Athlete Biological Passport

Operating Guidelines

& Compilation of Required Elements

Version 4.0

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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 detecting a particular Substance or 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 Athlete Biological Passport, 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:

a. To identify Athletes for specific analytical Target Testing through intelligent, timely interpretation of Passport data.

b. i) For the Haematological Module, this could be recombinant erythropoietin (EPO), or homologous blood transfusion tests.

c. ii) For the Steroidal Module, this could be the use of Isotope Ratio Mass Spectrometry (IRMS) to detect exogenous steroids.

d. In the absence of a positive analytical test (Adverse Analytical Finding, or AAF), a Passport may still be used to pursue an ADVR in accordance with 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.

1.2. Scope

The ABP is presented to equip Anti-Doping Organizations (ADOs) with a robust and viable framework in which to a) use biological data for intelligent Target Testing and b) pursue ADVRs in accordance with World Anti-Doping Code Article 2.2 (Use). The processes and framework outlined in these Operating Guidelines are intended to support both the Haematological and Steroidal Modules.

This document is divided into three sections.

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

Section 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.
Section 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. 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 for ease of reference, they should be considered International Standard for Testing (IST) and International Standard for Laboratories (ISL) TDs.

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 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 Two: Modules, Management and Administration

2.0 **ABP** Haemotological and Steroidal Modules

The Haematological Module collects information on *Markers* of blood doping. The Module aims to identify enhancement of oxygen transport, including use of erythropoiesis-stimulating agents and any form of blood transfusion or manipulation.

In addition to identifying the use of ‘Erythropoiesis-Stimulating Agents’ included under Section 2 of the *Prohibited List* (Peptide Hormones, Growth Factors and related Substances), the Haematological Module also seeks to identify the *Use of 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 count
- **RET%**: The percentage of reticulocyte
- **RET#**: Reticulocytes 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 when administered exogenously and other anabolic agents, such as selective androgen receptor modulators (SARMS) categorized under Section S1 of the Prohibited List.

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

- **T/E**: Testosterone/Epitestosterone ratio
- **T**: Testosterone
- **E**: Epitestosterone
- **A**: Androsterone
- **Etio**: Etiocholanolone
- **5α-diol**: 5α-androstane-3α,17β-diol
- **5β-diol**: 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, 5α-diol/5β-diol and 5α-diol/E.

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2.3. *Testing* and Defining the Target Population

An **ABP Testing** Program must follow the *IST* 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 tests 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* tests and *No-Advance Notice* tests 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 five (5) days apart. This does not preclude *Testing an Athlete twice in less than five (5) days when a specific doping scheme is suspected.]*

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

- **a.** 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 androgenic anabolic steroids use).

- **b.** Athletes who may warrant inclusion in such a program with respect to their possible risk for doping practice.

- **c.** Age of Athlete and their prospects for long-term, elite-level participation.

- **d.** Whether any Athletes under an ADO’s jurisdiction are already subject to the ABP program of another ADO.

- **e.** Inclusion of the Athlete in the ADO’s Registered Testing Pool to support intelligent *Testing* and provide supporting information for Expert interpretation.

- **f.** Inclusion of Athletes who are 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 IST, 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 IST 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 (DCF) and/or on associated Sample Collection paperwork, such as a Chain of Custody Form or other required (Haematological Module) supplementary report:

a. Location of Testing.

b. Event (if relevant).

c. Blood loss or gain, due to pathology or transfusion, (with estimated volume) in the three months preceding each Sample Collection.

d. Information on the Use of simulated hypoxic conditions in the prior two (2) weeks. The type of device and the manner in which it was used (frequency, duration, simulated altitude) shall be recorded.

e. Information on exposure to a high altitude (>1000 meters) in the prior two (2) weeks, including estimated altitude and duration.

f. Information on most recent training or physical activity, as applicable.
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:

a. 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.

b. An effective whereabouts management system to facilitate *Athlete* location (i.e. *ADAMS*).

c. Access to *ADAMS*, which contains the *Adaptive Model*.

d. A manager with relevant expertise and availability for ‘real-time’ management of ABP processes, or an arrangement with an external APMU.

e. An *Expert Panel* with interpretive and consultative skills, ideally accessed via an APMU.

f. **[3.2 Comments]**: A Guide describing the Biological Passport Module of *ADAMS* is available on *WADA*’s website:

http://adams-docs.wada-ama.org/display/EN/ADAMS+Biological+Passport+guide

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 Passport Finding* (ATPF) 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 Method or Substance and to apply traditional test methods and/or targeting 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:

a. Adapting, implementing and administrating an ABP in accordance with these Guidelines, including compliance with the IST.

b. Ensuring that recommendations received from the APMU is converted into effective, targeted, timely and appropriate follow-up Testing.

c. Following up on Adverse Passport Findings (APFs) in accordance with TD2014RMR (Appendix E) and Code Article 7.4.

3.3.2. Athlete Passport Management Unit

The APMU is responsible for:

a. Providing recommendations that can be converted into effective, targeted, timely and appropriate follow-up Testing by the ADO.

b. Real-time administrative management of the Passports, and liaising with Expert Panels as required.

c. Compiling all necessary information to establish an ABP Documentation Package.

d. Issuing all APFs to the ADO and WADA.

3.3.3. Laboratory

The WADA Accredited or WADA Approved Laboratory for the ABP is responsible for:

a. Adhering to TD2014BAR (Appendix C) for the Haematological Module and WADA External Quality Assessment Scheme (EQAS) Program to ensure robust,
standardized, and credible biological data is incorporated into an *Athlete’s Passport*.

b. Adhering to TD2014EAAS (Appendix D) for the Steroidal Module, including the appropriate WADA EQAS

c. Generating a Certificate of Analysis or *Laboratory Documentation Package* as applicable.

### 3.3.4. Expert Panel

The *Expert Panel* is responsible for:

a. 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* results.

b. Recommending any follow-up *Testing* or suggesting possible clinical *Testing* that may be required to a) confirm assessment or b) collect further evidence to support or confirm possible pathologies.

c. Reviewing any explanations of the *Athlete* and providing an opinion on if any *Atypical Passport Finding* (ATPF) was highly probable, given that a *Prohibited Substance* or *Prohibited Method* had been used.

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

### 3.3.5. World Anti-Doping Organization *(WADA)*

*WADA* is responsible for:

a. Providing access to the *ABP Module(s)* via *ADAMS* to the aforementioned partners to support coordinated, secure exchange of information.

b. Carrying out its monitoring and appeal rights and responsibilities as set forth in *Code* Article 20.7.

c. Providing ongoing support to *ADOs* operating *ABP* Programs, as required.

d. 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 *International Standard for the Protection of Privacy and Personal Information* (ISPPPI). Furthermore, ADAMS will facilitate prompt exchange of information between ADOs, AMPUs, WADA Accredited and/or WADA Approved Laboratories, Sample Collection Personnel, and WADA.

4.2. Recommended Administrative Sequence

The following outlines the suggested sequence of interactions between the Athlete, Doping Control Personnel, ADOs, Laboratory(ies), ADAMS, AMPUs, and Expert Panels to establish an individual Athlete’s Passport in an effective, 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 this Guideline suggests that 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-generated biological data with active test planning advice and intelligence. This APMU may be associated with a WADA Accredited 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**

- **Athlete Selection**
  - The ADO identifies the Athlete of interest for Testing.

- **Timing of Test**
  - The ADO identifies the ideal timing for Sample Collection, which could be upon the recommendation of the APMU.*

- **Issuing Request**
  - The ADO issues a Sample Collection request, which includes the type of Sample to be collected (blood and/or urine) based on the recommendations of the APMU. Preferably, the request will be delivered via ADAMS to restrict the dissemination of this information.

- **Accessing W/B**
  - The Sample Collection Authority accesses the pertinent whereabouts information of the Athlete via ADAMS (for only the period defined by the issuing organization) and any other relevant Testing instructions.

- **Sample Collection**
  - The Sample Collection Personnel locate the Athlete and collect the biological Sample(s), following the appropriate protocol. A DCF is to be completed as outlined in Appendix A, where the Doping Control includes an ABP blood Sample.

- **Transport of Sample**
  - The Sample Collection Personnel ensure the transport of the biological Sample(s) to a WADA Accredited or WADA Approved Laboratory for the ABP, in accordance with Appendix B.

- **ADAMS Entry**
  - The Sample Collection Agency or the Sample Collection Personnel should enter the ABP DCF into ADAMS immediately. This connects the results of Sample analysis to the Athlete’s unique Passport, and links the new Sample data with the Athlete’s historical data for review by the APMU and ADO.

- **Sample Analysis**
  - The WADA Accredited or WADA Approved Laboratory for the ABP analyzes the Sample(s) following the appropriate protocol for blood and/or urine as appropriate (Appendix C and/or D, respectively) and reports the biological results without delay into ADAMS.
When an ABP blood Sample is collected, the ADO must consider whether the collection of concomitant urine or blood Samples 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.

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 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 ADOs and Athletes alike.

Within the framework provided by ISPPPI, ADOs are encouraged to coordinate their activities where multiple ADOs have Testing jurisdiction over a single Athlete and multiple ADOs 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.

All results should be shared between respective ADOs where agreement has been reached on the provision of such information. In lieu of such an agreement, when an abnormality is identified that is a result of biological data from multiple ADOs, the International Federation (IF) will have the primary responsibility for these follow-up actions.

[4.4 Comment: If an Athlete is subject to Testing by multiple ABP Programs, then his/her IF and NADO(s) should seek to reach an agreement in advance on which organization will be responsible for the establishment of the Passport and any necessary follow-up action, such as Target Testing or results management proceedings. If no agreement can be found, any one of the ADOs may ask WADA to determine which ADO is responsible for the Athlete. WADA shall not rule on this without consulting the ADOs involved. 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 addition to the provisions set out in Code Article 15.4.1, for the purposes of the ABP, certain pre-conditions should be established for multiple ADOs to recognize one another’s activities and cooperate on a joint ABP Program for a single Athlete.

These pre-conditions assume that all Samples collected by ADOs and subsequently incorporated into a single Passport have adhered to the IST and Appendix A (ABP Blood Sample Collection Requirements) and Appendix B (ABP Blood Sample Transport Requirements), as applicable. Additionally, the concerned ADOs should agree upon a specific APMU that will be responsible for the management of a single Passport of interest to more than one party.
5.0 Terms and Definitions

5.1. 2009 World Anti-Doping Code Terms

**Anti-Doping Administration and Management System (ADAMS):** The secure, online 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.

**Adverse Analytical Finding (AAF):** A report from a Laboratory or other WADA Approved Testing entity 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.

**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 participates in sport at the international level (as defined by each International Federation), the national level (as defined by each National Anti-Doping Organization, including but not limited to, those Persons in its Registered Testing Pool), and any other competitor in sport who is otherwise subject to the jurisdiction of any Signatory or other sports organization accepting the Code. All provisions of the Code, including, for example, Testing and Therapeutic Use Exemptions must be applied to International- and National-Level Athletes. Some National Anti-Doping Organizations may elect to test and apply anti-doping rules to recreational-level or masters-level competitors who are not current or potential national-calibre competitors. National Anti-Doping Organizations are not required, however, to apply all aspects of the Code to such Persons. Specific national rules may be established for Doping Control for non-International-Level or non-National-Level Athletes without being in conflict with the Code. Thus, a country could elect to test recreational-level competitors, but not require Therapeutic Use Exemptions or whereabouts information.

Similarly, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not require advance Therapeutic Use Exemptions or whereabouts information. For purposes of Code Article 2.8
(Administration or Attempted Administration) 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: 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. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all Persons on national teams and all Persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes must be included in a National Anti-Doping Organization’s Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-calibre Athletes to competitors at lower levels of Competition. Competitors at all levels of Competition should receive the benefit of anti-doping information and education.]

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

**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, Therapeutic Use Exemptions, 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 other relevant Anti-Doping Organization, “In-Competition” means the period commencing 12 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.

**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.

**Marker:** A compound, group of compounds or biological variable(s) that indicate the use of a Prohibited Substance or Prohibited Method.
**No Advance Notice**: A *Doping Control* 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.

**Out-of-Competition**: Any Doping Control that is not In-Competition.

**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 so described on the Prohibited List.

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

[**Comment**: 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.]

**Target Testing**: Selection of *Athletes* for *Testing*, where specific *Athletes* or groups of *Athletes* are selected on a non-random basis for *Testing* at a specified time.

**Testing**: The parts of the *Doping Control* process involving *Test Distribution Planning*, *Sample Collection*, *Sample* handling, and *Sample* transport to the *Laboratory*.

**WADA**: The World Anti-Doping Agency.
5.2. International Standard for Testing (IST) Terms

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

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

**Doping Control Officer (DCO):** An official who has been trained and authorized by the *Anti-Doping Organization* with delegated responsibility for the on-site management of a *Sample Collection Session*.

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

**International Federation (IF):** An international non-governmental organization administering one or more sports at world level.

**Sample Collection Authority:** The *Anti-Doping Organization* or independent agency or subcontractor with responsibility for all processes related to *Sample Collection*, as specified in Clauses 5.0, 6.0, 7.0, 8.0 and 9.0.

**Sample Collection Equipment:** Containers or apparatus used to directly collect or hold the *Sample* at any time during the *Sample Collection* process. *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*
  - Sealable and tamper-evident bottles and lids for securing the *Sample*;
  - Partial *Sample* kit

- For blood *Sample Collection*:
  - Needles for collecting the *Sample*
  - Blood tubes with sealable and tamper-evident devices for holding the *Sample*. 
**Sample Collection Personnel**: A collective term for qualified officials authorized by the Anti-Doping Organization who may 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 notification until the Athlete leaves the Doping Control Station after having provided his/her Sample/s.

**Test Distribution Plan**: As defined in Clause 4.2.1.
5.3. Further Defined Terms Specific to the ABP Operating Guidelines and Related Technical Documents

**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.

**Adverse Passport Finding (APF)**: A report from an Athlete Passport Management Unit that is the end result of the evaluation of the longitudinal profile of Markers, other Passport information (such as training and competition schedules), and Expert review that is inconsistent with a normal physiological condition or known pathology and compatible with the Use of a Prohibited Substance or Prohibited Method.

**Athlete Biological Passport (ABP)**: The program and methods of gathering and collating Passports as described in this document which include the Operating Guidelines and the Technical Documents (Appendices).

**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.

**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.

**Atypical Passport Finding (ATPF)**: A report generated by the Adaptive Model which 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 investigations and/or analysis.

**Confirmation Procedure**: An analytical test procedure whose purpose is to identify the presence or concentration of one or more specific Prohibited Substance,
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 may also indicate a quantity of Prohibited Substance greater than a threshold value and quantify the amount of a Prohibited Substance in a Sample.]

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.

Initial Testing Procedure (Screen 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 in excess of a defined threshold.

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

Laboratory Internal Chain of Custody: Documentation of the sequence of Persons in custody of the Sample and any Aliquot of the Sample taken for analytical Testing.

[Comment: Laboratory Internal Chain of Custody is generally documented by a written record of the date, location, action taken, and the individual performing an action with a Sample or Aliquot.]

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

**Testing Authority(ies):** The *Anti-Doping Organization* that has authorized a particular test from their *Test Distribution Plan*, as specified in *IST* Article 4.0. For example, the International Olympic Committee, *World Anti-Doping Agency*, *International Federation*, National Sport Organization, *National Anti-Doping Organization*, *National Olympic Committee*, *Major Event Organization*, or other authority defined by the *Code* responsible for planning and initiating *Sample Testing* either *In-Competition* or *Out-of-Competition*.

**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*. 
Part Three: Technical Documents Appendices

6.0 IST and ISL Passport Operation Requirements

Adoption of the following TDs (level two documents) is mandatory to comply with the requirements of the ABP.

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 – TD 2014 BSCR

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<th>TD 2014 BSCR</th>
<th>Version Number:</th>
<th>1.0</th>
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<td>Date:</td>
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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 (IST) 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. The best practice for Sample Collection set out in the WADA Guidelines for Blood Sample Collection should also be considered, although remains non-mandatory. In the event of any discrepancy between the requirements set out in this Appendix and those set out in the IST or Blood Sample Collection Guidelines, this Appendix shall prevail for Sample Collection related to the ABP.

3. Timing of the 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. **The Commencement of the Collection Process and the 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 *Sample*.

5. **Doping Control Documentation**

The DCO/BCO shall use the DCF related to the ABP, if such a form is available. If a DCF related to the ABP is not available, the DCO/BCO shall use a regular DCF 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:

a. Confirm that there was no training or *Competition* in the last two hours before the blood test.

b. Did the *Athlete* train, compete or reside at an altitude greater than 1,000 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.

c. 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.

d. 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?
6. The Sample Collection Equipment

The DCO/BCO instructs the Athlete to select the Sample Collection Equipment in accordance with IST Article E.4.6. Vacutainer(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 Guidelines for Blood Sample Collection 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 IST Articles E.4.1 through E.4.15, with the additional elements:

a. The BCO ensures that the 10-minute (or more) time-out period has elapsed prior to performing venipuncture and drawing blood; and

b. The BCO ensures that the vacuum tubes were filled appropriately; and

c. 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 (3) times.

8. Post Venipuncture Procedure

a. The Athlete and the DCO/BCO sign the blood collection form(s).

b. The blood Sample is deposited and sealed in the Sample Collection container in accordance with the IST.
APPENDIX B: Blood Sample Transport Requirements for the Athlete Biological Passport

**WADA Technical Document – TD2014BSTR**

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<th>Version Number:</th>
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<td>Date:</td>
<td>TBD</td>
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<td>01.01.2014</td>
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1. **Objective**

This 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 ABP.

2. **Scope**

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

3. **Responsibility**

The IST 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 the Blood Sample Collection Requirements for the ABP, it shall be stored in accordance with IST Article 8 and the present protocol.

The storage procedure is the responsibility of the DCO.

5. Type of Storage Devices

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

a. Refrigerator.

b. Insulated cool box.

c. Isotherm bag.

d. 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 IST).

7. Transport Procedure

Blood Samples shall be transported in accordance with IST Article 9, consistent with the practices of the WADA Guidelines for Blood Sample Collection, and in conjunction with this protocol. The transport procedure is the responsibility of the DCO.
Samples shall be transported in a device that maintains the integrity of Samples over time, due to changes in external temperature.

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: The WADA Guidelines for Blood Sample Collection 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 – TD2014BAR

<table>
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<td>01.01.2014</td>
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1. Introduction

This TD has been established to harmonize the analysis of blood Samples collected, both In-Competition and Out-of-Competition, for the measurement of individual Athlete blood variables within the framework of the ABP.

The ISL is applicable to the analysis of blood Samples 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 Samples shall be analyzed in a Laboratory or WADA Approved Laboratory for the ABP. If not reasonably possible for technical and/or geographical reasons, blood Samples 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 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 shall be analyzed as soon as possible after its 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 Samples 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 Samples.

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 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 Laboratories 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 (7) consecutive times. Coefficients of variation shall be below 1.5% for haemoglobin and HCT and below 15% for percentage reticulocyte 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 the WADA External Quality Assessment Scheme (EQAS) for blood variables. The external quality controls shall be analyzed seven (7) times consecutively, and then the mean results of the following blood variables (full blood count) shall be returned:

<table>
<thead>
<tr>
<th>Blood Variable</th>
<th>Abbr.</th>
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<tbody>
<tr>
<td>Red Blood Cell (Erythrocyte) Count</td>
<td>RBC</td>
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<tr>
<td>Mean Corpuscular Volume</td>
<td>MCV</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>HCT</td>
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<tr>
<td>Haemoglobin</td>
<td>HGB</td>
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<tr>
<td>Mean Corpuscular Haemoglobin</td>
<td>MCH</td>
</tr>
<tr>
<td>Mean Corpuscular Haemoglobin Concentration</td>
<td>MCHC</td>
</tr>
<tr>
<td>White Blood Cell (Leukocyte) Count</td>
<td>WBC</td>
</tr>
<tr>
<td>Platelet (Thrombocyte) Count</td>
<td>PLT</td>
</tr>
<tr>
<td>Reticulocytes Percentage</td>
<td>%RETI</td>
</tr>
</tbody>
</table>

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 *Samples* 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.

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 % Reti analysis (if first measurement lower or equal to 1.00%); and
- 0.25 absolute difference for % Reti 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 **WADA Accredited** 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 – TD 2014 EAAS

<table>
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<td>Written by:</td>
<td>WADA Laboratory Expert Group</td>
<td>Approved by:</td>
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<tr>
<td>Date:</td>
<td>11 September 2013</td>
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1. Introduction

The purpose of this Technical Document 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 target Testing of the Athlete on a longitudinal basis. 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 aims to estimate the “steroid profile” in the Athlete’s Sample. A subsequent Confirmation Procedure is performed when the estimated “steroid profile” represents an ATPF. The Confirmation Procedure includes the quantification of the Markers of the “steroid profile” as described in this Technical Document as well as Gas Chromatography – Combustion - Isotope Ratio Mass Spectrometry (GC-C-IRMS) analysis which is considered in a separate Technical Document.

1.1 The “Steroid Profile”
Each urine Sample shall be analyzed to determine its “steroid profile”.

For the purposes of this Technical Document, 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 on hydrolysis by glucuronidase):

- Testosterone (T),
- Epitestosterone (E),
- Androsterone (A),
- Etioclanolone (Etio),
- $5\alpha$-androstane-3\(\alpha\),17\(\beta\)-dil (5\(\alpha\)Adiol),
- $5\beta$-androstane-3\(\alpha\),17\(\beta\)-dil (5\(\beta\)Adiol), and
- The ratio of Testosterone to Epitestosterone (T/E).

Other urinary steroids or ratios of steroid metabolites could be useful in evaluating a “steroid profile” (e.g. A/T, A/Etio, 5\(\alpha\)Adiol/5\(\beta\)Adiol, 5\(\alpha\)Adiol/E ¹).

The administration of EAAS can alter one or more of the Markers and/or ratios of the urinary “steroid profile”, resulting in increased or decreased concentrations and/or ratios of specific pairs of steroid metabolites. Additionally, alteration of the urinary “steroid profile” can occur for a number of reasons including, but not limited to:

- A large intake of alcohol (ethanol).
- The administration of ketoconazole, human chorionic gonadotrophin (hCG) in males or of other anabolic steroids (e.g. stanozolol).
- The administration of inhibitors of 5\(\alpha\)-reductase (e.g. finasteride).
- The use of masking agents (e.g. probenecid) and diuretics.
- Microbial growth.

2. Initial Testing Procedure

In the Initial Testing Procedure, the Laboratory shall use a method validated in urine that is appropriate for estimating the Markers of the “steroid profile” in the range of values determined in males and females.

¹ In ADAMS, the values of these four ratios are computed after the reporting of the “steroid profile” by the Laboratory.
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 standards should be analyzed periodically, and whenever a significant change is made to the analytical setup.
- A urine quality control (QC) sample containing representative levels of the analytes 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 verified with isotopically labeled A-glucuronide (or an equivalent scientifically recognized alternative).
- The completeness of the derivatization shall be verified through the monitoring of mono-O-TMS vs. di-O-TMS derivative of A.
- When needed, the volume\(^2\) of the Sample Aliquot may be adjusted as a function of its specific gravity (SG) and of the gender of the Athlete.
- The T/E ratios shall be determined from the ratios of the corrected chromatographic peak areas or peak heights\(^3\).
- The linearity of the method, established during method validation, shall cover the ranges of values normally found in males and females - the limit of quantification (LOQ) for T and E shall not be higher than 2 ng/mL\(^4\).

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2 Much lower levels of T and E are generally present in female Samples and in those Samples with low SG; therefore, larger Aliquot volumes may be required for a reliable measurement.

3 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).

4 The LOQ shall be determined as the lowest concentration that can be measured with the uncertainty criteria established for the given Marker of the “steroid profile” when applying the Initial Testing Procedure.

The LOQ for T, E, A, Eto, 5αAdiol and 5βAdiol shall be reported once in ADAMS by the Laboratory. The LOQ values shall be updated in ADAMS whenever a significant change is made to the analytical method.
• The relative standard combined uncertainty \( [u_c(\%)] \) for the determination of A, Etio, 5\( \alpha \)-Adiol, 5\( \beta \)-Adiol, T and E, as estimated during method validation of the Initial Testing Procedure, shall be not higher than 30\% at the respective LOQ;

For concentration values at five times the LOQ, the \( u_c(\%) \) shall be not higher 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 higher 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 higher than 5 ng/mL; for lower concentrations of T and E, the \( u_c(\%) \) for the T/E determinations shall not exceed 30\%.

• Evidence of microbial degradation (e.g. presence of 5\( \alpha \)- and 5\( \beta \)-androstanedione or 4-androstenedione) and the presence of 5\( \alpha \)-reductase inhibitors (e.g. finasteride) shall be monitored.

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

The Laboratory shall report in ADAMS the T/E ratio, the concentrations of T, E, A, Etio, 5\( \alpha \)-Adiol and 5\( \beta \)-Adiol, the SG and the validity of the Sample, as determined in the Initial Testing Procedure.

The “steroid profile” shall be reported in ADAMS as follows:

• The concentrations of T, E, A, Etio, 5\( \alpha \)-Adiol and 5\( \beta \)-Adiol shall be reported without adjustment for the SG of the Sample and to 2 significant figures (e.g. T = 5.2; 52; 520) \(^5\).

• The T/E shall be reported to 2 significant figures (e.g. T/E = 0.12; 1.2; 12). The validity of the Sample shall be reported in ADAMS as “yes” or “no”.

• A Sample showing signs of microbial degradation or containing any of the substances\(^6\) that may cause an alteration of the “steroid profile”, as described in Section 1.0 above, may not be suitable for inclusion in the “longitudinal steroid profile”. In such cases the validity of the “steroid profile” shall be reported in ADAMS as “no” and an explanation shall be included in the Test Report in ADAMS.

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\(^5\) Any concentration measured below the LOQ shall be reported as -1 by the Laboratory.

\(^6\) It is not mandatory that the Laboratory tests for the presence of ethanol metabolite(s) or ketoconazole during the Initial Testing Procedure.
• 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 a modified, validated Sample preparation and analysis (e.g. solid phase extraction, extraction with a different solvent or other equivalent procedure). However, when the problem cannot be resolved, the negatively impacted variable(s) of the “steroid profile” shall be reported as “-1”, the validity as “no”, and a comment shall be included in the Test Report in ADAMS stating that the Marker(s) could not be measured reliably.

The Laboratory may recommend in the Test Report in ADAMS that a Sample be submitted to confirmation analyses by GC-C-IRMS.

3. Confirmation Procedure

Confirmation Procedures for the exogenous administration of EAAS include the GC-MS or GC-MS/MS quantification and GC-C-IRMS analyses of the relevant Marker(s) of the “steroid profile”. GC-C-IRMS analyses are considered in a separate Technical Document.

• The Laboratory shall confirm the relevant “steroid profile” Marker(s) or ratio (e.g. the T/E ratio) measured in the Initial Testing Procedure when, upon reporting the results in ADAMS and following the application of the Adaptive Model of the ABP to the “longitudinal steroid profile” of the Athlete, the Laboratory is informed through ADAMS of an ATPF.

• In the case when the “longitudinal steroid profile” of the Sample cannot be processed by the Adaptive Model in ADAMS, the Laboratory shall proceed with the Confirmation Procedure(s) when one of the following criteria is met:
  o T/E ratio (calculated from the corrected chromatographic peak areas or heights) greater than 4.0.
  o Concentration of T or E (adjusted for the SG) greater than 200 ng/mL in males or greater than 50 ng/mL in females.

---

7 If the “steroid profile” of the Sample cannot be processed by the Adaptive Model in ADAMS, the Laboratory shall receive an automatic notification from ADAMS 14 calendar days after Sample reception. The Laboratory shall proceed with the Confirmation Procedure(s) unless, after contacting the Testing Authority, the Testing Authority can justify that the Confirmation Procedure(s) is not necessary.

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

\[
Conc_{corr} = Conc_{measured} \times \frac{(1.020 - 1)}{(SG - 1)}
\]
Concentration of A or Etio (adjusted for the SG\textsuperscript{9}) greater than 10,000 ng/mL combined with ratio of A/Etio lower than 0.4 in males (in the absence of inhibitors of 5\(\alpha\)-reductase) or greater than 4 in either sex.

3.1  \textit{GC-MS or GC-MS/MS quantification Confirmation Procedure}\n
The Laboratory shall identify (in compliance with the TDIDCR [1])\textsuperscript{9} and quantify the relevant Markers of an ATPF in one additional Sample Aliquot by a validated fit-for-purpose GC-MS or GC-MS/MS quantification method.

- If GC-C-IRMS analysis has been performed with negative or inconclusive results, the Laboratory shall confirm the T/E ratio only.
- In cases when the GC-C-IRMS analysis demonstrates the exogenous administration of EAAS, the Laboratory shall confirm the relevant variable(s) of the “steroid profile”. When the exogenous administration involves T, only the T/E ratio shall be confirmed.

During the Confirmation Procedure, the presence of conjugated metabolite(s) of ethanol or ketoconazole shall be determined as well as the signs of microbial degradation including, for example, the presence of the free forms of T, 5\(\alpha\)- and 5\(\beta\)-androstanedione, 4-androstenedione, or DHEA.

3.1.1  \textit{Method Characteristics for GC-MS or GC-MS/MS quantification Confirmation Procedure}\n
The same analytical requirements presented in 2.1 apply, with the following modifications:

- Calibration standards and urine QC samples shall be included;
- The \(u_c(\%)\) shall be not higher than 15\% for determinations of A, Etio, 5\(\alpha\)Adiol and 5\(\beta\)Adiol at concentrations representing five times the respective LOQ;
- For determinations of T, E and T/E ratios, the \(u_c(\%)\) shall be not higher than 15\% when the concentrations of T and E are higher than 5 ng/mL.

3.1.2 \textit{Reporting Results from the GC-MS or GC-MS/MS Confirmation Procedures}\n
The Laboratory shall report in ADAMS the confirmed values of the “steroid profile” (without adjustment for the SG of the Sample), the associated \(u_c\) expressed in units and the SG of the Sample.

\textsuperscript{9} For T/E values, only T needs to be identified if the concentration level and volume of the Sample are sufficient.
The presence of signs of microbial degradation, of conjugated metabolite(s) of ethanol, of inhibitors of 5α-reductase, or of any other substances that might have altered the “steroid profile” shall be reported.

4. References


APPENDIX E: Results Management Requirements for the Athlete Biological Passport

WADA Technical Document – TD 2014 RMR

<table>
<thead>
<tr>
<th>Document Number:</th>
<th>TD 2014 RMR</th>
<th>Version Number:</th>
<th>1.0</th>
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<tr>
<td>Written by:</td>
<td>WADA</td>
<td>Approved by:</td>
<td>WADA Executive Committee</td>
</tr>
<tr>
<td>Date:</td>
<td>TBD</td>
<td>Effective Date:</td>
<td>01.01.2014</td>
</tr>
</tbody>
</table>

1. Administrative management

These processes may be administered and managed by an APMU on behalf of or within an 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 and the Expert reviews shall be conducted in ADAMS.

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. An Expert then 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 ISL and TDs. The Athlete or other Person may rebut this presumption by establishing that a departure from the ISL and Technical Documents 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

The Adaptive Model is capable of identifying atypical values or profiles that warrant 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).

Hematological data is considered as atypical if a HGB and/or OFFS value falls outside the expected intra-individual ranges. Similarly, a longitudinal profile composed of HGB and/or OFFS values is considered as atypical when deviating from the expected ranges, as determined by the Adaptive Model.

Steroidal data is considered as atypical if it returns a T/E value outside the expected intra-individual ranges. Similarly, a longitudinal profile composed of T/E values 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 steroidal data, an ATPF will trigger a Confirmation Procedure as established in TD2014EAAS.

If the longitudinal “profile” consists of a unique haematological value (Athlete tested only once), and this unique value is deemed atypical by the Adaptive Model, the ADO may collect an additional Sample before sending it to a member of the Expert Panel for review. The APMU should suggest the optimal timing of the subsequent Sample.

If the longitudinal “profile” consists of a unique steroidal value (Athlete tested only once), and this unique value is deemed atypical as the T/E value was greater than 4:1, the TD2014EAAS shall apply, and Confirmation Procedures (e.g. IRMS analysis) be conducted. If the IRMS analysis is inconclusive, the ADO shall collect additional Sample(s) to establish a longitudinal profile that can be processed by the Adaptive Model and subsequently reviewed by the APMU, as appropriate.

[Comment: If there is a departure from WADA ABP requirements for collection, transport and analysis, the corresponding result should not be considered in the Adaptive Model calculations. However, the non-conforming biological result should be included (whenever possible) in the Athlete’s Passport for reference and targeting 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, the Sample will undergo Confirmation Procedures including IRMS analysis. If negative, then the APMU/ADO should do further testing and/or seek an Expert review. If the Haematological Module renders an ATPF, then the results/profile must be reviewed by an Expert chosen by the APMU or manager of the ADO. 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:

<table>
<thead>
<tr>
<th>Expert Evaluation</th>
<th>APMU Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal.</td>
<td>Continue normal Testing pattern.</td>
</tr>
<tr>
<td>Passport suspicious: Further data is required.</td>
<td>Alert ADO to do Target Testing and provide recommendations.</td>
</tr>
<tr>
<td>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.</td>
<td>Send to two other Experts, as per section 4 of this Appendix.</td>
</tr>
<tr>
<td>Considering the information within the Passport, it is highly likely that the Athlete has a pathological condition.</td>
<td>Inform the Athlete via the ADO (or send to other Experts).</td>
</tr>
</tbody>
</table>

[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 Substances or Methods. The Experts, via the APMU, will contact the Athlete, via the ADO, if there is a high likelihood of pathology. Nevertheless, 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 reviewed by a group of three Experts, 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 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 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 group of three Experts must follow the same logic as presented in section 3 of this document. The group of three Experts can confer before they finalize their opinion. The group of three Experts 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 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 pursue additional Testing.
5. **Follow up on the Expert reviews and the 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 it 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:

a. Age of the Athlete.

b. Gender of the Athlete.

c. Sport and discipline.

d. Type of test.

e. Sample code number.

f. Internal Laboratory (or WADA Approved Laboratory for the ABP) number.

g. Biological data and results obtained by the Adaptive Model.

h. Competition information.

i. Chain of Custody documentation.

j. Information from the DCFs for each Sample collected during the period, as determined by the APMU and Expert Panel.
For the Haematological Module, this additional information is required:

a. Information on possible exposure to altitude of the Athlete for the period defined by the Expert Panel.

b. Temperature conditions during the transport of the blood Samples.

c. Laboratory (or WADA Approved Laboratory for the ABP) documentation, including blood results.

d. Scatter grams.

e. Internal and external quality controls.

f. Information if 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:

a. pH.

b. Specific gravity.

c. Laboratory documentation, including screening and confirmed (when applicable) values of steroid concentrations and ratios.

d. IRMS results, when applicable.

e. Indications of ethanol consumption: urinary concentrations of ethanol and/or ethanol metabolites.

f. Indications of bacterial activities (e.g. A/5α-androstandione, pH, fraction of free forms of Testosterone, 5α- and 5β-androstanedione, 4-androstenedione).

g. Indications of medications taken (declared or detected) that may influence the steroidal profile, such as corticosteroids, 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, 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 APF. The ABP Documentation Package is then reviewed by the ADO.

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 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:

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

b. 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) above, then the ADO shall be informed by the APMU. The ADO will then proceed to results management in accordance with Code Article 7.4.

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 Method resulted in a manipulation of the haematological or steroidal Markers, respectively. In such instances, the Athlete’s Profile(s) would be reset from the time of the beginning of the sanction.
6.1 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. NADO and IF).

APPENDIX F: Collaboration Agreement

Between

[*]

(hereinafter referred to as “[A]”)

and

[*]

(Hereinafter referred to as “[B]”)

WHEREAS [A] is the [anti-doping organization] recognized by the World Anti-Doping Agency (WADA) and is responsible for Doping Control and Athlete Biological Passport programs for Athletes included in its Registered Testing Pool (RTP);

WHEREAS [B] is the [anti-doping organization] recognized by WADA and is responsible for Doping Control and Athlete Biological Passport programs for Athletes included in its RTP;

WHEREAS the principle of the Athlete Biological Passport 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 Athlete Biological Passport 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 (the “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 Operating Guidelines and related technical documents.

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 Athlete Biological Passport Operating Guidelines adopted by WADA and available on the WADA website.

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] RTPs 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 The APMU of [A], respectively [B], is responsible for managing the Athlete Biological Passport program of [A], respectively [B], in accordance with the Operating Guidelines. For Athletes included in [A] and [B] RTPs, [A] and [B] shall determine if the relevant Passports are reviewed after each test by either [A] APMU, respectively [B] APMU depending who is the Testing Authority for this test or on a Passport basis where it is agreed that [A] APMU or [B] APMU is in charge to review all data in the Passport independently if [A] or [B] is the Testing Authority that conducted the last test.

3.2 In the event that the Adaptive Model identifies an atypical result in Athletes who are included in both [A] and [B] RTPs, the APMU in charge of reviewing the relevant Passport shall inform both [A] and [B].

3.3 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.

3.4 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.

3.5 For the avoidance of doubt, Passports collected under this Agreement by [A] and [B] should, whenever possible, be combined for the purposes of pursuing a potential Anti-Doping Rule Violation 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 anti-doping rule violation.

4.2 Where the Party with responsibility for the results management of an Athlete’s case as set out above decides not to proceed with an asserted anti-doping rule violation, 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 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 World Anti Doping 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 WADA’s Anti-Doping Administration and Management System (“ADAMS”)” that the Parties entered into with WADA.

Clause 7 - Indemnity

1. 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 (ISPPI).

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 Section 7.2.

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]:

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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 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.
SCHEDULE 1

Definitions

1. Definitions from the 2009 World Anti-Doping Code

Anti-Doping Administration and Management System (ADAMS): The secure, online 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.

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 participates in sport at the international level (as defined by each International Federation), the national level (as defined by each National Anti-Doping Organization, including but not limited to, those Persons in its Registered Testing Pool), and any other competitor in sport who is otherwise subject to the jurisdiction of any Signatory or other sports organization accepting the Code. All provisions of the Code, including, for example, Testing and Therapeutic Use Exemptions must be applied to International- and National-Level Athletes. Some
National Anti-Doping Organizations may elect to test and apply anti-doping rules to recreational-level or masters-level competitors who are not current or potential national-calibre competitors. National Anti-Doping Organizations are not required, however, to apply all aspects of the Code to such Persons. Specific national rules may be established for Doping Control for non-International-Level or non-National-Level Athletes without being in conflict with the Code. Thus, a country could elect to test recreational-level competitors, but not require Therapeutic Use Exemptions or whereabouts information.

Similarly, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not require advance Therapeutic Use Exemptions or whereabouts information. For purposes of Code Article 2.8 (Administration or Attempted Administration) 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: 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. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all Persons on national teams and all Persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes must be included in a National Anti-Doping Organization’s Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-calibre Athletes to competitors at lower levels of Competition. Competitors at all levels of Competition should receive the benefit of anti-doping information and education.]

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, Therapeutic Use Exemptions, results management and hearings.

Registered Testing Pool: The pool of top-level Athletes established separately by each International Federation and National Anti-Doping Organization who are subject to both In-Competition and Out-of-Competition Testing as part of that International Federation’s or National Anti-Doping Organization’s test distribution plan. Each International Federation shall publish a list which identifies those Athletes included in its Registered Testing Pool either by name or by clearly defined, specific criteria.

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*.

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

**Prohibited Substance:** Any Substance so described on the Prohibited List.

**Target Testing:** Selection of *Athletes* for *Testing*, where specific *Athletes* or groups of *Athletes* are selected on a non-random basis for *Testing* at a specified time.

### 2. Definitions from the International Standard for the Protection of Data and Privacy

**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. Definitions from the International Standard for Laboratories

**Athlete Biological Passport:** The program and methods of gathering and collating Passports as described in this document which include the Operating Guidelines and the Technical Documents (Appendices).

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

**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*.

**Testing Authority(ies):** The *Anti-Doping Organization* that has authorized a particular test from their Test Distribution Plan, as specified in IST Article 4.0. For example, the International Olympic Committee, World Anti-Doping Agency,
International Federation, National Sport Organization, National Anti-Doping Organization, National Olympic Committee, Major Event Organization, or other authority defined by the Code responsible for planning and initiating Sample Testing either In-Competition or Out-of-Competition.