

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

### WADA Technical Document – TD2016RMR

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#### 1. Administrative Management

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

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

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

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

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

## 2. Review by the Adaptive Model

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

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

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

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

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

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

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

### 3. The Initial Expert Review

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

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

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

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

<b><u>Expert</u> Evaluation</b>	<b><u>APMU</u> Action</b>
Normal.	Continue normal <i>Testing</i> pattern.
<i>Passport</i> suspicious: Further data is required.	Alert <i>ADO</i> to do Target <i>Testing</i> and provide recommendations.
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 likely may be the result of the <i>Use of a Prohibited Substance or Prohibited Method</i> .	Send to two other <u>Experts</u> , as per section 4 of this Appendix.
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 <u>Experts</u> ).

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

#### **4. Review by Three Experts**

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

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

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

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

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

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

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

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

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

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

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

For the Haematological Module, this additional information is required:

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

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

For the Steroidal Module, this additional information is required:

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

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

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

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

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

The *ADO* will then be responsible for:

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

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- b. Providing the *Athlete* and WADA the ABP Documentation Package.
  - c. Inviting the *Athlete* to provide his/her own explanation, in a timely manner, of the data provided to the ADO.

## 6. Review of Explanation From *Athlete*

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

- d. Unanimous opinion of the Panel that based on the information in the *Passport*, it is highly likely that the *Athlete* used a *Prohibited Substance* or *Prohibited Method*, and that it was unlikely to find the *Passport* abnormal assuming any other cause; or
- e. Based on the available information, the Panel is unable to unanimously reach an opinion and, in such a case, the Panel may or may not recommend further investigation or *Testing*.

## 7. Disciplinary Proceeding

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

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

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