

WADA Technical Document – ~~TD2023APMU~~ISL TD2027APMU

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Written by:	<u>WADA Science/APMU Working Group</u>	Approved by:	WADA Executive Committee
<u>Reviewed by:</u>	<u>WADA Laboratory Expert Advisory Group</u>		
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ATHLETE PASSPORT MANAGEMENT UNIT REQUIREMENTS AND PROCEDURES

Athlete Passport Management Unit Requirements and Procedures

1.0 Introduction

This *Technical Document (TD)*, which constitutes an integral part of the *International Standard for Laboratories (ISL)* ^[1], has been established to harmonize effective management of *Athlete Passports* by providing specific requirements that an *Athlete Passport Management Unit (APMU)* shall meet in order to be a WADA-approved *APMU*.

2.0 APMU Athlete Passport Management Unit Roles and Responsibilities

2.1 The APMU is the dedicated unit that is responsible for the timely management of Passports in the *Anti-Doping Administration and Management System (ADAMS)* on behalf of the Passport Custodian (PC). Passport management by the APMU involves:

- a) Performing Passport assessments to make timely ~~Target Testing~~ recommendations for Target Testing, Further Analysis and long-term storage to the Passport Custodian PC via the APMU Report in *ADAMS* when appropriate; and
- b) Managing the review of atypical Passports according to Annex C of the *International Standard for Results Management (ISRM)* ^[42], including, but not limited to, the following:
 - i. Issuing and updating APMU Reports in *ADAMS*;
 - ii. In case of an *Atypical Passport Finding (ATPF)*, or when a review is otherwise justified, assigning and liaising with the Expert panel as required,
 - iii. Compiling all necessary information to establish an *Athlete Biological Passport (ABP) Documentation Package*, and
 - iv. Declaring *Adverse Passport Findings (APFs)* to the Passport Custodian PC and WADA.

2.2 The APMU shall assess and manage Passport Sample validity in *ADAMS*, in consultation accordance with ~~the Experts or Laboratories when necessary, per~~ Article 8.25 of this *TD*.

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2.3 The APMU shall provide support to the Passport CustodianPC in defining priorities in order to optimize the efficiency of their Athlete Biological Passport (ABP) program. These priorities may include, but are not limited to, cost efficiency, special analyses, Test Distribution Plans (TDP), and Target Testing.

3.0 APMU Hosting

3.1 An APMU shall be hosted by a Laboratory.

[Comment to Article 3.1: Hosting in this context is defined as the provision of staff, facilities and resources for the efficient functioning of the APMU.]

~~**3.2** APMU hosting by a Laboratory does not preclude the use of qualified APMU managers employed by ADOs or other Laboratories.~~

~~**3.33.2** Passport management shall be carried out in ADAMS using dedicated APMU accounts associated with the host Laboratory regardless of the physical location of the APMU manager(s).~~

~~**3.43.3** The host Laboratory shall implement procedures to maintain the operational independence of the APMU, including the appointment of dedicatedtrained personnel with a specified time commitment dedicated to the APMU ~~and a separate allocation in the budget~~ so that the APMU can continue to function should ~~the WADA~~ accreditation of the Laboratory be suspended (see Article ~~7.1.57.1 e~~) of this *TD*).~~

4.0 APMU Personnel

~~**4.1** APMU personnel shall be employed by the host Laboratory.~~

~~**4.14.2** The host Laboratory shall have a Person qualified to function as the designated head of the APMU by assuming professional, organizational, educational, and administrative responsibility of the APMU. The APMU Director is responsible for ensuring the APMU operates in compliance with this *TD* and applicable *International Standards*. In particular, the APMU Director assumes the responsibility of signing and delivering all APFs to the Passport CustodianPC and WADA.~~

~~*[Comment: The head of the APMU is termed “Director” herein, however use of this title is not a requirement and can be adjusted according to the needs of the organization.]*~~

The APMU Director’s qualifications shall ensure that this individual is competent and capable of leading the APMU operations, including:

- A doctoral degree (or equivalent) in one of the natural sciences or medicine, or in the absence of a doctoral degree, a master’s degree (or equivalent) with extensive and appropriate anti-doping science experience and training (*i.e.*, minimum of five (5) years);
- Management experience;

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- Ability to oversee compliance with ~~quality management practices~~applicable International Standards and TDs; and
- Good command of at least one of WADA's two official languages, English and French.

It is acknowledged that the APMU Director plays an essential role in the APMU operations and that WADA APMU approval is delivered based upon appointment of a proper candidate. WADA reserves the right to review the credentials of such ~~appointment~~appointments in accordance with the above qualifications.

- The APMU Director is responsible for ~~maintaining~~ensuring documentation is available for each personnel employed by, ~~or under contract to,~~ the APMU. Such documentation shall contain copies of the curriculum vitae or qualification form, a job description, and records of initial and ongoing training related to anti-doping.
- Any personnel changes to the position of APMU Director shall be communicated to WADA no later than one (1) month prior to the date the APMU Director is scheduled to vacate the position. A succession plan shall be submitted to WADA.
- The APMU Director is notably responsible for monitoring the quality of Passport management and ensuring that other APMU personnel have the experience and training necessary to perform their duties.

[Comment to Article 4.2: The head of the APMU is termed "Director" herein, however use of this title is not a requirement and can be adjusted according to the needs of the organization.]

4.24.3 The APMU shall use qualified scientific personnel to serve as APMU manager(s) to manage the Passport review process and Sample validity, and to provide Target Testing, Further Analysis and Analytical Testinglong-term storage recommendations through APMU Reports in ADAMS. ~~APMU manager(s) shall be employed by the host Laboratory or be under contract by an ADO or another Laboratory.~~ The APMU should have at least one APMU manager per module of the ABP, where one manager may supervise multiple modules based on their qualifications.

[Comment: The designation of "manager" is used herein, however use of this title is not a requirement and can be adjusted according to the needs of the organization. The APMU Director can also serve in the role of APMU manager as required. Where the APMU manager is employed by an ADO, it is assumed that this individual will have access to the identity and other privileged or confidential information about the Athlete, past Testing and/or Results Management and investigations history. This additional information shall not be shared by the APMU manager in the APMU Report but is recognized to be important to contribute to effective Target Testing.]

- APMU manager(s) shall have qualifications in one or more modules of the ABP. The qualifications are at minimum:

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- i. Bachelor’s degree (or equivalent) in one of the natural or health sciences. Documented experience of three (3) years or more in anti-doping or similar scientific training is equivalent to a Bachelor’s degree for this position; and
 - ii. Adequate training in one or more modules of the *ABP*, including the capacity to understand and evaluate analytical results ~~and~~ the physiological response to the Use of Prohibited Substances and Prohibited Methods, as well as the impact of confounding factors, and criteria relevant for *Target Testing*, Further Analysis and long-term storage requests.
- b) Where the APMU manager ~~has strong qualifications~~ is qualified in Laboratory steroid analysis, steroid doping ~~and~~ steroid metabolism and/or clinical endocrinology, ~~and is not employed by the Passport Custodian~~, the APMU manager can act as a first Expert for the Steroidal Module of the *ABP*.

[Comment to Article 4.3: The designation of “manager” is used herein; however, use of this title is not a requirement and can be adjusted according to the needs of the organization. The APMU Director can also serve in the role of APMU manager as required. Additional levels of APMU staff (e.g. manager or senior manager) can be designated by the APMU based on their training and experience related to the ABP.]

4.34.4 The APMU should have administrative personnel to coordinate with the Passport Custodian PC to compile the necessary documentation required for the ABP Documentation Packages, manage communication with various stakeholders and assist with the organization of APMU-related documentation.

5.0 APMU Confidentiality and Security

5.1 All APMU related activities shall be carried out in accordance with the confidentiality requirements of the *Code* ^[3] and *International Standards*.

5.2 While APMU activities are typically carried out using Passport data associated with a unique ID, and while APMU staff generally do not have access to data that would enable them to identify *Athletes* in *ADAMS*, APMUs may access Personal Information where additional information is needed to assess a Passport (e.g., when assessing a Passport that has generated an *ATPF*). In such contexts, Personal Information shall only be processed for the purposes set out in this *TD*; and shall be handled by the APMU in accordance with the *International Standard* for ~~the~~ Data Protection of Privacy and Personal Information (ISPPPI) ^[2] (ISDP) ^[4] and applicable laws.

5.3 Without limiting the above, the APMU shall adhere to those information retention times set forth in Annex A of the ~~ISPPPI~~ ISDP ^[4]. In consultation with the Passport Custodian PC, the APMU shall develop specific plans and procedures to ensure the secure retention and eventual destruction of Personal Information.

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5.4 The APMU shall develop, maintain, implement and ensure ~~ongoing~~ compliance with a written information security ~~program~~policy that includes physical, organizational, technical, environmental and operational safeguards appropriate to the sensitivity of the information in its custody or to which it has access. Such program shall be based on a threat and risk assessment by expert(s) in the relevant field; and shall ensure the confidentiality of its procedures and security of its information systems regardless of the physical location of the APMU personnel at the time of Passport management, ~~such as when the APMU manager is physically located in an ADO, another Laboratory or when travelling.~~

6.0 ABP ~~Expert Panel~~Experts

6.1 The APMU shall engage the services of ~~qualified~~ Experts for the review of Passports in accordance with Annex C of the *ISRM* ^[2]. The APMU shall maintain a pool of Experts for each module permitting the formation of distinct Expert panels according to the criteria outlined in Article 6.3 of this *TD*.

*[Comment to Article 6.1¹: A list of Experts, including their field(s) of expertise (see Article 6.3 of this *TD*), is provided by WADA to all APMUs for each module of the ABP, on a regular basis.]*

~~6.16.2~~ The APMU ~~should~~shall inform WADA and their clients about any changes in their pool of Experts.

~~6.26.3~~ The As required during the review process of a particular Passport (see Article C.3 of the *ISRM* ^[2]), the APMU shall establish, ~~in consultation with the Passport Custodian, a list of Experts who are qualified to comprise an Expert panel for the review of Passports, that shall consist of Experts with complementary knowledge such that all the following relevant fields are represented:~~

- For the Hematological Module, the Expert panel ~~should consist~~shall be composed of at least three (3) Experts who have qualifications in one or more of the fields of clinical and laboratory hematology, sports medicine and exercise physiology, as they apply to blood doping.
- For the Steroidal Module, the Expert panel ~~should~~shall be composed of at least three (3) Experts with who have qualifications in one or more of the fields of ~~laboratory~~laboratory steroid analysis, steroid doping, (in urine and/or serum), and clinical endocrinology, as it applies to steroid *Marker* metabolism.
- For the Endocrine Module, the Expert panel ~~should~~shall be composed of at least three (3) Experts with who have qualifications in one or more of the fields of endocrine biomarker analysis, doping with growth hormone and related compounds, and ~~for~~ clinical endocrinology, as it applies to growth hormone *Marker* metabolism.

~~For each module, an Expert panel should consist of Experts with complementary knowledge such that all relevant fields are represented.~~

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All three (3) Experts forming an Expert panel assigned to review a particular Passport shall not be of one and the same nationality and no two (2) Experts shall have a primary affiliation with the same organization, institution or company, including, but not limited to, universities, hospitals and research institutes.

~~Where applicable, at least one Expert on the Expert panel should currently serve or have previously served as an Expert and reviewed Passports for a WADA-approved APMU.~~

~~6.36.4~~ The APMU shall ensure that each Expert:

- Has access to relevant ABP Expert education resources provided by WADA;
- Has an Expert account in ADAMS for the anonymous review of Passports assigned by the APMU;
- Is independent of the Passport CustodianPC and has no conflicts of interest in reviewing Passports, as documented in a conflict-of-interest declaration; and
- Has signed the WADA ABP Expert Code of Conduct Declaration.

[Comment to Article 6.4: An APMU manager may also concurrently serve as an Expert for other APMUs, provided all requirements of Article 6.0 of this TD are met.]

7.0 Process and Requirements for WADA APMUAthlete Passport Management Unit Approval

Passports shall only be managed by APMUs that have been approved by WADA.

7.1 Applying for WADA APMUAthlete Passport Management Unit Approval

- Expression of Interest

The candidate APMU shall officially contact WADA in writing to express its interest in the WADA APMU approval process.

- Preliminary Discussion with WADA

The purpose of this discussion is to clarify issues with regard to the approval process and to obtain information about different aspects of the APMU relevant to the approval process. Such a discussion could be conducted prior to or during the approval process.

- Description of the Candidate APMUAthlete Passport Management Unit

The candidate APMU shall then complete a detailed application form provided by WADA and submit it to WADA no later than eight (8) weeks following receipt. The application form includes, but is not limited to, the following:

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- i. List of staff, their qualifications and intended ~~role~~ roles within the APMU;
- ii. Description of the APMU information security program (see Article 5.4 of this *TD*), including a description of the physical, organizational, technical, environmental and operational security measures implemented to protect records and computer systems;
- iii. ~~List~~ Tentative list of external Experts, their contact information, their qualifications and signed ABP Expert Code of Conduct Declaration Declarations;
- iv. Business Plan plan for the APMU and letters of support from ADOs that demonstrate a commitment to manage, according to Article 2.0 of this *TD*, a minimum of 100 active hematological Passports and 500 active steroidal Passports from Signatories annually, within one year of receiving approval. An eligible Business Plan business plan shall demonstrate a commitment to provide in ADAMS, at least 200 APMU Reports for hematological Passports and 500 APMU Reports for steroidal Passports per year.

[Comment: to Article 7.1 c): A Passport is considered active when at least one Sample collection is planned during the first year of operation of the APMU. There is no minimum number of active endocrine Passports required for the business plan.]

d) Liability Insurance Coverage

The APMU shall provide documentation to WADA that professional liability risk insurance coverage or equivalent has been obtained which covers the APMU to an amount of no less than (≥) 2 million USD annually, and should ensure that the Expert panel has suitable professional liability risk insurance or equivalent coverage.

e) Operational Independence

The APMU shall ensure a degree of operational independence from the host Laboratory such that the APMU can continue to fulfil its responsibilities in compliance with this *TD* should the WADA accreditation of the Laboratory be suspended, where the reason for the Suspension does not have an impact on the function of the APMU. Operational independence implies that the APMU shall have ~~a separate allocation in the budget and~~ sufficient technical and human resources to permit the APMU to manage its own affairs without hindrance or interference by the host ~~Laboratories~~ Laboratory.

f) Compliance with the WADA APMU Code of Ethics

The candidate APMU shall implement and comply with the provisions in the WADA APMU Code of Ethics. The APMU shall provide the APMU Code of Ethics to APMU personnel and ensure their understanding and compliance with all aspects. The candidate APMU shall provide ~~to~~ WADA with a letter of compliance with the APMU Code of Ethics, signed by the APMU director.

g) WADA Recommendation for Approval

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After ~~receipt of~~receiving the application form, WADA will complete and submit a report to the candidate APMU. The report will include a recommendation concerning approval of the candidate APMU. In the case where the recommendation is that the APMU should not be approved, the report will identify improvements required in order to be re-considered for designation as a WADA-approved APMU. In the case where the recommendation is that the APMU should be approved, the report and recommendation will be submitted to the WADA Executive Committee for approval.

h) Issuing Approval Letter and Publishing APMU List on WADA’s Website

A letter signed by a duly authorized representative of WADA shall be issued in recognition of approval of an APMU, specifying the name of the APMU. ~~Approval may be granted with retroactive effect.~~ An updated list of approved APMUs shall be published by WADA on WADA’s website.

i) Training of Approved APMUs

After receiving approval by WADA, and before evaluating any Passports in ADAMS, an APMU must complete an in-person training provided by WADA to ensure the efficient management of Passports. Any costs associated with this training shall be borne by the APMU.

7.2 Maintaining WADA Approval

An APMU shall continue to function if the Laboratory’s accreditation is suspended, provided that the APMU continues to meet other criteria for approval, and that any non-conformities related to the Suspension of the Laboratory’s accreditation do not have an impact on the APMU. The APMU’s approval shall be revoked if the WADA accreditation of the associated Laboratory is revoked.

[Comment to Article 7.2: Suspension or Revocation of APMU approval shall not be considered in decisions on Suspension or Revocation of Laboratory accreditation unless the APMU non-compliance has a clear impact on the function of the Laboratory.]

a) Minimum Number of Passports and APMU Reports

In order to maintain proficiency, WADA-approved APMUs are required to review a minimum number of Passports and provide APMU Reports for Passports of Signatory Passport Custodians-PCs. WADA shall monitor the total number of Passports under the responsibility of the APMU and the number of APMU Reports issued by the APMU. If the annual number falls below 100 active hematological Passports, 500 active steroidal Passports, 200 hematological APMU Reports or 500 steroidal APMU Reports, WADA APMU approval may be suspended or revoked.

[Comment: to Article 7.2 a): For the purposes of WADA APMU monitoring, a Passport is considered active when at least one Sample is collected and matched to the Passport during the previous twelve months period at the time of

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the assessment. There is no minimum number of active endocrine Passports or APMU Reports required to maintain APMU approval.]

b) Documenting Compliance with the WADA APMU Code of Ethics

The APMU shall annually provide ~~to~~ WADA with a letter of compliance with the provisions of the APMU Code of Ethics, signed by the APMU Director. All APMU personnel shall sign the WADA APMU Code of Ethics ~~on a yearly basis~~, and the signed documents shall be kept as part of their personnel file. The APMU may be asked to provide documentation demonstrating compliance with the provisions of the APMU Code of Ethics.

c) Documenting Sharing of Knowledge

The APMU shall proactively share knowledge with other WADA-approved APMUs. The APMU should participate at least once annually in a WADA Working Group or an anti-doping symposium or conference. The APMU shall supply an annual report on sharing of knowledge with WADA. A description of this sharing of knowledge is provided in the WADA APMU Code of Ethics.

d) Maintaining Professional Liability Insurance Coverage

The APMU shall maintain an ongoing professional liability risk insurance coverage or equivalent which covers the APMU to an amount of no less than (\geq) 2 million USD annually, and should ensure that the Expert panel has suitable professional liability risk insurance or equivalent coverage. Proof of the corresponding coverage shall be provided to WADA upon request.

e) APMU Compliance Monitoring by WADA

WADA shall monitor the compliance of APMUs against the requirements listed in applicable International Standards and TDs. In addition, WADA shall also conduct periodic audits of APMU compliance to assess the overall performance of each APMU and to decide its approval status. Following compliance monitoring of the APMU by WADA, a dedicated training may also be required for an already approved APMU (e.g., where there has been significant turnover of APMU staff or upon request by the APMU), where the associated costs shall be borne by the APMU.

f) APMU Assessment by WADA

WADA reserves the right to conduct document-based audits as well as inspect and assess the APMU through on-site or remote assessments at any time, at WADA's expense. The notice of an on-site assessment will be made in writing to the APMU Director. In exceptional circumstances, the on-site assessment may be unannounced.

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g) Suspension or Revocation of Approval

Suspension or Revocation of APMU approval may occur whenever the APMU fails to comply with applicable *International Standards* and/or ISL TDs, or where such measure is otherwise required in order to protect the interests of the anti-doping community.

Without limitation, the following nonconformities in the routine operations of an APMU may be considered in support of Suspension:

- i. Failure to comply with any of the requirements listed in applicable *International Standards* and/or ISL TDs;
- ii. Failure to cooperate with *WADA* or the relevant PC, Testing Authority (TA), or Results Management Authority (RMA) in providing documentation;
- iii. Noncompliance(s) with the APMU Code of Ethics;
- iv. Major changes in key staff without proper and timely notification to *WADA*;
- v. Failure to cooperate in any *WADA* inquiry in relation to the activities of the APMU;
- vi. Noncompliance(s) identified from APMU assessment(s); or
- vii. Loss of resources jeopardizing the quality and/or viability of the APMU.

Noncompliance(s) in APMU performance will be assessed by *WADA* on a case-by-case basis considering the severity and consequences to the anti-doping system. Evidence of serious or multiple noncompliance(s) will be reported by *WADA* to an external assessment panel, who will make a recommendation to *WADA* regarding the approval status of the APMU and the required corrective actions and associated deadlines. *WADA* reserves the right to provisionally suspend an APMU's approval pending a full investigation. Such a decision may be taken by the Chair of *WADA*'s Executive Committee.

The period and terms of Suspension shall be proportionate to the seriousness of the noncompliance(s) and the need to ensure reliable management of *Athlete Passports*. A period of Suspension shall be of a duration to be decided by *WADA* and up to a maximum of six (6) months, during which time any nonconformity(ies) must be corrected and such correction documented and reported to *WADA*. If the nonconformity(ies) is/are not corrected during the initial Suspension period, the Suspension shall either be further extended or the APMU approval revoked. The Suspension period may be extended up to a maximum of an additional six (6) months, based on justifiable delays in implementing the satisfactory corrective actions. If the APMU has provided evidence determined to be satisfactory by *WADA* that the noncompliance(s) are corrected, the APMU's approval shall be re-instated. If the APMU has not provided evidence determined to be satisfactory by *WADA* at the end of the extended Suspension period, not to exceed twelve (12) months, the APMU's approval shall be revoked.

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During the period of Suspension of the APMU, the management of all Athlete Passports shall be transferred by the ~~Passport Custodian~~PC to another WADA-approved APMU after signing an agreement with this other APMU.

The WADA Executive Committee shall revoke the approval of any APMU if it determines that Revocation is necessary to ensure reliable management of Athlete Passports. Revocation may be based on, but not limited to, the following noncompliance(s) in the routine operations of an APMU:

- i. Repeated suspensions of WADA APMU approval;
- ii. Systematic failure to comply with applicable *International Standards* and/or ISL TDs;
- iii. Failure to correct a lack of compliance with any of the requirements listed in applicable *International Standards* and/or ISL TDs during a Suspension period;
- iv. A serious or repeated violation of the APMU Code of Ethics;
- v. Repeated and/or continuous failure to cooperate in any WADA inquiry in relation to the activities of the APMU;
- vi. Serious noncompliance(s) identified from APMU assessment(s); or
- vii. Loss of resources jeopardizing the quality and/or viability of the APMU.

h) Appeals

WADA's decision to suspend or revoke an APMU's approval may be appealed in writing by the APMU before CAS within twenty-one (21) days of the date of receipt of notification.

8.0 Passport Management and Administration

The APMU shall manage all Passports under the custody of the ~~Passport Custodian~~PC.

8.1 Passport Review Process

The APMU shall carry out the Passport review process as described in Annex C of the *ISRM* ^[42].

~~a) When assessing a newly matched Sample in a Passport:~~

- ~~• The APMU shall assess the validity of individual Samples contained within the Passport in *ADAMS* and address any observed irregularities according to Article 8.2 of this *TD* by updating the APMU Report;~~
- ~~• The APMU shall review any new Samples within the updated Passport and provide Target Testing, Sample analysis or other recommendations via the APMU Report as required;~~

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- ~~Where required for its analysis, the APMU may request further information from the Passport Custodian including, but not limited to, circumstances and details of Sample collection, transport, and analysis, redacted Athlete Competition schedule, travel history, Athlete performance, redacted Athlete medical information, information on an Adverse Analytical Finding (AAF) that is potentially relevant in the context of the Passport, or altitude/whereabouts information which may help them interpret the new Sample;~~
- ~~Where the Passport includes elements justifying a review or upon request by the Passport Custodian, the APMU shall send the Passport for review in ADAMS by an Expert.~~

[Comment: One of the benefits of the ABP is the ability to focus resources on atypical results requiring attention. As such, it is not mandatory for an APMU to review all newly matched Samples under their responsibility that do not generate a specific notification requiring mandatory follow-up. Nevertheless, at the discretion of the Passport Custodian, an APMU may be requested to review normal Passports.]

b) ~~When assessing a Passport that generated an ATPF:~~

- ~~All ATPFs shall be reviewed by a Laboratory-based APMU manager;~~

[Comment: ATPFs are generated by the following primary Markers: hemoglobin (HGB) and the OFF-Score for the Hematological Module; the testosterone to epitestosterone ratio (T/E) in urine, and testosterone (T) and/or the testosterone to androstenedione ratio (T/A4) in blood for the Steroidal Module; and the GH-2000 score for the Endocrine Module.]
- ~~The APMU shall review any previous APMU Reports associated with the Passport;~~
- ~~The APMU shall assess the validity of individual Samples contained within the Passport in ADAMS, address any irregularities according to Article 8.2 of this TD and update the APMU Report accordingly;~~
- ~~The APMU shall evaluate the need for urgent Target Testing of the Athlete and communicate Testing recommendations to the Passport Custodian via the APMU Report as required;~~
- ~~The APMU shall assess the need for additional analysis of existing Samples by specific methods (e.g., Agents Affecting Erythropoiesis, Gas Chromatography / Combustion / Isotope Ratio Mass Spectrometry [GC/C/IRMS], Steroid Esters, hGH Isoform Differential Immunoassay, etc.) and communicate these to the Passport Custodian via the APMU Report as required. The APMU may also recommend specific Sample(s) to be placed in long-term storage.~~
- ~~If an Expert has previously recommended that follow-up Testing include a minimum number of Samples before further review of an Athlete's Passport data, the APMU may delay sending the Passport for Expert review until the planned number of Samples have been collected and analyzed;~~

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- If, after managing the Sample validity, the Passport remains atypical, the APMU shall, without delay, send the Passport for review in ADAMS by an Expert according to Article C.2.2 of the ISRM^[4]. In the event of an Expert opinion of:

- “Likely Doping”: the APMU shall update the APMU Report indicating “Likely Doping”, specifying any detailed analysis or Testing recommendations from the Expert (if provided), and continue the Passport review process according to Article C.3 of the ISRM^[4];
- “Suspicious”: the APMU shall update the APMU Report indicating “Suspicious”, highlighting the main atypical features, and outline a Target Testing strategy (if necessary) based on the Expert recommendations, or recommend further analysis (e.g., GC/C/IRMS);
- “Normal”: the APMU shall update the APMU Report indicating “Normal”, summarizing the review by the Expert and outlining any Testing recommendations provided by the Expert;
- “Likely Medical Condition”: the APMU shall update the APMU Report indicating “Likely Medical Condition” with submission to additional Experts if recommended in the Expert evaluation and should inform the Athlete via the Passport Custodian. If the first Expert is not a medical doctor, the Passport should be sent to a medical doctor from the Expert panel prior to contacting the Passport Custodian.

[Comment: the APMU recommendation in ADAMS should mirror the Expert's opinion(s) and any changes in the status of the APMU recommendation should be based on a change in Expert opinion(s) upon further review of the Passport.]

- e) When assessing a urine Sample that generated an Atypical Passport Finding – Confirmation Procedure Request (ATPF-CPR); see TD EAAS^[3] for the steroidal Passport:
 - The APMU shall assess the validity of the Sample generating the Confirmation Procedure (CP) request in ADAMS, address any irregularities according to Article 8.2 of this TD and update the APMU Report accordingly;
 - When the ATPF-CPR has been triggered for a Sample where the presence of ethanol or other factors impacting the steroid profile have been reported, the APMU shall evaluate the need to perform CP(s) and update the APMU Report accordingly within seven (7) days. Justification not to proceed with CP(s) may include:
 - the presence of ethanol glucuronide (EtG) in a Sample from an Athlete with previous similar findings in their Passport with negative GC/C/IRMS results (indicating a pattern of alcohol abuse); or

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- ~~○ communication of the existence of other AAFs reported for the Sample to the APMU by the Passport Custodian or Testing Authority, as applicable, which would likely lead to a maximum sanction; or~~
- ~~○ communication of the existence of a Therapeutic Use Exemption (TUE) for the Athlete to the APMU by the Passport Custodian or Testing Authority, as applicable.~~
- ~~— [Comment: As stated in the TD EAAS, in such cases, the Passport Custodian, or Testing Authority as applicable, shall advise the Laboratory, in writing and within fifteen (15) days following reception of the ATPF-CPR notification, whether or not to proceed with CP(s) of the Sample's steroid profile.]~~
- In cases when an ATPF-CPR is generated for two (2) or more Samples, which are linked to a single Sample Collection Session from the same Athlete, the APMU should advise the Passport Custodian, and Testing Authority as applicable, to prioritize the confirmation of the Sample with the highest concentration of Markers of the steroid profile. In such cases, the Passport Custodian, or Testing Authority as applicable, shall advise the Laboratory, in writing and within fifteen (15) days following reception of the ATPF-CPR notification, whether or not to proceed with CP(s) of the Sample's steroid profile.

d) ~~When assessing a Suspicious Steroid Profile Confirmation Procedure Request (SSP-CPR):~~

The APMU will receive an SSP-CPR notification through ADAMS when there is no existing urine steroidal Passport for the Athlete in ADAMS (i.e. this is the first Sample in the Athlete's steroidal Passport), and the Sample's "steroid profile" meets any of the following criteria:

- a) T/E ratio > 4.0;
- b) Concentration of T or E (adjusted for the SG) > 200 ng/mL in males or > 50 ng/mL in females;
- c) Concentration of A or Etio (adjusted for the SG) > 10,000 ng/mL;
- d) Concentration of 5 α Adiol (adjusted for the SG) > 250 ng/mL in males or > 150 ng/mL in females.

Upon receipt of an SSP-CPR notification:

- The APMU shall assess the validity of the Sample generating the CP request in ADAMS, address any irregularities according to Article 8.2 of this TD and update the APMU Report accordingly.
- The APMU shall evaluate the need to perform CP(s) and update the APMU Report accordingly within seven (7) days of receipt of the SSP-CPR notification. The Passport Custodian, or Testing Authority as applicable, shall advise the Laboratory, in writing and within fifteen (15) days following reception of the SSP-CPR notification, whether the Laboratory shall proceed with CP(s).

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~~[Comment: In the absence of an ATPF-CPR or SSP-CPR, the APMU may also make a recommendation for GPs of the steroid profile, based on assessment by the APMU.]~~

8.2 ~~Expert~~ Primary and Secondary Markers

The Adaptive Model automatically processes in ADAMS primary and secondary Markers, where primary Markers are the most specific to doping and secondary Markers provide supporting evidence of doping in isolation or in combination with other Markers. The following primary and secondary Markers are processed in ADAMS:

Table 1: Primary and Secondary Markers of the ABP

Module	Sample type	Primary Markers	Secondary Marker(s)
Hematological	Whole blood	Hemoglobin (HGB) Reticulocyte percentage (RET%) OFF-score (OFFS)	Abnormal Blood Profile Score (ABPS)
Steroidal	Urine	Testosterone to Epitestosterone ratio (T/E) 5 α -Androstane-3 α ,17 β -diol to Epitestosterone ratio (5 α Adiol/E)	5 α -Androstane-3 α ,17 β -diol to 5 β -Androstane-3 α ,17 β -diol ratio (5 α Adiol/5 β Adiol) Androsterone to Etiocholanolone ratio (A/Etio)
	Serum	Testosterone (T) Testosterone to Androst-4-ene-3,17-dione ratio (T/A4)	
Endocrine	Serum	GH-2000 score Insulin-like growth factor-I (IGF-I)	N-terminal pro-peptide of type III collagen (P-III-NP)

8.3 Passport Status in ADAMS

- a) The status “Atypical” is given to a Passport where the last matched Sample triggered an Atypical Passport Finding (ATPF) by the Adaptive Model in ADAMS, which identifies primary Marker(s) value(s) as being outside the Athlete’s intra-individual range at a specificity of 99%, assuming a normal physiological condition ^[2].
- b) The status “Sequence” is given to a Passport generating a sequence abnormality, where the longitudinal profile consisting of (up to) the last five (5) valid primary Marker values is identified as deviating from expected ranges by the Adaptive Model at a specificity of 99.9%, assuming a normal physiological condition.

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- c) The status “Flagged” is given to a Passport where the last matched *Sample* has at least one secondary *Marker(s)* value(s) outside the *Athlete’s* intra-individual range, as identified by the Adaptive Model in *ADAMS* at a specificity of 99%, assuming a normal physiological condition.
- d) The status “Normal” is given to a Passport not identified by the above criteria. A normal Passport could still contain features warranting further scrutiny.

8.4 Passport Review of Normal

- a) The APMU shall review all Passports and submit an APMU Report as soon as possible, and no later than seven (7) days following matching of the *Sample* in *ADAMS*, where a newly matched *Sample* generates an *ATPF* or sequence abnormality.
- a)b) The APMU shall review all **Passports** and submit an APMU Report as soon as possible, and no later than seven (7) days following matching of the *Sample* in *ADAMS*, where a newly matched whole blood *Sample* analyzed for the Hematological Module or a newly matched serum *Sample* analyzed for the Endocrine Module generates a Flag for a secondary *Marker*.
- c) The **APMU** should ~~provide the Experts from time to time with review all normal Passports with either a newly matched whole blood *Sample* analyzed for review, even when the Hematological Module or a newly matched serum *Sample* analyzed for the Endocrine or Steroidal Modules and submit an APMU Report.~~
- [Comment to Article 8.4 c): The review of whole blood or serum Samples not generating an ATPF, sequence abnormality or Flag may be carried out by qualified ADO staff using the PC Report in ADAMS.]*
- d) The APMU shall review all Passports with newly confirmed *Marker* values ~~are within normal ranges and presenting no suspicious elements, as and/or Further Analysis results triggered by the *ABP* (i.e., results from GC/C/IRMS or the hGH Isoform Differential Immunoassay initiated following a Confirmation Procedure (CP) Request, see Article 8.6 of this will ensure that Experts are provided a balanced perspective *TD*) and submit an APMU Report.~~

Table 2: Passport review by the APMU

	<u>Module</u>	<u>Hematological</u>	<u>Steroidal</u>		<u>Endocrine</u>
	<u>Sample type</u>	<u>Whole blood</u>	<u>Urine</u>	<u>Serum</u>	<u>Serum</u>
<u>Passport status</u>	<u>Atypical /Sequence</u>	<u>Mandatory</u>	<u>Mandatory</u>	<u>Mandatory</u>	<u>Mandatory</u>
	<u>Flagged</u>	<u>Mandatory</u>	<u>APMU-PC Agreement**</u>	<u>NA***</u>	<u>Mandatory</u>
	<u>Normal</u>	<u>Recommended*</u>		<u>Recommended*</u>	<u>Recommended*</u>

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** see comment to Article 8.4 c) above, ** see comment to Article 8.4 below, *** no secondary blood steroid Markers*

[Comment to Article 8.4: The systematic review of “Flagged” and “Normal” Passports based only on the Athletes’ Passports-urinary steroid Markers is not mandatory and its potential benefit should be discussed between the APMU and the PC to outline a Passport review strategy suited to the needs of the PC.]

8.28.5 Management of Sample Validity

- a) The APMU shall assess and manage the validity of urine, ~~blood (serum)~~ and ~~blood ABP (whole blood)~~ Samples in ADAMS according to applicable *International Standards* and ISL TDs, including the ISL^[1], ISRM^[4,2], ISL TD EAAS^[3] ~~International Standard for Laboratories (ISL)~~^[4] USM^[5], ISL TD BSM^[6], ISL TD ENDO^[7], ISL TD HEM^[8], and the *International Standard for Testing and Investigations (ISTI)*^[6] ~~(IST)~~^[9]. The APMU may consult with Laboratories, Experts, the PC, or TA, as required, to obtain additional information relevant to the validity of the Sample.
- b) Any changes in Sample validity made by the APMU shall be noted in the applicable fields in ADAMS and in the APMU Report.
- c) Where multiple Samples were provided by an Athlete during a single Sample Collection Session and are present in a Passport, the APMU shall invalidate all but one Sample based on assessment by the APMU.
- d) Where multiple Samples were provided by an Athlete on the same day from different Sample Collection Sessions and are present in a Passport, the APMU may invalidate all but one Sample after assessment by the APMU in consultation with the Passport CustodianPC, as required.
- e) For urine and/or serum Samples where a substance(s) that may alter the steroid profile/Markers is detected by the Laboratory (e.g., alcohol), the APMU may invalidate the Sample when it is considered to affect the sensitivity of the Adaptive Model to detect changes in future Samples.
- f) For whole blood ABP Samples of suspicious profiles/hematological Passports where the Blood Stability Score (BSS) could not be calculated, the APMU shall assess the collection-to-analysis time (CAT), any available temperature logger data, and the potential degradation of ~~blood~~the Markers, including scattergrams, in order to evaluate Sample validity, liaising with (an) Expert(s) as required.

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8.6 Assessment of a Sample that generated a Confirmation Procedure Request

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CP requests are automatically generated in ADAMS based on Passport data in order to indicate the need for confirmation of the Marker values measured during the Initial Testing Procedure and/or for Further Analysis of existing Samples.

- a) The criteria for the generation of an ATPF-CPR and an Endocrine-CPR are defined in ISL TD USM ^[5], ISL TD BSM ^[6] and ISL TD ENDO ^[7].
- b) A Suspicious Steroid Profile-Confirmation Procedure Request (SSP-CPR) notification is generated through ADAMS when there is no existing urine steroidal Passport for the Athlete in ADAMS (i.e. this is the first urine Sample in the Athlete's steroidal Passport), and the urinary steroid Marker(s) of the Sample meets any criteria listed in Table 3.

Table 3: Criteria to generate an SSP-CPR.

	Females	Males
T/E ratio	> 4.0	
Concentration of T*	> 50 ng/mL	> 200 ng/mL
Concentration of E*	> 100 ng/mL	> 200 ng/mL
Concentration of A or Etio*	> 10'000 ng/mL	
Concentration of 5αAdiol*	> 150 ng/mL	> 250 ng/mL

* Adjusted for SG

- c) The APMU shall review a Passport generating an ATPF-CPR, SSP-CPR or Endocrine-CPR as soon as possible, and no later than seven (7) days following receipt of the notification in ADAMS, and recommend whether or not to proceed with the CP.
- d) Justification to recommend not to proceed with a CP may include:
- i. cases where a CP request is generated for two (2) or more Samples that are linked to a single Sample Collection Session from the same Athlete, the APMU should advise the PC (who will advise the TA, if different), to prioritize the confirmation of the Sample with the highest concentration of Markers; or
 - ii. communication of the existence of other AAFs reported for the Sample to the APMU by the PC or TA, as applicable, which would likely lead to maximum Consequences; or
 - iii. communication of the existence of a Therapeutic Use Exemption (TUE) for the Athlete to the APMU by the PC or TA, as applicable; or
 - iv. the presence of ethanol glucuronide (EtG) or other factors impacting the steroid Markers in a Sample from an Athlete with previous similar findings in their Passport for Samples with negative GC/C/IRMS results.

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In such cases, the PC, or TA (or Results Management Authority, if different) as applicable, shall advise the Laboratory, in writing as soon as possible and no later than fourteen (14) days following reception of the CP request, whether or not to proceed with CP(s) of Markers in the Sample.

- e) Where an Endocrine-CPR has been triggered for a Sample due to high IGF-I levels, the APMU shall review the results of the CP for the blood endocrine Markers, and the results of the hGH Isoform Differential Immunoassay where applicable (see ISL TD ENDO ^[7]), before assigning the Passport to an Expert.
- f) In the absence of an automated CP request in ADAMS, the APMU may also make a recommendation to perform CPs based on assessment of the Passport by the APMU.

8.38.7 APMU Report

The APMU Report is a central element in the administrative sequence of the *ABP* that shall be entered and maintained by the APMU in *ADAMS*. The APMU Report provides an up-to-date overview of the current status of an *Athlete's Passport* together with recommendations, as appropriate, for efficient follow-up by the Passport-Custodian-PC. The APMU Report serves to update the Passport-Custodian-PC, WADA and other *ADOs* with whom the Passport is shared. In addition, it provides a record of events associated with a Passport in *ADAMS*.

The APMU Report may include, without limitations:

- a) Assessments of Sample When assessing a Passport, according to Article 8.4 of this ISL *TD*, the APMU shall, via the APMU Report:
- i. manage the validity by the APMU and/or of any newly matched Sample(s);
 - ii. provide Target Testing recommendations, as appropriate;
- ~~recommend Further Analysis of new or Experts;~~
 - i.iii. Recommendations for complementary Analytical Testing previously collected Sample(s) (e.g., Agents Affecting Erythropoiesis, HIF stabilizers, Homologous Blood Transfusion, confirmation of steroid profile the Markers, GC/C/IRMS, long-term steroid Metabolites, IGF-I analogs, Steroid Esters, hGH Isoform Differential Immunoassay etc.) on Samples collected.), as appropriate;
 - ~~Recommendations for further Analytical Testing on Samples collected previously;~~
 - ~~Recommendations for request long-term storage of Samples for Further Analysis;~~
 - ii.iv. Target Testing recommendations based on available data and Experts' recommendations; and, as appropriate;
 - v. A summary of provide any other recommendations, as appropriate; and/or

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~~iii.vi.~~ iii.vi. summarize any recent Expert reviews.

~~a)b)~~ a)b) APMU Reports shall be written in English and should not contain any information that could identify the Athlete.

~~a) The APMU Report shall not contain any reference to an AAF that may be known to the APMU, with the exception of when the AAF is used by the APMU as a reason not to perform CP(s) following an ATPF-CPR or SSP-CPR for the steroid profile (see Articles 8.1.3 and 8.1.4 of this TD). If the APMU assessment leads to an Expert review, the APMU may, however, separately inform the Expert(s) of the existence of the AAF. Depending on the result of the Expert review, the APMU shall further inform the Results Management Authority managing the AAF of the result of the Expert review, via the Passport Custodian, if that information is potentially relevant in the context of the Results Management based on the AAF.~~

~~[Comment: While Passport sharing is strongly encouraged to enhance ADO efficiencies and program effectiveness through exchange of information and mutual recognition of program outcomes, this must be carried out within the framework of the ISPPPL^[2] and Article 14.1.4 of the Code^[6]. The information regarding an AAF shall therefore not be recorded in the APMU Report and shall not be disclosed unnecessarily. Only those individuals and/or organizations involved in the applicable Results Management process should be privy to this information.]~~

~~8.3.3 Target Testing~~ recommendations shall be included in the APMU Report with a sufficient level of detail for the Passport Custodian to conduct effective, timely and appropriate Testing.

- ~~c)~~ c) Any recommendations shall have a sufficient level of detail to support follow-up actions from the PC. The APMU Report shall refer to the Sample collection date and/or Sample code, as appropriate. The ordinal number of the Sample within the Passport may be used in addition to the Sample collection date and/or Sample code.
- ~~d)~~ d) When required for Passport interpretation, the APMU may request redacted additional information from the PC including, but not limited to, circumstances and details of Sample collection, transport, and laboratory analysis, travel, altitude information, Athlete Competition schedule, Athlete medical information, information on an Atypical Finding (ATF) or Adverse Analytical Finding (AAF) that is potentially relevant in the context of the Passport.

8.8 Assigning Passports for Expert(s) review

~~a)~~ a) If, after managing the Sample validity, the Passport remains atypical, or upon request by the PC, the APMU shall promptly send the Passport for review in ADAMS by an Expert according to Article C.2.2 of the ISRM^[2].

~~[Comment to Article 8.8 a): Any delays in assigning a Passport for Expert review according to C.2.2.2 or C.2.2.3 of the ISRM shall be clearly explained in the APMU Report.]~~

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- b) Prior to assigning the Passport for Expert(s) review, the APMU shall evaluate the need for urgent Target Testing of the Athlete and communicate Testing recommendations to the PC via the APMU Report as required (see Article 8.4 of this ISL TD).
- c) Following Expert(s) review, the APMU shall submit an APMU Report as soon as possible and within 7 days of submission of the Expert review. The APMU recommendation in ADAMS should reflect the Expert's opinion and comments and any change in the APMU recommendation in the APMU Report should be based on updated Expert opinions.
- d) If the Expert is a medical doctor and issues an opinion of "Likely Medical Condition", the APMU shall update the APMU Report accordingly and indicate "Likely Medical Condition". If the first Expert is not a medical doctor, the Passport should be sent to a medical doctor from the Expert panel prior to informing the PC to contact the Athlete, according to Article C.2.3 of ISRM [2]. In such cases, the APMU may inform the medical doctor (second Expert) that the reason for the review is to confirm the opinion of "Likely Medical Condition".
- e) The APMU should provide the Experts, from time to time, with Passports for review, even when the values are within normal ranges and presenting no suspicious elements, as this will ensure that Experts are provided a balanced perspective on the Athletes' Passports.

8.48.9 Investigating Urine Exchange

When the Markers of a urine Sample steroid profile is/are not consistent with Markers of other urine Sample(s) from the Athlete's Passport, urine exchange with the urine of another individual may be suspected and confirmed using DNA analysis across multiple *Samples*. This process is managed and reported according to the following steps:

1. When evaluating a newly matched urine *Sample*, where other *Samples* exist in the *Athlete's Passport*, the APMU shall evaluate the likelihood that all *Samples* are from the same individual. If a *Sample* shows inconsistency compared to others in the *Passport* (e.g. differences in *Marker* levels), the APMU shall update the APMU Report indicating "Suspicion of Urine Exchange".
2. If the APMU suspects urine exchange, an investigation shall be launched by the Passport Custodian PC, with support from the APMU, using a combination of actions such as Sample storage, verifying the correct attribution of the Sample(s) to the Passport, confirmation of the urinary steroid profiles/Markers of relevant *Samples*, Sample storage, collection of additional *Samples*, and/or DNA analysis, as applicable.

The outcomes of this investigation may indicate:

- a) Confirmation by DNA analysis that all *Samples* belong to the same *Athlete*. In this case, the APMU shall update the APMU Report accordingly.

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- b) Multiple DNA profiles are present: where at least two (2) different DNA profiles are identified across different *Samples*, where each urine *Sample* corresponds to a single DNA profile, however the DNA profile corresponding to the *Athlete* under investigation is not known. A strategy shall be undertaken in order to obtain additional *Samples* and the APMU shall update the APMU Report accordingly indicating “Multiple DNA Profiles Identified”.
- c) Confirmed urine exchange: where at least two (2) different DNA profiles have been identified, where each urine *Sample* corresponds to a single DNA profile, and the DNA profile belonging to the *Athlete* is confirmed with a reasonable degree of certainty (e.g. using multiple *Samples*, different *Sample* types, different Sample Collection Personnel). In such cases, the APMU shall update the APMU Report, indicating “Urine Exchange Confirmed”.
- d) Mixed *Samples*: where multiple DNA profiles are found within individual *Samples*. In such cases, the APMU shall liaise with the Passport CustodianPC, or Testing AuthorityTA as applicable, regarding the *Sample* in question to explore whether the Laboratory should consider further investigations towards declaring an AAF for *Sample Tampering* or *Attempted Tampering*.

[Comment: to Article 8.9 d): Where Tampering or Attempted Tampering of a *Sample* can be established by the analyzing Laboratory based on evidence from that *Sample* alone (e.g., substitution with another fluid, mixing of urines, addition of proteases to the *Sample*), the Laboratory can report the finding as an AAF or Atypical Finding for Tampering or Attempted Tampering (see Article 4.0 of the TD EAAS ^[3]; Technical Letter TL27 ^[10]). In contrast, when urine exchange can be established based on the urinary steroid profileMarkers and/or DNA evidence across multiple *Samples*, the APMU shall report the finding of confirmed urine exchange to the Passport CustodianPC, who shall proceed with Results Management according to Code Article 2.2 ^[63]

8.5 Analysis of Steroid Esters

~~When blood *Samples* demonstrate atypical or suspicious steroid *Markers*, or have been collected during the same Sample Collection Session as urine *Samples* identified with an atypical or suspicious “steroid profile”, the APMU, in consultation with the Passport Custodian, should consider requesting analysis to detect the presence of Steroid Ester(s) in the associated blood *Samples*.~~

~~The detection of Steroid Ester(s) in blood also constitutes an unequivocal demonstration of the exogenous origin of the steroid(s). On the other hand, the absence of detectable Steroid Ester(s) in blood shall not invalidate an AAF based on the GC/C/IRMS analysis in urine.~~

8.68.10 Compiling the ABP Documentation Package

- a) The APMU shall be responsible for compiling the ABP Documentation Package using the template provided by WADA. The Passport CustodianPC shall collect information and bear the cost of compiling ABP Documentation Packages unless it has established an agreement to share the costs with relevant Testing AuthoritiesTAs.

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Date:	November 2022 <u>17 March 2026</u>	Effective date:	1 January 2023 <u>2027</u>

a) ~~Upon request by the APMU and as needed to compile the ABP Documentation Package, the Passport Custodian shall provide a detailed Athlete Competition and altitude schedule, relevant information from DCFs, temperature logger and Chain of Custody documentation to the APMU.~~

- b) ~~The APMU shall confer with the Expert panel to determine the scope of such compilation, including the recommended elements and the number of tests that need to be included documentation required to include in the ABP Documentation Package for each Sample. It is only mandatory to have a full ABP Laboratory Documentation Package for those Samples that are deemed essential by the Expert panel (see ISL TD LDOC ^[71]). Other relevant Samples, Sample(s), for example those that confirm the baseline levels of a Marker, only require an ABP Laboratory Certificate of Analysis (see ISL TD LDOC ^[7]–^[11]). Where the Passport Custodian PC is not the Testing Authority TA of the test Sample(s) requiring Laboratory documentation, the Passport Custodian shall coordinate with PC or the Testing Authority to obtain APMU (which may have been bestowed such authority by the PC) may request such documentation on behalf of the TA. In such cases, the PC shall copy the relevant TA on all written requests to the Laboratory.~~

[Comment: to Article 8.10 b): Where a Laboratory Documentation Package for a specific analysis (e.g. GC/C/IRMS, ERA analysis or hGH Isoform Differential Immunoassay) is requested during the compilation of an ABP Documentation Package, a request should be addressed to the Laboratory as per the specific Annexes of the ISL TD LDOC–^[11]]

- c) The following key information shall be included in an ABP Documentation Package regardless of the module (Hematological, Steroidal, or Endocrine):
- i. For the *Athlete*: age (excluding the date of birth), gender, and sport/discipline;
 - ii. For all *Samples*: date and time of collection, ADAMS ordinal number in the Passport, Sample code, Marker values and graphical results obtained by the Adaptive Model;
 - iii. For *Samples* selected by the APMU and Expert panel:
 - ABP Laboratory Documentation Package(s) and/or ABP Certificate(s) of Analysis from the relevant Laboratory(-ies) and/or ABP Laboratory(-ies) (see ISL TD LDOC ^[71]); and
 - ~~The Passport Custodian PC shall provide Chain of Custody documentation, DCF information and a detailed the Athlete Competition calendar schedule and altitude information, as required, covering the relevant period defined by the selected Samples; and.~~
- d) For the Hematological Module, the following additional information shall be provided by the PC for the *Samples* selected by the APMU and Expert panel:
- i. Temperature profile during the transportation of the whole blood–ABP Sample and, when available, the BSS; and

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- ii. Responses provided by the *Athlete* on the ABPBlood Collection Supplementary Report Form during the Sample Collection Session.
- e) For the Steroidal Module, the following additional information shall be provided by the PC for the Samples selected by the APMU and Expert panel:
- i. Urine Samples
- pH;
 - Specific gravity (SG); measured by the Laboratory;
 - Laboratory documentation, including screeninginitial and confirmed values (where applicable) of steroid concentrations and ratios (see ISL TD USM ^[5] and ISL TD LDOC ^[7] and TD EAAS ^[311]);
 - GC/C/IRMS results, where applicable;
 - Indication of ethanol consumption: urinary concentrations of ethanol and/or ethanol Metabolite(s); Metabolites;
 - Indication of microbial growth (see ISL TD EAAS ^{[3]USM} ^[5]); and
 - Information on the presence or absence of substances that may alter the steroid profile (see ISL TD EAAS ^{[3]USM} ^[5]).
- ii. BloodSerum Samples
- Laboratory documentation, including screeninginitial and confirmed concentrations (where applicable) of steroid Markers (see ISL TD LDOC ^{[7];¹¹⁾); and}
 - Temperature profile during the transportation of the serum Sample.
- f) For the Endocrine Module, the following additional information shall be provided by the PC for the tests selected by the APMU and Expert panel:
- i. Laboratory documentation, including screeninginitial and confirmed concentrations (where applicable) of Markers of the Endocrine Module (see ISL TD LDOC ^{[7];¹¹⁾); and}
- ii. Temperature profile during the transportation of the serum Sample.

9.0 References

[1] The World Anti-Doping Code International Standard for Laboratories.

~~[1]~~[2] The World Anti-Doping Code International Standard for Results Management.

~~[2]~~[3] The World Anti-Doping Code International Standard for the Protection of Privacy and Personal Information.

[4] The World Anti-Doping Code International Standard for Data Protection.

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~~[3]~~[5] WADA Technical Document ISL TD ~~EAAS: Measurement~~ USM: Analytical and Reporting ~~of Endogenous Anabolic-Androgenic Steroid (EAAS) Requirements for the Urinary Markers~~ of the ~~Urinary Steroid Profile~~ Steroidal Module of the *Athlete Biological Passport*.

~~[6]~~ WADA Technical Document ISL TD BSM: Analytical and Reporting Requirements for the Blood Markers of the Steroidal Module of the *Athlete Biological Passport*.

~~[7]~~ WADA Technical Document ISL TD ENDO: Analytical and Reporting Requirements for the Blood Markers of the Endocrine Module of the *Athlete Biological Passport*.

~~[8]~~ WADA Technical Document ISL TD HEM: Analytical and Reporting Requirements for the Markers of the Hematological Module of the *Athlete Biological Passport*.

~~[4]~~[1] ~~The World Anti-Doping Code International Standard for Laboratories.~~

~~[5]~~[9] The World Anti-Doping Code *International Standard for Testing and Investigations*.

~~[6]~~ ~~The World Anti-Doping Code.~~

~~[10]~~ WADA Technical Letter TL27 - *Sample Manipulation (Tampering or Attempted Tampering)*.

~~[7]~~[11] WADA Technical Document ISL TD LDOC: *Laboratory Documentation Packages*.

[Comment to Article 9.0: Current versions of WADA ~~ISL~~ International Standards and Technical Documents may be found at <https://www.wada-ama.org/en/anti-doping-partners/laboratories> ~~https://www.wada-ama.org/en/what-we-do/international-standards~~]