5αAdiol/5βAdiol, 5αAdiol/E), the APMU should advise the *Testing* Authority in the APMU report on whether the *Sample* shall be subjected to Confirmation Procedures, including GC-C-IRMS analysis.

If the result of the GC-C-IRMS Confirmation Procedure is negative or inconclusive the APMU shall seek an Expert review. When the APMU is associated to a Laboratory, the APMU can replace the initial Expert and provides a review through the APMU report in *ADAMS*. An APMU or Expert review is not required when the GC-C-IRMS Confirmation Procedure renders a positive result and is reported by the Laboratory as an *Adverse Analytical Finding* (*AAF*). In such cases, a normal Results Management process shall be followed by the *ADO* which constitutes the Results Management Authority.

If the Haematological Module renders an *ATPF*, then the results/profile must be reviewed by an Expert chosen by the APMU. This should occur in a timely manner.

The Expert shall review the *Passport* anonymously (without reference to the specific *Athlete* by name) and conduct his/her activities in strict confidence. The Expert shall evaluate the *Passport* and respond back to the APMU, which will trigger further APMU action:

Expert Evaluation	**APMU Action**
Normal.	Continue normal *Testing* pattern.
Passport suspicious: Further data is required.	Alert *ADO* to do Target *Testing* and provide recommendations.
Considering the information within the *Athlete's Passport*, it is highly unlikely that the longitudinal profile is the result of a normal physiological or pathological condition, and likely may be the result of the *Use* of a *Prohibited Substance* or *Prohibited Method*.	Send to two other Experts, as per section 4 of this Appendix.
Considering the information within the *Passport*, it is highly likely that the *Athlete* has a pathological condition.	Inform the *Athlete* via the *ADO* (or send to other Experts).

[Comment: The ABP is not intended as a health check or for medical monitoring but rather is a tool to detect the possible Use of Prohibited Substance(s) or Prohibited Method(s). Nevertheless, the Experts, via the APMU, will contact the Athlete, via the ADO, if there is a high likelihood of pathology. It is important that the ADO educates the Athletes to ensure that they undergo regular health monitoring and not rely on the ABP for this purpose.]

4. Review by Three Experts

In the event that the evaluation of the appointed Expert in the initial review supports the proposition that the profile is unlikely to be the result of a normal physiological or pathological condition, the *Passport* shall then be sent by the APMU to a group of three Experts for review, composed of the Expert appointed in the initial review and two other Experts chosen by the APMU from the Expert Panel

For the review of a Haematological *Passport*, the group of three Experts should be composed of individuals with knowledge in the fields of clinical haematology, sport medicine and/or exercise physiology. For the review of the Steroidal *Passport*, the group of three Experts should be composed of individuals with knowledge in the fields of Laboratory analysis, steroid doping and/or clinical endocrinology.

The APMU is responsible for liaising with the Experts and for advising the *ADO* of the subsequent Expert assessment. The review of the three Experts must follow the same logic as presented in section 3 of this document. The group of Experts can confer before they finalize their opinion. The group can also seek advice from an appropriate outside Expert, although this must be done with strict confidentiality.

If more information is required to review the file, the Experts can request further details, such as those related to medical issues, sport practice and/or training. Such requests are directed via the APMU to the *ADO*. The Experts will conduct the review based on the *Athlete*'s blood or urine profile data, and any additional information requested from *ADO(s)* or Laboratories relating to any *Sample* in the *Athlete*'s profile.

A unanimous opinion among the three Experts is necessary in order to proceed with possible results management which means that all three Experts come to the conclusion that considering the available information contained within the *Passport* at this stage, it is highly likely that a *Prohibited Substance* or *Prohibited Method* had been used, and unlikely that it is the result of any other cause. The conclusion of the Experts must be reached with the three Experts assessing the *Athlete*'s *Passport* with the same data (i.e three Expert opinions cannot be accumulated over time, as data is added to a profile).

If there is no unanimity among the three Experts, the APMU may follow up on requests for additional information or expertise, or recommend the *ADO* to pursue additional *Testing*

5. Follow up on Expert Reviews and Compilation of the *ABP* Documentation Package

If the evaluation of the three Experts supports the proposition that the *Athlete* has likely used a *Prohibited Substance* or *Prohibited Method*, and that the result is unlikely due to any another cause, the APMU shall be responsible for the compilation of the *ABP* Documentation Package. The APMU might confer with the group of Experts to determine the scope of such compilation, including the recommended elements and the number of tests that need to be included.

[Comment: It is only mandatory to have a full Laboratory Documentation Package for those tests that are deemed essential by the APMU and Expert Panel. The other tests, for example those that confirm the baseline levels of a Marker, only require a Certificate of Analysis. A template of the Certificate is available to Laboratories and WADA-Approved Laboratories for the ABP upon request to WADA.]

The following key information needs to be included in both Haematological and Steroidal Modules of the *ABP* Documentation Package:

- Age of the *Athlete*.
- Gender of the *Athlete.*
- Sport and discipline.
- Type of test.
- *Sample* code number.
- Internal Laboratory (or *WADA*-Approved Laboratory for the *ABP*) *Sample* number.
- Biological data and results obtained by the Adaptive Model.
- *Competition* information.
- Chain of Custody documentation.
- Information from the *Doping Control* forms for each *Sample* collected during the period, as determined by the APMU and Expert Panel.

For the Haematological Module, this additional information is required:

- Information on possible exposure to altitude of the *Athlete* for the period defined by the Expert Panel.
- Temperature conditions during the transport of the blood *Samples*.
- Laboratory (or *WADA*-Approved Laboratory for the *ABP*) documentation, including blood results.
- Scatter grams.

- Internal and external quality controls.
- Information on whether the *Athlete* received a blood transfusion and/or suffered significant blood loss in the prior three months.

For the Steroidal Module, this additional information is required:

- pH of the urine *Sample*.
- Specific gravity of the urine *Sample*.
- Laboratory documentation, including screening and confirmed (when applicable) values of steroid concentrations and ratios.
- GC-C-IRMS results, when applicable.
- Indications of ethanol consumption: estimated urinary concentrations of ethanol and/or ethanol *Metabolites*.
- Indications of bacterial activities (e.g. 5α-androstandione/A and/or 5β-androstandione/Etio ratio, pH, fraction of free forms of T or DHEA).
- Indications of medications taken (declared or detected) that may influence the "steroid profile," such as glucocorticoids, human chorionic gonadotrophin (hCG), ketoconazole, contraceptives and 5α-reductase inhibitors.

The *ABP* Documentation Package shall be sent to the same three-member Expert Panel, which will subsequently review the additional information. The Expert Panel is responsible for providing a joint evaluation to be signed by all three Experts and included in the *ABP* Documentation Package.

If the Expert Panel confirms their previous position, considering the information within the *Passport* at this stage, that it is highly likely that a *Prohibited Substance or Prohibited Method* had been used, and unlikely that it is the result of any other cause, the APMU will declare an *Adverse Passport Finding* (*APF*). The *ABP* Documentation Package is then reviewed by the *ADO.*

The *APF* represents the end result of the Expert review of the longitudinal profile of *Markers* and other *Passport* information (such as training and *Competition* schedules), concluding that the finding is inconsistent with a normal physiological condition or known pathology and compatible with the *Use* of a *Prohibited Substance* or *Prohibited Method*.

The review at this stage is anonymous, however it is accepted that some specific information provided may allow one to identify the *Athlete*. This shall not affect the validity of the process.

The *ADO* will then be responsible for:

a. Advising the *Athlete* and *WADA* that the *ADO* is considering the assertion of an anti-doping rule violation (ADRV) against the *Athlete*.

b. Providing the *Athlete* and *WADA* the *ABP* Documentation Package.

c. Inviting the *Athlete* to provide his/her own explanation, in a timely manner, of the data provided to the *ADO*.

6. Review of Explanation From *Athlete*

Upon receipt of explanation and supporting information from the *Athlete* (or in the event no explanatory information is provided), the Expert Panel shall review the information provided by the *ADO*, the information (if any) provided by the *Athlete* and any additional information that the Panel considers necessary to render its opinion in coordination with both the *ADO* and the APMU. It is accepted that this review may no longer be anonymous. The Panel shall then reassess or reassert its previous opinion that includes one of the following statements:

d. Unanimous opinion of the Panel that based on the information in the *Passport*, it is highly likely that the *Athlete* used a *Prohibited Substance* or *Prohibited Method*, and that is was unlikely to find the *Passport* abnormal assuming any other cause; or

e. Based on the available information, the Panel is unable to unanimously reach an opinion and, in such a case, the Panel may or may not recommend further investigation or *Testing*.

7. Disciplinary Proceeding

If the Expert Panel expresses the opinion set forth in a. of section 6, then the *ADO* shall be informed by the APMU. The *ADO* will then proceed to results management in accordance with *Code* Article 7.5.

In the event the *Athlete* has been found to have committed an ADRV based on the *Passport,* the *Athlete*'s *Passport* shall be reset upon their return to *Competition*, following completion of the relevant period of suspension to maintain their anonymity for potential APMU and Expert Panel reviews conducted in the future.

When an *Athlete* is sanctioned by means other than the *ABP*, the Haematological and/or Steroidal *Passport* will remain in effect, except in those cases where the *Prohibited Substance* or *Prohibited Method* resulted in an alteration of the haematological or steroidal *Markers*, respectively (e.g. for *AAF* reported for anabolic androgenic steroids, hCG, masking agents or diuretics, which may affect *the Markers* of the "steroid profile," or for the *Use* of Erythropoiesis-Stimulating Agents or blood transfusions, which would alter the haematological *Markers*). In such instances, the *Athlete's* profile(s) would be reset from the time of the beginning of the sanction.

Templates

A non-mandatory template sharing of information agreement is contained herein to facilitate the sharing and mutual recognition of biological data between *ADOs* that share *ABP* interests on the same *Athlete* (eg. *National Anti-Doping Organization* and International Federation).

APPENDIX F: Collaboration Agreement

Between

[•]

(hereinafter referred to as "[A]")

and

[•]

(Hereinafter referred to as "[B]")

WHEREAS [A] is the [*Anti-Doping Organization* (*ADO*)] recognized by the World Anti-Doping Agency (*WADA*) and is responsible for *Doping Control* and *Athlete Biological Passport* (*ABP*) Programs for *Athletes* included in its *Registered Testing Pool (RTP)*;

WHEREAS [B] is the [*ADO*] recognized by *WADA* and is responsible for *Doping Control* and *ABP* Programs for *Athletes* included in its *RTP*;

WHEREAS the principle of the *ABP* is to have one and only *Passport* for each *Athlete*;

WHEREAS it is therefore of utmost importance that organizations that test the same *Athlete* collaborate to ensure that only one organization consolidate all result for a single *Athlete* and ensure result management of this *Athlete Passport*;

WHEREAS [A] and [B] now wish to collaborate on the planning, *Testing* and results management of the *Doping Control* and *ABP* Programs of the *Athletes* included in their respective *RTPs*, in accordance with the terms of this Agreement.

PURPOSE

The purpose of this Agreement is to provide a framework for collaboration between [A] and [B] (each a Party and collectively the Parties) in relation to the collection and exchange of *Athletes' Passports* and related results management procedures.

THEREFORE, it is agreed upon between the Parties:

Clause 1 - Definitions

Capitalized and italicized terms used in this Agreement shall have the meanings ascribed to them under the World Anti-Doping Code ("*Code*") and the *International Standards*, both as amended from time to time. For ease of reference, relevant definitions have been reproduced in Schedule 1 attached hereto.

Additional definitions created for the purposes of this Agreement shall be underlined and have the following meanings:

1.1 "Agreement" means this Collaboration Agreement.

1.2 "Passport Purposes" means the gathering and collation of *Passports* according to the *ABP* Operating Guidelines and related Technical Documents (TDs).

1.3 "Confidential Information" means all information (however recorded or preserved) disclosed by a Party or its Representatives to the other Party and that Party's Representatives after the date of this Agreement concerning:

(a) the existence and terms of this Agreement;

(b) any information that would be regarded as confidential by a reasonable business person relating to:

(i) the business, affairs, customers, clients, suppliers or future plans of the disclosing Party; or

(ii) the operations, processes, product information, know-how, designs, trade secrets or software of the disclosing Party; and

(c) any information collected, developed or exchanged by the *Parties* in the course of carrying out this Agreement, including, but not limited to, *Passports* and other relevant or potentially relevant doping-related information.

1.4 "Operating Guidelines" means the most recent version of the *ABP* Operating Guidelines adopted by *WADA* and available on *WADA's* Web site.

1.5 "Representative" means an employee, officer, representative, agent or adviser of a Party.

Clause 2 – *Passport Testing* and Information Sharing

2.1 [A] and [B] agree to provide each other with a copy of its updated *RTP* for *Passport* Purposes upon request and to discuss the composition of the respective [A] and [B] *RTP*s where appropriate, in particular when [A] and [B] have *Testing* jurisdiction over the same *Athlete.*

2.2 [A] shall conduct *Testing* of the *Athletes* in [A]'s *RTP* for *Passport* Purposes and [B] shall conduct *Testing* of *Athletes* in [B]'s *RTP* for *Passport* Purposes, including by means of *Target Testing*. For such purposes:

2.2.1 [A] or [A] APMU and [B] or [B] APMU may share intelligence with each other as regards the *Target Testing* of *Athletes* on [A]'s *RTP* or [B]'s *RTP*, as the case may be.

2.2.2 [A] and [B] shall each ensure that it has *Testing* jurisdiction with regard to the tests conducted under this Agreement.

2.2.3 For the avoidance of doubt, nothing in this Clause 2 shall prevent [A] or [B] from *Testing* any *Athlete* within its jurisdiction for *Passport* Purposes at any time, irrespective of the *Athlete's* status on [A]'s *RTP* for *Passport* Purposes or [B]'s *RTP* for *Passport* Purposes.

2.2.4 All *Samples* under this Agreement will be collected in compliance with the International Standard for Testing, the International Standard for Laboratories, and the Operating Guidelines.

2.2.5 [A] and [B] shall each bear its own costs of *Testing* (including the costs of storage, transportation and analysis of *Samples*).

2.3 Each Party agrees that it shall, at its own cost, exclusively use *ADAMS*, and ask the relevant APMU to use *ADAMS*, for recording doping control forms and *Passports* relating to any *Athlete* tested for *Passport* Purposes under this Agreement.

2.4 In any case where an *Athlete* has been tested under this Agreement for *Passport* Purposes, the relevant Party shall record the *Passport* on *ADAMS*, or ensure that it is being recorded by the relevant APMU, as soon as reasonably practical following the test and shall take whatever steps are necessary to ensure that the other Party is able to access the relevant *Passport* through *ADAMS*. If for whatever reason the *Passport* cannot be accessed by the other Party through *ADAMS*, the Party shall provide the relevant *Passport* to the other Party in such other form as the other Party may reasonably request.

2.5 [A] and [B] shall use the *Passports* under this Agreement for *Passport* Purposes only. The relevant *Testing* Authority in each case shall ensure that the *Athlete*'s prior written consent has been obtained for the sharing of the *Passports* with the other Party for such purposes.

Clause 3 – *Passport* Results Management Process

3.1 For each *Athlete* included in both [A] and [B] *RTPs*, the Parties shall establish which of [A] or [B] is the *Passport* Custodian.

3.2 The APMU of the *Passport* Custodian is responsible for results management in accordance with the most recent TD on Result Management Requirements for the *ABP* adopted by *WADA*. For *Athletes* included in both [A] and [B] *RTPs*, *Passports* shall be reviewed after each test by the APMU of the *Passport* Custodian independently of if [A] or [B] was the *Testing* Authority that conducted the last test.

3.3 In *ADAMS*, the Party assigned as the *Passport* Custodian may share the *Athlete's Passport* with the other Party, including the APMU report, targeting recommendations and Expert reviews.

3.4 The Parties have established an Expert Panel ([A] Expert Panel and [B] Expert Panel respectively) working with respectively [A] APMU or [B] APMU in accordance with the Operating Guidelines. Parties shall determine the members of their *ABP* Expert Panel from time to time, and shall notify each other upon request of an updated list of their *ABP* Expert Panel.

3.5 Parties shall immediately notify each other in writing of the referral of any *Athlete*'s case for review by the other Party's *ABP* Expert Panel in accordance with the Operating Guidelines, as well as the outcome of such review.

3.6 For the avoidance of doubt, *Passport* data collected under this Agreement by [A] and [B] should, whenever possible, be combined for the purposes of pursuing a potential anti-doping rule violation (ADRV) or other results management procedure pursued against an *Athlete* in accordance with the *Code* and *International Standards*.

Clause 4 – *Passport* Disciplinary Procedures

4.1 If upon review the [A] *ABP* Expert Panel or [B] *ABP* Expert Panel (as appropriate) decides that there is no known reasonable explanation for the profile information contained in the *Passport* other than the use by the *Athlete* of a *Prohibited Substance* or *Prohibited Method*, the *Athlete*'s case shall proceed as an asserted ADRV.

4.2 Where the *Passport* Custodian Party decides not to proceed with an asserted ADRV, such decision will not affect the ability of the other Party or *WADA* to appeal such decision.

Clause 5 – Effective Date and Termination

5.1 This Agreement shall become effective on the date of signature and will remain in effect until terminated.

5.2 Notwithstanding Clause 5.3, if either Party wishes to terminate this Agreement, it shall give thirty (30) days' written notice to the other Party of its intention to terminate the Agreement. Upon receipt of the written notice of termination, this Agreement will terminate thirty (30) days after such notice is delivered.

5.3 Either Party may terminate this Agreement immediately if the other Party commits a material breach of any term of this Agreement and (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being notified in writing of the breach.

5.4 The Parties agree that after the effective date of termination of this Agreement each Party may continue to use all *Passports* and Confidential Information provided to it by the other Party, provided that it is only used for anti-doping purposes and for a period up to, but not exceeding, the statute of limitations of the *Code* then in force (currently 8 years). The Parties will thereafter, upon request, return, destroy, aggregate or anonymize all *Passports* and Confidential Information in its control or possession provided to it by the other Party, unless applicable law or other applicable regulations prevents the Party from returning or destroying all or part of the *Passports* or Confidential Information.

Clause 6 – Authority

6.1. The Parties hereby represent that they have the full power and authority to enter into and perform this Agreement, and the Parties know of no agreement, promises, or undertakings that would prevent the full execution and performance of this Agreement.

6.2. Notwithstanding the above and for the avoidance of doubt, the Parties acknowledge and agree that nothing in this Agreement affects or modifies their respective rights and obligations, and those of other relevant Third Parties, under the "Agreement Governing the Use and Sharing of Information in *ADAMS*" that the Parties entered into with *WADA*.

Clause 7 - Indemnity

Each Party (the "Breaching Party") shall indemnify and hold harmless the other Party (the "Non-Breaching Party") against any and all costs, charges, damages, expenses and losses (including costs incurred in recovering same) that are incurred by the Non-Breaching Party as a result of any breach of this Agreement by the Breaching Party up to a maximum of [•]. The provisions of this Clause 8 shall survive termination of this Agreement.

Clause 8 – Confidentiality

8.1 The Parties shall at all times keep confidential (and ensure that their Representatives keep confidential) any Confidential Information which they may acquire in accordance with this Agreement and shall not disclose or use such Confidential Information other than in fulfillment of the Agreement except:

(i) with the consent of the other Party; or

(ii) if such information has come into the public domain otherwise than by breach by that Party of this clause; or

(iii) as required by law or other applicable regulations.

8.2. The duties of the Parties in this Clause 8 shall survive the expiration or earlier termination of this Agreement.

8.3. The receiving Party agrees that it will only disclose the disclosing Party's Confidential Information to its directors, employees, consultants or professional advisors on a strictly need-to-know basis in connection with *Passport* Purposes and then only after such person has been advised of the requirements of this Agreement.

Clause 9 – Data Privacy

9.1 The Parties acknowledge that the sharing of Personal Information under this Agreement is necessary to allow each Party to fulfill its obligations under the *Code* and is in accordance with applicable data protection laws.

9.2 The Parties shall collect, Process, store and disclose all Personal Information under this Agreement with the *Athlete*'s consent and in accordance with the International Standard for the Protection of Privacy and Personal Information (ISPPPI).

9.3 Each Party shall notify the other Party promptly of any accidental, unauthorized, or unlawful destruction, loss, alteration, or disclosure of, or access to, the Personal Information ("Security Breach"), and take immediate steps to rectify any Security Breach.

9.4 Neither Party shall disclose *Passports* collected under this Agreement to any Third Party (save for the purposes of the [A] *ABP* Expert Panel or [B] *ABP* Expert Panel review), without the express prior written consent of the other Party unless such disclosure is required by law or occurs as a result of Clause 9.2.

Clause 10 – Miscellaneous

10.1 This Agreement is intended to be the sole and complete statement of obligation of the Parties as to the subject matter hereof, and supersedes all previous agreements, understandings, negotiations and proposals as to such subject matter.

10.2 The failure of either Party at any time to demand strict performance of the terms of the Agreement shall not be construed as a waiver of the right to demand or receive complete performance of all rights, promises and covenants in this Agreement.

10.3 This Agreement does not establish either Party to be the agent of the other Party or create a joint venture or similar relationship between the Parties and no Party shall have the power to obligate or bind the other Party in any manner whatsoever. The Parties hereto shall act in all respects as independent contractors.

10.4 Neither Party may assign, directly or indirectly, by operation of law, change of control or otherwise, this Agreement or any of its rights and obligations hereunder, without the prior written consent of the other Party, which shall not be unreasonably withheld.

10.5 The Parties agree that any and all amendments to this Agreement must be made in writing to be signed by the Parties; no amendment can be made by electronic means.

10.6 If any provision or provisions of this Agreement shall be held to be invalid, illegal, or unenforceable, such provision shall be enforced to the fullest extent permitted by applicable law and the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

10.7 A *Person* who is not a party to this Agreement shall not have any rights under or in connection with this Agreement. The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any person that is not a party to this Agreement.

10.8 Section and other headings in this Agreement are for convenience of reference only and shall not constitute a part of or otherwise affect the meaning or interpretation of this Agreement.

Clause 11 - Notices

11.1 Any notice required to be given under this Agreement shall be in writing and shall be delivered personally, sent by fax or sent by commercial courier, to the other Party required to receive the notice at its address as set out below:

(i) [A]:

Address: [•]
For the attention of: [•]
Fax number: [•]

(ii) [B]:

Address: [•]
For the attention of: [•]
Fax number: [•]

or at such other address as the relevant Party may specify by notice in writing to the other Party.

11.2 Any notice shall be deemed to have been duly given:

(a) if delivered personally, at the time of delivery at the address referred to in Clause 12.1;

(b) if delivered by commercial courier, at the time of signature of the courier's receipt; or

(c) if sent by fax, at the time of transmission.

Clause 12 – Applicable Law and Jurisdiction

12.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter shall be governed by and construed in accordance with the law of [•].

12.2 Both Parties accept and agree to comply with any relevant and applicable laws and regulations.

12.3 The Parties agree that any dispute, arguments or claims arising with respect to or in connection with the execution of this Agreement (as well as any subsequent amendment hereof, including, for example, its structure, validity, effectiveness, interpretation, execution, infringement or termination, and also any non-contractual claim relating hereto) shall be the object of an amicable resolution. In the absence of amicable resolution, the dispute shall be submitted to the exclusive jurisdiction of the Court of Arbitration for Sport (*CAS*) in Lausanne, Switzerland, and settled definitively in accordance with the Code of Sports-related Arbitration. The panel will consist of one arbitrator. The language of the arbitration will be [•].

Clause 13 - Signatories

The signatories to this Agreement hereby warrant that they have read and agree to the terms, conditions and provisions of this Agreement, including any Appendices, and have full power and authority to sign for and bind their respective organizations.

Clause 14 - Counterparts

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

In the name and on behalf of
[A]

_____

……..[Name, Position]

Date: _____

In the name and on behalf of
[B]

_____

……..[Name, Position]

Date: _____