Athlete Biological Passport

Operating Guidelines

& Compilation of Required Elements

Version 5.0

October 2014
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Part One: Introduction, Objective and Scope

1.0 Introduction to the Athlete Biological Passport

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

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

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

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

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

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

1.1 Objective

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

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

   i) For the Haematological Module, this could be for Erythropoiesis- Stimulating Agents (ESAs) or homologous blood transfusion (HBT).
ii) For the Steroidal Module, this could be the use of Gas Chromatography-Combustion-Isotope Ratio Mass Spectrometry (GC-C-IRMS) to detect exogenous steroids.

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

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

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

1.2 Scope

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

   a. Use biological data for intelligent Target Testing and

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

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

This document is divided into three parts.

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

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

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

These TDs set out the minimum requirements for Sample collection, Sample transport, Sample analysis, and results management.
Included as appendices for ease of reference, they should be considered International Standard for Testing and Investigations (ISTI) and International Standard for Laboratories (ISL) TDs. Some TDs are intended for a more specific audience, e.g. the TD2014EAAS for Laboratory personnel.

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

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

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

1.3 Definitions

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

Definitions are provided in Guidelines Section 5.0.

Part Two: Modules, Management and Administration

2.0 ABP Haematological and Steroidal Modules

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

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

The following markers are considered within the ABP Haematological Module:

- **HCT**: Haematocrit
- **HGB**: Haemoglobin
- **RBC**: Red blood cell (erythrocyte) count
- **RET%**: Reticulocytes percentage
- **RET#**: Reticulocyte count
- **MCV**: Mean corpuscular volume
- **MCH**: Mean corpuscular haemoglobin
- **MCHC**: Mean corpuscular haemoglobin concentration
- **RDW-SD**: Red cell distribution width (standard deviation)
- **IRF**: Immature reticulocyte fraction

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

2.2 Steroidal Markers

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

The following markers are considered within the ABP Steroidal Module (the “steroid profile”), as detailed in TD2014EAAS (Appendix D):

- **T/E**: Testosterone/Epitestosterone ratio
- **T**: Testosterone
- **E**: Epitestosterone

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A: Androsterone  
Etio: Etiocholanolone  
5αAdiol: 5α-androstane-3α,17β-diol  
5βAdiol: 5β-androstane-3α,17β-diol

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

2.3 Testing and Defining the Target Population

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

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

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

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

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

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

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

3.0 ABP Partner Roles and Responsibilities

3.1 Objective

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

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

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

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

3.3 Specific Partner Responsibilities

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

3.3.1 Anti-Doping Organization

The ADO is responsible for:

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

The [APMU](#) is responsible for:

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

3.3.3 **Laboratory**

The [WADA](#)-accredited [Laboratory](#) or [WADA-Approved Laboratory](#) for the [ABP](#) is responsible for:

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

3.3.4 **Expert Panel**

The [Expert Panel](#) is responsible for:

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

### 3.3.5 World Anti-Doping Agency

**WADA** is responsible for:

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

### 4.0 ABP Administration

#### 4.1 Objective

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

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

#### 4.2 Recommended Administrative Sequence

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

The recommended sequence outlined below may be modified or adapted to merge with existing anti-doping infrastructure, procedures and mechanisms as required. However these Guidelines suggest *ADOs* establish a process that ensures transparency and, ideally, independence between the planning, interpretation and results management aspects of an *ABP*. 
To create a framework for such independence, the sequence set out herein includes the incorporation of an APMU that would be the central hub connecting Laboratory- or WADA-Approved Laboratories for the ABP-generated biological data with active test planning advice and intelligence. This APMU may be associated with a Laboratory’s operations, or be managed under the responsibility of an ADO. The key element of an APMU is that it requires a Person or Persons to manage the Passport, including requesting further Testing, seeking Expert input and coordinating communication.

### 4.3 ABP Administrative Sequence Graphic

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

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

3. **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.

4. **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.

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

6. **Transport of Sample**
   - For blood ABP Samples, the Sample Collection Personnel ensure transport to a Laboratory or WADA-Approved Laboratory for the ABP, in accordance with Appendix B. Urine Samples should be rapidly transported to a Laboratory, with minimal exposure to high temperature.
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.

**ADOs should make all efforts to ensure that Doping Control forms are entered into ADAMS without delay. The use of paperless Doping Control procedures will expedite this process.**
To provide Experts with a more balanced view of the longitudinal profiles of the Athlete population, the APMU should regularly provide a random set of profiles to the Experts, and not solely those deemed atypical by the Adaptive Model.

4.4 Passport Custodianship and Sharing

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

Within the framework provided by the ISPPPI, ADOs are encouraged to coordinate their activities where multiple ADOs have Testing jurisdiction over a single Athlete and multiple 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 with all results collated in a unique Athlete's Passport. Any individual Athlete shall have a Passport Custodian that ensures that all ADOs that have Testing jurisdiction over the Athlete do not work in isolation.

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

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

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

* Custodianships existing before August 2014 remain unaffected, to preserve existing sharing arrangements between ADOs.
** When the Athlete is first tested by a Major Event Organizer (MEO), Passport custody is attributed to the IF. When a NADO first tests an Athlete with a different sport nationality, Passport custody is attributed to the IF. This can later be reassigned to another NADO if appropriate.
*** If no agreement can be found on the Passport custodianship, WADA shall determine which ADO is the Athlete’s Passport Custodian. WADA shall not rule on this without consulting the ADOs involved.
5.0 Definitions

5.1 2015 Code Defined Terms

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

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

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

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

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

**Athlete:** Any **Person** who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each **National Anti-Doping Organization**). An **Anti-Doping Organization** has discretion to apply anti-doping rules to an **Athlete** who is neither an **International-Level Athlete** nor a **National-Level Athlete**, and thus to bring them within the definition of “Athlete.” In relation to **Athletes** who are neither **International-Level** nor **National-Level Athletes**, an **Anti-Doping Organization** may elect to: conduct limited **Testing** or no **Testing** at all; analyze **Samples** for less than the full menu of **Prohibited Substances**; require limited or no whereabouts information; or not require advance **TUEs**. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any **Athlete** over whom an **Anti-Doping Organization** has authority who competes below the international or...
national level, then the Consequences set forth in the Code (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any Person who participates in sport under the authority of any Signatory, government, or other sports organization accepting the Code is an Athlete.

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

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

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

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

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

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

**Competition:** A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a Competition and an Event will be as provided in the rules of the applicable International Federation.
Consequences of Anti-Doping Rule Violations (Consequences): An Athlete’s or other Person’s violation of an anti-doping rule may result in one or more of the following: (a) Disqualification means the Athlete’s results in a particular Competition or Event are invalidated, with all resulting Consequences including forfeiture of any medals, points and prizes; (b) Ineligibility means the Athlete or other Person is barred on account of an anti-doping rule violation for a specified period of time from participating in any Competition or other activity or funding as provided in Article 10.12.1; (c) Provisional Suspension means the Athlete or other Person is barred temporarily from participating in any Competition or activity prior to the final decision at a hearing conducted under Article 8; (d) Financial Consequences means a financial sanction imposed for an anti-doping rule violation or to recover costs associated with an anti-doping rule violation; and (e) Public Disclosure or Public Reporting means the dissemination or distribution of information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with Article 14. Teams in Team Sports may also be subject to Consequences as provided in Article 11.

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

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

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

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

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

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

[Comment to International-Level Athlete: Consistent with the International Standard for Testing and Investigations, the International Federation is free to determine the criteria it will use to classify Athletes as International-Level Athletes, e.g., by ranking, by participation in particular International Events, by type of license, etc. However, it
must publish those criteria in clear and concise form, so that Athletes are able to ascertain quickly and easily when they will become classified as International-Level Athletes. For example, if the criteria include participation in certain International Events, then the International Federation must publish a list of those International Events.]

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

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

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

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

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

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

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

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

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

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

**Prohibited List:** The List identifying the Prohibited Substances and Prohibited Methods.
**Prohibited Method**: Any method so described on the Prohibited List.

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

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

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

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

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


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

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

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

### 5.2 ISTI Defined Terms

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

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

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

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

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

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

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

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

- For blood *Sample* collection:
  - Needles for collecting the *Sample*;
  - Blood tubes with sealable and tamper-evident devices for storing and transporting the *Sample* securely.

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

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

**Test Distribution Plan (TDP):** A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has *Testing Authority*, in accordance with
the requirements of Article 4 of the International Standard for Testing and Investigations.

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

### 5.3 **ABP Operating Guidelines and Related TDs Defined Terms**

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

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

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

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

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

**Results Management:** Pre-hearing administration of potential anti-doping rule violations.
5.4 ISL Defined Terms

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

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

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

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

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

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

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

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

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

**WADA-Approved Laboratory for the ABP**: Laboratory(ies) not otherwise accredited by *WADA*; applying test methods and processes in support of an *Athlete*
Biological Passport program and in accordance with the criteria for approval of non-accredited laboratories for the Athlete Biological Passport.

5.5 ISPPPI Defined Terms

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

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

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

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

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

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

ISTI and ISL *Passport* Operation Requirements

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

All TDs identified herein are found in the relevant *International Standards* documentation, but are included in these Appendices for ease of reference. The requirements of these Appendices are applicable to the *ABP* only, and are not applicable to blood collected for any other *Doping Control* purpose.
APPENDIX A: Blood Sample Collection Requirements for the Athlete Biological Passport

WADA Technical Document – TD2015BSCR

<table>
<thead>
<tr>
<th>Document Number:</th>
<th>TD2015BSCR</th>
<th>Version Number:</th>
<th>1.0</th>
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<tr>
<td>Written by:</td>
<td>WADA</td>
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<tr>
<td>Date:</td>
<td>20 September 2014</td>
<td>Effective Date:</td>
<td>01 January 2015</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 and Investigations (ISTI) is applicable to the collection of blood Samples carried out in connection with the measurement of individual Athlete blood variables within the framework of the ABP. This Appendix describes additional requirements for blood storage and transport related to the ABP. WADA’s Blood Sample Collection Guidelines should also be considered for best practices moving forward. In the case of any discrepancy between the requirements set out in this Appendix and those set out in the ISTI or Blood Sample Collection Guidelines, this Appendix shall prevail for Sample collection related to the ABP.

3. Timing of Sample Collection

If collection occurs after training or Competition, test planning shall consider the Athlete’s whereabouts information to ensure Testing does not occur within two hours of such activity. If the Athlete has trained or competed less than two hours before the time the Athlete has been notified of his/her selection, the DCO, BCO or other Sample Collection Personnel shall chaperone the Athlete until this two-hour period has elapsed. If for some reason, the Sample was taken within two hours of training or Competition, the nature, duration and intensity of the exertion shall be recorded by the DCO to make this information available to the APMU and subsequently, to Experts.
4. **Commencement of the Sample Collection Session and 10-Minute Time-out**

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

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

5. **Doping Control Documentation**

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

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

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

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

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

7. **The Sample Collection Procedure**

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

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

8. **Post-Venipuncture Procedure**

- The Athlete and the DCO/BCO sign the blood collection form(s).
- The blood *Sample* is deposited and sealed in the *Sample* collection container in accordance with the ISTI.
APPENDIX B: Blood Sample Transport Requirements for the Athlete Biological Passport

WADA Technical Document – TD2015BSTR

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<td>01 January 2015</td>
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</table>

1. Objective

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

2. Scope

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

3. Responsibility

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

4. Storage

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

Storage procedure is the DCO’s responsibility.
5. **Type of Storage Devices**

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

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

6. **Capabilities of the Storage Device**

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

6.1 **Security of the Storage Device**

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

7. **Transport Procedure**

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

The transport procedure is the **DCO**’s responsibility.

7.1 **Security of the Transport Device**

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

7.2 **Remarks Concerning the Storage and Transport Procedure**

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

*Comment: WADA’s Blood Sample Collection Guidelines reflect these protocols and include practical information on the integration of ABP Testing into “traditional”*
Testing activities. A table has been included that identifies which particular timelines for delivery are appropriate when combining particular test types (i.e. ABP + hGH, ABP + HBT, etc.), and which types of Samples may be suited for simultaneous transport.
APPENDIX C: Blood Analytical Requirements for the Athlete Biological Passport

WADA Technical Document – TD2015BAR

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<td>20 September 2014</td>
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</table>

1. Introduction

This Technical Document (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 Athlete Biological Passport (ABP).

The International Standard for Laboratories (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 Sample collection and the analysis; the temperature of the Sample during that period; or any other deviation from collection or transportation requirements.
2. Timing

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

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

To standardize analytical results in the ABP framework, it is important to have blood 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 the manufacturer’s specifications.

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

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

At least one internal quality control from the manufacturer (either level 1, 2 or 3) shall be conducted after every 30 to 50 blood Sample analyses. Once a day, and after all blood Sample analyses are completed, one internal quality control (either level 1, 2 or
3) shall be analyzed once again to demonstrate continuous stability of the instrument and the quality of the analyses done.

4. **External Quality Assessment Scheme**

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

<table>
<thead>
<tr>
<th>Blood Variable</th>
<th>Abbreviation</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>
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<tr>
<td>Haematocrit</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>
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<tr>
<td>Mean Corpuscular Haemoglobin Concentration</td>
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<td>White Blood Cell (Leukocyte) Count</td>
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<tr>
<td>Platelet (Thrombocyte) Count</td>
<td>PLT</td>
</tr>
<tr>
<td>Reticulocytes Percentage</td>
<td>RET%</td>
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</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 consecutively.

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

- 0.1 g/dL for HGB analysis;
- 0.15 absolute difference for RET% analysis (if first measurement lower or equal to 1.00%); and
- 0.25 absolute difference for RET% analysis (if first measurement higher than 1.00%).
The data from the second injection is used to confirm the first injection data. Therefore, if the absolute differences between the results of the analyses are within the criteria above, then only the first injection data is reported. If absolute differences between the results of the two analyses are greater than those defined above for a specific Sample, the analysis shall be started again in accordance with this section 5. The reason for repetition shall be documented.

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

6. Reporting

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

The purpose of this Technical Document (TD) is to harmonize the approaches to the measurement and reporting of endogenous anabolic androgenic steroids (EAAS) in urine, including data in support of the Steroidal Module of the Athlete Biological Passport (ABP) or “steroid profile.”

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

The Steroid Module 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” constitutes an ATPF, as determined by the Adaptive Model, or represents a suspicious “steroid profile” finding. The Confirmation Procedure includes the quantification of the Markers of the “steroid profile” as described in this TD and the Gas Chromatography – Combustion - Isotope Ratio Mass Spectrometry (GC-C-IRMS) analysis, which is considered in a separate TD, TDIRMS [1].
1.1 The “Steroid Profile”

Each urine Sample shall be analyzed to determine its “steroid profile.”

For the purposes of this TD, the “steroid profile” is composed of the following Markers (as free steroid content obtained from the free steroid fraction plus those released from the conjugated fraction on hydrolysis by glucuronidase):

- Testosterone (T),
- Epitestosterone (E),
- Androsterone (A),
- Etocholanolone (Etio),
- 5α-androstane-3α,17β-diol (5αAdiol),
- 5β-androstane-3α,17β-diol (5βAdiol), 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, 5αAdiol/5βAdiol, 5αAdiol/E).

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 5α-reductase (e.g. finasteride).
- The use of masking agents (e.g. probenecid) and diuretics.
- Microbial growth.

---

1 In ADAMS, the values of these four ratios are computed after the reporting of the “steroid profile” by the Laboratory.
2.0 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.

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

\(^2\) 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).
quantification (LOQ) for T and E shall not be higher than 2 ng/mL.4

- The relative standard combined uncertainty \([u_c(\%)]\) for the determination of A, Etio, 5αAdiol, 5βAdiol, T and E, as estimated during method validation of the Initial Testing Procedure, shall be not 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 or E, the \([u_c(\%)]\) for the T/E determinations shall not exceed 30%.

- Evidence of microbial degradation (e.g. presence of 5α- and 5β-androstane-dione or 4-androstenedione) and the presence of 5α-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, 5αAdiol and 5βAdiol (without adjustment for the SG of the Sample), the SG and the validity of the Sample, as determined in the Initial Testing Procedure.5, 6

The validity of the Sample shall be reported in ADAMS as “yes” or “no.”

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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, Etio, 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.

5 When reporting the “steroid profile” in ADAMS, the Laboratory shall report the values of concentrations for T, E, A, Etio, 5αAdiol and 5βAdiol, and the T/E ratio as measured (without correction for a specific number of significant figures).

However, an automatic correction of reported values to 2 significant figures will be made in ADAMS upon application of the Adaptive Model of the ABP to the “longitudinal steroid profile” of the Athlete.

6 Any concentration measured below the LOQ shall be reported as “-1” by the Laboratory.
• A Sample showing signs of microbial degradation or containing any of the substances\(^7\) 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.

• 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).
  
  - When (a) Marker(s) of the “steroid profile” cannot be measured accurately (i.e. below the LOQ of the assay), the concentration of the negatively impacted Marker(s) shall be reported as “-1”\(^6\). However, if the T/E ratio of the Sample can be determined from the ratios of the corrected chromatographic peak areas or peak heights, the “steroid profile” of the Sample shall be considered as valid and reported in ADAMS as “yes.”

  - When the T/E ratio cannot be determined from the ratios of the corrected chromatographic peak areas or peak heights, the T/E value shall be reported as “-1” and the validity of the Sample shall be reported as “no.” A comment shall be included in the Test Report in ADAMS stating that the T/E ratio 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.

3.0 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 TD, the TDIRMS [1].

“ATPF Confirmation Procedure Request” Notification

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

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\(^7\) It is not mandatory that the Laboratory tests for the presence of ethanol metabolite(s) or ketoconazole during the Initial Testing Procedure.
in *ADAMS* and following the application of the *Adaptive Model* of the *ABP* to the “longitudinal steroid profile” of the *Athlete*, the *Laboratory* receives an automatic “*ATPF Confirmation Procedure Request*” notification through *ADAMS*.

The *Adaptive Model* will generate an *ATPF* notification when the following criteria are met:

i). The *Sample* is matched with a *Doping Control* form (DCF) in *ADAMS*, allowing the automatic inclusion of the *Sample’s* “steroid profile” in the *Athlete’s Steroidal Passport*,

ii). There is an already existing “longitudinal steroid profile” of the *Athlete* in *ADAMS*,

iii). The *Sample’s* T/E ratio is abnormal, as determined by the *Adaptive Model*, when compared with the previous longitudinal T/E values of the *Athlete*, and/or

iv). The *Sample’s* “steroid profile” meets any of the following two criteria:

- Concentration of T or E (adjusted for the SG<sup>8</sup>) greater than 200 ng/mL in males or greater than 50 ng/mL in females.
- Concentration of A or Etio (adjusted for the SG<sup>8</sup>) greater than 10,000 ng/mL combined with ratio of A/Etio lower than 0.4 in males or greater than 4 in either sex.

Following the performance of the confirmation analyses, the *Laboratory* shall update the *ADAMS* record for the *Sample* based on the results of the *Confirmation Procedure(s)* (refer to the TDIRMS [1]).

**“Suspicious Steroid Profile Confirmation Procedure Request” Notification**

The *Laboratory* will receive an automatic “Suspicious Steroid Profile Confirmation Procedure Request” notification through *ADAMS* if:

i). The *Sample* is matched with a *Doping Control* form in *ADAMS*, but there is no existing “longitudinal steroid profile” of the *Athlete* in *ADAMS*, or

ii). The *Sample* cannot be matched with a *Doping Control* form in *ADAMS* within 14 calendar days after the reception of the *Sample* by the *Laboratory*, and therefore the “steroid profile” of the *Sample* cannot be processed by the *Adaptive Model* in *ADAMS*, and

---

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

\[
\text{Conc}_{\text{corr}} = \text{Conc}_{\text{measured}} \times \frac{(1.020 - 1)}{(SG - 1)}
\]
iii). The Sample’s “steroid profile” meets any of the following three criteria:

- T/E ratio (calculated from the corrected chromatographic peak areas or heights) greater than 4.0.
- Concentration of T or E (adjusted for the SG\textsuperscript{8}) greater than 200 ng/mL in males or greater than 50 ng/mL in females.
- Concentration of A or Etio (adjusted for the SG\textsuperscript{8}) 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\textalpha-reductase) or greater than 4 in either sex.

- Upon reception of the “Suspicious Steroid Profile Confirmation Procedure Request” notification, the Laboratory shall proceed with the Confirmation Procedure(s) unless, after contacting the Testing Authority, the Testing Authority can justify within 7 calendar days that the Confirmation Procedure(s) is not necessary.

- If the Testing Authority justifies that confirmation is not necessary, the Laboratory shall update the ADAMS report for the Sample with a comment stating the Testing Authority considered that the Confirmation Procedure(s) were not necessary, and the explanation provided by the Testing Authority.

- If the Testing Authority cannot justify that confirmation is not necessary, the Laboratory shall proceed with the confirmation analyses and subsequently update the ADAMS record for the Sample based on the results of the Confirmation Procedure(s) (refer to the TDIRMS [1]).

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

The Laboratory shall identify (in compliance with the TDIDCR [2])\textsuperscript{9} and quantify the relevant Markers of an ATPF or a suspicious “steroid profile” finding 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 ketoconazoleshall be determined, and the signs of microbial degradation

\textsuperscript{9} For T/E values, only T needs to be identified if the concentration level and volume of the Sample are sufficient.
including, for example, the presence of the free forms of T, 5α- and 5β-androstanedione, 4-androstenedione, or DHEA, shall be determined.

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

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

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

3.1.2 Reporting Results From the GC-MS or GC-MS/MS Confirmation Procedures

The Laboratory shall report in ADAMS the confirmed values of the “steroid profile” (without adjustment for the SG of the Sample)$^{5,6}$, the associated $u_c$ expressed in units and the SG of the Sample.

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.

4.0 References


1. WADA Technical Document TDIRMS (current version): Detection of synthetic forms of Endogenous Anabolic Androgenic Steroids by GC-C-IRMS.
APPENDIX E:  Results Management Requirements for the
Athlete Biological Passport

WADA Technical Document – TD2015RMR

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<th>Version Number:</th>
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<td>WADA</td>
<td>Approved by:</td>
<td>WADA Executive Committee</td>
</tr>
<tr>
<td>Date:</td>
<td>20 September 2014</td>
<td>Effective Date:</td>
<td>01 January 2015</td>
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1.  Administrative Management

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

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

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

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

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

2. Review by the Adaptive Model

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).

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

For the Steroidal Module, an ATPF is generated when the value of the T/E ratio of the last test falls outside the expected intra-individual ranges. In addition, the “longitudinal steroid profile” composed of (up to) the last 20 valid values of the T/E ratio is considered as atypical when deviating from the expected ranges, as determined by the Adaptive Model. An ATPF is only generated by the Adaptive Model on values of the primary Marker T/E ratio.

A specificity of 99% is used to identify both haematological and steroidal ATPFs that warrant further investigation and/or results management. In the case of a “longitudinal steroidal profile,” an ATPF caused by an atypically high T/E value will trigger a Confirmation Procedure as established in the TD2014EAAS.

If the longitudinal profile consists of a unique value (Athlete tested only once), and this unique value is deemed atypical by the Adaptive Model (with a negative or inconclusive IRMS if applicable, see TD2014EAAS for details on the management of Confirmation Procedures and IRMS analyses in case of a first test result), the ADO should consider collecting 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.

[Comment: If there is a departure from WADA ABP requirements for collection, transport and analysis of Samples, the corresponding result should not be considered in the Adaptive Model calculations. However, the non-conforming biological result should remain in the Athlete’s Passport and may be used for reference and Target Testing purposes. Any non-conforming result (e.g. a blood result analyzed after 48 hours) may be included in the Expert Panel assessment of a profile provided, if the
Expert Panel’s attention is drawn to this particular result. The APMU will coordinate with the appropriate Laboratory or WADA-Approved Laboratory for the ABP and Expert Panel to ensure the validity of any non-conforming result.]

3. The Initial Expert Review

For the Steroidal Module, if a result rendered by a Laboratory represents an ATPF caused by an atypically high T/E value, the Sample will undergo Confirmation Procedures, including GC-C-IRMS analysis. If the result of the GC-C-IRMS Confirmation Procedure is negative or inconclusive, then the APMU should advise the ADO on further Testing and/or seek an Expert review. An Expert review is not required when the GC-C-IRMS Confirmation Procedure renders a positive result and is reported by the Laboratory as an Adverse Analytical Finding (AAF). In such cases, a normal Results Management process shall be followed by the ADO which constitutes the Results Management Authority.

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

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

<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 Substance(s) or Prohibited Method(s). Nevertheless, the Experts, via the APMU, will contact the Athlete, via the ADO, if there is a high likelihood of pathology. It is important that the ADO educates the Athletes to ensure that they undergo regular health monitoring and not rely on the ABP for this purpose.]

4. **Review by Three Experts**

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

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

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

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

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

If there is no unanimity among the three Experts, the APMU may follow up on requests for additional information or expertise, or recommend the ADO to pursue additional Testing.
5. **Follow up on Expert Reviews and Compilation of the ABP Documentation Package**

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

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

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

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

For the Haematological Module, this additional information is required:

- Information on possible exposure to altitude of the Athlete for the period defined by the Expert Panel.
- Temperature conditions during the transport of the blood Samples.
- Laboratory (or WADA-Approved Laboratory for the ABP) documentation, including blood results.
- Scatter grams.
- Internal and external quality controls.
- Information on whether the Athlete received a blood transfusion and/or suffered significant blood loss in the prior three months.

For the Steroidal Module, this additional information is required:
- pH of the urine Sample.
- Specific gravity of the urine Sample.
- Laboratory documentation, including screening and confirmed (when applicable) values of steroid concentrations and ratios.
- GC-C-IRMS results, when applicable.
- Indications of ethanol consumption: urinary concentrations of ethanol and/or ethanol Metabolites.
- Indications of bacterial activities (e.g. A/5α-androstandione ratio, pH, fraction of free forms of Testosterone, 5α- and 5β-androstenedione, 4-androstenedione or DHEA).
- Indications of medications taken (declared or detected) that may influence the “steroid 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, that it is highly likely that a Prohibited Substance or Prohibited Method had been used, and unlikely that it is the result of any other cause, the APMU will declare an Adverse Passport Finding (APF). The ABP Documentation Package is then reviewed by the ADO.

The review at this stage is anonymous, however it is accepted that some specific information provided may allow one to identify the Athlete. This shall not affect the validity of the process.
The ADO will then be responsible for:

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

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

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

6. **Review of Explanation From Athlete**

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

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

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. of section 6, then the ADO shall be informed by the APMU. The ADO will then proceed to results management in accordance with Code Article 7.5.

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

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

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

APPENDIX F: Collaboration Agreement

Between

[*]

(hereinafter referred to as “[A]”)

and

[*]

(Hereinafter referred to as “[B]”)

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

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

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

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

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

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

THEREFORE, it is agreed upon between the Parties:

Clause 1 - Definitions

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

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

1.1 “Agreement” means this Collaboration Agreement.

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

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

(a) the existence and terms of this Agreement;

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

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

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

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

1.4 “Operating Guidelines” means the most recent version of the ABP Operating Guidelines adopted by WADA and available on WADA’s Web site.

1.5 “Representative” means an employee, officer, representative, agent or adviser of a Party.
Clause 2 – Passport Testing and Information Sharing

2.1 [A] and [B] agree to provide each other with a copy of its updated RTP for Passport Purposes upon request and to discuss the composition of the respective [A] and [B] 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 For each Athlete included in both [A] and [B] RTPs, the Parties shall establish which of [A] or [B] is the Passport Custodian.

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

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

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

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

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

Clause 4 – Passport Disciplinary Procedures

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

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

Clause 5 – Effective Date and Termination

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

5.2 Notwithstanding Clause 5.3, if either Party wishes to terminate this Agreement, it shall give thirty (30) days’ written notice to the other Party of its intention to terminate the Agreement. Upon receipt of the written notice of termination, this Agreement will terminate thirty (30) days after such notice is delivered.
5.3 Either Party may terminate this Agreement immediately if the other Party commits a material breach of any term of this Agreement and (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being notified in writing of the breach.

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

Clause 6 – Authority

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

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

Clause 7 - Indemnity

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

Clause 8 – Confidentiality

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

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

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

(iii) as required by law or other applicable regulations.
8.2. The duties of the Parties in this Clause 8 shall survive the expiration or earlier termination of this Agreement.

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

Clause 9 – Data Privacy

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

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

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

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

Clause 10 – Miscellaneous

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

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

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

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

10.5 The Parties agree that any and all amendments to this Agreement must be made in writing to be signed by the Parties; no amendment can be made by electronic means.
10.6 If any provision or provisions of this Agreement shall be held to be invalid, illegal, or unenforceable, such provision shall be enforced to the fullest extent permitted by applicable law and the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

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

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

Clause 11 - Notices

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

(i) [A]:
   Address: [•]
   For the attention of: [•]
   Fax number: [•]

(ii) [B]:
   Address: [•]
   For the attention of: [•]
   Fax number: [•]

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

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

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

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

or

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

Clause 12 – Applicable Law and Jurisdiction
12.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter shall be governed by and construed in accordance with the law of [•].

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

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

Clause 13 - Signatories

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

Clause 14 - Counterparts

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

In the name and on behalf of [A]

……………………………………

…………………..[Name, Position]

Date: _______________________

In the name and on behalf of [B]

……………………………………

…………………..[Name, Position]

Date: _______________________