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Guidelines for Implementing the Technical Document for Sport Specific Analysis

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Introduction

Welcome to the Guidelines for Implementing the Technical Document for Sport Specific Analysis (Guidelines), a third-level, non-mandatory document that supports the Technical Document for Sport Specific Analysis (TDSSA).

Where the TDSSA state the requirements of what Anti-Doping Organizations (ADOs) must do, the Guidelines aim to assist ADOs in understanding how to do it, giving practical examples and suggestions, and demonstrate to ADOs how to go above and beyond the requirements, where possible.

The processes outlined in this document promote good practice, assisting ADOs to meet the requirements of the TDSSA. Where the interpretation of any text within the Guidelines is in contradiction with the TDSSA, the TDSSA shall prevail.

ADOs are encouraged to provide WADA with any further questions they may have on the TDSSA or its implementation by contacting <u>testing@wada-ama.org.</u>

Additional guidance to assist ADOs in conducting a Risk Assessment and to optimize the effectiveness of their Testing programs, WADA developed a document titled <u>Guidelines - Implementing an Effective</u> <u>Testing Program</u> to assist ADOs with conducting the overall Risk Assessment and elements of their TDP. These guidelines focus on the development of 'smart' testing programs based on a more qualitative approach rather than strictly a quantitative one and is updated to be in line with the <u>ISTI</u>.

Section 1: Objectives and Compliance

This section outlines what the Technical Document for Sport Specific Analysis (TDSSA) is, to whom it applies and what are its objectives. It also sets out the Prohibited Substances that are within the scope of the TDSSA and how WADA will monitor ADOs' compliance with the TDSSA.

Chapter 1: Purpose of the TDSSA

The TDSSA is a tool to assist ADOs implementing intelligent and effective testing programs for sports or disciplines by requiring a minimum level of analysis (MLAs) for prohibited substances and/or prohibited methods that are not currently part of the standard sample analysis menu. It came into effect on 1 January 2015 and since then it has been revised on an annual basis.

The TDSSA is mandated by 2023 International Standard for Testing and Investigations (<u>ISTI</u>) Article 4.2.3. It is intended to ensure that the prohibited substances and/or prohibited methods within the scope of the TDSSA and other tools that support the detection of prohibited substances and/or identify the use of prohibited methods such as the Athlete Biological Passport (ABP) are subject to an appropriate and more consistent level of use and adoption by all ADOs that conduct testing on those sports or disciplines deemed to be at risk of doping using the prohibited substances and/or prohibited methods within the scope of the TDSSA.

ISTI 4.2.3

In developing its Test Distribution Plan, the *Anti-Doping Organization* shall incorporate the requirements of the TDSSA.

The TDSSA is a mandatory Level 2 document that applies to all ADOs that are signatories to the World Anti-Doping Code (Code) and authorize the collection of samples. This includes International Federations (IFs), National Anti-Doping Organizations (NADOs), Regional Anti-Doping Organizations (RADOs) and Major Event Organizations (MEOs).

Development of the TDSSA and the MLAs

A drafting group of experts with science, laboratory, exercise physiology and anti-doping backgrounds, covering a number of stakeholder groups (Expert Group), was appointed by WADA to develop the TDSSA.

The Expert Group undertook an extensive consultation process with the IFs of Olympic, IOC Recognized and Non-IOC Recognized sports and sports disciplines, and evaluated the prohibited substances and/or prohibited methods within the scope of the TDSSA from a physiological risk and ergogenic benefit perspective. WADA also consulted with other ADOs, including NADOs and MEOs.

The MLA requirements contained in Appendices 1 to 4 of the TDSSA are listed as a percentage of total eligible tests in each specific analysis category. These MLAs are based on a physiological risk assessment that considered physiological demands and non-physiological factors in each sport or discipline, as well as WADA-accredited laboratory analytical capacity for the prohibited substances and/or prohibited methods, analyses conducted historically by ADOs, and a relative physiological and non-physiological comparison of sports or disciplines within similar categories. The input of the ADOs, particularly IFs, who have direct expertise in their sport, was critical in determining the assessments described above.



When establishing the MLAs, factors other than physiological and non-physiological demand, such as financial gain, sport culture in a country, country performance, intelligence or gender, were not considered. These factors should be considered by each ADO as part of the wider risk assessment that ADOs are required to conduct in accordance with <u>ISTI</u> Article 4.2, which is an important step in the development of their Test Distribution Plan (TDP).

The Expert Group that developed the TDSSA was expanded in 2020 and was replaced with the <u>Strategic</u> <u>Testing Expert Advisory Group</u> (STEAG) that focuses on development of testing related matters that fall under the <u>ISTI</u>.

Objectives of the TDSSA

The objectives of the TDSSA are to contribute to effective testing by:

- Outlining well-reasoned and proportionate MLAs for those prohibited substances and/or prohibited methods within the scope of the TDSSA in particular sports or disciplines;
- Establishing criteria by which all ADOs shall apply MLAs within a TDP while recognizing the need for flexibility within the diversity of Code-compliant anti-doping programs;
- Ensuring the TDSSA supports the implementation of all Modules of the ABP to continue to allow for intelligent testing and targeted analysis e.g., for ERAs; and
- Informing ADOs on testing and analysis best practices for those prohibited substances and/or prohibited methods within the scope of the TDSSA in particular sports or disciplines.

Prohibited Substances within the Scope of the TDSSA

The prohibited substances and/or prohibited methods within the scope of the TDSSA are not part of a standard sample analysis conducted by laboratories and require additional analysis methods (see **Section 2**).

The prohibited substances and/or prohibited methods within the scope of the TDSSA are:

- Erythropoietin receptor agonists (ERAs¹);
- Growth hormone (GH); and
- Growth hormone releasing factors (GHRFs) including growth hormone-releasing hormone (GHRH) and its analogues, growth hormone secretagogues (GHS) and its mimetics, and growth hormone-releasing peptides (GHRPs).

WADA also developed <u>templates and checklists</u> to assist you with this important planning exercise. Specifically, these can be found on WADA's website and on WADA's Anti-Doping e-Learning platform (ADEL), under the resources section of the <u>ISTI</u>.

Note: The MLAs are minimum requirements and hence, ADOs are encouraged to exceed those minimums, especially if their risk assessment or any other relevant information specific to the sport or discipline and the athlete/s concerned, indicate they should do so.

¹ The acronym 'ERAs' is used in the TDSSA to describe the substances analyzed according to the applicable WADA Technical Document for EPO in force.

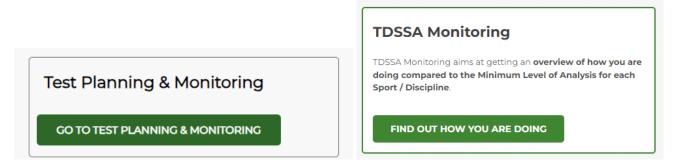
Chapter 2: Compliance with the TDSSA

WADA is monitoring ADOs' compliance with the TDSSA through the Anti-Doping Administration and Management System (ADAMS) on an ongoing basis. This includes, but is not limited to, the following elements:

- The total number of tests and types of analyses conducted in the applicable 12-month period between 1 January and 31 December;
- The MLA achieved for each prohibited substance category within the scope of the TDSSA for each sport or discipline listed in the ADO's TDP;
- The number of athletes tested; and
- The Implementation/effective application of the Hematological Module of the ABP for sports or disciplines with an ERAs MLA equal to or greater than 30%, for Registered Testing Pool (RTP) athletes (see **Section 4**).

Any ADO that implements the Hematological Module of the ABP for sport or disciplines with an ERAs MLA less than 30% will have such program monitored to ensure it fulfills the mandatory requirements required when implementing the Hematological Module of the ABP even though it is not mandatory to implement it.

ADAMS Next Gen includes a TDSSA Monitoring tool in its Test Planning and Monitoring section (see relevant ADAMS Next Gen pictures below), which monitors an ADO's application of the TDSSA MLAs in real time. It is strongly recommended that ADOs utilize the monitoring tool in ADAMS to self-monitor their own application of the TDSSA, identify any shortfalls and adjust their testing program accordingly. For more information on the TDSSA Monitoring tool in ADAMS Next Gen, ADOs can refer to either the Reporting Guide to Monitor Testing on WADA's website or the ADAMS <u>Help Center</u>.



A wider evaluation of ADOs' compliance with the TDSSA is being addressed through WADA's Compliance and Monitoring program. The evaluation includes the review of the methods applied by ADOs to the implementation of the tests to meet the MLAs, including but not limited to the assessment of risk among athletes within the jurisdiction of the ADO, and the use of information and intelligence in the selection and timing of tests on defined athletes.

If the MLAs are partially or not being met, ADOs will be given the opportunity to justify their strategy. As part of this monitoring program, WADA may request an ADO that has shortfalls to conduct retrospective analysis for the prohibited substances and/or prohibited methods within the scope of the TDSSA on samples already collected by the ADO and which may be in storage at the laboratory(ies). Any retrospective analysis for the prohibited substances within the scope of the TDSSA requested by ADOs will count towards compliance with the TDSSA requirements of the year that the sample was collected rather than the year the retrospective analysis is requested/performed.



ADOs that are not currently conducting the required MLAs will be requested to review how they can optimize the use of existing resources within their anti-doping program or seek additional funding from their funding bodies. Below are key messages for ADOs to take to their funding bodies when seeking additional resources to implement the requirements of the TDSSA:

- The TDSSA is a tool that provides greater protection to the clean athletes by ensuring that the prohibited substances within its scope, which are not part of the standard sample analysis menu, are subject to an appropriate and consistent level of analysis.
- The TDSSA implementation will increase the deterrence effect.
- The TDSSA provides minimum targets for particular test numbers, where many experienced ADOs are conducting significantly greater numbers of tests.
- The TDSSA is a mandatory level two document of the Code that Code signatories are required to implement.
- The TDSSA will be part of WADA's measurement of ADOs' Code compliance.

Code Article 23.3:

Signatories shall devote sufficient resources in order to implement anti-doping programs in all areas that are compliant with the *Code* and the *International Standards*.

Section 2: Prohibited Substances within the Scope of the TDSSA and WADA-Accredited Laboratories

This section outlines information on the prohibited substances within the scope of the TDSSA, where an ADO can find the TDSSA analysis capacity per WADA-accredited laboratory, and information on other prohibited substances that are currently outside the scope of the TDSSA.

Chapter 1: General

As indicated in **Section 1**, **Chapter 1**, the prohibited substances and/or prohibited methods within the scope of the TDSSA are:

- Erythropoietin receptor agonists (ERAs);
- Growth hormone (GH); and
- Growth hormone releasing factors (GHRFs)

The <u>TDSSA analysis capacity per WADA-accredited laboratory</u> can be found on WADA's website. All WADA-accredited laboratories can analyze for ERAs and GHRFs (GHS/GHRP – small peptides) in urine, and GH (isoforms method) in blood serum. A number of laboratories can also analyze for GHRFs (GHRH - large peptides), for ERAs (serum and/or plasma) and for the GH biomarkers using either the specific assay pairing for the <u>Endocrine Module of the ABP</u> or the <u>GH Biomarkers Test</u>. ADOs are encouraged to confirm the analysis menu and the specific methods available with the WADA-accredited laboratories they collaborate with.

Where applicable, WADA will identify and encourage the expansion of the necessary capacity within those Laboratories where particular analytical methods are deemed a priority for surrounding regions to implement the TDSSA, and in doing so, attempt to minimize shipping time and costs.

Any prohibited substance or prohibited method that is added to the Prohibited List and has an approved analytical method such as IRMS may be subject to inclusion in the TDSSA as part of the TDSSA's ongoing review and development (if their analysis is not included in the standard sample analysis menu).

Where the ADO's TDP requires the collection of blood samples, the ADO is required to put in place the necessary measures (recruitment of Blood Collection Officers, training, etc.) to comply with the collection and analysis of blood samples for GH and ERAs MLAs and the Hematological Module of the ABP including the necessary shipping requirements² to ensure the blood and/or blood ABP samples arrive to the laboratory in good condition.

If blood and/or blood ABP samples arrive to the nearest laboratory outside the required shipping times due to distance, transport delays or issues with export or import into the country that hosts a laboratory or an ABP laboratory, the sample may not be fit for analysis. ADOs should evaluate the circumstances to determine where the issue lies and consider the necessary solution/s to avoid such delays.

Chapter 2: Erythropoietin Receptor Agonists (ERAs)

The TDSSA outlines that ERAs can be analysed in urine or blood. This does not mean that an ADO has to collect both a blood and a urine sample each time to conduct ERAs testing. An ADO has the choice as to whether it wishes to analyze ERAs in either urine or blood. However, it is noted that the detection method for continuous erythropoietin receptor activator (CERA) is more effective in blood than in urine. When laboratories analyze for CERA in blood serum or plasma, they will also be applying methods capable of detecting other ERAs in addition to CERA (recombinant ERAs, NESP, etc.).

Testing strategies around the targeting of athletes for ERAs analysis is contained within the TDSSA Testing Guide for ERAs. ADOs should obtain a copy by contacting testing@wada-ama.org.

Chapter 3: Growth Hormone (GH)

Several analytical methods exist for GH analysis. The GH <u>Isoform Differential Immunoassay</u> method has been applied since the Athens Olympic Games in 2004. Commercial test kits have been available since 2008 and the method is now available at all WADA-accredited Laboratories. The GH Isoforms method may detect GH doping up to 24-48 hours after administration.

The second method (the GH Biomarkers Test) was initially implemented during the 2012 London Olympic and Paralympic Games and measures changes in concentration levels of two main markers, namely Insulin-like Growth Factor-I (IGF-I) and N-terminal Pro-peptide of Type III Collagen (P-III-NP), which are naturally present in blood and whose concentrations are increased following GH administration. The GH-2000 score is then calculated using a formula including IGF-I and P-III-NP and compared to population-based decision limits in order to report a Negative, Atypical (ATF) or Adverse Analytical Finding (AAF) test result for an individual blood sample. Following the withdrawal from the market of one of its assays, the method had to undergo a process of re-validation of new component assays. The assays were revalidated in 2015 and the method is available in a number of accredited Laboratories (see <u>TDSSA</u> analysis capacity per WADA-accredited laboratory on WADA's website).

The third and most recent method for GH detection has been implemented in 2023 and is used to generate data for the Endocrine Module of the ABP. This analytical method is also available in a number of accredited Laboratories (see <u>TDSSA analysis capacity per WADA-accredited laboratory</u> on WADA's website). Similar to other modules of the ABP, the Endocrine Module compiles analytical data from

² See <u>Sample Collection Guidelines</u>, Chapter 16, Section 5

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multiple samples in a longitudinal manner for the same athlete to construct a Passport. This Passport is then interpreted by an Athlete Passport Management Unit (<u>APMU</u>) and potentially ABP endocrine experts to provide recommendations to the ADO about further actions that may result in an anti-doping rule violation according to Code Article 2.1 (where the Endocrine Module may be used to direct the Isoform Differential Immunoassay) or Code Article 2.2, where the longitudinal profile can be used to establish the use of a Prohibited Substance or Method.

It is recommended that ADOs prioritize the Endocrine Module when testing for GH as it can be used to target samples for analysis by the Isoform Differential Immunoassay and also identify suspicious athletes for further testing or investigation. Application of the Isoform Differential Immunoassay, not based on the results of the Endocrine Module of the ABP, can still be employed in a TDP, for example on the first sample of an athlete's profile or for lower-level athletes not included in an ADO's RTP. ADOs can contact WADA's ABP team at athletepassport@wada-ama.org to receive the Frequently Asked Questions (FAQs) document for the Endocrine Module of the ABP for further information on testing strategies.

Application of the GH MLAs is optional and compliance with the GH MLAs is postponed and will be reassessed once the Endocrine Module of the ABP has been implemented further by ADOs. Nevertheless, ADOs are strongly encouraged to conduct GH testing by prioritizing the higher-risk sports or disciplines listed in the TDSSA. Implementation of the Endocrine Module of the ABP for those sports/disciplines for which the GH MLA is 15% or higher is strongly recommended. For the sports/disciplines with a GH MLA of 10%, ADOs are encouraged to consider the benefits of implementing the Endocrine Module of the ABP as part of their testing strategy. Where recommended by their <u>APMU</u> based on the evaluation of an endocrine passport, and/or where a sample is reported as ATF for the Isoforms Differential Immunoassay and/or Biomarkers Test, and/or where investigations indicate reliable intelligence on possible GH abuse, ADOs should prioritize athletes for further GH-related testing. This implies that ADOs should ensure a budget for reactive GH-related testing throughout the year based on evolving information. In addition, ADOs are strongly encouraged to store serum samples in the long-term for further analysis when technological advancements for GH analysis are available.

Testing strategies around the targeting of athletes for GH analysis is contained within the TDSSA Testing Guide for GH. ADOs should obtain a copy by contacting <u>testing@wada-ama.org</u>.

The <u>WADA Technical Document for GH in force</u> states that a blood sample should be analyzed with the GH Isoforms method at a WADA-accredited laboratory within a maximum of 4 days from sample collection. The equivalent period for a blood sample that will be analyzed with the GH Biomarkers method, is a maximum of 5 days².

Chapter 4: Growth Hormone Releasing Factors (GHRFs)

Growth hormone-releasing factors (GHRFs) are categorized into three different groups within the WADA Prohibited List including:

- Natural growth hormone-releasing hormone (GHRH), its peptides and non-peptidyl analogs;
- Growth hormone secretagogues (GHS) and its mimetics; and
- Synthetic growth hormone-releasing peptides (GHRPs)

There is a number of laboratories that include analysis for GHRFs (GHS/GHRP – small peptides) in their standard sample analysis menu. ADOs are encouraged to contact their laboratory to receive more information.

Testing strategies around the targeting of athletes for GHRFs analysis is contained within the TDSSA Testing Guide for GHRFs. ADOs should obtain a copy by contacting <u>testing@wada-ama.org</u>.

Chapter 5: Other Prohibited Substances Outside the Scope of the TDSSA

If a prohibited substance is not within the current scope of the TDSSA and is not included within a standard urine analysis, this should not prevent any ADO to order testing on such substance, based on their risk assessment, experience and/or intelligence-based targeting.

ADOs can find the <u>full list of specific methods</u> that are not included in the standard sample analysis menu and are available in WADA-accredited laboratories on WADA's website. ADOs are encouraged to consult a WADA-accredited laboratory for recommendations.

For example, analysis of hemoglobin-based oxygen carriers (HBOCs) and homologuous blood transfusion (HBT) should be requested on a discretionary but targeted basis applying analytical knowledge gained from the implementation of the Hematological Module of the ABP program and non-analytical intelligence:

- HBOCs: any blood sample collected (either for the Hematological Module of the ABP or for the detection of prohibited substances and/or methods when an A and B sample is collected) which shows plasma red coloration beyond reasonable hemolysis after centrifugation or sedimentation.
- HBT: any blood sample collected (either for the Hematological Module of the ABP or for the detection of prohibited substances and/or methods when an A and B sample is collected) which shows a sudden increase of hemoglobin and/or reduction of the percentage of reticulocytes, or if there is a suspicion based on a high phthalates measurement.

Insulin and insulin-mimetics have been known to be used in conjunction with other prohibited substances such as ERAs and GH, and so testing is recommended for those sports and disciplines that are at a high risk to both these prohibited substances. HBOCs, HBT and Insulins all remain on the prohibited list and are prohibited in all sports and disciplines.

Section 3: Implementing the TDSSA and Test Planning

This section outlines the levels of athlete that the TDSSA applies to, explains how to apply the TDSSA MLAs in an ADO's TDP.

Chapter 1: Level of Athlete

The TDSSA only applies to National-Level and International-Level athletes, as defined by NADOs and IFs in their anti-doping rules. ADOs may conduct additional analysis on recreational or other athletes at any time but such tests will not be counted towards achieving the required MLAs of the TDSSA. For the purpose of the TDSSA all athletes competing in events which are under the jurisdiction of an MEO will be presumed to be International-Level athletes or National-Level athletes. However, the level of the athlete should not prevent any athlete from being tested for all prohibited substances and/or prohibited methods on the Prohibited List at any time by any ADO that has jurisdiction to do so. Further information on the definition of an athlete can be found in the Code definitions and ISTI Article 4.3

As per TDSSA Article 7.3, it is mandatory that ADOs record the level of the athlete in ADAMS, for the purposes of monitoring its TDP progress and its compliance with the application of the MLAs to those defined athletes only.

The Testing Authority (TA) who authorized or requested the test is responsible for recording the level of athlete being tested, as defined by the IF or NADO, in ADAMS.

If the test is authorized by a NADO and conducted on an athlete within the NADO's definition of National-Level athlete, the level of the athlete should be "national". If the IF authorizes the test on an athlete within the IF's definition of International-Level athlete and requests a NADO or other sample collection service provider to conduct a test on its behalf, the athlete should be recorded as "international". Tests conducted on athletes outside of the IF's or NADO's definition of athlete should be recorded as "other level".

Chapter 2: Applying the TDSSA MLAs to the Test Distribution Plan

An ADO should decide how to allocate specific analysis of tests collected under the TDSSA among athletes based on its risk assessment, TDP and whereabouts pool management and through utilizing available information (e.g., ranking, performance, Athlete Biological Passport (ABP) status, intelligence) or recommendations from an <u>APMU</u>. The aim is to test the right athletes for the right prohibited substance(s) and/or prohibited method(s) at the right time.

Information about the prohibited substances and/or prohibited methods within the scope of the TDSSA and guidance on testing strategies for each prohibited substance is provided within the TDSSA Testing Guides. ADOs can contact testing@wada-ama.org for a copy of these TDSSA Testing Guides. In addition, a Testing Guide on strategic application of Gas Chromatography/Combustion/Isotope Ratio Mass Spectrometry (GC/C/IRMS) for the detection of exogenous application of endogenous steroids (ex. testosterone) is also available to ADOs upon request.

Calculating the MLAs within a Test Distribution Plan

A test shall be the basis of the calculation of the MLA. One test includes any number and type of samples collected from one athlete during a sample collection session. For example, a sample collection session in which one urine sample, one blood ABP sample and one dried blood spot sample are collected will count as one test. Blood ABP and/or dried blood spot tests, conducted in isolation, shall not be included in this calculation of MLA compliance.

Once an ADO has applied the number of tests to a sport or discipline following its risk assessment, it then applies the MLA percentages to those tests. Multiple analyses can be conducted on one sample, whether it be blood or urine collected during one sample collection session. The athletes and samples to which those analyses are applied are at the ADO's discretion.

As an example, if an ADO plans to conduct 100 tests in a sport or discipline and the MLAs are 60% for ERAs, 10% for GH and 10% for GHRFs, the minimum number of analyses an ADO should conduct is as follows:

- 60 ERAs analyses to be conducted in either urine or blood;
- 10 GH analyses in blood (serum); and
- 10 GHRFs analyses in urine

ADOs can request multiple analyses on samples collected during the same sample collection session. In this example, the minimum number of sample collection sessions or tests on which to apply the required analyses would be 60, based on the calculated minimum requirement for ERAs analyses. This is on the basis that GH and GHRFs analyses could be performed on those same athletes/samples also being tested for ERAs.

The remaining 40 tests from the 100 tests would be subject to either the standard urine analysis or a greater level of TDSSA or other analysis, which ADOs are encouraged to do according to their own risk assessment.

Any MLA calculation that does not equal a whole number when applying the respective MLA percentage to the total number of tests shall be rounded up or down, as applicable, to the nearest whole number. For example, if the number of ERAs analysis based on the number of tests planned in a particular sport or discipline yields a value of 4.2, the ADO will be required to conduct a minimum of four ERAs analyses. Respectively, if the number of ERAs analysis based on the number of tests planned in a particular sport or discipline results in a value of 0.6, the ADO will be required to conduct a minimum of one ERAs analysis.

In circumstances where the ADO, following the MLA calculation, is required to conduct one analysis but has information/intelligence that the one analysis would be more effective if applied to a sport/discipline/athlete of higher risk in its TDP, the ADO may transfer the one analysis from the lower risk sport or discipline to a higher risk sport or discipline.

MLAs of five percent (5%)

To increase flexibility and to enable ADOs to focus resources on higher risk sports or disciplines, compliance with the TDSSA requirements for sport or disciplines with an MLA of 5% is optional. However, ADOs are strongly encouraged to meet the 5% MLAs for the respective sports or disciplines listed in the TDSSA to maintain deterrence.

Calculating TDSSA analysis

ADOs should note that two analyses towards the relevant MLA shall be counted when ERAs analysis is conducted on both a urine and a blood sample collected during a sample collection session on the same athlete.

When calculating GH MLA application, two analyses are counted towards the MLA requirement when both the analysis for Biomarkers Test and the Isoform Differential Immunoassay are applied on a single blood sample collected during a sample collection session on an athlete. All samples analyzed as part of the Endocrine Module of the ABP will also count towards the GH MLAs of the respective sport or discipline.

Finally, when calculating GHRFs MLA application, two analyses are counted towards the MLA requirement when both the analysis for GHRFs (GHS/GHRP – small peptides) and for GHRFs (GHRH - large peptides) are applied on a single urine sample collected during a sample collection session on an athlete.

Blood ABP Samples and/or Dried Blood Spot samples

Blood ABP samples and/or dried blood spot samples, conducted in isolation, do not count as tests for the purposes of MLA compliance and therefore shall not be included in the number of tests that is the basis for the calculation of the application of MLAs. If either a urine or blood sample is collected in addition to a blood ABP sample and/or a dried blood spot sample and from the same athlete during a sample collection session, that session will count as one test.

Chapter 3: Other Considerations when Implementing the TDSSA

The TDSSA is a sport and discipline-specific document that relates to International-Level and National-Level athletes. ADOs shall comply on an individual basis with the TDSSA for every sport/discipline within their jurisdiction in which they plan to test as part of their TDP. If a sport or discipline is not contained within an ADO's TDP, the TDSSA requirements do not apply to that ADO for that sport or discipline.



The MLAs are minimums. ADOs are encouraged to exceed those minimums, especially if their risk assessment or any other relevant information specific to the sport or discipline and the athlete/s concerned, indicate they should do so.

The TA is responsible for ensuring it is meeting the required TDSSA MLAs regardless of which Sample Collection Authority (SCA) collects the sample(s). Clear communication to the WADA accredited laboratory requested to analyze the samples is important to ensure that the correct TDSSA analysis is applied to the applicable sample(s).

Any plans to conduct TDSSA analyses should be clearly outlined within a testing service agreement between the TA and SCA. This situation also applies where a NADO who is the SCA wishes to conduct additional analysis on samples (at its own cost) that it collects on behalf of an IF or MEO under Article 5.2.6 of the Code. In such cases, if the sport or discipline contains MLAs in the TDSSA, the IF or MEO (as the TA) would receive credit for such analyses towards meeting their individual MLA requirements.

In some situations, an athlete may be subject to testing under the authority of their IF, NADO or an MEO. Any MLA analyses conducted on an athlete are counted towards meeting the MLA requirements of the TA that requested the test.

It is important that an ADO's DCF contains the sport/discipline and this information is legible on the laboratory copy of the DCF so that the laboratory can assign a discipline to the sport when reporting the results and type of analysis into ADAMS. If the discipline is not provided, the analysis statistics by sport and discipline will not be accurate for that ADO, which will affect the evaluation of the ADO's implementation of the TDSSA.

ADOs that sub-contract out their sample collection services should ensure that the SCA is made aware of these requirements.

Where the sport and discipline are listed the same way in Appendices 1 to 4 of the TDSSA (e.g., weightlifting/weightlifting), they shall be recorded in ADAMS and on the DCF as listed in the TDSSA.

Where a sport has the discipline listed as "All" in Appendices 1 to 4 of the TDSSA, the ADO has the discretion to distribute the MLAs equally across the disciplines of the sport, or to those disciplines the ADO identifies as having the higher risk(s) of abuse of those prohibited substances and/or prohibited methods within the scope of the TDSSA. The actual discipline of the sport being tested shall be recorded on the DCF and ADAMS.

Where an athlete competes in a range of sports/disciplines and is tested out-of-competition, the athlete's discipline should be recorded on the DCF as the one that has the highest MLA percentage. If an athlete competes in more than one discipline (as listed in the TDSSA) at an event, the discipline in which the athlete competed when selected for in-competition testing would be the discipline to which the MLA applies and is recorded on the DCF.

With regards to the correct selection of a TDSSA discipline for para-athletics and para-swimming based on the athlete's class, ADOs can use the <u>Doping Control Guide for Testing Athletes in Para Sport</u> from the International Paralympic Committee's (IPC) website for further clarification on the classification of these sports and their disciplines.

If an ADO or a Doping Control Officer (DCO) is not clear about an athlete's class, the IPC recommends that the ADO/DCO asks the athlete for it.

MEOs Implementation of the TDSSA for Multi-Sports Events

The priorities for MEOs when implementing the TDSSA into multi-sport events should be the incorporation of the MLA requirements into the TDP as early as possible. In doing so, the MEO should apply the majority of the MLAs in the out-of-competition period leading into the event (this may include where the MEO has extended event jurisdiction i.e., in the period prior to the opening ceremony of the multi-sport event) and/or immediately upon arrival of athletes within the country hosting the event and prior to the competition starting.

MEOs should attempt to obtain test history on high-risk sports and disciplines from NADOs and IFs in advance of the event so the application of TDSSA MLAs can be better targeted. It is also important that the application of the TDSSA MLAs is planned and targeted during the in-competition period as well.

Advising Laboratories of the Type of Specific Analysis for a Sample

As per TDSSA Article 7.2, the type of analysis required shall not be recorded on the DCF.

ADOs shall ensure that the type(s) of analysis required for each sample is/are recorded at a minimum on the chain of custody documentation (or equivalent) shipped with the samples to the laboratory. This requires that clear instructions are provided to the DCO who is authorized to collect the sample(s).

In certain situations, an ADO may request further analysis of a sample following the results of another sample collected at the same or an earlier time. As an example, an ADO may collect a blood ABP sample at the same time as a urine sample and, following the review of the hematological profile in the ABP, may request ERAs analysis on the corresponding urine sample. In such circumstances, the ADO shall notify the laboratory of this request for further analysis in writing. ADOs are reminded that samples are routinely stored by laboratories for a maximum of three months in accordance with the requirements of the International Standard for Laboratories. Any further storage of samples should be negotiated with the applicable laboratory and should be considered as part of an ADO's overall TDP strategy in term of what criteria should trigger the long-term storage of such samples.

Note: Any samples stored long-term can be logged into the long-term storage ADAMS module. For further information, ADOs are encouraged to refer to the <u>long-term storage module section</u> on <u>ADAMS</u> <u>Help Center</u>.

Section 4: Implementation of the Hematological Module of the ABP

This section outlines how an ADO can apply the Hematological Module of the ABP, what are the mandatory criteria an ADO has to meet when utilizing the Hematological Module of the ABP and other relevant information.

Chapter 1: General

The Hematological Module of the ABP plays an important part in the targeting of athletes for testing, the detection of ERAs, and prosecution of anti-doping rule violations for the use of prohibited substances or methods affecting blood parameters (i.e. "blood doping"). As outlined in TDSSA Article 3.3, its implementation is a mandatory component of compliance with the TDSSA for sports or disciplines with an ERAs MLA of 30% or greater where an athlete is a member of an ADO's RTP. It is also strongly recommended that, when testing athletes in any sport or discipline with an ERAs MLA of 15%, an ADO implements the Hematological Module of the ABP. ADOs testing those sports or disciplines with an ERAs MLA of 10% are encouraged to consider the benefits of implementing the Hematological Module of the ABP, especially where dictated by their risk assessment.



Implementation of the Hematological Module of the ABP also enables ADOs to apply for flexibility in the implementation of the MLA percentage for ERAs of up to 50%, subject to meeting the criteria outlined in Article 6.1 of the TDSSA (see **Section 5**).

WADA's ABP team (<u>athletepassport@wada-ama.org</u>) can provide the necessary support required to ADOs in establishing and/or optimizing the use of the Hematological Module of the ABP.

Chapter 2: Setting up the Hematological Module of the ABP

In order to set up the Hematological Module of the ABP, the mandatory aspects of its implementation are detailed in <u>ISTI</u> Annex I, the International Standard for Results Management (<u>ISRM</u>) Annex C and the applicable <u>Technical Document for Athlete Passport Management Units</u> in force. For an ADO, these elements include:

- Ensuring the collection and transportation of blood ABP samples is carried out in accordance with <u>ISTI</u> Annex I;
- Contracting a WADA-approved <u>APMU</u> to manage the passport review process on behalf of the ADO;
- Consulting with the <u>APMU</u> to establish a list of experts who are qualified to comprise an Expert Panel for the review of passports according to section 6.0 of the applicable <u>Technical Document for Athlete</u> <u>Passport Management Units</u> in force; and
- Establishing properly configured access to the ABP in ADAMS in order to carry out the mandatory results management steps outlined in the <u>ISRM</u> Annex C in a timely manner.

Chapter 3: Mandatory Criteria for the Implementation of the Hematological Module of the ABP

The implementation of the Hematological Module of the ABP shall include the following mandatory criteria;

- As indicated in **Chapter 1 of Section 4**, include all athletes from those sports or disciplines with an ERAs MLA of 30% or greater (as identified in the TDSSA) that are included in an ADO's TDP, and are part of the ADO's Registered Testing Pool (RTP);
- As indicated in Chapter 2 of Section 4, the ABP program shall be compliant with all applicable ABP Technical Documents and International Standards, including the <u>ISTI</u>, the <u>ISRM</u> and the applicable Technical Document for Athlete Passport Management Units in force;
- At a minimum, an average of three blood ABP tests shall be planned annually across all athletes from those sports or disciplines with an ERAs MLA of 30% or greater who are part of the RTP of an ADO and therefore part of the ADO's ABP Hematological Module program; and
- The distribution of these tests shall be carried out according to the status of the Athlete's Passport, as well as any intelligence the ADO may have access to and the recommendations of the <u>APMU</u>, so that athletes with atypical/suspicious passports receive more tests than those with normal passports.

As a guide to WADA's assessment of the required number of blood ABP tests per ADO, the annual number of blood ABP tests conducted by the ADO and recorded in ADAMS will be divided by the number of athletes in the RTP from the sports or disciplines with an ERAs MLA of 30% or greater. As an example, if an ADO has 100 athletes in its RTP, of which 25 are from sports or disciplines with an ERAs MLA of 30% or greater, the ADO shall focus on these 25 athletes from sports or disciplines with an ERAs MLA of 30% or greater and plan to conduct a minimum of 75 blood ABP tests (an average of three tests x 25 RTP Athletes) during the course of that year.

RTP athletes with atypical or suspicious passports, as identified by the <u>APMU</u>, should be subject to greater than three blood ABP tests during the course of the year. RTP athletes with normal passports



shall have at least one blood ABP test during the year. For an RTP athlete from a sport or discipline with an ERAs MLA of 30% or greater with no previous blood ABP tests, the ADO shall plan to conduct a minimum of three blood ABP tests within the first year to establish a baseline and then adjust the testing frequency, in consultation with the ADO's <u>APMU</u> and intelligence to which the ADO may have access.

ADOs are required to report the details of their RTP to WADA through ADAMS. An ADO's compliance in relation to its Hematological Module of the ABP will be monitored by WADA as part of its wider compliance monitoring program based on the criteria outlined above and as per the <u>ISTI</u> (see **Section 1**, **Chapter 2**).

Note: If an ADO implements a hematological ABP program for a sport or discipline that has an ERAs MLA of less than 30%, the ADO is responsible for ensuring that all requirements related to the implementation of a hematological ABP program, are in compliance with the <u>ISTI</u>, and any related technical documents.

Chapter 4: Other Considerations when Implementing the Hematological Module of the ABP

If an athlete is in both an IF's and a NADO's RTP, both ADOs are encouraged to collaborate on testing programs for athletes over whom they have joint jurisdiction over to ensure they are conducted effectively. In such cases, the minimum number of blood ABP tests for athletes can be shared between the IF and the NADO.

Where ADOs collaborate and share blood ABP testing on the same RTP athlete, the ADO should reallocate testing resources for blood ABP testing by a) increasing testing on athletes with atypical/suspicious passports, b) adding additional athletes to the RTP from sports or disciplines with an ERAs MLA of 30% or greater, or c) expanding blood ABP testing on other athletes.

Upon WADA's request, ADOs should be in a position to provide justification on why the minimum level of blood ABP tests was not met.

An <u>APMU</u> plays a key role in reviewing hematological profiles and guiding the ADO when target testing should be conducted based on the <u>APMU</u>'s recommendations for which the ADO is responsible for acting upon. Because <u>APMU</u> recommendations for additional testing can occur at any time, ADOs must ensure a) a dedicated budget for reactive testing; and b) dedicated personnel managing the ABP within the ADO who can receive and rapidly act on <u>APMU</u> recommendations.

For the Hematological Module in particular, the ability to order a follow up test within days of the <u>APMU</u> recommendation can be key towards uncovering the use of a prohibited substance or method.

With respect to ERAs analysis, there may be times when the athlete's passport does not clearly reflect blood manipulation and therefore the ADO should also rely on other intelligence and risk factors to guide them with the targeting for ERAs.

Permitted Shipping Times to a WADA-Accredited Laboratory or ABP Laboratory for a Blood ABP Sample

WADA has developed a Blood Stability Score (BSS) which permits a shipping time of a blood ABP sample to the laboratory of up to 60 hours based on the sample being shipped in properly cooled conditions. The relevant information is outlined in <u>ISTI</u> Annex I.

If a urine sample is collected from a non-RTP athlete in a sport or discipline with an ERAs MLA of 30% or greater, it is not mandated that blood ABP samples shall be collected from such athlete. However,



ADOs are encouraged to either collect blood ABP samples from these athletes and/or, where possible, increase the number of athletes in their RTP in sports or disciplines with an ERAs MLA of 30% or greater to ensure high-performing and ranked athletes are covered by the Hematological Module of the ABP.

When collecting a sample for the Hematological Module of the ABP, an ADO should also collect a urine sample during the same sample collection session. The benefit of collecting a urine sample with a sample for the Hematological Module of the ABP is that if the ABP sample is atypical, an ERAs analysis can then be requested on the urine sample collected at the same time. This is a much more efficient use of resources and intelligence. If there is no urine sample to analyse, the window of opportunity to detect ERAs may be lost due to the time required to collect a follow-up urine sample. ADOs should also be aware of the possibility to perform ERAs analysis on blood ABP samples however, this requires rapid communication between the <u>APMU</u>, the ADO and the laboratory.

ISTI Annex I

I.4.3. The integrity of the *Markers* used in the hematological module of the *Athlete Biological Passport* is guaranteed when the Blood Stability Score (BSS) remains below 85, where the BSS is computed as:

BSS = 3 * T + CAT

with CAT being the Collection to Analysis Time (in hours), and T the average Temperature (in degrees Celsius) measured by the data logger between *Sample* collection and analysis.

I.4.4 Within the framework of the BSS, the following table can be used by the <u>DCO/BCO</u> to estimate the maximal transport time to a <u>Laboratory</u> or <u>ABP Laboratory</u>, called the Collection to Reception Time (CRT), for a given average temperature T, e.g., if shipped at 4°C, the maximal CRT is 60 h.:

T [°C]	CRT [h]
15	27
12	36
10	42
9	45
8	48
7	51
6	54
5	57
4	60

I.4.5 The <u>DCO/BCO</u> shall as soon as possible transport the Sample to a <u>Laboratory</u> or <u>ABP</u> <u>Laboratory</u>.

MEOs should collaborate with the respective IFs (as the passport custodian) for the sports or disciplines with an ERAs MLA equal to 30% or greater in advance of the Major Event to determine whether the IF requires any blood ABP samples to be collected on athletes under their jurisdiction who are participating in the Major Event. As MEOs cannot be passport custodians of athletes, they should discuss with the



respective IFs in advance of the Major Event to determine the number of blood ABP samples, or the athletes to be targeted, etc. related to the Hematological Module of the ABP and based on input from the respective <u>APMU</u> of the IF or the NADO, where applicable.

During the Major Event, the ADO's <u>APMU</u> should review sample profiles and provide real time (and rapid) feedback on tests conducted by the MEO such as any follow-up test recommendations or ERAs analysis on blood or urine samples taken. The MEO should take these recommendations into consideration when applying their TDP.

Section 5: Flexibility in Implementing the MLAs

This section outlines the reasons for which an ADO could apply for flexibility in the implementation of the TDSSA requirements, what criteria shall be met if the application for flexibility is based on the implementation of the Hematological Module of the ABP, and what other non-ABP related criteria could be utilized for an ADO to apply.

Chapter 1: What are the Benefits to Apply for Flexibility?

ISTI 4.7.2

An *Anti-Doping Organization* may apply to *WADA* for flexibility in the implementation of the minimum levels of analysis specified for *Prohibited Substances* or *Prohibited Methods* as outlined in the <u>TDSSA</u>.

In accordance with <u>ISTI</u> Article 4.7.2, an ADO can apply to WADA for flexibility in the implementation of the MLAs contained in the TDSSA. In order for WADA to consider flexibility in the implementation of the MLAs, the ADO has two options, the first is to demonstrate its implementation of the Hematological Module of the ABP and the second option is the implementation of a non-ABP related program that includes intelligence-led testing strategies and/or tools and how such approaches lead to the most effective and efficient use of the available testing resources. Compliance with the TDSSA alone is not sufficient to demonstrate intelligence-led testing.

The ADO is required to complete a self-assessment against set criteria and submit to WADA relevant documents such as the ADO's risk assessment, TDP and RTP. The ADO will then automatically qualify for flexibility in the implementation of the MLAs of up to 50% for the sports or disciplines the ADO seeks flexibility for, subject to a review by WADA. The online application form can be found in WADA's <u>Code</u> <u>Compliance Center</u>. WADA has also developed and published the <u>Application for Flexibility User Guide</u> to assist ADOs with their application for flexibility.

Flexibility in the implementation of the MLAs will remain valid for a maximum period of two years provided that the ADO continues to comply with the list of criteria included in **Chapter 2** and **Chapter 3** below. If the ADO no longer meets the criteria contained within its application for flexibility, the ADO shall notify WADA. Should an ADO wish to extend the validity period of its flexibility, the ADO shall contact WADA in advance of its expiration.

Requests for flexibility in the implementation of the MLAs of more than 50% will not be accepted, and sports or disciplines with MLAs of 10% or less are not eligible for flexibility. WADA withholds the right to request further information from the ADO to justify the requested flexibility. WADA may deny, withdraw or reduce the level of flexibility if the self-assessment was incorrectly answered or relevant documents requested are partially/not submitted within the requested timelines or the ADO's testing program is found not to be compliant with the <u>ISTI</u>.

If the level of flexibility is denied, withdrawn or reduced following a review by WADA, ADOs will be contacted by and/or are encouraged to contact WADA at <u>testing@wada-ama.org</u> to discuss the reasons for the denial, withdrawal or reduction of their level of flexibility and agree on required measures to restore or increase the level of flexibility.

Chapter 2: Application for Flexibility for Implementing the Hematological Module of the ABP

An ADO can apply for flexibility in the implementation of the TDSSA requirements if they are implementing the Hematological Module of the ABP. To be eligible for flexibility of up to 50% of the ERAs MLAs for sports or disciplines based on the adoption of the Hematological Module of the ABP, the ADO shall be able to demonstrate that it meets all the criteria below:

- The ABP program of the sport or discipline has been fully operational for at least 12 months;
- The ABP program is managed by a WADA-approved <u>APMU</u> in accordance with the applicable Technical Document for <u>APMU</u>s in force.
- The ABP program implements target testing that acts upon the recommendations of an <u>APMU</u> with reference to ERAs.
- All relevant ABP data, including Doping Control forms (DCFs), are available in ADAMS, which permits oversight by WADA; and
- All criteria described in TDSSA Article 3.3 are met (see Section 4, Chapter 3).

The application form can be found online in WADA's <u>Code Compliance Center</u>.

Chapter 3: Application for Flexibility for Non-ABP Related Criteria

An application for flexibility in the implementation of the TDSSA requirements can also be submitted for non-ABP related criteria. The ADO has to demonstrate that the criteria below are actively part of the ADO's anti-doping program. Such criteria include (but are not limited to):

10% flexibility for each of the following criteria

- Target testing to be the majority of testing for both in-competition and out-of-competition;
- The implementation of alternative testing strategies including the application of specific analysis for other prohibited substances and/or prohibited methods outside the scope of the TDSSA, the collection of dried blood spot samples, the collection of blood samples for the Steroidal Module of the ABP, the use of the Endocrine Module of the ABP, etc.;
- Regular review of samples in long-term storage to assess and implement further analysis as needed; and
- Use of an electronic system (i.e., "paperless") to conduct sample collection sessions (e.g., by utilizing WADA's DCO Central application)

5% flexibility for each of the following criteria

- Anti-doping intelligence received is collated and analyzed to establish patterns, trends and relationships that assist in the further development of an effective anti-doping strategy; and
- The development and implementation of policies and procedures for the sharing of information with other ADOs and law enforcement, and for the facilitation and encouragement of confidential sources.

ADOs will receive the applicable flexibility in the implementation of the MLAs for meeting each criterion listed above. For example, if an ADO can demonstrate that target testing is the majority of testing for both



in-competition and out-of-competition, a regular review of samples in long-term storage, and that antidoping intelligence received is collated and analyzed to establish patterns, trends and relationships that assist in the further development of an effective anti-doping strategy, the ADO will qualify for flexibility in the implementation of the MLAs of up to 25% for the sports or disciplines the ADO seeks flexibility for.