

### **SUPPORTING DOCUMENT - B**

# FREQUENTLY ASKED QUESTIONS (FAQs) ON THE Technical Document for Sport Specific Analysis (TDSSA)<sup>1</sup>

#### General

### 1. What is the TDSSA?

The TDSSA is a tool that is intended 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 routine urine analysis menu.

The TDSSA is mandated by Article 5.4.1 of the 2015 World Anti-Doping Code (WADC2015) which all signatories approved 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 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?

- Erythropoiesis Stimulating Agents (ESAs)<sup>2</sup>;
- Human Growth Hormone (GH) and;
- Growth Hormone Releasing Factors (GHRFs) including Growth Hormone Releasing Hormone (GHRH) and its analogues, Growth Hormone Secretagogues (GHS) and Growth Hormone Releasing Peptides (GHRPs).

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

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

<sup>&</sup>lt;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.

<sup>&</sup>lt;sup>2</sup> Now referred to in the WADA *Prohibited List* under Section S2.1 as Erythropoietins (EPO) and agents affecting erythropoiesis.



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 National Anti-Doping Organizations (NADOs) and Major Event Organizations (MEOs).

The MLA requirements contained in Appendix 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 demand 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.

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 International Standard for Testing and Investigations (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 "Guidelines for Implementing an Effective Testing Program" 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.

WADA prepared a Risk Assessment template which is available to ADOs since February 2017.

8. Is WADA monitoring ADO compliance with the TDSSA?

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

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/not met.

10. Is the TDSSA implementation part of the overall 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.

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

For those ADOs whose TDPs already exceed the MLAs, there will be no impact on their programs and they should continue with their current levels of analyses and not reduce them.

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.

Where additional funding is not available or the redistribution of resources/programs within an ADO is not possible, a reduction in Test numbers by the ADO may occur in order to reach the MLA. However, it should not reduce the Test numbers to a level where a program becomes ineffective.

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

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

- **12.1.** 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;
- **12.2.** 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;
- **12.3.** Ensuring the TDSSA supports the implementation of the haematological module of the ABP to continue to allow for intelligent Testing and targeted Erythropoiesis Stimulating Agents (ESA) analysis; and
- **12.4.** 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 routine urine 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 WADC2015 (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 WADC2015 that 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 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 WADC2015 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 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 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 his or her IF, NADO or an MEO. Any MLA analyses conducted on an Athlete are counted towards meeting the MLA requirements based on who the Testing Authority 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).

# 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 and two blood Samples are collected will count as one Test.

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 ESAs, 10% for GH and 10% for GHRFs, the minimum number of analyses an ADO should conduct is as follows:

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

The remaining 40 Tests from the 100 Tests would then be subject to either the standard routine 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 Tests, collected in isolation, count as Tests?

**No.** Blood ABP Tests, 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 an ABP blood Sample and from the same Athlete during a Sample Collection Session, then that session will count as a Test.

21. What should an ADO do if a sport or discipline, which has been allocated a small number of Tests has a 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 their 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 e.g. ESAs 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 (4) ESA analyses. Respectively, if the number of e.g. ESAs analysis based on the number of Tests planned in a particular sport or discipline results in the calculation of 0.6, the ADO will be required to conduct a minimum of one (1) ESA 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, then 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 Athlete on the Doping Control Form?

No. However, ADOs shall utilize ADAMS to record the level of Athlete, for the purpose of monitoring their TDP progress and their 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 should be recorded on the DCF and ADAMS.

## 30. How should 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 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 ABP blood Sample at the same time as a urine Sample and following the review of the profiles in the ABP Sample may request ESA analysis on the urine Sample. In such circumstances the ADO would have to 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 ADOs overall TDP strategy in term of what criteria should trigger the long-term storage of such Samples.

As per the 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?

WADA has made the following changes to ADAMS to support the implementation of the TDSSA.

- The list of disciplines of the sports listed in the TDSSA is updated annually and in line with the latest version of the TDSSA.
- The ability to record the level of Athlete is mandatory.

In addition WADA has developed and published the **Reporting Guide to Monitor Testing** to assist ADOs in the monitoring of their TDSSA programs. All ADOs are encouraged to use this new Reporting Guide which can be found on WADA's website.

Before the end of 2019, ADAMS Next Gen will include the TDSSA Monitoring tool, which will monitor the implementation of the TDSSA MLAs automatically.

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 Testing Authority, 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 WADC2015. 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 para-swimming?

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

Sport	Discipline	Classes included		
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 website for further clarification on the classification of para-athletics and para-swimming.

https://www.paralympic.org/athletics/classification

https://www.paralympic.org/swimming/classification

Explanatory quide to Paralympic classification



If an ADO/DCO is confused about an Athlete's class, they are advised by the International Paralympic Committee (IPC) to ask 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 haematological module of the Athlete Biological Passport (ABP)

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

Yes. For sports or disciplines with an ESAs MLA of 30% or greater this became a mandatory component of compliance with the TDSSA since 1 January 2019. 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 haematological module of the ABP plays an important part in the targeting of Athletes for Testing, the detection of ESAs and prosecution of anti-doping rule violations for Use of blood doping methods.

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

Implementation of the ABP haematological module also enables ADOs to apply for flexibility in the implementation of the MLA percentage for ESAs 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 setup the haematological module of the ABP?

In order to setup the haematological module of the ABP, the mandatory aspects of its implementation are detailed in Annex K and L of the ISTI, and the Technical Document for Athlete Passport Management Units (TD2019APMU). For an ADO these elements include:

 Ensuring the collection and transportation of ABP blood Samples is carried out in accordance with Annex K 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 TD2019APMU.

For further information on how to set up the implementation of the haematological module of the ABP, please contact athletepassport@wada-ama.org

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

The implementation of the haematological module of the ABP shall include the following mandatory criteria:

- Apply to all Athletes from those sports or disciplines with an ESAs MLA of 30% or greater (as identified in the TDSSA) that are referenced in an ADO's TDP, and are part of the ADO's Registered Testing Pool (RTP);
- The program shall be compliant with all applicable ABP Technical Documents and International Standards, including the ISTI and TD2019APMU;
- At a minimum, an average of three blood ABP Tests shall be planned annually across all Athletes from those sports/disciplines with an ESAs MLA of 30% or greater who are part of the RTP of an ADO and therefore part of the ADO's ABP haematological 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 will be 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 ESAs MLA of 30% or greater, how many ABP blood tests shall I conduct to comply with the mandatory criteria?

The ADO should plan on a minimum of 75 blood ABP tests for these 25 Athletes.

41. Our ADO includes Athletes from sports or disciplines with an ESAs 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 ABP blood Tests for Athletes in a sport or discipline with an ESAs 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. As per the minimum number of planned OOC tests for RTP Athletes can be shared between ADOs, the same principle applies to ABP blood tests.

Where ADOs collaborate and share ABP blood testing on the same RTP Athlete, the ADO should re-allocate testing resources for ABP blood testing by 1) increasing testing on Athletes with atypical/suspicious passports, 2) adding additional Athletes to the RTP from sports or disciplines with an ESA MLA of 30% or greater or 3) expanding ABP blood testing on other Athletes.

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

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

No, however, ADOs are encouraged to either collect ABP blood Samples from these Athletes and/or where possible increase the number of Athletes in their RTP in sports or disciplines with an ESA MLA of 30% or greater.

44. When implementing an ESAs analysis program that is supported by the haematological 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 a reduction in ESA 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 ESAs.

45. When collecting an ABP haematological 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 ESAs should the Athlete's passport be atypical. The benefit of collecting a urine Sample with an ABP haematological Sample is that if the ABP Sample is atypical an ESAs 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 analyse, the window of opportunity to detect ESAs 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 haematological module on sports/disciplines with an ESAs MLA equal to 30% or greater?



Ideally, MEOs should collaborate with the respective IFs (as the passport custodian) for the sports/disciplines with an ESAs MLA equal to 30% or greater in advance of the Major Event to determine whether the IF requires any ABP blood 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 ABP blood Samples, or the Athletes to be targeted, etc. related to the haematological 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 ESA 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 the MLAs

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

In accordance with Article 6.4.2 of the WADC2015, 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 Code Compliance Center (from 1 January 2020) and the hardcopy application form can be found in TDSSA Supporting Document A on WADA's website.

# 48. What criteria is required to be met in accordance with Article 6.4.2 of the WADC2015 to support an ADOs 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 an ADO seeks flexibility for.

# 49. Given my application for flexibility in the implementation of the MLA 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 tdssa@wada-ama.org 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 haematological program of an ADO result in an automatic reduction of the ESAs MLAs?

No. WADA recognizes that the ABP haematological program is an important tool in implementing effective Testing programs for certain sports or disciplines. The TDSSA Expert Group considered whether a reduction of up to 50% in ESAs MLAs, which ADOs can apply for on the basis that they are implementing an effective ABP haematological program, should be automatic. It was agreed that ADOs shall still apply for flexibility to the ESAs MLAs in accordance with Section 6 of the TDSSA. The application form and process has been streamlined and can be found either online in WADA's Code Compliance Center (from 1 January 2020) or is contained within Supporting Document A of the TDSSA.

### Prohibited Substances within the scope of the TDSSA & 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 Samples are 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 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 24-48h 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 conducted 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 WADA Technical Document – TD2019GH 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 for an ABP blood Sample?

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

The integrity of the Markers used in the haematological 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/BCO to estimate the maximal transport time to a Laboratory or WADA-Approved Laboratory for the ABP, called the Collection to Reception Time (CRT), for a given average temperature T:

T [°C]	CRT [h]
15	35
12	41
10	46
9	48
8	50
7	53 55
6	55
5	58
4	60

The DCO/BCO apply a conservative approach and rapidly transport the Sample to a Laboratory or WADA-Approved Laboratory for the ABP located close to the Sample collection site.



## 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
- 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 ESAs 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 ESAs (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 ESAs can be analyzed in urine or blood. Does this mean that an ADO has to collect a blood and urine Sample each time to conduct ESAs 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 ESAs in either urine or blood. However, it is noted that the detection method for 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 ESAs in addition to CERA (recombinant EPOs, NESP, etc.).

One analysis towards the minimum level requirement shall be counted irrespective of whether a single or multiple ESAs 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 they don't have the capacity i.e. BCOs to collect blood Samples or if they are unable to ship blood Samples to the nearest Laboratory within the required shipping times due to distance or issues with the export or import into a country that hosts a WADA-accredited Laboratory of blood Samples?



If the ADO does not have trained Blood Collection Officers (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 ESA MLAs and ABP haematological 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. WADA will consider such situations as part of the global strategy.

# 62. The original scope of the TDSSA included Haemoglobin 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 were removed from 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 ESAs 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 be analyzed 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 haemoglobin 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 by 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 Prohibited Substances or Prohibited Methods that are included in the WADA Prohibited List be added to the TDSSA in the future or will these new Prohibited Substances or Prohibited Methods be part of the standard routine urine analysis?

Any Prohibited Substance or Prohibited Method that is added to the Prohibited List and has an approved analytical method may be subject to inclusion on the TDSSA as part of its ongoing review and development (if their analysis is not included in the standard routine urine analysis).

**Note:** ADOs are encouraged to provide WADA with any further questions they may have on the TDSSA or its implementation.



Table 1: TDSSA analysis per WADA-accredited Laboratory (as of 30 September 2019)

	ESAs			•	GH	GHRFs	
Laboratory	Urine	Serum	Plasma	Isoforms	Biomarkers	GHRPs/GHS	GHRH
Ankara, Turkey	*	*		*	*	*	
Athens, Greece	*	*		*		*	
Bangkok, Thailand	*	*	*	*		*	
Barcelona, Spain	*	*	*	*	*	*	*
Beijing, China	*	*	*	*	*	*	
Bloemfontein, SA	*	*	*	*		*	
Bucharest, Romania	*	*	*	*		*	
Cologne, Germany	*	*		*	*1	*	*
New Delhi, India	*	*		*		*	
Doha, Qatar	*	*	*	*		*	
Dresden, Germany	*	*	*	*	*	*	
Ghent, Belgium	*	*	*	*	*	*	
Havana, Cuba	*	*		*		*	
Helsinki, Finland <sup>2</sup>	*	*		*		*	
Lausanne, Switzerland	*	*	*	*	*	*	
London, UK	*	*	*	*	**	*	
Los Angeles, USA	*			*	*	*	
_	*	*	*	*	*	*	
Madrid, Spain	*	*	*	*	**	*	
Montreal, Canada							
Oslo, Norway	*	*	*	*	*	*	
Paris, France	*	*	*	*	*	*	
Rio de Janeiro, Brazil	*	*	*	*	**	*	*
Rome, Italy	*	*	*	*	*	*	*
Seibersdorf, Austria	*	*	*	*	*	*	*
Seoul, Korea	*	*	*	*	**	*	*
Stockholm, Sweden	*	*	*	*	*	*	
Sydney, Australia	*	*	*	*	*	*	
Mexico City, Mexico	*	*		*		*	*
Tokyo, Japan	*	*		*	*	*	
Salt Lake City, USA	*	*	*	*	**	*	*
Warsaw, Poland	*	*	*	*	*	*	
** Only these laboratories ca	an conduct c	onfirmation	of the GH Bio	l markers method			<u> </u>
<sup>1</sup> Only IGF-I by LC-MS							
<sup>2</sup> Self-suspended Laboratory	·						



**Table 2: Status of Specific Methods** 

Method (List class)		Mandatory by all Laboratories	Applied to all samples
hGH (S2.2.3)	Isoforms	Yes	No - upon TA request
	Biomarkers	No	No - upon TA request
GHRF (S2.2.3)	GHRP / GHS	Yes	No – upon TA request with the exception of some Laboratories
	GHRH	No	No - upon TA request
ESA (S2.1.1)		Yes	No - upon TA request
HIF activating agents (S2.1.2)	Roxadustat, Molidustat	Yes	Yes
	Daprodustat Vadadustat	No	No - upon TA request
Intact hCG (S2.2.1)	Screening	Yes	Yes
,	Confirmation (second assay)	No	Subcontract to another Lab if no capacity
LH (S2.2.1)	,	No	No (labs with capacity do test all urine samples)
GnRF (S2.2.1)		Yes <sup>3</sup>	No (usually done when GHRPs required – same method – or if needed to confirm elevated LH findings. Some Laboratories apply to all samples.
Large peptides	IGF-I analogues (S2.3)	No	No - upon TA request
	Insulins (S4.5.2)		
Myostatin Inhibitors (S4.4)	Bimagrumab	No	No - upon TA request
GC/C/IRMS	Markers steroid profile (S1.1)	Yes	Yes
	19-NA (S1.2), Boldenone (S1.2), Boldenone Metabolites (S1.2), Formestane (S4.1), prednisone (S9), prednisolone (S9)	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
Steroid esters (S1.1) (serum/plasma)		No	No - upon TA request
DNA analysis (M2.1)		No	No - upon TA request if suspicious of sample switch
Proteases (M2.1)		No	No - upon TA request if suspicious of tampering
Homologous Blood Transfusion (M1.1)		No	No - upon TA request
HBOCs (M1.2)	Hemopure, Oxyglobine, Polyheme	No	No - upon TA request

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<sup>&</sup>lt;sup>3</sup> The test for GHRPs/GHS (small peptides) also includes GnRFs (S2.2.1), AOD9604 (S2.2.3), TB-500 (S2.3) and desmopressin (S5)