

# **Frequently Asked Questions**

# Technical Document for Sport Specific Analysis<sup>1</sup>

**Supporting Document A** 

<sup>1</sup> The FAQs on the TDSSA is a supporting document to assist ADOs with the implementation of the TDSSA. Where the interpretation of any text within the FAQ is in contradiction with the TDSSA, the TDSSA shall prevail.

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## General

### 1. What is the Technical Document for Sport Specific Analysis?

The Technical Document for Sport Specific Analysis (TDSSA) is a tool to assist Anti-Doping Organizations (ADOs) in contributing to more intelligent and effective Testing programs for sports/disciplines by requiring a minimum level of analysis for Prohibited Substances and/or Prohibited Methods that are not currently part of the standard sample analysis menu.

The TDSSA is mandated by Article 4.2.3 of the 2023 International Standard for Testing and Investigations (ISTI) and 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, analysis and adoption by all ADOs that conduct Testing on those sports/disciplines deemed at risk.

### 2. When did the TDSSA become effective?

The TDSSA came into effect on 1 January 2015.

#### 3. To whom does the TDSSA apply?

The TDSSA applies to all ADOs that 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).

### 4. Which Prohibited Substances are within the scope of the TDSSA?

- Erythropoietin receptor agonists (ERAs' <sup>2</sup>);
- 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).

# 5. What was the process by which the TDSSA and the Minimum Levels of Analysis (MLAs) were developed?

A drafting group of experts with science, Laboratory, exercise physiology and anti-doping backgrounds, covering a number of stakeholder groups, 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.

<sup>&</sup>lt;sup>2</sup> The acronym 'ERAs' is used in this Technical Document to describe the substances analyzed according to the applicable WADA Technical Document for EPO in force.



The MLA requirements contained in Appendices 1 and 2 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/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/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.

The TDSSA Expert Group was expanded in 2020 and was replaced with the Strategic Testing Expert Advisory Group that focuses on development of testing related matters that fall under the ISTI.

# 6. Were factors other than physiological and non-physiological demand, such as financial gain, sport culture in a country, country performance, intelligence or gender, considered when establishing the MLAs?

No, these factors should be considered by each ADO as part of the wider Risk Assessment that ADOs shall conduct in accordance with Article 4.2 of the ISTI, which is an important step in the development of their Test Distribution Plan (TDP).

# 7. Is there a guideline to assist ADOs in conducting a Risk Assessment and to optimize the effectiveness of their Testing programs?

Yes. WADA developed a document titled <u>Guidelines - Implementing an Effective Testing Program</u> to assist ADOs with conducting the overall Risk Assessment and elements of their TDP. The Guideline focuses 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 ISTI.

WADA also prepared two checklists: one for an ADO's Risk Assessment and one for Planning Effective Testing. Both checklists can be found in WADA's website and WADA's Anti-Doping e-Learning platform (ADEL), under the resources section of the ISTI.

### 8. Is WADA monitoring ADO compliance with the TDSSA?

Yes, monitoring compliance with the TDSSA requirements began on 1 January 2016 and is ongoing.

### 9. Will ADOs be given the opportunity to justify any shortfalls?

Yes, as part of WADA's ongoing monitoring process, ADOs will be given the opportunity to justify their position when the MLAs are partially or not being met.

# 10. Is the TDSSA implementation part of the overall 2021 World Anti-Doping Code (Code) compliance process? If so, how will compliance with the TDSSA be monitored?

Yes. The TDSSA will be monitored and evaluated through ADAMS. A wider evaluation of ADOs' compliance with the TDSSA is being addressed through WADA's compliance and monitoring program and includes the review of the methods the ADOs applied to the implementation of the Tests to meet the MLAs as outlined in the ISTI Article 4. ADOs should use the TDSSA monitoring tool in ADAMS to self-monitor their own implementation of the TDSSA.



### 11. How should the cost implications of the TDSSA be managed?

Those ADOs that are not currently conducting the required MLAs will need to review how they can optimize the use of existing resources within their anti-doping program or seek additional funding from their funding bodies.

### 12. What are the objectives of the TDSSA?

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

- Maintaining 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 the hematological module of the ABP to continue to allow for intelligent Testing and targeted analysis 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.

# 13. What messages can ADOs 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.
- Article 23.3 of the Code (Implementation of Anti-Doping Programs) states:

## "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".

- 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.

## Implementing the TDSSA and Test Planning for NADOs and IFs

### 14. Which Athletes are subject to the TDSSA?

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.

Further information on the definition of an Athlete can be found in the Code definitions and Article 4.3 of the ISTI.

#### 15. Does an Athlete need to know what level of Athlete they are at the time of a Test?

No. 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, then 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, then 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".

The level of the Athlete does not prevent any Athlete 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.

#### 16. If an Athlete is subject to Testing by multiple ADOs, which ADO receives credit for the MLA?

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 based on who the TA was that requested the Test.

# 17. How should specific analysis of Tests collected under the TDSSA be allocated between Athletes?

ADOs should make this decision as part of their Risk Assessment, TDP management and through utilizing available information (e.g., intelligence) or recommendations from an Athlete Passport Management Unit (APMU). The aim is to test the right Athletes for the right Prohibited Substance(s) and/or Prohibited Method(s) at the right time.

# 18. Should NADOs apply the MLAs in each sport that is listed separately on the TDSSA or only in those sports and disciplines that are part of the NADO's TDP?

The TDSSA is a sport/discipline specific document that relates to International-Level and National-Level Athletes. NADOs shall comply on an individual basis with the TDSSA for every sport or discipline within their jurisdiction in which they plan to test as part of their TDP.

#### 19. How should an ADO calculate the MLAs and apply them to its TDP?

A Test shall be the basis of the calculation of the MLA. One Test includes any number and type of Samples that may be 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.

Once an ADO has applied the number of Tests to a sport/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 absolute minimum number of Sample Collection Sessions or Tests could be 60. This is on the basis that GH and GHRFs analyses are performed on those Athletes who are also being Tested for ERAs.

The remaining 40 Tests from the 100 Tests would then be subject to either the standard urine analysis or a greater level of TDSSA or other analysis, which ADOs are encouraged to do.

The application of these analyses to Athletes subject to the TDSSA should be based on intelligence and identified risk factors particular to each Athletes' circumstances.

# 20. Do blood ABP Samples and/or dried blood spot Samples, collected in isolation, count as Tests?

No. Blood ABP Samples and/or dried blood spot Samples, conducted in isolation, do not count as Tests and therefore, shall not be included in the number of Tests that is the basis for the calculation of the 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.

# 21. What should an ADO do if a sport or discipline which has been allocated a small number of Tests has an MLA that results in the required number of analyses under the TDSSA being one?

In circumstances where the ADO has intelligence that the "1" analysis would be more effective if applied to a sport/discipline/Athlete of higher risk in its TDP, the ADO may transfer the "1" analysis from the lower risk sport or discipline to a higher risk sport or discipline.

# 22. What should an ADO do if the MLA calculation of a sport or discipline results in a portion of a type of analysis e.g., 4.2 or 0.6?

In this situation, any MLA that does not equal a whole number when applied to total Tests shall be rounded up or down 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 results in the calculation 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 the calculation of esuits in the calculation of 0.6, the ADO will be required to conduct a minimum of one ERAs analysis.

### 23. Is the implementation of the MLAs of five percent (5%) optional?

Yes. 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 continue their best efforts to meet the 5% MLAs for the respective sports or disciplines listed in the TDSSA to maintain deterrence.

### 24. What sport/discipline should be applied to the Doping Control Form (DCF) for Out-of-Competition Samples collected from an Athlete who competes in a broad range of sport disciplines?

The Athlete's discipline should be recorded as the one that has the highest MLA percentage.



# 25. If an Athlete competes in more than one discipline (as listed in the TDSSA) at an event, what MLA applies if they are different?

The discipline in which the Athlete competed and was selected for Testing should be the discipline to which the MLA applies.

### 26. Is it important that an ADO records the discipline of a sport on the DCF?

Yes. An ADO's DCF shall contain the discipline of a sport 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. 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 Sample Collection Authority is made aware of these requirements.

### 27. Is it mandatory that an ADO record the level of the Athlete on the Doping Control Form?

No. However, as per TDSSA Article 7.3, it is mandatory that the ADOs record the level of the Athlete in ADAMS, for the purpose of monitoring its TDP progress and its compliance with the application of the MLAs to those defined Athletes only.

### 28. What if a sport does not have a discipline listed in the TDSSA?

Where the sport and discipline are listed the same in the TDSSA (e.g., Weightlifting/Weightlifting), they shall be recorded in ADAMS and on the DCF this way.

# 29. Where a sport has the discipline listed as "All" in the TDSSA, how should the ADO apply the MLAs to the disciplines of that sport and how should the disciplines be listed in ADAMS and on the DCF?

In this case, the ADO has the discretion to distribute the MLAs across the disciplines of the sport equally or to those disciplines the ADO identifies as having the higher risk(s) to 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.

### 30. How shall ADOs advise the Laboratories of the type of analysis they require on a Sample?

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 or via another system that the ADO has agreed with the Laboratory. This requires that clear instructions are provided to the Doping Control Officer 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 an blood ABP Sample at the same time as a urine Sample and, following the review of the profiles in the ABP Sample, may request ERAs analysis on the urine Sample. In such circumstances, the ADO shall notify the Laboratory of this request for Further Analysis (which may be by email). 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.

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

# 31. How has ADAMS been modified to assist ADOs with the implementation of the TDSSA and to report accurate statistics so ADOs and WADA can monitor the implementation of the TDSSA?

ADAMS Next Gen includes a TDSSA Monitoring tool, which monitors an ADO's implementation of the TDSSA MLAs in real time. ADOs are encouraged to utilize the new monitoring tool in ADAMS, 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 <u>Reporting Guide to Monitor</u> <u>Testing</u> on WADA's website or the ADAMS <u>Help Center</u>.

In addition, the list of disciplines of the sports listed in the TDSSA is updated annually and in line with the latest version of the TDSSA, and the ability to record the level of the Athlete is made mandatory.

# 32. In the case where an ADO collects Samples as a service provider for another ADO, which ADO is accountable for meeting the MLAs?

In such situations, the organization requesting the Tests, known as the TA, is responsible for ensuring it is meeting the required TDSSA MLAs.

Any such plans by the TA to conduct analyses under the TDSSA should be clearly outlined within a Testing service agreement. This situation also applies where a NADO who is the service provider 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/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.

### 33. What if an ADO exceeds the MLAs?

The MLAs are minimums. ADOs are encouraged to exceed those minimums if their Risk Assessment or any other relevant information indicates they should do so.

### 34. Where could an ADO find more information on the disciplines of para-athletics and paraswimming?

More information on the classes per TDSSA discipline of para-athletics can be found in the Matrix below.



Sport	Discipline	Classes	
Para-Athletics	Wheelchair Racing (All Distances and Classes)	T32-T34, T51-T54	
Para-Athletics	Running- Sprint (100m - 400m - All Classes)	T11-13, T20, T35-38, T42-44, T45-47, T61-64	
Para-Athletics	Jumping (All Classes)	T11-13, T20, T35-38, T42-44, T45-47, T61-64	
Para-Athletics	Running Middle Distance (800m - 1500m - All Classes)	T11-13, T20, T35-38, T42-44, T45-47, T61-64	
Para-Athletics	Running- Endurance (Greater than 1500m - All Classes)	T11-13, T20, T35-38, T42-44, T45-47, T61-64	
Para-Athletics	Standing Throws (All Classes)	F11-13, F20, F35-38, F40-41, F42-44, F45-46, F61-64	

ADOs can also use the below links from the International Paralympic Committee's (IPC) website for further clarification on the classification of para-athletics and para-swimming.

- <u>https://www.paralympic.org/athletics/classification</u>
- https://www.paralympic.org/swimming/classification
- https://www.paralympic.org/classification

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.

### 35. How should MEOs implement 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) 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 analysis for TDSSA MLAs is planned and targeted during the In-Competition period as well.

## Implementation of the Hematological Module of the ABP

### 36. Is the hematological module of the ABP subject to the TDSSA?

Yes., its is a mandatory component of compliance with the TDSSA for sports or disciplines with an ERAs MLA of 30% or greater. The TDSSA is intended to ensure that the tools that support the detection of Prohibited Substances and/or identify the Use of Prohibited Methods such as the ABP are subject to an appropriate level of analysis and adoption by all ADOs that conduct Testing in those sports or disciplines deemed at risk.

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 Use of blood doping methods.



As outlined in TDSSA Article 3.3, it is strongly recommended that any sport or discipline with an ERAs MLA of 15% implements the hematological module of the ABP. Those sports or disciplines with an ERAs MLA of 10% are encouraged to consider the benefits of implementing the hematological module of the ABP. When implementing the hematological module of the ABP for sports or disciplines with an ERAs MLA of 15% or less, ADOs are encouraged to apply the criteria as outlined in TDSSA Article 3.3.

Implementation of the ABP hematological module 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 of the TDSSA.

WADA will provide the necessary support required to ADOs in establishing ABP programs.

### 37. How does an ADO set 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 Annex I of the ISTI, Annex C of the International Standard for Results Management (ISRM) and the applicable Technical Document for Athlete Passport Management Units in force. For an ADO, these elements include:

- Ensuring the collection and transportation of blood ABP Samples is carried out in accordance with Annex I of the ISTI.
- Appointing an APMU to manage the passport review process on behalf of the ADO. Effective on 1 January 2020, the use of a WADA approved APMU is mandatory.
- Consulting with the APMU 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 Technical Document for Athlete Passport Management Units in force.

For further information on how to set up the implementation of the hematological module of the ABP, please contact <u>Athletepassport@wada-ama.org.</u>

# 38. Which are the mandatory criteria for the implementation of the hematological module of the ABP, in order for it to comply with the TDSSA?

The implementation of the hematological module of the ABP shall include the following mandatory criteria;

- Apply to 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);
- The ABP program shall be compliant with all applicable ABP Technical Documents and International Standards, including the ISTI, the ISRM 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/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 APMU, so that Athletes with atypical/suspicious Passports receive more Tests than those with normal Passports.



ADOs are required to report the details of their RTP to WADA through ADAMS.

#### 39. When did these criteria come into effect?

These criteria came into effect on 1 January 2019.

40. If I have 100 Athletes in my RTP, of which 25 are from sports or disciplines with an ERAs MLA of 30% or greater, how many blood ABP Tests shall I conduct to comply with the mandatory criteria?

The ADO shall plan a minimum of 75 blood ABP Tests for these 25 Athletes - an average of three Tests x 25 RTP Athletes.

# 41. Our ADO includes Athletes from sports or disciplines with an ERAs MLA of 30% or greater in the RTP for deterrence purposes but cannot afford to Test them three times. What shall we do?

The provision of whereabouts information by the Athlete is considered to be proportionate when this information is being used to direct appropriate levels of Testing. Thus, the inclusion of Athletes in an RTP for deterrence purposes, where there is no intention to appropriately Test the Athlete, is not recommended.

# 42. If an Athlete is in both an IF's and NADO's RTP, how should we plan to meet the minimum number of blood ABP Tests for Athletes in a sport or discipline with an ERAs MLA of 30% or greater?

ADOs are encouraged to collaborate on Testing programs for Athletes that they have joint jurisdiction over to ensure they are conducted effectively. The minimum number of blood ABP Tests for Athletes, who are in both an IF's and a NADO's RTP, 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 re-allocate Testing resources for blood ABP Testing by 1) increasing Testing on Athletes with atypical/suspicious passports, 2) adding additional Athletes to the RTP from sports or disciplines with an ERAs MLA of 30% or greater, or 3) 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.

# 43. If urine Samples are collected from a non-RTP Athlete in a sport or discipline with an ERAs MLA of 30% or greater, do blood ABP Samples need be collected from the same Athlete?

No, 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.

# 44. When implementing an ERAs analysis program that is supported by the hematological module of an ABP, should any target Tests be based solely on the review of blood profiles by an APMU?

An APMU plays a key role in reviewing blood profiles and guiding the ADO when Target Testing should be conducted. This is one reason why flexibility in the ERAs MLAs is available for those ADOs that are implementing an effective ABP program. However, 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.

# 45. When collecting an ABP hematological Sample, should the ADO also collect a urine Sample during the same Sample Collection Session?

Yes, an ADO should collect a urine Sample during the same Sample Collection Session to enable the analysis of ERAs, should the Athlete's passport be atypical. The benefit of collecting a urine Sample with an ABP hematological Sample is that if the ABP Sample is atypical, an ERAs analysis can then be requested on the urine Sample. This is a much more efficient use of resources and intelligence. If there is no urine Sample to analyze, the window of opportunity to detect ERAs may be lost due to the time required to collect a follow-up urine Sample.

# 46. What are the obligations of MEOs with regards to the implementation of an ABP hematological module on sports/disciplines with an ERAs MLA equal to 30% or greater?

Ideally, MEOs should collaborate with the respective IFs (as the passport custodian) for the sports/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 its Athletes 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.

During the Major Event, the IF's APMU should review Sample profiles and provide real time feedback on Tests conducted by the MEO such as any follow-up Test recommendations or ERAs analysis on blood or urine Samples taken. This information should be provided to the MEO through the IF. The MEO should take these recommendations into consideration when applying their TDP.

## Application for Flexibility in the Implementation of MLAs

### 47. What is the process for obtaining flexibility in the implementation of MLAs?

In accordance with Article 4.7.2 of the ISTI, an ADO can apply to WADA for flexibility in the implementation of the MLAs contained in the TDSSA. Further information on the criteria is located in Article 6 of the TDSSA. The online application form can be found in WADA's <u>Code Compliance</u> <u>Center</u>. WADA has also developed and published the <u>Application for Flexibility User Guide</u> to assist ADOs with their application for flexibility.

# 48. What criteria are required to be met in accordance with Article 4.7.2 of the ISTI to support an ADO's application for flexibility in implementing the MLAs?

Following the completion of a self-assessment against set criteria found in TDSSA Article 6, and the submission to WADA of relevant documents to support the application, such as the ADO's Risk Assessment, TDP and RTP, an ADO will automatically be pre-approved for flexibility in the implementation of the MLAs of up to 50% for the sports or disciplines the ADO seeks flexibility for.

# 49. Given my application for flexibility in the implementation of the MLAs to WADA is automatically pre-approved, will WADA review it?

Yes, an ADO's application is subject to review by WADA to ensure the application accurately meets the criteria.



WADA withholds the right to request further information from the ADO to justify the requested flexibility. WADA may 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 are found not to be compliant with the ISTI.

# 50. What do I need to do if my level of flexibility is 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 withdrawal or reduction of their level of flexibility and agree on required measures to restore or increase the level of flexibility.

# 51. Does a robust and effective ABP hematological program of an ADO result in an automatic reduction of the ERAs MLAs?

No. WADA recognizes that the ABP hematological program is an important tool in implementing effective Testing programs for certain sports or disciplines. However, ADOs shall still apply for flexibility to the ERAs MLAs in accordance with Section 6 of the TDSSA. The application form can be found online in WADA's <u>Code Compliance Center</u>.

# Prohibited Substances within the scope of the TDSSA and WADA-Accredited Laboratories

### 52. Is the mandatory implementation of the GH MLAs for all sports/disciplines postponed?

Yes. Compliance with the GH MLAs is postponed until the endocrine module of the ABP is ready for implementation.

## 53. Should ADOs stop Testing for GH?

No. ADOs are strongly encouraged to continue their best efforts to conduct GH Testing by prioritizing the higher risk sports or disciplines listed in the TDSSA.

In situations where a Sample is reported as atypical for GH, and/or where investigations indicate reliable intelligence on possible GH abuse, ADOs should Target Test the Athlete for GH analysis. In addition, ADOs are strongly encouraged to store serum Samples for future and Further Analysis when further technological advancements for GH analysis are available.

### 54. What are the analysis methods for GH?

There are two complementary methods for GH analysis: The Isoforms Differential Immunoassays (the GH Isoforms method) and the GH Biomarkers method.

The GH Isoforms 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 second method (GH Biomarkers) was initially implemented during the 2012 London Olympic and Paralympic Games. 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.



These two GH analytical methods are complementary in nature: while the GH Isoforms method detects GH doping up to 24-48 hours after administration, the GH Biomarkers method, which measures changes in concentration levels of two main markers of GH biological action, namely IGF-1 and P-III-NP, may not detect GH in the initial phase of use but does at later times and for a longer period that the GH Isoforms method.

It is recommended that ADOs conduct both analytical methods when Testing for GH as they provide a greater ability to detect GH when applied together.

One analysis towards the minimum level requirement shall be counted irrespective of whether the GH Isoforms and/or the GH Biomarkers method is used on a blood Sample collected during a Sample Collection Session on an Athlete.

## 55. What is the permitted shipping time to a WADA-accredited Laboratory for a blood Sample that will be analyzed for GH?

The applicable WADA Technical Document for GH in force outlines 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, which will be analyzed with the GH Biomarkers method, is a maximum of 5 days.

# 56. What is the permitted shipping time to a WADA-accredited Laboratory or ABP Laboratory for a blood ABP Sample?

WADA has developed a Blood Stability Score (BSS) which can increase the shipping time of a blood ABP Sample to the Laboratory from 36 hours up to 60 hours based on the Sample being shipped in constant cooled conditions.

The integrity of the Markers used in the hematological module of the ABP 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.

Within the framework of the BSS, the following table can be used by the DCO/Blood Control Officer (BCO) to estimate the maximal transport time to a WADA-accredited or ABP Laboratory, 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

The DCO/BCO shall as soon as possible transport the Sample to a WADA-accredited Laboratory or ABP Laboratory.

## 57. What are the different categories of 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)

# 58. Will the TDSSA have a direct impact on WADA-accredited Laboratories' capacity to analyze for those Prohibited Substances within the scope of the TDSSA?

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 GH using the biomarkers method, for GHRFs (GHRH - large peptides) and for ERAs (serum and/or plasma).

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.

### 59. Which WADA-accredited Laboratory can Test for the Prohibited Substances on the TDSSA?

The TDSSA analysis capacity per WADA-accredited Laboratory can be found in **Table 1** below. ADOs are encouraged to confirm the analysis menu and the specific methods available with the WADA-accredited Laboratories they collaborate with.

# 60. The TDSSA outlines that ERAs can be analysed in urine or blood. Does this mean that an ADO has to collect a blood and urine Sample each time to conduct ERAs Testing or can an ADO decide for either blood or urine (and sometimes both)?

The 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 urine. When Laboratories analyze for CERA in blood serum or plasma, they will also be applying methods, such as IEF-PAGE or SAR-PAGE, capable of detecting other ERAs in addition to CERA (recombinant ERAs, NESP, etc.).

One analysis towards the minimum level requirement shall be counted irrespective of whether a single or multiple ERAs analysis is conducted on a urine and/or blood Sample collected during a Sample Collection Session on the same Athlete.

# 61. What should an ADO do if it does not have the capacity (i.e. BCOs) to collect blood Samples or if it is unable to ship blood Samples to the nearest Laboratory within the required shipping times due to distance or issues with the export or import of blood Samples into a country that hosts a WADA-accredited Laboratory?

If the ADO does not have trained BCOs to conduct blood Testing, the ADO should put the necessary measures in place (recruitment of BCOs, training, etc.) to comply with the collection and analysis of blood Samples for GH and ERAs MLAs and ABP hematological module as soon as possible.

If the ADO is unable to ship blood Samples to the nearest Laboratory within the required shipping times due to distance or issues with export or import into the country that hosts a WADA-accredited Laboratory of blood Samples, the ADO should contact WADA immediately and explain the particular circumstances on the matter.

### 62. The original scope of the TDSSA included Hemoglobin Based Oxygen Carriers (HBOCs), Homologous Blood Transfusion (HBT) and Insulins. Why are these not included in the TDSSA?

HBOCs and HBT should be Tested on a discretionary but targeted basis applying analytical knowledge gained from the implementation of an effective ABP program and non-analytical intelligence. On the basis of the relative performance benefit, as well as detection efficacy and health risks of these methods, they are no longer included in the scope of the TDSSA. This decision remains subject to review. However, this should not prevent any ADO to order such Testing based on experience and/or intelligence-based targeting.

Insulins 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.

## 63. Which Samples should the Laboratory analyse for HBOCs and HBT?

- HBOCs: any blood Sample collected (either for 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 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.



64. Are there any other specific methods of analysis that are not included in the standard urine analysis menu and can be requested from the Laboratory?

ADOs can find the full list of available specific methods that are not included in the standard urine analysis menu in **Table 2** below. ADOs are encouraged to consult a WADA-accredited Laboratory for recommendations.

# 65. Will any other Prohibited Substances or Prohibited Methods that are included in the WADA Prohibited List be added to the TDSSA in the future?

Any Prohibited Substance or Prohibited Method that is added to the Prohibited List and has an approved analytical method 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 urine analysis).

**Note:** 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>

## Table 1: TDSSA analysis per WADA-Accredited Laboratory (as of September 2022)

		ERAs		GH		GHRFs	
Laboratory	Urine	Serum	Plasma	Isoforms	Biomarkers	GHRPs/GHS	GHRH
Ankara, Turkey	*	*	*	*	*	*	
Bangkok, Thailand	*	*	*	*		*	
Barcelona, Spain	*	*	*	*	*	*	*
Beijing, China	*	*	*	*	*1	*	
Bloemfontein, South Africa	*	*	*	*		*	
Bucharest, Romania	*	*	*	*		*	
Cologne, Germany	*	*	*	*	*	*	*
Doha, Qatar	*	*	*	*		*	
Dresden, Germany	*	*		*	*	*	
Ghent, Belgium	*	*	*	*	*	*	*
Havana, Cuba	*	*		*		*	*
Helsinki, Finland	*	*		*		*	
Lausanne, Switzerland	*	*	*	*	*	*	
London, UK	*	*	*	*	**	*	
Los Angeles, USA	*			*	*	*	
Madrid, Spain	*	*	*	*	*	*	
Montreal, Canada	*	*	*	*	**	*	
New Delhi, India <sup>1</sup>	*	*		*		*	
Oslo, Norway	*	*	*	*	*	*	
Paris, France	*	*	*	*	*	*	
Rio de Janeiro, Brazil	*	*	*	*		*	*
Rome, Italy	*	*	*	*	**	*	*
Salt Lake City, USA	*	*	*	*	**	*	*
Seibersdorf, Austria	*	*	*	*	*	*	*
Seoul, Korea	*	*	*	*	**	*	*
Stockholm, Sweden	*	*	*	*	*	*	
Sydney, Australia	*	*	*	*		*2	*3
Tokyo, Japan	*	*	*	*	*	*	*
Warsaw, Poland	*	*	*	*	**	*	

\*\* Only these laboratories can conduct confirmation of the GH Biomarkers method

<sup>1</sup> Due to the limitation of critical reagent procurement and importation, the CP methods for Biomarkers is temporarily available for Beijing 2022 Games only. Only ITP methods are available afterwards.

<sup>2</sup> ASDTL has notified WADA that their instrument for the analysis of GHRFs is broken and ASDTL is subcontracting to Tokyo. ASDTL has purchased a new instrument and as soon as it is delivered and installed, the validation of the peptides method has been set as the priority.

Validated, but not yet in scope

## **Table 2: Status of Specific Methods**

List class	Targets	Matrix (sample type)	Mandatory by all	Applied to all samples
			Laboratories	
Steroid esters (S1.1)	Testosterone, Nandrolone, etc	serum <sup>3</sup> plasma <sup>4</sup> capillary blood <sup>5</sup>	No	No - upon TA request
GC/C/IRMS	Markers urinary steroid profile (S1.1)	urine	Yes	Yes (if needed as a confirmation Test or if requested by TA/RMA/WADA)
	19-NA (S1.1), Boldenone (S1.1), Boldenone Metabolites (S1.1), Formestane (S4.1), 6α-hydroxy- androstenedione (S1.1)	urine	Yes (presence) No (IRMS confirmation)	Presence tested for in all Samples, but if GC/C/IRMS confirmation needed, subcontract to another Laboratory if no capacity
ERAs <sup>5</sup> (S2.1.1)	recEPO, dEPO, CERA, EPO-Fc	urine serum <sup>3</sup> plasma <sup>4</sup> capillary blood <sup>5</sup>	Yes	No - upon TA request
HIF activating agents (S2.1.2)	Daprodustat, Molidustat, Roxadustat, Vadadustat	Urine	Yes	Yes
	Cobalt Xenon	urine	No	No - upon TA request
Intact hCG (S2.2.1)	Screening (intact or total hCG)	urine	Yes	Yes
	Confirmation (intact hCG, different from screening assay)	urine	No	Subcontract to another Lab if no capacity
LH (S2.2.1)		urine	No	No (Labs with capacity do Test all urine Samples)
Corticotrophins (S2.2.2)	Corticorelin	urine	No	No - upon Testing Authority (TA) request
hGH (S2.2.3)	hGH Isoforms	serum <sup>3</sup>	Yes	No - upon Testing Authority (TA) request
	hGH Biomarkers (IGF-I, P-III-NP)	serum <sup>3</sup>	No	No - upon TA request
Small peptides	GnRF (S2.2.1) AOD-9604, hGH 176-191 (S2.2.3) GHS (2.2.4) GHRP (2.2.4) TB-500 (S2.3) Desmopressin, Felypressin (S5)	urine capillary blood <sup>5</sup>	Yes	No - upon TA request. GnRH also done if needed to confirm elevated LH findings. Some Laboratories apply small peptides method to all Samples (agreement with TA).
Large peptides	GHRH (S2.2.3) IGF-I analogues (S2.3) Insulins (S4.4.2)	urine serum <sup>3</sup> plasma <sup>4</sup>	No	No - upon TA request

 <sup>&</sup>lt;sup>3</sup> Obtained after centrifugation of venous blood collected in serum tubes
 <sup>4</sup> Obtained after centrifugation of venous blood collected in EDTA tubes
 <sup>5</sup> Obtained using Dried Blood Spot (DBS) sample collection devices



List class	Targets	Matrix (sample type)	Mandatory by all	Applied to all samples
			Laboratories	
		capillary blood <sup>5</sup>		
Anti-activin receptor IIB antibodies (S4.3) Myostatin Inhibitors (S4.3)	e.g., Bimagrumab	urine serum <sup>3</sup> plasma <sup>4</sup>	No	No - upon TA request
Homologous Blood Transfusion (M1.1)	Minor Red Blood Cell Antigens	whole blood <sup>6</sup>	No	No - upon TA request
HBOCs (M1.2)		serum <sup>3</sup> plasma <sup>4</sup> capillary blood <sup>5</sup> whole blood <sup>6</sup>	No	No - upon TA request
DNA analysis (M2.1)		urine serum <sup>3</sup> plasma <sup>4</sup> whole blood <sup>6</sup>	No	No - upon TA request if suspicious of Sample switch or upon WADA request if needed as part of investigation into recEPO finding
Proteases (M2.1)		urine serum <sup>3</sup> plasma <sup>4</sup>	No	No - upon TA request if suspicious of tampering
Gene Doping (M3.1)		capillary blood <sup>5</sup> whole blood <sup>6</sup>	No	No - upon TA request
siRNA (M3.1)	e.g., Myostatin siRNA	urine	No	No - upon TA request
Hematological Module of ABP	Blood Markers of ABP	whole blood <sup>6</sup>	No	No – upon collection of ABP samples
Blood Steroidal Module of ABP	Testosterone, Androstenedione (S1.1)	serum <sup>3</sup>	No	No - upon TA request
Endocrine Module of the ABP	hGH Biomarkers (IGF-I <sup>7</sup> , P-III-NP <sup>8</sup> )	serum <sup>3</sup>	No	No - upon TA request

 <sup>&</sup>lt;sup>6</sup> Venous blood collected in EDTA tubes
 <sup>7</sup> Measured with top-down LC-MS/MS
 <sup>8</sup> Measured with Siemens Advia Centaur immunoassay