WORLD ANTI-DOPING AGENCY

Athlete Biological Passport

Operating Guidelines

& Compilation of Required Elements

Version 4.0

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Part One: Introduction, Objective and Scope

1.0 Introduction to the Athlete Biological Passport

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

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

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

The ABP intends to establish that an *Athlete* is manipulating his/her physiological variables, without necessarily detecting a particular *Substance* or *Method*. This approach has proven effective in establishing *Anti-Doping Rule Violations (ADRVs)*, without having to rely on traditional analytical approaches and *Target Testing* those likely to be doping. The ABP does not replace traditional *Testing* methods, but rather complements analytical methods to further refine and strengthen overall anti-doping strategies.

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

1.1. Objective

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

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

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

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

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

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

1.2. Scope

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

This document is divided into three sections.

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

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

Section Three is a series of Appendices of Technical Documents (TDs) which are mandatory protocols to be followed by the *ADOs* choosing to apply the ABP. The sharing and mutual recognition of information between programs is only possible through this standardization of procedure. These TDs set out the minimum requirements for *Sample* Collection, *Sample* transport, *Sample* analysis, and results management. Included for ease of reference, they should be considered *International Standard* for *Testing (IST)* and *International Standard* for Laboratories (ISL) TDs.

These mandatory protocols have been established to harmonize the results of monitored biological *Markers* within the ABP to ensure both legal fortitude and scientific certainty. Each *ADO* remains free to adapt the recommended process suggested herein to reflect its own resources and context, but to operate an ABP as defined in this document, the attached protocols provided herein as Appendices must be rigorously observed. Only programs that fully adhere to these TDs herein and fully utilize *ADAMS* can be considered ABP Programs.

Part Two: Modules, Management and Administration

2.0 ABP Haemotological and Steroidal Modules

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

In addition to identifying the use of 'Erythropoiesis-Stimulating Agents' included under Section 2 of the *Prohibited List* (Peptide Hormones, Growth Factors and related Substances), the Haematological Module also seeks to identify the *Use of Methods* categorized under Section M1 of the *Prohibited List* (Manipulation of Blood and Blood Components).

2.1. Haematological *Markers*

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

HCT: Haematocrit

HGB: Haemoglobin

RBC: Red blood cell count

RET%: The percentage of reticulocyte

RET#: Reticulocytes count

MCV: Mean corpuscular volume

MCH: Mean corpuscular haemoglobin

MCHC: Mean corpuscular haemoglobin concentration

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

IRF: Immature reticulocyte fraction

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

2.2. Steroidal *Markers*

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

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

T/E: Testosterone/Epitestosterone ratio

T: Testosterone

E : Epitestosterone

A: Androsterone

Etio: Etiocholanolone

5α-diol: 5α-androstane-3α,17β-diol

5β-diol: 5β-androstane-3α,17β-diol

Together with the specific gravity of the urine sample, further urinary ratios of steroid *Metabolites* to be considered include A/T, A/Etio, 5α-diol/5β-diol and 5α-diol/E.

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

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

2.3. *Testing* and Defining the Target Population

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

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

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

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

a. Sports and/or disciplines within the jurisdiction of the *ADO* with an aerobic or endurance component (risk of blood doping) or with a power/strength component (risk of androgenic anabolic steroids use).

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

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

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

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

f. Inclusion of *Athletes* who are currently screened by other methods or programs.

2.4. Athlete Information

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

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

a. Location of *Testing*.

b. *Event* (if relevant).

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

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

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

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

3.0 ABP Partner Roles and Responsibilities

3.1. Objective

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

3.2. Resources

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

a. Access to a network of *Doping Control* Officers (DCOs) and Blood Collection Officers (BCOs) where necessary, operating in locations where target *Athletes* will be present.

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

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

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

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

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

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

If an *ADO* chooses not to establish an APMU in advance of *Testing*, either because of resource limitations or because insufficient *Testing* is conducted to warrant such arrangements, the *ADO* must liaise with the analyzing Laboratory or *WADA* Approved Laboratory for the ABP for guidance when a steroidal *Atypical* Passport *Finding* (ATPF) has been identified.]

3.3. Specific Partner Responsibilities

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

3.3.1. Anti-Doping Organization

The *ADO* is responsible for:

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

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

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

3.3.2. *Athlete* Passport Management Unit

The APMU is responsible for:

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

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

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

d. Issuing all APFs to the *ADO* and *WADA*.

3.3.3. Laboratory

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

a. Adhering to TD2014BAR (Appendix C) for the Haematological Module and *WADA* External Quality Assessment Scheme (EQAS) Program to ensure robust,

standardized, and credible biological data is incorporated into an *Athlete's* Passport.

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

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

3.3.4. Expert Panel

The Expert Panel is responsible for:

a. Reviewing Passport data and results from the Adaptive Model provided by the APMU to identify any possible pathological or confounding conditions that may have impacted an *Athlete*'s results.

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

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

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

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

WADA is responsible for:

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

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

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

d. Continuing to enhance and develop the ABP for all stakeholders.

4.0 ABP Administration

4.1. Objective

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

The majority of administrative standardization is achieved by following all steps and processing all data in *ADAMS*. This ensures that all mandatory requirements are met, and that the *Athlete* Passports are shared and stored securely, and in accordance with the *International Standard* for the Protection of Privacy and Personal Information (ISPPPI). Furthermore, *ADAMS* will facilitate prompt exchange of information between *ADOs*, AMPUs, *WADA* Accredited and/or *WADA* Approved Laboratories, *Sample* Collection Personnel, and *WADA*.

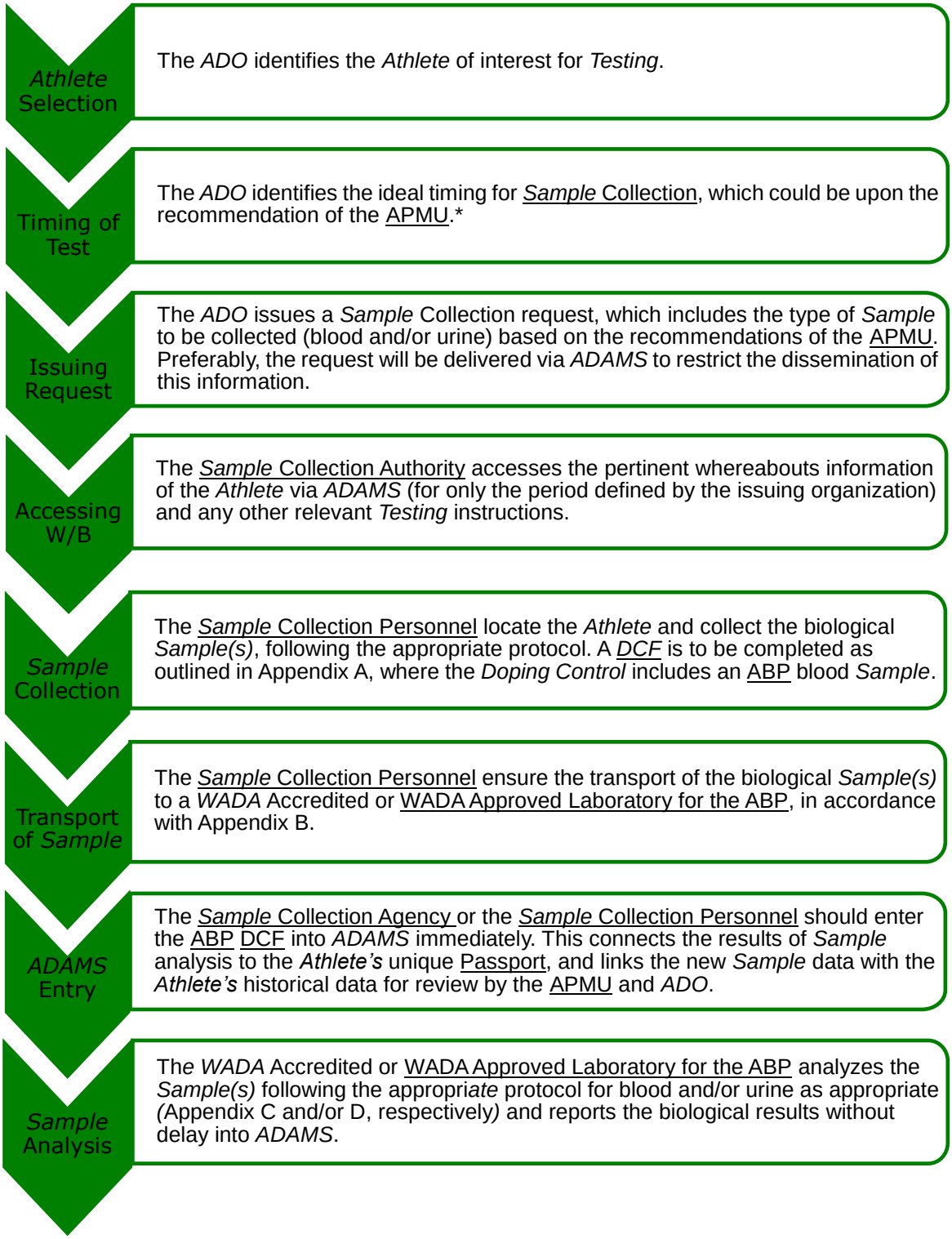
4.2. Recommended Administrative Sequence

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

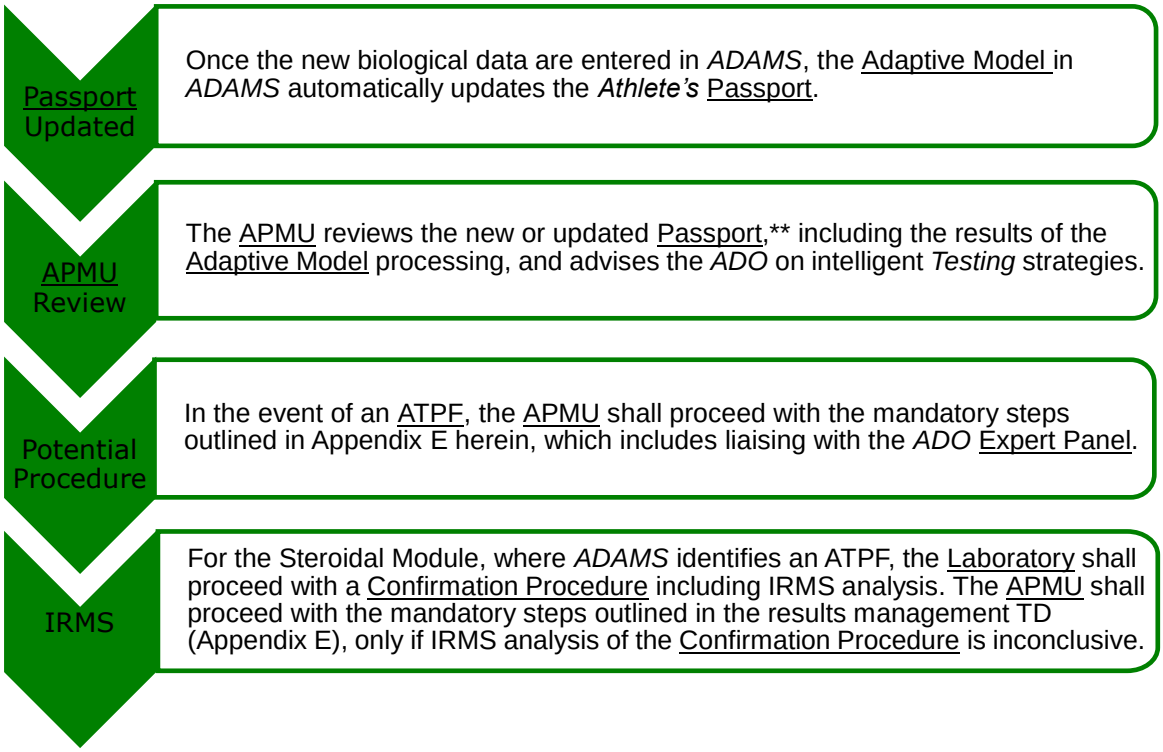
The recommended sequence outlined below may be modified or adapted to merge with existing anti-doping infrastructure, procedures and mechanisms as required. However this Guideline suggests that *ADOs* establish a process that ensures transparency and, ideally, independence between the planning, interpretation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

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

4.3. ABP Administrative Sequence Graphic



ABP Administrative Sequence Graphic, *cont.*



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

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

4.4. Passport Sharing

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

Within the framework provided by *ISPPPI, ADOs* are encouraged to coordinate their activities where multiple *ADOs* have *Testing* jurisdiction over a single *Athlete* and multiple *ADO*s may wish to perform *Passport Testing*. In the interests of a 'one *Athlete* – one Passport' principle, *ADOs* are encouraged to work cooperatively to see that *Testing* is coordinated appropriately.

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

[4.4 Comment: If an *Athlete* is subject to *Testing* by multiple ABP Programs, then his/her IF and *NADO(s)* should seek to reach an agreement in advance on which organization will be responsible for the establishment of the Passport and any necessary follow-up action, such as *Target Testing* or results management proceedings. If no agreement can be found, any one of the *ADOs* may ask *WADA* to determine which *ADO* is responsible for the *Athlete*. *WADA* shall not rule on this without consulting the *ADOs* involved. *WADA* has developed a template agreement for the sharing of Passport information between multiple *ADOs* (supported by *ADAMS*), which is included herein as Appendix F.]

In addition to the provisions set out in *Code* Article 15.4.1, for the purposes of the ABP, certain pre-conditions should be established for multiple *ADOs* to recognize one another's activities and cooperate on a joint ABP Program for a single *Athlete*.

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

5.0 Terms and Definitions

5.1. 2009 World Anti-Doping *Code* Terms

***Anti-Doping Administration and Management System (ADAMS)*:** The secure, online database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.

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

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

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

Similarly, a Major *Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance *Therapeutic Use Exemptions* or whereabouts information. For purposes of *Code* Article 2.8

(*Administration* or *Attempted Administration*) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all *International*- and *National-Level Athletes* are subject to the anti-doping rules of the *Code*, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and *National Anti-Doping Organizations*, respectively. At the national level, anti-doping rules adopted pursuant to the *Code* shall apply, at a minimum, to all *Persons* on national teams and all *Persons* qualified to compete in any national championship in any sport. That does not mean, however, that all such *Athletes* must be included in a *National Anti-Doping Organization's Registered Testing Pool*. The definition also allows each *National Anti-Doping Organization*, if it chooses to do so, to expand its anti-doping program beyond national-calibre *Athletes* to competitors at lower levels of *Competition*. Competitors at all levels of *Competition* should receive the benefit of anti-doping information and education.**]**

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

***Doping Control*:** All steps and processes from Test Distribution Planning through to ultimate disposition of any appeal, including all steps and processes in between, such as provision of whereabouts information, *Sample* Collection and handling, Laboratory analysis, *Therapeutic Use Exemptions*, results management and hearings.

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

***In-Competition*:** Unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, *"In-Competition"* means the period commencing 12 hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition*, and the *Sample* Collection process related to such *Competition*.

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

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

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

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

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

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

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

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

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

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

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

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

5.2. International Standard for Testing (IST) Terms

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

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

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

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

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

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

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

- For urine Sample Collection:
  - Collection vessels for collecting the *Sample* as it leaves the *Athlete's* body
  - Sealable and tamper-evident bottles and lids for securing the *Sample;*
  - Partial *Sample* kit
- For blood Sample Collection:
  - Needles for collecting the *Sample*
  - Blood tubes with sealable and tamper-evident devices for holding the *Sample*.

***Sample* Collection Personnel:** A collective term for qualified officials authorized by the *Anti-Doping Organization* who may carry out or assist with duties during the *Sample* Collection Session.

***Sample* Collection Session:** All of the sequential activities that directly involve the *Athlete*, from notification until the *Athlete* leaves the *Doping Control* Station after having provided his/her *Sample/s*.

Test Distribution Plan: As defined in Clause 4.2.1.

5.3. Further Defined Terms Specific to the ABP Operating Guidelines and Related Technical Documents

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

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

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

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

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

***Atypical* Passport *Finding* (ATPF):** A report generated by the Adaptive Model which identifies either a single *Marker* value or a longitudinal profile of *Marker* values as being outside the *Athlete*'s intra-individual range, assuming a normal physiological condition. An *Atypical* Passport *Finding* requires further investigations and/or analysis.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or concentration of one or more specific *Prohibited Substance*,

Metabolite(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Method* in a *Sample*.

[Comment: A Confirmation Procedure may also indicate a quantity of *Prohibited Substance* greater than a threshold value and quantify the amount of a *Prohibited Substance* in a *Sample*.**]**

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

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

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

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

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

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

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

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

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

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

Part Three: Technical Documents Appendices

6.0 *IST* and ISL Passport Operation Requirements

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

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

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

WADA Technical Document – TD 2014 BSCR

Document Number:	TD 2014 BSCR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	TBD	Effective Date:	01.01.2014

1. Objective

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

2. Scope

The *International Standard* for *Testing (IST)* is applicable to the collection of blood *Samples* carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the ABP. This Appendix describes additional requirements for blood storage and transport related to the ABP. The best practice for *Sample* Collection set out in the *WADA* Guidelines for Blood *Sample* Collection should also be considered, although remains non-mandatory. In the event of any discrepancy between the requirements set out in this Appendix and those set out in the *IST* or Blood *Sample* Collection Guidelines, this Appendix shall prevail for *Sample* Collection related to the ABP.

3. Timing of the *Sample* Collection

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

Competition, the nature, duration and intensity of the exertion shall be recorded by the DCO to make this information available to the APMU and subsequently, to Experts.

4. The Commencement of the Collection Process and the 10 Minute Time-out

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

5. Doping Control Documentation

The DCO/BCO shall use the DCF related to the ABP, if such a form is available. If a DCF related to the ABP is not available, the DCO/BCO shall use a regular DCF but he/she shall collect and record the following additional information on a related form or supplementary report to be signed by the *Athlete* and the DCO/BCO:

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

b. Did the *Athlete* train, compete or reside at an altitude greater than 1,000 meters within the prior two weeks? If so, or if in doubt, the name and location of the place where the *Athlete* had been and the duration of his/her stay shall be recorded. The estimated altitude shall be entered, if known.

c. Did the *Athlete* use any form of altitude simulation such as a hypoxic tent, mask, etc. during the prior two weeks? If so, as much information as possible on the type of device and the manner in which it was used (e.g. frequency, duration, intensity) should be recorded.

d. Did the *Athlete* receive any blood transfusion(s) during the prior three months? Was there any blood loss due to accident, pathology or donation in the prior three months? What was the estimated volume?

6. The *Sample* Collection Equipment

The DCO/BCO instructs the *Athlete* to select the *Sample* Collection Equipment in accordance with *IST* Article E.4.6. 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* Guidelines for Blood *Sample* Collection have been updated to reflect these requirements, and include practical information on the integration of ABP *Testing* into 'traditional' *Testing* activities. In these Guidelines, a table has been included that identifies which particular equipment is appropriate when combining particular test types (i.e. ABP + hGH; ABP + HBT, etc.)

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

7. The *Sample* Collection Procedure

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

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

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

c. After the blood flow into the tube ceases, the BCO removes the tube from the holder and gently homogenizes the blood in the tube manually by inverting the tube gently at least three (3) times.

8. Post Venipuncture Procedure

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

b. The blood *Sample* is deposited and sealed in the *Sample* Collection container in accordance with the *IST*.

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

WADA Technical Document – TD2014BSTR

Document Number:	TD2014BSTR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	TBD	Effective Date:	01.01.2014

1. Objective

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

2. Scope

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

3. Responsibility

The *IST* is applicable to the storage and transport of blood *Samples* carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the ABP. This protocol describes certain specificities of blood storage and transport related to the ABP.

4. Storage

Once a blood *Sample* has been collected in accordance with the Blood *Sample* Collection Requirements for the ABP, it shall be stored in accordance with *IST* Article 8 and the present protocol.

The storage procedure is the responsibility of the DCO.

5. Type of Storage Devices

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

a. Refrigerator.

b. Insulated cool box.

c. Isotherm bag.

d. Any other device that possesses the capabilities mentioned below.

6. Capabilities of the Storage Device

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

6.1. Security of the storage device

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

7. Transport Procedure

Blood *Samples* shall be transported in accordance with *IST* Article 9, consistent with the practices of the *WADA* Guidelines for Blood *Sample* Collection, and in conjunction with this protocol. The transport procedure is the responsibility of the DCO. Blood

Samples shall be transported in a device that maintains the integrity of *Samples* over time, due to changes in external temperature.

7.1. Security of the transport device

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

7.2. Remarks concerning the storage and transport procedure

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

[Comment: The *WADA* Guidelines for Blood *Sample* Collection reflect these protocols and include practical information on the integration of ABP *Testing* into 'traditional' *Testing* activities. A table has been included that identifies which particular timelines for delivery are appropriate when combining particular test types (i.e. ABP + hGH, ABP + HBT, etc.), and which types of *Samples* may be suited for simultaneous transport.]

APPENDIX C: Blood Analytical Requirements for the Athlete Biological Passport

WADA Technical Document – TD2014BAR

Document Number:	TD2014BAR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date: TBD		Effective Date:	01.01.2014

1. Introduction

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

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

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

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

2. Timing

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

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

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

3. Instrument check

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

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

On a regular basis (as determined by the head of the Laboratory or *WADA* Approved Laboratories for the ABP), one fresh blood *Sample* shall be homogenized for a minimum period of 15 minutes on an appropriate mixer (e.g. roller mixer) and then analyzed seven (7) consecutive times. Coefficients of variation shall be below 1.5% for haemoglobin and HCT and below 15% for percentage reticulocyte count to confirm the appropriate precision of the instrument.

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

4. External Quality Assessment Scheme

The Laboratories (or as otherwise approved by *WADA*) shall take part in and meet the requirements of the *WADA* External Quality Assessment Scheme (EQAS) for blood variables. The external quality controls shall be analyzed seven (7) times consecutively, and then the mean results of the following blood variables (full blood count) shall be returned:

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

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

5. Analysis of Blood *Samples*

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

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

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

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

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

6. Reporting

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

APPENDIX D: Endogenous Anabolic Androgenic Steroids

Measurement and Reporting

WADA Technical Document – TD 2014 EAAS

Document Number:	TD2014EAAS	Version Number:	1.0
Written by:	WADA Laboratory Expert Group	Approved by:	WADA Executive Committee
Date:	11 September 2013	Effective Date:	1 January 2014

1. Introduction

The purpose of this Technical Document is to harmonize the approaches to the measurement and reporting of endogenous anabolic androgenic steroids (EAAS) in urine, including data in support of the steroidal module of the *Athlete* Biological Passport (ABP) or "steroid profile".

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

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

EAAS *Testing* and reporting follows a two-step procedure: an Initial Testing Procedure aims to estimate the "steroid profile" in the *Athlete's Sample*. A subsequent Confirmation Procedure is performed when the estimated "steroid profile" represents an ATPF. The Confirmation Procedure includes the quantification of the *Markers* of the "steroid profile" as described in this Technical Document as well as Gas Chromatography – Combustion - Isotope Ratio Mass Spectrometry (GC-C-IRMS) analysis which is considered in a separate Technical Document.

1.1 The "Steroid Profile"

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

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

- Testosterone (T),
- Epitestosterone (E),
- Androsterone (A),
- Etiocholanolone (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 [1]).

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

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

2. Initial Testing Procedure

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

[1] In *ADAMS*, the values of these four ratios are computed after the reporting of the "steroid profile" by the Laboratory.

The Initial Testing Procedure is conducted on a single Aliquot.

2.1 Method Characteristics

- Gas chromatography combined with mass spectrometry (GC-MS or GC-MS/MS) of TMS derivatives (keto and hydroxyl groups) is required.
- Calibration standards should be analyzed periodically, and whenever a significant change is made to the analytical setup.
- A urine quality control (QC) sample containing representative levels of the analytes should be included in each sequence of analysis.
- The enzymatic hydrolysis shall be carried out with purified β-glucuronidase from *E. coli* (*H. pomatia* mixtures are not acceptable).
- The completeness of hydrolysis of the glucuroconjugated urinary steroids shall be verified with isotopically labeled A-glucuronide (or an equivalent scientifically recognized alternative).
- The completeness of the derivatization shall be verified through the monitoring of mono-O-TMS vs. di-O-TMS derivative of A.
- When needed, the volume[2] of the *Sample* Aliquot may be adjusted as a function of its specific gravity (SG) and of the gender of the *Athlete*.
- The T/E ratios shall be determined from the ratios of the corrected chromatographic peak areas or peak heights[3].
- The linearity of the method, established during method validation, shall cover the ranges of values normally found in males and females - the limit of quantification (LOQ) for T and E shall not be higher than 2 ng/mL[4].

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

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

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

The LOQ for T, E, A, 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.

- 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 and E, the u_c(%) for the T/E determinations shall not exceed 30%.

- Evidence of microbial degradation (*e.g.* presence of 5α- and 5β-androstanedione 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, the SG and the validity of the *Sample*, as determined in the Initial Testing Procedure.

The "steroid profile" shall be reported in *ADAMS* as follows:

- The concentrations of T, E, A, Etio, 5αAdiol and 5βAdiol shall be reported without adjustment for the SG of the *Sample* and to 2 significant figures (e.g. T = 5.2; 52; 520) [5].
- The T/E shall be reported to 2 significant figures (e.g. T/E = 0.12; 1.2; 12).

The validity of the *Sample* shall be reported in ADAMS as "yes" or "no".

- A *Sample* showing signs of microbial degradation or containing any of the substances[6] that may cause an alteration of the "steroid profile", as described in Section 1.0 above, may not be suitable for inclusion in the "longitudinal steroid profile". In such cases the validity of the "steroid profile" shall be reported in *ADAMS* as "no" and an explanation shall be included in the Test Report in *ADAMS*.

[5] Any concentration measured below the LOQ shall be reported as -1 by the Laboratory.

[6] It is not mandatory that the Laboratory tests for the presence of ethanol metabolite(s) or ketoconazole during the Initial Testing Procedure.

- When the measurement of a *Marker* of the "steroid profile" is not possible due to, for example, dilution, unusual matrix interferences, inhibition of the enzymatic hydrolysis or incomplete derivatization, the Laboratory should repeat the analysis with a modified, validated *Sample* preparation and analysis (*e.g.* solid phase extraction, extraction with a different solvent or other equivalent procedure). However, when the problem cannot be resolved, the negatively impacted variable(s) of the "steroid profile" shall be reported as "-1", the validity as "no", and a comment shall be included in the Test Report in *ADAMS* stating that the *Marker(s)* could not be measured reliably.

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

3. Confirmation Procedure

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

- The Laboratory shall confirm the relevant "steroid profile" *Marker(s)* or ratio (*e.g.* the T/E ratio) measured in the Initial Testing Procedure when, upon reporting the results in *ADAMS* and following the application of the Adaptive Model of the ABP to the "longitudinal steroid profile" of the *Athlete*, the Laboratory is informed through *ADAMS* of an ATPF.
- In the case when the "longitudinal steroid profile" of the *Sample* cannot be processed by the Adaptive Model in *ADAMS*, the Laboratory shall proceed with the Confirmation Procedure(s) when one of the following criteria is met[7]:
    - 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 [8]) greater than 200 ng/mL in males or greater than 50 ng/mL in females.

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

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

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

- Concentration of A or Etio (adjusted for the SG[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 5α-reductase) or greater than 4 in either sex.

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

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

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

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

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*), the associated u_c expressed in units and the SG of the *Sample*.

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[9] For T/E values, only T needs to be identified if the concentration level and volume of the *Sample* are sufficient.

The presence of signs of microbial degradation, of conjugated metabolite(s) of ethanol, of inhibitors of 5α-reductase, or of any other substances that might have altered the "steroid profile" shall be reported.

4. References

http://www.wada-ama.org/en/Science-Medicine/Anti-Doping-Laboratories/Technical-Documents/

1. *WADA* Technical Document TDIDCR (current version): Identification Criteria for Qualitative Assays incorporating Column Chromatography and Mass Spectrometry.

APPENDIX E: Results Management Requirements for the Athlete Biological Passport

WADA Technical Document – TD 2014 RMR

Document Number:	TD 2014 RMR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	TBD	Effective Date:	01.01.2014

1. Administrative management

These processes may be administered and managed by an APMU on behalf of or within an *ADO*. The APMU will initially review profiles to facilitate targeting recommendations to the *ADO* when appropriate, or refer to the Expert Panel as appropriate. Management and communication of the biological data and the Expert reviews shall be conducted in *ADAMS*.

This Appendix describes a step-wise approach to the review of an *Athlete's* Passport. The review begins with the creation of a longitudinal profile and application of the Adaptive Model. An Expert then conducts an initial screening and returns an evaluation based on the information available at that time.

The process may culminate in the creation of an ABP Documentation Package and Expert Panel opinion following the reception of all information, including any explanation from the *Athlete*.

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

2. Review by the Adaptive Model

The Adaptive Model is capable of identifying atypical values or profiles that warrant further attention and review. The Adaptive Model predicts for an individual an expected range within which a series of *Marker* values falls assuming a normal physiological condition. Outliers correspond to those values out of the 99%-range (0.5 - 99.5 percentiles).

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

Steroidal data is considered as atypical if it returns a T/E value outside the expected intra-individual ranges. Similarly, a longitudinal profile composed of T/E values is considered as atypical when deviating from the expected ranges, as determined by the Adaptive Model.

A specificity of 99% is used to identify both haematological and steroidal ATPFs that warrant further investigation and/or results management. In the case of steroidal data, an ATPF will trigger a Confirmation Procedure as established in TD2014EAAS.

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

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

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

3. The initial Expert review

For the Steroidal Module, if a result rendered by a Laboratory represents an ATPF, the *Sample* will undergo Confirmation Procedures including IRMS analysis. If negative, then the APMU/ADO should do further testing and/or seek an Expert review. If the Haematological Module renders an ATPF, then the results/profile must be reviewed by an Expert chosen by the APMU or manager of the *ADO*. This should occur in a in a timely manner.

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

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

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

4. Review by three Experts

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

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

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

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

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

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

5. Follow up on the Expert reviews and the compilation of the ABP Documentation Package

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

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

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

a. Age of the *Athlete*.

b. Gender of the *Athlete.*

c. Sport and discipline.

d. Type of test.

e. *Sample* code number.

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

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

h. *Competition* information.

i. Chain of Custody documentation.

j. Information from the DCFs for each *Sample* collected during the period, as determined by the APMU and Expert Panel.

For the Haematological Module, this additional information is required:

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

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

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

d. Scatter grams.

e. Internal and external quality controls.

f. Information if the *Athlete* received a blood transfusion and/or suffered significant blood loss in the prior three months.

For the Steroidal Module, this additional information is required:

a. pH.

b. Specific gravity.

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

d. IRMS results, when applicable.

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

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

g. Indications of medications taken (declared or detected) that may influence the steroidal profile, such as corticosteroids, human chorionic gonadotrophin (hCG), ketoconazole, contraceptives and 5α-reductase inhibitors.

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

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

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

The *ADO* will then be responsible for:

a. Advising the *Athlete* and *WADA* that the *ADO* is considering the assertion of an *ADRV* against the *Athlete*.

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

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

6. Review of Explanation from *Athlete*

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

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

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

7. Disciplinary Proceeding

If the Expert Panel expresses the opinion set forth in (a) above, then the *ADO* shall be informed by the APMU. The *ADO* will then proceed to results management in accordance with *Code* Article 7.4.

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

When an *Athlete* is sanctioned by means other than the ABP, the Haematological and/or Steroidal Passport will remain in effect, except in those cases where the *Prohibited Substance* or *Method* resulted in a manipulation of the haematological or steroidal *Markers*, respectively. In such instances, the *Athlete's* Profile(s) would be reset from the time of the beginning of the sanction.

6.1 Templates

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

APPENDIX F: Collaboration Agreement

Between

[•]

(hereinafter referred to as "[A]")

and

[•]

(Hereinafter referred to as "[B]")

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

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

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

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

WHEREAS [A] and [B] now wish to collaborate on the planning, *Testing* and *Results Management* of the *Doping Control* and *Athlete Biological Passport* programs of the *Athletes* included in their respective *RTP*s in accordance with the terms of this Agreement.

PURPOSE

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

THEREFORE, it is agreed upon between the Parties:

Clause 1 - Definitions

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

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

1.1 "Agreement" means this Collaboration Agreement.

1.2 "Passport Purposes" means the gathering and collation of *Passports* according to the Operating Guidelines and related technical documents.

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

(a) the existence and terms of this Agreement;

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

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

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

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

1.4 "Operating Guidelines" means the most recent version of the Athlete Biological Passport Operating Guidelines adopted by *WADA* and available on the WADA website.

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

Clause 2 – Passport Testing and information sharing

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

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

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

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

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

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

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

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

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

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

Clause 3 – Passport Results Management Process

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

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

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

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

3.5 For the avoidance of doubt, *Passports* collected under this Agreement by [A] and [B] should, whenever possible, be combined for the purposes of pursuing a potential Anti-Doping Rule Violation or other results management procedure pursued against an *Athlete* in accordance with the *Code* and *International Standards*.

Clause 4 – Passport Disciplinary Procedures

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

4.2 Where the Party with responsibility for the results management of an *Athlete*'s case as set out above decides not to proceed with an asserted anti-doping rule violation, such decision will not affect the ability of the other Party or *WADA* to appeal such decision.

Clause 5 – Effective date and termination

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

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

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

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

Clause 6 – Authority

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

6.2. Notwithstanding the above and for the avoidance of doubt, the Parties acknowledge and agree that nothing in this Agreement affects or modifies their respective rights and obligations, and those of other relevant third parties, under the "Agreement Governing the Use and Sharing of Information in WADA's Anti-Doping Administration and Management System ("*ADAMS"*)" that the Parties entered into with *WADA*.

Clause 7 - Indemnity

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

Clause 8 – Confidentiality

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

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

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

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

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

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

Clause 9 – Data privacy

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

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

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

9.4 Neither Party shall disclose *Passports* collected under this Agreement to any third party (save for the purposes of the [A] ABP Expert Panel or [B] ABP Expert Panel review), without the express prior written consent of the other Party unless such disclosure is required by law or occurs as a result of Section 7.2.

Clause 10 – Miscellaneous

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

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

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

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

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

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

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

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

Clause 11 - Notices

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

(i) [A]:

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

(ii) [B]:

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 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: _____ 2012

In the name and on behalf of
[B]

_____

……..[Name, Position]

Date: _____ 2012

SCHEDULE 1

Definitions

1. Definitions from the 2009 World Anti-Doping Code

Anti-Doping Administration and Management System (ADAMS)*:* The secure, online database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their anti-doping operations in conjunction with data protection legislation.

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

Athlete**:** Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization,* including but not limited to, those *Persons* in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and *Therapeutic Use Exemptions* must be applied to *International-* and *National-Level Athletes*. Some

National Anti-Doping Organizations may elect to test and apply anti-doping rules to recreational-level or masters-level competitors who are not current or potential national-calibre competitors. *National Anti-Doping Organizations* are not required, however, to apply all aspects of the *Code* to such *Persons.* Specific national rules may be established for *Doping Control* for non-*International-Level* or non-*National-Level Athletes* without being in conflict with the *Code.* Thus, a country could elect to test recreational-level competitors, but not require *Therapeutic Use Exemptions* or whereabouts information.

Similarly, a Major *Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance *Therapeutic Use Exemptions* or whereabouts information. For purposes of *Code* Article 2.8 (*Administration* or *Attempted Administration*) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all *International*- and *National-Level Athletes* are subject to the anti-doping rules of the *Code*, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and *National Anti-Doping Organizations*, respectively. At the national level, anti-doping rules adopted pursuant to the *Code* shall apply, at a minimum, to all *Persons* on national teams and all *Persons* qualified to compete in any national championship in any sport. That does not mean, however, that all such *Athletes* must be included in a *National Anti-Doping Organization's Registered Testing Pool*. The definition also allows each *National Anti-Doping Organization*, if it chooses to do so, to expand its anti-doping program beyond national-calibre *Athletes* to competitors at lower levels of *Competition*. Competitors at all levels of *Competition* should receive the benefit of anti-doping information and education.**]**

***Doping Control*:** All steps and processes from Test Distribution Planning through to ultimate disposition of any appeal, including all steps and processes in between, such as provision of whereabouts information, *Sample* Collection and handling, Laboratory analysis, *Therapeutic Use Exemptions*, results management and hearings.

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

***International Standard*:** A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures

addressed by the *International Standard* were performed properly. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard*.

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

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

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

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

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

3. Definitions from the International Standard for Laboratories

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

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

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

***Testing* Authority(ies):** The *Anti-Doping Organization* that has authorized a particular test from their Test Distribution Plan, as specified in *IST* Article 4.0. For example, the International Olympic Committee, World Anti-Doping Agency,

International Federation, National Sport Organization, *National Anti-Doping Organization*, *National Olympic Committee*, Major *Event Organization*, or other authority defined by the *Code* responsible for planning and initiating *Sample Testing* either *In-Competition* or *Out-of-Competition*.