



The World Anti-Doping Code

**ATHLETE
BIOLOGICAL
PASSPORT
OPERATING GUIDELINES**

**AND COMPILATION OF REQUIRED
ELEMENTS**

January 2012

Version 3.0

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PART ONE: INTRODUCTION, PROVISIONS AND DEFINITIONS

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 selected haematological variables measurements (*Markers* of blood doping) was identified as a means to define an individual’s haematological profile. WADA, in conjunction with a number of stakeholders and medical experts began to further develop, harmonize and validate this concept. The result was a formal guideline and mandatory standards that form the model known as the *Athlete Biological Passport*, which was first published in late 2009.

The typical *Doping Control* approach based on the detection of *Prohibited Substances* or their *Metabolites* in an *Athlete’s Sample* remains an effective approach; however it has limitations when an *Athlete* may be using substances on an intermittent and low-dose basis. Furthermore, new substances or modifications of *Prohibited Substances* (designer drugs) may be difficult to detect by conventional analytical means. In recent years, doping regimes have become much more scientifically planned and have taken full advantage of the weaknesses in traditional protocols. This underscores the need for a more sophisticated and complementary strategy to effectively fight doping – the *Athlete Biological Passport*.

The objective of integrating the *Athlete Biological Passport* into the larger framework of a robust anti-doping program may include the following:

- a) To identify and target *Athletes* for specific analytical *Testing* (e.g., recombinant EPO test, homologous blood transfusion test) by intelligent and timely interpretation of blood *Passport* data;
- b) To pursue possible *Anti-Doping Rule Violations* in accordance with *Code* Article 2.2.

An *Anti-Doping Organization* is free to build its own structure to implement the *Athlete Biological Passport*. However, the framework proposed in this guideline aims to build upon existing anti-doping infrastructure and promote harmonization in ABP programs to facilitate exchange of information, mutual recognition of data, and consequently to enhance efficiencies in the operation of anti-doping activities. *Anti-Doping Organizations* should consider how to best integrate the *Athlete Biological Passport* into their existing programs by weighing all factors including the required resources and capacity to operate such a program.

2.0 Objective and Scope

The *Athlete Biological Passport* is presented in order to equip *Anti-Doping Organizations* with a robust and viable framework in which to pursue anti-doping rule violations in accordance with Article 2.2 of the World Anti-Doping Code and simultaneously use biological data for intelligent, targeted *Testing*. While the processes and framework outlined in this guideline are intended for a haematological module, it will also be applicable to future modules, such as steroid and endocrine. This document is divided into two sections.

The first section provides a guideline which aims to explain the principles behind the *Athlete Biological Passport* and how an *Anti-Doping Organization* may consider implementation within the context of their ongoing activities. This guideline is created both to assist organizations, and to foster consistency and harmonization in application without mandating specific administrative or procedural elements. This allows for some discretion in how the *Athlete Biological Passport* may be implemented.

The second section is a compilation of Technical Documents which are a series of mandatory protocols which must be followed by the *Anti-Doping Organizations* choosing to apply the *Athlete Biological Passport*. The sharing and mutual recognition of information between programs is only possible through this standardization of procedure. These Technical Documents set out the minimum requirements for *Sample Collection*, *Sample Transport*, *Sample Analysis*, and results management. Whilst these protocols are included herein for ease of reference, they are incorporated in whole in the *International Standard for Testing* and *International Standard for Laboratories* as appropriate. These mandatory protocols have been established to harmonize the results of monitored variables within the *Athlete Biological Passport* to ensure both legal fortitude and scientific certainty. Each *Anti Doping Organization* remains free to adapt the recommended process suggested herein to reflect its own resources and context, but to operate an *Athlete Biological Passport* as defined in this document the attached protocols provided herein as Appendices must be rigorously observed.

Finally, although this guideline seeks to harmonize longitudinal profiling programs, it in no way undermines the validity of existing *Anti-Doping Organization* programs. There are a number of useful and sound methodologies available to review blood data, manage intelligent *Doping Control* programs and pursue anti-doping rule violations; however the model offered in this document has the endorsement of *WADA*, as well as the infrastructure necessary within the network of *WADA* accredited Laboratories and is harmonized in such a fashion that *ADOs* may work cooperatively to enhance program efficiency and effectiveness.

The *Athlete Biological Passport*, when implemented in accordance with the Technical Documents, is a reliable method for indirectly detecting doping that can withstand legal and scientific challenges at the highest level.

PART TWO: GUIDELINES FOR PASSPORT OPERATION

3.0 Terms and Definitions

3.1 Defined Terms from the 2009 Code

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

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 competitors. Some *National Anti-Doping Organizations* may elect to test and apply anti-doping rules to recreational-level or masters 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 competitors 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.

In the same manner, 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 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-calibre 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 twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

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 parameter(s) that indicate the use of a *Prohibited Substance* or *Prohibited Method*.

No Advance Notice: A *Doping Control* which 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* which 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.

3.2 Defined Terms Specific to the *International Standard for Testing (IST)*

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

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

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

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

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

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

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

- For urine *Sample* collection:
 - Collection vessels for collecting the *Sample* as it leaves the *Athlete's* body;
 - Sealable and tamper-evident bottles and lids for securing the *Sample*;
 - Partial *Sample* kit;

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

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

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

Test Distribution Plan: As defined in Clause 4.2.1.

3.3 Defined Terms Specific to the *International Standard for Laboratories*

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

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

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

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

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or 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 APMU, who are responsible for providing an evaluation of the Passport. For the haematological module, experts will have knowledge in one or more of the fields of clinical hematology (diagnosis of blood pathological conditions), sports medicine or exercise physiology.

This Panel may include a pool of appointed experts and any additional ad-hoc expert who may be required upon request of any of the appointed *Experts* or by the Athlete Passport Management Unit of the *Anti-Doping Organization*.

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

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

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

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

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

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

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

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

4.0 Roles and Responsibilities of the Partners

4.1 Objective

In order to protect the rights of the *Athlete* and implement a credible and viable passport 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.

4.2 Specific Partner Responsibilities

The purpose of the *Athlete Biological Passport* program is to establish the possible use of a *Prohibited Method* or *Substance* indirectly and also to use biological data to apply traditional doping controls and/or targeting more intelligently. Distinctions with respect to the various roles and responsibilities in the *ABP* process clarify the precise functions of all partners in order to establish accountability, consistency and credibility.

4.2.1 The Anti-Doping Organization(s) is/are responsible for:

- a) Adopting, implementing and administrating an *Athlete Biological Passport* in accordance with these Guidelines including compliance with the *International Standard for Testing*;
- b) Ensuring that recommendations received from the *APMU* is converted into effective, targeted, timely and appropriate follow-up testing; and
- c) Following up on *Adverse Passport Findings* in accordance with TD2012RMR (Appendix D) and Article 7.4 of the Code.

4.2.2 The Athlete Passport Management Unit (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; and
- d) Issuing all Adverse Passport Findings to the ADO and WADA.

4.2.3 The WADA Accredited Laboratory is responsible for:

- a) Adhering to TD2012BAR (Appendix C) and WADA EQAS program to ensure robust, standardized, and credible biological data is incorporated into an *Athlete's Passport*; and
- b) Providing the necessary information to compile all required Documentation Packages.

4.2.4 The WADA Approved Laboratory for the ABP is responsible for:

- a) Adhering to TD2012BAR (Appendix C) and WADA EQAS program to ensure robust, standardized, and credible biological data is incorporated into an *Athlete's Passport*;
- b) Meeting and maintaining the criteria for approval of non-WADA accredited Laboratories for the Athlete Biological Passport program; and
- c) Providing the necessary information to compile all required Documentation Packages.

4.2.5 The Expert Panel is responsible for:

- a) Reviewing *Passport* data and results from the Adaptive Model provided by the APMU in order to identify any possible pathological or confounding conditions which may have impacted an *Athlete's* results;
- b) Recommending any follow-up *Testing* or suggest possible clinical testing that may be required to confirm assessment or to collect further evidence to support or confirm possible pathologies;
- c) Reviewing any explanations of the *Athlete* and give an opinion on whether any *Atypical Finding(s)* was highly probable given that a *Prohibited Substance* or *Prohibited Method* had been used; and
- d) Working with the relevant APMU as required and provide evidentiary support as necessary throughout any results management process.

4.2.6 WADA is responsible for:

- a) Providing access to *ADAMS* to relevant *ADOs* to support coordinated and secure exchange of information between the aforementioned partners;
- b) Providing access to the Adaptive Model (ABP software) to those *ADOs* adhering to the mandatory ABP Technical Documents;
- c) Carrying out its monitoring and appeal rights and responsibilities as set forth in *Code* Article 20.7;
- d) Providing ongoing support to *ADOs* operating ABP programs as required; and
- e) Continuing to enhance and develop the ABP for all stakeholders.

5.0 Athlete Biological Passport Administration

5.1 Objective

Although the administrative organization of the *Athlete Biological Passport* may be adapted to best suit the relevant *Anti-Doping Organization*, this guideline seeks to foster harmonization in the interests of mutual recognition of *Athletes' Passports*, standardized practice and to ensure efficiency in program application more generally.

The majority of administrative standardization should be achieved with the use of the ABP software (Adaptive Model) and by processing of all steps and data in *ADAMS* in order to ensure that all mandatory requirements are met and that the *Athlete Passports* are shared and stored appropriately in accordance with the *International Standard* for the Protection of Privacy and Personal Information (ISPPi). Furthermore, *ADAMS* will facilitate prompt exchange of information between *Anti-Doping Organizations*, Athlete Passport Management Unit, *WADA* accredited Laboratories, Sample Collection Personnel and *WADA*. *ADAMS* will also furnish access to the *Athlete* to their biological data upon request.

5.2 Recommended Administrative Sequence

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

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

To create a framework for such independence, the sequence set out herein includes the incorporation of an Athlete Passport Management Unit which should be the central hub connecting Laboratory-generated biological data with active test planning advice and intelligence.

This central hub (the APMU) may be associated with a WADA accredited Laboratory's operations, or be managed under the responsibility of an ADO. While all such options are acceptable provided that their processes conform to the necessary requirements set out in Appendix D (TD2010rnr), WADA will support the establishment of Laboratory-affiliated APMUs as the preferred method of ABP practice and engagement going forward.

1. The *Anti-Doping Organization* identifies the *Athlete* of interest and identifies what may be necessary for his or her *Passport* based on what information is already available including the information outlined in Article 3.2. This may include information such as the *Athlete's* past *Testing* history, existing *Passport* information, available whereabouts and past Athlete Passport Management Unit recommendations.
2. The *Anti-Doping Organization* identifies suitable timing for *Sample* collection upon the recommendation of the Athlete Passport Management Unit as appropriate.
3. The *Anti-Doping Organization* issues a *Sample* collection request ("mission order") based on the recommendations of the Athlete Passport Management Unit, to a *Sample* collection agency or to Doping Control Personnel. Preferably this will be delivered via ADAMS to restrict the dissemination of this information.
4. The Sample Collection Authority accesses the pertinent whereabouts information of the *Athlete* via ADAMS for only the period defined by the issuing organization as well as any other relevant *Testing* instructions.

5. The Doping Control Officer and/or Blood Collection Officer locate the *Athlete* and collect the biological *Sample* following the appropriate protocol (Appendix A herein). This *Sample* is accompanied by passport documentation to be completed in an ABP Doping Control form as outlined in Article 7.3.
6. The Sample Collection Personnel are responsible for the transport of the biological *Sample(s)* to a *WADA* accredited or approved Laboratory following the appropriate protocol (Appendix B herein).
7. Following the Sample Collection Session, the *Sample* collection agency or the Sample Collection Personnel should transcribe the Athlete Biological Passport Doping Control form into *ADAMS* immediately to provide prompt access to the relevant data for the Laboratory, APMU and *Anti-Doping Organization* as required.
8. The *WADA* accredited Laboratory analyzes the *Sample(s)* following the appropriate analytical protocol (Appendix C herein) and reports the biological results without delay into *ADAMS*.
9. Once the new biological data are entered in *ADAMS*, a notification is sent to the *APMU* which updates the *Athlete's Passport* and applies the Adaptive Model using the *ABP* software.

Comment: If there is a departure from the WADA Requirements for the collection, transport and analysis for the Athlete Biological Passport, the corresponding result should not be considered in the calculations by the Adaptive Model. The non-conforming biological result however should be included (whenever possible) in the Athlete's Passport for reference and targeting purposes. Any non-conforming result (for example, a result analyzed after 36 hours) may be included in the Expert Panel assessment of a profile provided that the Expert Panel attention is drawn to this particular result. The Athlete Passport Management Unit (APMU) will coordinate with the appropriate Laboratory and haematological experts in order to ensure the validity of any non-conforming result.

10. The Athlete Passport Management Unit reviews the new or updated Passport including the results of the Adaptive Model processing, and advises the ADO on intelligent Testing strategies.

11. In the event that the Athlete's Haemoglobin (HGB) and/or OFF-hr-Score (OFFS) values are beyond the 99.9 percentile of the expected ranges returned by the Adaptive Model, the Athlete Passport Management Unit shall proceed with the mandatory steps outlined in Appendix D herein which includes liaising with the Expert Panel of the ADO.

12. The APMU should also regularly provide a random set of profiles, that do not exceed the 99.9 percentile, in order to provide experts with a more balanced view of the Athlete population.

5.3 Sharing and Exchange of Passports

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

Within the framework provided by the *International Standard on Privacy and Data Protection (ISPP)*, *ADOs* are encouraged to coordinate their activities where multiple *ADOs* have *Testing* jurisdiction over a single *Athlete* and multiple *ADOs* may wish to perform *Passport Testing*. In the interests of a 'one *Athlete* – one *Passport*' principle, *ADOs* are encouraged to work cooperatively to see that *Testing* is coordinated appropriately.

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

[4.3 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 who will be responsible for the establishment of the Passport and any necessary follow-up action such as a 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 with the ADOs involved.

5.3.1 Mutual Recognition and Respect of Program Activities

In addition to the provisions set out in *Code* Article 15.4.1, for the purposes of the Athlete Biological Passport certain pre-conditions should be established in order for multiple *ADOs* to recognize one another's activities and cooperate on a joint *ABP* program for a single *Athlete*. These include, at a minimum, that all *Samples* collected by *ADOs* and subsequently incorporated into a single *Passport* have:

- a) Adhered to Appendix A (*Sample* Collection Requirements);
- b) Adhered to Appendix B (*Sample* Transportation Requirements); and
- c) Adhered to Appendix C (Analytical Requirements).

Additionally, the concerned *ADOs* should:

- a) Agree upon a specific APMU that will be responsible for the management of a single *Passport* of interest to more than one party;
- b) Ensure that this APMU will liaise with an agreed upon Expert Panel as required by Appendix D; and
- c) Ensure that this APMU be advised on appropriate *Target Testing*.

6.0 Program Implementation of the Haematological Module

6.1 Introduction

The *Athlete Biological Passport* involves regular monitoring of biological *Markers* on a longitudinal basis to facilitate indirect detection of *Prohibited Substances and Methods*. From this perspective, the *Prohibited Substance* itself is not detected but rather its effects on the body become evident. The effect of the drug remains longer than the substance itself, which may be quickly excreted or degraded and therefore go undetected unless *Testing* is carried out at a very specific time.

In order to establish an effective longitudinal monitoring program, the list of relevant *Markers* for a specific class of substance (e.g. substances enhancing oxygen transfer such as recombinant EPO) must be identified and monitored on a regular basis for a given *Athlete*. The collection and monitoring of values corresponding to these identified *Markers* will constitute an individual longitudinal profile. Such profiles are the cornerstones of the *Athlete Biological Passport*, with a subject becoming his/her own point of reference.

The *Markers* will be specifically selected based on the relevant doping scenario. For instance, *Markers* of an altered erythropoiesis will be taken into consideration to confirm blood manipulation or aerobic performance enhancement. Steroid *Markers* in urine, on the other hand, may be used to demonstrate the use of anabolic steroid(s).

6.2 Haematological Markers

The Haematological Module collects information on *Markers* of blood doping. It 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 *S2*.

Peptide Hormones, Growth Factors and related Substances, of the Prohibited List, the haematological module also seeks to identify the Use of Methods categorized under section M1. of the Prohibited List, 'Enhancement of Oxygen Transfer.'

The following *Markers* are considered within the *Athlete Biological Passport* haematological module:

HCT:	Hematocrit
HGB:	Haemoglobin
RBC:	Red blood cells count
RET%:	The percentage of reticulocyte
RET#:	Reticulocytes count
MCV:	Mean corpuscular volume
MCH:	Mean corpuscular haemoglobin
MCHC:	Mean corpuscular haemoglobin concentration

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 MCHC².

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.

6.3 Athlete Information

The *Passport* for a haematological module should also incorporate individual *Athlete* profile information to provide context for the interpretation of the *Markers* outlined in 3.1. This additional information which may be collected by various means, both prior to and after testing as appropriate, includes but is not limited to:

- a) Gender, date of birth, sport, and discipline
- b) Location and date of each *Sample* collection;
- c) Information on the transport conditions of the *Sample(s)*;
- d) Whereabouts information for the month prior to each *Sample* collection which includes:
 - In- and out-of-competition activities; and
 - Location information that demonstrates relevant altitude exposure.
- e) Information on blood loss or gain (pathology or transfusion) in the three months preceding each *Sample collection*; and
- f) Information on use of hypoxic devices (altitude simulation).

6.4 Testing and Defining the Target Population

An *Athlete Biological Passport Testing* program must follow the *International Standard for Testing* (IST) and the applicable Technical Documents specific to the *Athlete Biological Passport*.

Targeted tests that follow the recommendations of the *Athlete Passport Management Unit* should be privileged over random tests to improve the sensitivity of the *Athlete Biological Passport*. In general, the sensitivity of the *Athlete Biological Passport* to detect doping is improved where both *In-* and *Out-of Competition* tests and *No-Advance Notice* tests are distributed throughout the year. Data points are most statistically independent when *Samples* have been collected at least five days apart.

The criteria listed below may be considered in determining the target population for the *Athlete Biological Passport* and the context of an *Anti-Doping Organization's* overall Test Distribution Plan.

- a) Sports and/or disciplines within the jurisdiction of the *ADO* at higher risk for blood-based doping (i.e. sports with an aerobic or endurance component);
- 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 *ADOs* jurisdiction are already subject to the *Athlete Biological Passport* 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; and
- f) Inclusion of *Athletes* that are currently screened by other methods or programs.

6.5 Resources

The following resources are required in order to adopt and implement the *Athlete Biological Passport*:

- a) Access to a network of Doping Control Officers (DCO) and Blood Collection Officers (BCO) operating in locations where target *Athletes* will be present;
- b) An effective whereabouts management system to facilitate *Athlete* location (i.e. *ADAMS*);
- c) Database *management* capacity for storing the *Athletes' Passports* (i.e. *ADAMS* and ABP Software);

[7.5 c. Comment: The ABP software is made freely available by WADA to any ADO that follow these Guidelines. The ABP Software allows the user to create, manage, evaluate and share Athletes' Passports. This software will be integrated into ADAMS in the future.]

- d) Access to an Athlete Passport Management Unit with relevant expertise and availability for 'real-time' management of ABP processes as highlighted in Article 4.2 below;
- e) Access to a Expert Panel for interpretive and consultative capacity via the Athlete Passport Management Unit; and
- f) Results management capacity including resources for enforcing the program.

7.0 Athlete Biological Passport Documentation

7.1 Objective

Given that additional information is required from *Athletes* beyond what is collected on traditional anti-doping documentation pursuant to the IST, supplemental or revised documentation may be required. The *Athlete Biological Passport* documentation therefore should ensure that the required information is collected on-site to accompany all *Athlete Samples* for Laboratory information and *Anti-Doping Organization* assessment as required.

7.2 General

Depending on whether *Samples* are also being collected for conventional analysis and the *Athlete Biological Passport* at the same time, some information for the *Athlete Biological Passport* may already be included on the standard collection form.

7.3 Requirements¹

In addition to the mandatory information set out in Article 7.4.5 of the *International Standard for Testing* that must be recorded as a part of all Sample Collection Sessions, the following minimum information, should be included on the *Athlete Biological Passport Doping Control* Form and/or on associated *Sample* collection paperwork such as a Chain of Custody Form or other required Supplementary Report:

¹ Template documentation which meets the requirements of Article 7.3. is available from WADA for all *Anti-Doping Organizations* wishing to implement the *Athlete Biological Passport* program.

- a) Location of *Testing*;
- b) *Event* (if relevant);
- c) Blood loss or gain (pathology or transfusion) in the three months (with estimated volume) preceding each sample collection;
- d) Information on the use of simulated hypoxic conditions in the previous two weeks - if so, 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 previous two weeks including estimated altitude and duration; and
- f) Information in relation to most recent training or physical activity as applicable.

PART THREE: REQUIREMENTS FOR PASSPORT OPERATION FROM INTERNATIONAL STANDARD FOR TESTING AND INTERNATIONAL STANDARD FOR LABORATORIES

Adoption of the following Technical Documents (level two documents) is mandatory in order to comply with the requirements of the Haematological Module of the *Athlete Biological Passport*. All technical requirements identified herein are found in the relevant *International Standards* as Technical Documents but are included in these Appendices for ease of reference. The requirements of these Appendices are applicable to the *Athlete Biological Passport* only and are not applicable to blood collected for any other *Doping Control* purpose.

APPENDIX A

Blood Collection Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2010BSCR

Document Number:	TD2010BSCR	Version Number:	2.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date: 15.11.2011		Effective Date:	01.01.2012

Blood *Sample* Collection Requirements for the *Athlete Biological Passport*

1. Objective

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

2. Scope

The *International Standard for Testing* 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 *Athlete Biological Passport*. 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 *Athlete Biological Passport*.

3. The 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. In case the *Athlete* has trained or competed less than two hours before the time the *Athlete* has been notified of his/her selection, the DCO or the BCO or a Chaperone shall monitor the *Athlete* until this two hour period has elapsed, after which the blood collection shall take place. The nature of the exertion (*Competition*, training, etc.) as well as the duration and general intensity shall also be recorded by the Doping Control Officer.

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

Following notification to the *Athlete* that they have 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. The Athlete Biological Passport Doping Control Documentation

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

- 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 1000 meters within the previous two weeks? If so, or if in doubt, the name and location of the place where the *Athlete* had been as well as the duration of this/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 previous two weeks? If so, as much information as possible on the type of device and the manner in which it was used (frequency, duration, intensity, etc.) should be recorded.

- d) Did the *Athlete* receive any blood transfusion(s) during the previous three months? Was there any blood loss due to accident, pathology or donation in the previous 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 Article E.4.6 of the IST. Vacutainer(s) shall be labelled with a unique *Sample* code number by the DCO/BCO prior to the blood being drawn if they are not pre-labelled and the *Athlete* shall check that the code numbers match.

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

Although the ABP requires only a single tube of blood, the Blood 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 *Athlete Biological Passport* is consistent with the procedure set out in IST Appendix 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) 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 Transport Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2010BSTR

Document Number:	TD2010BSTR	Version Number:	2.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	15.11.2011	Effective Date:	01.01.2012

Blood Sample Transport Requirements for the *Athlete Biological Passport*

1. Objective

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

2. Scope

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

3. Responsibility

The *International Standard for Testing (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 *Athlete Biological Passport*.

4. Storage

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

The storage procedure is the responsibility of the *Doping Control Officer*.

5. Type of Storage Devices

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

- a) A refrigerator;
- b) An insulated cool box;
- c) An 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 Article 9 of the IST, consistent with the practices of the *WADA Blood Collection Guideline* 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 *Anti-Doping Organization* authorized transport method.

7.2 Remarks concerning the storage and transport procedure

Blood *Samples* shall be transported rapidly to a Laboratory so that analysis can ideally be performed within 36 hours of *Sample* collection.

*[Comment: The WADA Blood Collection Guidelines have been revised to reflect these protocols and include practical information on the integration of Athlete Biological Passport Testing into 'traditional' Testing activities. A table has been included which identifies which particular timelines for delivery are appropriate when combining particular test types (the Athlete Biological Passport + hGH, the Athlete Biological Passport + 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 – TD2010BAR

Document Number:	TD2010BAR	Version Number:	2.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date: 15.11.2011		Effective Date:	01.01.2012

Blood Analytical Requirements for the *Athlete Biological Passport*

1. Introduction

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

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

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

The blood *Sample* shall be analyzed within 36 hours of *Sample* collection.

If the Laboratory has taken delivery of the *Sample* after 36 hours from the time of *Sample* collection, the Laboratory shall analyze the *Sample* as soon as possible, however the *Athlete Passport Management Unit (APMU)* and

Testing Authority shall be advised of such delay and departure from the requirement.

The Athlete Passport Management Unit (APMU) will coordinate with the appropriate Laboratory and haematological experts in order to ensure the validity of any result analyzed after 36 hours.

Analytical procedure

In order to standardize analytical results in the Athlete Biological Passport framework, it is important to have blood *Samples* analyzed in an appropriate dedicated network of Laboratories (e.g. *WADA* accredited Laboratories or as otherwise approved by *WADA*) using analyzers with comparable technical characteristics. It is necessary that the instrumentation is validated to provide comparable results prior to analysis of *Doping Control Samples*).

2. Instrument check

Before performing any blood analyses, all reagents shall be verified to ensure that they are within their expiration dates and that they comply with the reagent manufacturer's recommendations. Then, the operational parameters of the instrument shall 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 exclusively be furnished by the manufacturer of the instrument. These controls shall be 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), one fresh blood *Sample* shall be homogenized for a minimum period of 15 minutes on an appropriate mixer (e.g. roller mixer) and then analyzed seven consecutive times. Coefficients of variation shall be below 1.5 % for haemoglobin and HCT and below 15 % for percentage reticulocyte count in order 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 and 3) shall be analyzed once again to demonstrate continuous stability of the instrument and the quality of the analyses done.

3. 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 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.

4. Analysis of Blood Samples

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

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

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

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

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

5. Reporting

The results of the *WADA* accredited or approved Laboratory analysis shall be reported promptly in *ADAMS*.

APPENDIX D

Results Management Requirements for the *Athlete Biological Passport*

WADA Technical Document – TD2010RMR

Document Number:	TD2010BAR	Version Number:	2.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	15.11.2011	Effective Date:	01.01.2012

Results Management Requirements for the *Athlete Biological Passport*

1. Administrative management

An *Athlete Passport* Management Unit (APMU) shall be responsible for administering and managing elements of the *Athlete Biological Passport* within or on behalf of an *Anti-Doping Organization*. This mechanism should allow for all *Athletes' Passports* to be distributed to experts for review as soon as the analysis results are known and the *Athlete's* profile to be updated by the *Anti-Doping Organization* as required. Management of biological data shall be the responsibility of the APMU and such information shall be stored in *ADAMS* and/or the ABP software. The APMU will initially review all profiles in order to facilitate targeting recommendations to the *ADO* when appropriate, or to refer to the Expert Panel as appropriate. The members of the APMU involved in this task will conduct all their activities in strict confidence.

In this appendix a step-wise approach to review of an Athlete's Passport is described. It begins with the creation of a longitudinal profile and the application of the Adaptive Model. There is an initial screening by an expert who will return an evaluation based on the information available at that time.

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

WADA accredited Laboratories or approved Laboratories are presumed to have conducted the *Sample* analysis and custodial procedures in accordance with the *International Standard* for Laboratories and technical documents. The *Athlete* or other *Person* may rebut this presumption by establishing that a departure from the *International Standard* for Laboratories and technical documents occurred which could reasonably have significantly modified the result, in such case the *ADO* shall have the burden to establish why such a departure does not invalidate such 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 99.9-range (0.05-99.95 percentiles).

A *Sample* is considered as atypical if it returns a HGB and/or OFFS value 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.

A value lower than 99.9 can be chosen by the individual *Anti-Doping Organization* to identify atypical *Samples* and/or profiles that warrant further investigation and/or results management.

In the event that the longitudinal “profile” consists of a unique value (athlete tested only once) and that this unique value was deemed atypical by the Adaptive Model, the *Anti-Doping Organization* 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.

3. The expert review

In the event that a result rendered by a *WADA* accredited or approved Laboratory is an atypical value or triggers an atypical longitudinal profile, the *Passport* must be reviewed by an expert chosen by the Athlete Passport Management Unit of the *Anti-Doping Organization*. The Athlete Passport Management Unit is responsible to liaise with this expert to ensure a review of the *Passport* in a timely manner.

The expert shall review the *Passport* anonymously (without reference to the specific *Athlete* by name) and conduct his or 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	<u>APMU</u> Action
Normal	Continue normal <i>Testing</i> pattern
<i>Passport</i> suspicious: Further data is required	<i>Target Test as recommended by APMU and/or expert</i>
Considering the information within the <i>Athlete’s Passport</i> , it is highly unlikely that the longitudinal profile is the result of a normal physiological or pathological condition and may be the result of the use of a <i>Prohibited Substance or Prohibited Method</i> .	Send to two other experts (refer to section 4)
Considering the information within the <i>Passport</i> it is highly likely that the <i>Athlete</i> has a pathological condition	Inform the <i>Athlete</i> via the <i>ADO</i> (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 to rely on the ABP for this purpose.

4. Formal review by a group of 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 condition 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 *Athlete Passport Management Unit* from the Expert Panel. The group of three experts should be composed of individuals with knowledge in the fields of clinical haematology (diagnosis of blood pathological conditions), sport medicine or exercise physiology. The *Athlete Passport Management Unit* is responsible for liaising with the experts and for advising the *Anti-Doping Organization* of the subsequent expert assessment. The review of the group of three experts must follow the same logic as presented in 3. 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 on an anonymous basis with strict confidentiality and in collaboration with the APMU.

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 request is handled jointly by the *Athlete Passport Management Unit* and *Anti-Doping Organization*. The experts will conduct the review based on the *Athlete's* blood profile data, and any additional information requested from *Anti-Doping Organization(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 recommend additional Testing be pursued by the *Anti-Doping Organization*.

5. Follow up on expert opinions

In the event that the evaluation of the group of 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 Athlete Passport Management Unit shall be responsible for the compilation of the Athlete Biological Passport 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.

The *Athlete Biological Passport Documentation Package* shall contain:

- a) The age and gender of the *Athlete*, the sport and discipline;
- b) The biological data and the results obtained by the Adaptive Model;
- c) Information on possible exposure to altitude of the *Athlete* for the period defined by the Expert Panel;
- d) Competition information; documentation on the Chain of Custody, temperature conditions during the transport of the *Samples*;

- e) The Laboratory documentation including blood results, the scatter grams, the Chain of Custody, the internal and external quality controls;
- f) Information from the *Doping Control* forms for each *Sample* collected during the period, as defined by the APMU and Expert Panel, including information if the athlete received a blood transfusion and/or suffered significant blood loss in the previous three months; and
- g) Any other relevant information provided by the ADO.

The *Athlete Biological Passport Documentation Package* shall be sent to the same panel of three experts who will subsequently review the additional information. The panel of three experts is responsible to provide a joint evaluation that shall be signed by all three experts and included in the *Athlete Biological Passport Documentation Package*. If the panel of three experts confirms their previous position that 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 *Athlete Passport Management Unit* will declare an *Adverse Passport Finding*. The *Athlete Biological Passport Documentation Package* is then reviewed by the *Anti-Doping Organization*.

The review at this stage is anonymous, however it is accepted that in some cases 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 *Anti-Doping Organization* is considering the assertion of an anti-doping rule violation against the *Athlete*;
- b) Providing the *Athlete and WADA* the *Athlete Biological Passport Documentation Package*; and
- 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 panel of three experts shall review the information provided by the *Anti-Doping Organization*, 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 it 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 panel expresses the opinion set forth in (a) above, then the *Anti-Doping Organization* shall be informed by the APMU. The *ADO* will then proceed to results management in accordance with Article 7.4 of the *Code*.

In the event the *Athlete* has been found to have committed an ADRV based on the Passport, the *Athlete's Passport* shall be re-set upon their return to Sport following completion of the relevant period of suspension in order 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 *Athlete's Passport* will remain in effect except in those cases where the *Prohibited Substance* or *Method* resulted in a manipulation of the haematological variables. In those instances, the *Athlete's* profile would be reset from the time of the sanction.