| **Angaben zum Laboratorium** | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | | | | | | | | | | |
| Anschrift: |  | | | | | | | | | | |
| Aktenzeichen: |  | |  | |  | | | | | | |
| Verfahrensnummer | | Phase | |  | | | | | | |
| Datum Begutachtung: |  | | | | | | | | | | |
| Begutachtungsvorgang: | Bitte wählen | | | | | | | | | | |
| Begutachtungstyp[[1]](#footnote-1) : |  | | | | | | | | | | |
| Laboratorium mit mehreren Standorten: | | | | Ja | | | | Nein | | | |
| Name / Anschrift begutachteter Standorte: | | | | | | | | | | | |
|  | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Arbeitsbereich: | Innerhalb fester Einrichtungen | | | | | | Vor Ort | | | Mobiles Labor | |
| **Angaben zum Begutachter** | | | | | | | | | | | |
| Name: |  | | | | | | | | | | |
| Status[[2]](#endnote-1) : | LB | SB | | | | FB | | | FE | | H |

Im Interesse der Lesbarkeit wird grundsätzlich die männliche Form von Funktionsbezeichnungen verwendet; dies schließt die weibliche Form ein.

**Hinweise zur Anwendung durch das Laboratorium (blau gefärbte Bereiche):**

* Auf Seite 1 werden nur Name und Anschrift des Laboratoriums eingetragen.

In die Spalte „Referenzdokumente / Erläuterungen“ trägt das Laboratorium folgende Informationen ein:   
Wo ist die Umsetzung dieser Anforderung dokumentiert? (Angabe der konkreten Referenzdokumente, z. B. Bezeichnung des Dokuments/Kapitel/Abschnitt).   
Ggf. wie ist die Anforderung umgesetzt?  
Nicht zutreffende Anforderungen sind entsprechend zu kennzeichnen.

Vom Laboratorium sind keine weiteren Eintragungen vorzunehmen.

**Hinweise zur Anwendung durch den Begutachter**

**B**: **Bewertung durch den Begutachter**

Bitte die Nummer der Abweichung angeben, z. B. A x/y. Die Formulierung und Bewertung der Abweichung erfolgt in den Formblättern **FO-B\_Abweichungsbericht** und **FO-B\_PL\_K\_17025-2018** (Teilbegutachtungsbericht/Checkliste).

| **ISL Kapitel** | **ISL Anforderungen** | **Referenzdokument / Erläuterungen** | **B** |
| --- | --- | --- | --- |
| **5.0 Application of ISO/IEC 17025 to the Analysis of Samples** | |  |  |
| **5.1 Introduction and Scope** | |  |  |
|  | This section of the ISL is intended as an extension of the application of ISO/IEC 17025 to the field of Doping Control. Any aspect of Analytical Testing or management not specifically discussed in this document or in the relevant Technical Documents, Technical Letters or Laboratory Guidelines shall be governed by ISO/IEC 17025  (or ISO 15189, as applicable for ABP Laboratories). The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory’s performance as a Laboratory or ABP Laboratory, and are therefore significant in the evaluation and accreditation process.  This section introduces the specific performance standards for a Laboratory or ABP Laboratory, as applicable. The conduct of Laboratory Analytical Testing is considered a process within the definitions of ISO 17000. Performance standards are defined according to a process model where the Laboratory practice is structured into three (3) main categories of processes:  - Structural and Resource Requirements,  - Process Requirements,  - Management Requirements. |  |  |
| **5.2 Structural and Resource Requirements** | |  |  |
| **5.2.1 General** | |  |  |
|  | General structure and resource requirements shall be provided in accordance with the requirements  of ISO/IEC 17025.  The Laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its Laboratory activities. |  |  |
| **5.2.2 Laboratory Personnel** | |  |  |
|  | The Laboratory Director is responsible for ensuring that the Laboratory personnel are adequately trained and have the experience and skills necessary to perform their duties.  All personnel shall have a thorough knowledge of their responsibilities including the security of the Laboratory, the Code of Ethics, confidentiality of Analytical Testing results, Laboratory Internal Chain of Custody protocols, and the Standard Operating Procedures (SOPs) for any Analytical Testing Procedure that they perform.  The Laboratory shall have access to records for every Person employed by, or under contract with, the Laboratory including a curriculum vitae or qualification form(s)/certificate(s), a job description, records of completed and ongoing training and records of authorization to perform their defined duties.  Specific criteria shall be met by the Laboratory Director, Laboratory Quality Manager, Laboratory Certifying Scientists, and Laboratory Supervisory Personnel, as outlined below |  |  |
| **5.2.2.1 Laboratory Director** | The Laboratory shall have a qualified Person as the Laboratory Director, whose priority is to assume and focus on the professional, organizational, educational, operational and administrative responsibilities of the Laboratory’s operations. The Laboratory Director plays an essential role in the anti-doping Laboratory’s operations and the WADA accreditation is delivered based upon such qualification as well as on the Laboratory’s operational performance.  The Laboratory Director shall be a full-time appointment and his/her qualifications shall include:  - Doctoral degree (Ph.D. or equivalent) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area; or  - In the absence of a Doctoral degree, a postgraduate degree (e.g. Master’s degree) in one of the natural sciences and appropriate anti-doping science experience and training (e.g. a senior Laboratory position for a minimum of five (5) years), including the documented ability to develop analytical methodology and oversee research projects; or  - In the absence of a postgraduate degree, a Bachelor degree in one of the natural sciences and extensive and appropriate anti-doping science experience and training (e.g. a senior Laboratory position for a minimum of ten (10) years), including the documented ability to develop analytical methodology and oversee research projects;  - Experience and competence in the analysis of chemical and biological material for the classes of substances and methods used in doping;  - Demonstrated working knowledge of drug metabolism and pharmacokinetics;  - Proficiency in English to an extent that allows adequate performance of functions as part of the international anti-doping community and in accordance with the Code, the ISL, Technical Documents, Technical Letters and Laboratory Guidelines.  Any personnel changes to the position of Laboratory Director shall be communicated to WADA no later than one (1) month prior to the scheduled date the Laboratory Director vacates his/her position. A succession plan shall be forwarded to WADA. WADA reserves the right to review the credentials of such appointment and either approve it or reject it in accordance with the above qualifications. |  |  |
| **5.2.2.2 Laboratory Quality Manager** | The Laboratory shall have a single staff member appointed as the Laboratory Quality Manager. The Quality Manager shall have responsibility and authority to implement and ensure compliance with the Management System. The Quality Manager’s priority and functions shall be focused on quality assurance and quality control activities. The Quality Manager should remain independent, as much as possible, from routine Laboratory analytical activities.  The Laboratory Quality Manager qualifications shall include:  - At least a Bachelor degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical sciences;  - Appropriate experience of two (2) years or more in laboratory analytical procedures;  - Appropriate documented qualifications and training in laboratory quality management, including ISO/IEC 17025;  - Ability to ensure compliance with the Management System and quality assurance processes. |  |  |
| **5.2.2.3 Laboratory Certifying Scientists** | The Laboratory shall have qualified personnel to serve as Certifying Scientists to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and to attest to the validity of the Laboratory’s test results.  The qualifications of Certifying Scientists shall include:  - At least a Bachelor degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area. In the absence of a Bachelor degree, documented experience of five (5) years or more in a Laboratory as senior scientist (e.g. supervisor, section head) may be considered equivalent to a Bachelor degree for this position;  - Appropriate training and experience (e.g. three (3) years or more) including theoretical knowledge and technical competence in the analysis and interpretation of results for chemical or biological materials, including the classes of substances and methods used in doping;  - Knowledge of relevant Technical Documents, Technical Letters, Laboratory Guidelines and other technical standards;  - Experience in the use of relevant analytical techniques such as chromatography, immunoassays, electrophoresis or mass spectrometry;  - Adequate training in the Laboratory’s Management System and thorough understanding of its application into Laboratory processes. |  |  |
| **5.2.2.4 Laboratory Supervisory Personnel** | The Laboratory shall have qualified personnel to serve as Laboratory Supervisors. All Laboratory Supervisors shall have a thorough understanding of the Laboratory’s Management System including the review, interpretation and reporting of test results, the maintenance of Laboratory Internal Chain of Custody, and proper implementation of corrective and preventive actions in response to analytical problems.  The qualifications for a Laboratory Supervisor shall include:  - At least a Bachelor degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area. Documented experience of two (2) years or more in a Laboratory may be considered equivalent to a Bachelor degree for this position;  - Experience in the use of relevant analytical techniques such as chromatography, immunoassays, electrophoresis or mass spectrometry;  - Ability to comply with the Management System and quality assurance processes. |  |  |
| **5.2.3 Laboratory Facilities and Environmental Conditions** | |  |  |
| **5.2.3.1 Laboratory Facilities** | The Laboratory shall have Fit-for-Purpose facilities including sufficient space for dedicated administrative, Sample handling, Sample storage and analytical areas, which comply with the security requirements outlined below:  - A Person shall be assigned as the security officer, who has overall knowledge of the security system and/or serves as the liaison Person with the security services of the host organization (e.g. university, hospital, research institute);  - The Laboratory shall have a policy for the security of its facilities, equipment and systems against unauthorized access, which may include a threat and risk assessment performed by expert(s) in the relevant field;  - Two (2) main levels of access shall be defined in the Management System and evaluated in the threat assessment plan:  o Reception Zone: An initial point of control beyond which unauthorized individuals shall not be permitted;  The Laboratory shall have a system to register visitors and authorized individuals to the Laboratory. They shall be supplied with an identification badge while in the Laboratory facilities.  o Controlled Zones: Access to these areas shall be monitored (e.g. through the use of electronic access system(s) such as biometric and/or personal identification cards) and records of access by visitors shall be maintained;  Access to the Laboratory Controlled Zones shall be monitored and restricted to Laboratory staff and temporarily approved/authorized personnel (e.g. maintenance engineers, auditing teams). All other visitors to the Laboratory Controlled Zones shall be continuously escorted by Laboratory staff member(s). Access to the Laboratory Controlled Zones shall be defined in the Laboratory’s Management System.  - The Laboratory shall have a dedicated and restricted area within the Controlled Zone for Sample receipt and Aliquot preparation;  Access to the Laboratory’s Sample receipt and Aliquot preparation area shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.  - The Laboratory shall have a dedicated and restricted Sample storage area;  Access to stored Samples\* shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.  Samples may be transported for long-term storage to a specialized, secure Sample storage facility, which is located outside the Laboratory’s permanent controlled zone, to another Laboratory, or to another Fit-for-Purpose facility under the responsibility of the Testing Authority, which has ownership of the Sample(s) pursuant to Article 10.1 of the ISTI. Long-term storage facilities shall maintain security requirements comparable to the security requirements applicable to a Laboratory’s short-term storage of Samples. If the external Sample storage facility is not covered by the Laboratory’s ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall have its own ISO accreditation or accredited certification (e.g. 17025, 20387, 9001). The transfer of the Samples to the long-term storage facility shall be recorded.  - The Laboratory may implement additional security measures, which should be assessed on a case-by-case basis.  \* This refers to “A” and “B” Samples stored in Sample collection containers (urine collection bottles, blood collection tubes) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical Testing Procedures. |  |  |
| **5.2.3.2 Relocation of Laboratory Facilities** | In cases where a Laboratory is to relocate to a new physical space, on a permanent or temporary basis, a report containing the following information shall be provided to WADA no later than three (3) months prior to the relocation:  - Description of the circumstances for moving Laboratory operations into a new space and anticipated effect on capabilities;  - Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;  - Expected date(s) of assessment of the new facilities by the Accreditation Body (evidence of continued accreditation and/or acceptance of suitability of the new Laboratory facilities required when made available by the Accreditation Body);  - New Laboratory contact information and coordinates;  - Assessment of the effect of the Laboratory relocation on client operations. |  |  |
| **5.2.3.3 Environmental Control** | The Laboratory shall have a written safety policy and compliance with Laboratory safety policies shall be enforced.  The Laboratory’s storage and handling of controlled substances shall comply with applicable national legislation.  The Laboratory shall:  - Ensure appropriate electrical service (for example, by provision of an alternative power supply such as an UPS system and/or power generators) and environmental conditions (space, temperature, humidity, as applicable) for all Laboratory instrumentation and equipment critical to Laboratory operations, such that service is not likely to be interrupted;  - Have policies in place to ensure the integrity of refrigerated and/or frozen stored Samples in the event of an electrical or freezer/refrigerator equipment failure. |  |  |
| **5.2.3.4 Confidentiality of Data, Information and Operations** | The Laboratory should implement a clean desk policy and either file securely any confidential or sensitive information or properly destroy it before disposal. Laboratory staff shall be trained on how to comply with a clean desk policy, on how to ensure confidentiality of information and operations, as well as on the risks of corruption attempts by third parties.  Laboratory staff shall be trained to protect their personal access badge during and outside of working hours.  In order to minimize any attempts of fraud or counterfeit, the Laboratory should implement a policy to ensure that discarded urine and blood Sample containers, as well as the seals and rings, cannot be collected by unauthorized Persons or recovered after disposal (for example, bottles should be destroyed, or trash containers should be properly secured). |  |  |
| **5.2.3.5 Control and Security of Electronic Data and Information** | The Laboratory shall implement all reasonable measures, based on a thorough risk and vulnerability assessments (e.g., by a competent third party), to prevent and to detect unauthorized access and copying of Laboratory data and information from local and/or cloud-based computerized systems. Laboratories shall implement technical and organizational safeguards consistent with best practice and any applicable governmental regulations.  Access to Laboratory computer terminals, computers, servers or other operating equipment shall be restricted to authorized personnel (e.g. by using access passwords).  The Laboratory shall implement a data and information management system, a software-based solution that supports and maintains proper traceability of Laboratory operations (e.g. a Laboratory Information Management System, LIMS) with secure and restricted access to stored electronic data by authorized personnel as well as information and data exchange capabilities including between the Laboratory and ADAMS.  [Comment: The data and information management system may also feature workflow management, data tracking support, Sample and Aliquot Laboratory Internal Chain of Custody, control of stocks of Reference Materials, etc.]  The Laboratory shall utilize a secure data storage system that prevents unauthorized access and data loss (e.g. failed hard drive, fire, flooding). The Laboratory shall ensure that at least two (2) independent, regularly backed-up copies of all relevant analytical/LIMS/instrument software files are available.  - If the Laboratory is utilizing a non-cloud-based system, then at least one (1) backup copy shall be stored in a restricted and secure environment either in the Laboratory (e.g. fire and waterproof safe) or in a secure off-site location (e.g. in a mirrored server that guarantees the integrity of the server and the stored data);  - If the Laboratory is using a cloud-based system, the Laboratory data shall be, at a minimum, replicated in two different physical locations (e.g. between two different availability zones within the same region or between different regions) in order to minimize the possibility of data loss.  The software utilized by the Laboratory shall prevent the changing of data and test results, unless there is a system to record the change with audit trail capabilities which is limited to users with authorized access. The audit trail shall record the Person performing the editing task, the date and time of the edit, the reason(s) for the change to the original data and allow the retention of the original data.  If the Laboratory utilizes third-party computerized systems or software, the Laboratory shall ensure the provider or operator complies with all applicable requirements of the Code and the ISL and shall implement and maintain technical and organizational controls necessary to safeguard Laboratory data. |  |  |
| **5.2.4 Laboratory Equipment** | |  |  |
|  | The Laboratory shall have access to equipment that is required for the correct performance of Analytical Testing activities. The Laboratory shall maintain sufficient instrumental capacity to minimize the risk of operational delays and meet the analytical and results reporting obligations of the ISL and its related Technical Documents, Technical Letters and Laboratory Guidelines. A list of available equipment shall be established and maintained.  As part of its Management System, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025. Calibrations are only required where the setting can change the test result. A maintenance schedule, at least in accordance with the manufacturer’s recommendations or local regulations, if available, shall be established for general Laboratory equipment that is used in Analytical Testing Procedure(s).  General Laboratory equipment (fume hoods, centrifuges, evaporators, etc.) that is not used for analytical measurements should be maintained by visual examination, safety checks, performance verification and cleaning, as necessary.  Equipment or volumetric devices used in measuring shall have periodic performance checks and/or calibrations along with servicing, cleaning, and repair.  Qualified vendors may be contracted to service, maintain, and repair equipment. All maintenance, service, and repair of equipment shall be recorded. |  |  |
| **5.2.5 Metrological Traceability** | |  |  |
| **5.2.5.1 Reference Materials** | When available, Reference Materials of substances traceable to a national standard or certified by a body of recognized status (e.g. USP, BP, Ph. Eur. WHO) or a Reference Material producer accredited to ISO 17034 should be used.  When a Reference Material is not certified, the Laboratory shall verify its identity and check its purity by comparison with published data and/or by chemical characterization. |  |  |
| **5.2.5.2 Reference Collections** | Samples or isolates may be obtained from in vitro or in vivo sources [e.g. (i) an external quality control sample, (ii) an isolate from a urine or blood sample after an authenticated administration, or (iii) an “in-vitro” incubation with liver cells, microsomes or biological fluids] and be used as Reference Collections.  Reference Collections shall be traceable to a Prohibited Substance or a Prohibited Method, and the analytical data shall be sufficient to establish the identity of the Analyte. |  |  |
| **5.2.6 Subcontracting of Analysis** | |  |  |
|  | A Laboratory or ABP Laboratory shall perform all work with qualified personnel and equipment within its accredited or approved facility, respectively.  A Laboratory may subcontract an analysis to another Laboratory, in consultation with the Testing Authority. The conditions that justify subcontracting include, for example:  - A specific technology or Analyte(s) that are not within the Laboratory’s Scope of ISO/IEC 17025 Accreditation;  - An Analytical Testing Restriction decision;  - Other justifications such as a need for higher sensitivity or specific equipment or expertise, temporary workload or technical incapacity);  - In exceptional circumstances, WADA may elect to grant specific authorization to subcontract analyses using specific methods to an ISO/IEC 17025-accredited laboratory approved by WADA, which has the necessary technique within its Scope of ISO/IEC 17025 Accreditation (for example, DNA analysis or genomic profiling);  - Other specific investigations, such as, without limitation, forensic examinations which need to be performed in the course of the Analytical Testing process may also be subcontracted by the Laboratory.  [Comment: Alternatively, the analysis may be contracted by the Testing Authority. In this case, the Laboratory shall nevertheless be in charge of ensuring the Sample chain of custody in connection with the transfer of the Sample(s) to the other Laboratory(-ies) or expert(s) as the case may be.]  In all such cases, the Laboratory subcontracting the analysis is only responsible for the maintenance of the appropriate chain of custody up to Sample reception by the subcontracted Laboratory. Such arrangements shall be clearly recorded as part of the Sample’s documentation and included in the Laboratory Documentation Package, if applicable.  Recommendations to facilitate the implementation of subcontracted analyses and Further Analysis are provided in the WADA Laboratory Guidelines on “Conducting and Reporting Subcontracted Analysis and Further Analysis for Doping Control”. |  |  |
| **5.2.7 Purchasing of Services and Supplies** | |  |  |
|  | Chemicals and reagents shall be Fit-for-Purpose and be of appropriate purity. Documentation indicating the purity of Reference Materials/Standards shall be obtained when available and retained in the Management System documentation. Chemicals, reagents and kits labelled e.g. “Research Only” or “Forensic Use Only” may be utilized for the purposes of Doping Control as long as they are demonstrated to be Fit-for-Purpose by the Laboratory and/or WADA.  In the case of rare or difficult to obtain Reference Materials, or Reference Collections for use in qualitative Analytical Testing Procedures, the expiration date can be extended if adequate documentation exists confirming that no significant deterioration has occurred or that appropriate purification or verification of Fitness-for-Purpose has been performed. The process to extend the expiration date of a Reference Material, Reference Collection, or solution shall be described in the Laboratory’s Management System documentation.  The Laboratory shall maintain control and proper records of use of controlled chemicals and reagents in accordance with national laws and other relevant regulations.  Waste disposal shall be in accordance with national laws and other relevant regulations. This includes biohazard materials, chemicals, controlled substances, and radioisotopes, if used.  Environmental health and safety policies shall be in place to protect the staff, the public, and the environment. |  |  |
| **5.3 Process Requirements** | |  |  |
|  | The Laboratory shall maintain paper or electronic Laboratory Internal Chain of Custody in compliance with the Technical Document TD LCOC. |  |  |
| **5.3.1 Reviewing of Requests, Tenders and Contracts** | |  |  |
|  | Review of legal documents or agreements related to Analytical Testing shall meet the requirements of ISO/IEC 17025. |  |  |
| **5.3.2 Reception, Registration and Handling of Samples** | |  |  |
|  | The Laboratory may receive Samples, which have been collected, sealed and transported to the Laboratory according to the ISTI.  The transfer of the Samples from the courier or other delivery Person shall be recorded including, at a minimum, the date, the time of receipt, the initials or (electronic) signature of the Laboratory representative receiving the Samples and the courier company tracking number, if available. This information shall be included into the Laboratory Internal Chain of Custody record(s) of the Sample(s).  The Sample transport container shall be inspected, and any irregularities recorded.  Each individual Sample shall be inspected, and any irregularities recorded (see Article 5.3.3.1). However, Samples transferred for long-term storage purposes are not subject to an individual inspection by the receiving Laboratory until a Sample has been selected for Further Analysis.  The Laboratory shall have a system to uniquely identify the Samples and associate each Sample with the collection document or other external chain of custody information. |  |  |
| **5.3.3 Acceptance of Samples for Analysis** | |  |  |
|  | The Laboratory shall analyze each Sample received, unless the Sample meets any of the following conditions:  - In cases where the Laboratory receives two (2) urine Samples, which are linked to a single Sample Collection Session from the same Athlete according to the Doping Control Forms (DCF), the Laboratory shall analyze both Samples collected, unless otherwise instructed by the Testing Authority;  [Comment: The Laboratory may combine Aliquots from the two (2) Samples, if necessary, in order to have sufficient volume to perform the required Analytical Testing Procedure(s).]  - In cases where the Laboratory receives three (3) or more urine Samples, which are linked to a single Sample Collection Session from the same Athlete according to the DCF(s), the Laboratory shall prioritize the analysis of the first and the subsequent collected Sample with the highest specific gravity (SG), as recorded on the DCF:  [Comment: The Laboratory may conduct analyses on the additional collected Samples, if deemed necessary, with the agreement of the Testing Authority. The Laboratory may also combine Aliquots from multiple Samples, if necessary, in order to have sufficient volume to perform the required Analytical Testing Procedure(s).  With the agreement of the Testing Authority, the Laboratory may store the additional collected, non-analyzed Samples for Further Analysis.]  - If the Sample(s) meet documented Sample rejection criteria, which have been agreed with the Testing Authority.  [Comment: If justified by the Sample irregularities observed (see Article 5.3.3.1), the Laboratory shall seek instructions from the Testing Authority on the performance of Analytical Testing on the Sample. The Testing Authority shall inform the Laboratory in writing within seven (7) days whether a Sample with noted irregularities should be analyzed or not, and/or of any further measures to be taken (e.g. splitting the Sample in accordance with Article 5.3.3.2, forensic analysis, DNA analysis), or that the Sample should be stored for Further Analysis. The communication between the Laboratory and the Testing Authority shall be recorded as part of the Sample’s documentation.]  - Except as provided in this Article 5.3.3, Samples shall not be accepted by a Laboratory for the sole purpose of being put into long-term storage or for later analysis without first being subject to an Analytical Testing Procedure. |  |  |
| **5.3.3.1 Samples with Irregularities** | With the exception of the situation when a large number of Samples, which have already been analyzed, are received for long-term storage only (e.g. from a Major Event Organization), as described in Article 5.3.11.3, the Laboratory shall observe and document conditions that exist at the time of Sample reception or registration that may adversely impact on the integrity of a Sample or on the performance of Analytical Testing Procedures. Only unusual conditions shall be recorded.  Irregularities to be noted by the Laboratory may include, but are not limited to:  - Sample transport conditions (e.g. delivery time, temperature), which may impact the integrity of the Sample for Analytical Testing, as determined by the Laboratory;  - Sample collection information (including Sample identification code), which is necessary to conduct the requested Analytical Testing menu, is not provided, e.g. missing or incomplete DCF;  - Sample identification is questionable. For example, the number on the Sample container does not match the Sample identification number on the DCF;  - Athlete information is visible on the Laboratory copy of the DCF or any other document transferred to the Laboratory;  - Sample identification numbers are different between the “A” and the “B” Sample containers of the same Sample;  - Tampering or adulteration of the Sample is evident;  - Sample is not sealed with tamper-evident device or not sealed upon receipt;  - Sample volume does not meet the Suitable Volume of Urine for Analysis or is otherwise inadequate to perform the requested Analytical Testing menu;  - The Sample condition(s) is unusual – for example: color, odor, presence of turbidity or foam in a urine Sample; color, haemolysis, freezing or clotting of a blood Sample; unusual differences in Sample appearance (e.g. color and/or turbidity) between the “A” and the “B” Samples\*.  When an analysis on a Sample with documented irregularities is performed, the Laboratory shall record the irregularities in the Test Report.  \*Further guidance on assessing the differences between “A” and “B” Samples is provided in a Technical Letter. |  |  |
| **5.3.3.2 Sample Splitting Procedure** | In cases when either the “A” or “B” Sample is not suitable for the performance of the analyses (e.g. there is insufficient Sample volume; the Sample container has not been properly sealed or has been broken; the Sample’s integrity has been compromised in any way; the Sample is heavily contaminated, the “A” or “B” Sample is missing), the Laboratory shall notify and seek authorization from the Testing Authority to split the other Sample container (“A” or “B”, as applicable), provided that it is properly sealed. The Testing Authority shall inform the Laboratory of its decision in writing within seven (7) days of notification by the Laboratory. If the Testing Authority decides not to proceed with the Sample splitting procedure, then the Laboratory shall report the Sample as Not Analyzed in ADAMS, including the noted Sample irregularities and the documented reasons if provided by the Testing Authority.  The first fraction of the split Sample shall be considered as the “A” Sample and shall be used for the Initial Testing Procedure(s), unless the Initial Testing Procedure(s) have already been performed, and the “A” Confirmation Procedure(s), if necessary. The second fraction, considered as the “B” Sample, shall be resealed and stored frozen for “B” Confirmation Procedure(s), if necessary.  The process of opening and splitting the Sample and resealing of the remaining second fraction shall be conducted in accordance with Article 5.3.6.2.3 as for a customary “B” Sample opening, including an attempt to notify the Athlete that the opening of the Sample to be split will occur on a specified date and time and advising the Athlete of the opportunity to observe the process in person and/or through a representative. When the Athlete cannot be located, does not respond or the Athlete and/or his/her representative does not attend the opening and splitting of the Sample, the procedure shall be done in the presence of an Independent Witness that is assigned by the Laboratory.  [Comment: If the Athlete chooses to witness the Sample splitting procedure, the Athlete takes responsibility for forfeiting his/her anonymity.]  When the splitting procedure concerns blood Samples, which have been collected for Analytical Testing on the blood serum/plasma fraction, the sealed, intact (“A” or “B”) Sample shall be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction. The centrifuged Sample shall be stored frozen in the sealed Sample collection tube according to established protocols until the Sample opening/splitting procedure can be conducted. The opening of the Sample for the splitting of the serum/plasma fraction and resealing of the second fraction shall be carried out as described immediately above. |  |  |
| **5.3.4 Initial Storage and Sample Aliquoting for Analysis** | |  |  |
|  | It is recommended that the Laboratory assign specific staff member(s) to Sample aliquoting, and that the process of aliquoting is performed in a specifically designated area (see Article 5.2.3.1).  The Aliquot preparation procedure for any Initial Testing Procedure or Confirmation Procedure shall minimize the risk of contamination of the Sample or Aliquot. The Laboratory shall use new material(s) (e.g. new test tubes) to take Aliquots for Confirmation Procedures. |  |  |
| **5.3.4.1 Urine Samples** | In order to maintain the stability and integrity of the urine Samples, the Laboratory shall implement Sample storage procedures that minimize storage time at room and refrigerated temperatures as well as Sample freeze/thaw cycles.  For urine Samples, the Laboratory shall obtain, following proper homogenization of the Sample, an initial Aliquot containing enough Sample volume for all analytical procedures (all Initial Testing Procedures or all intended Confirmation Procedures, as applicable), by decanting the Aliquot from the urine Sample container into a secondary container (e.g. a Falcon tube). Procedure-specific Aliquot(s) shall then be taken from the secondary container.  The Laboratory shall measure the pH and SG of urine Samples once, using one Aliquot, during the Initial Testing Procedure and the Confirmation Procedure(s) (“A” and “B” Samples). Other tests that may assist in the evaluation of adulteration or manipulation may be performed if deemed necessary by the Laboratory (refer to the Technical Document on measuring and reporting the steroid profile, TD EAAS).  Urine “A” Samples should be frozen after Aliquots are taken for the Initial Testing Procedure(s) to minimize risks of Sample microbial degradation. Urine “B” Samples shall be stored frozen after reception until analysis, if applicable. |  |  |
| **5.3.4.2 Blood Samples** | The Laboratory shall follow the applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines for handling and storing blood Samples.  For blood Samples, the Laboratory shall obtain Aliquot(s) from the blood Sample container by using disposable pipettes or pipettes with disposable, non-reusable tips.  a) Samples for which Analytical Testing will be performed on blood serum/plasma fraction only (not on cellular components).  Blood Samples (“A” and “B” Samples), for which Analytical Testing will be performed on the plasma/serum fraction only should be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction\*.  The “A” Sample serum or plasma fraction (contained in the “A” Sample collection tube) and/or the “A” Sample serum or plasma Aliquots may be stored refrigerated for a maximum of 24 hours (but not surpassing the maximum allowed time from Sample collection established in the applicable Technical Document, Technical Letter or Laboratory Guidelines) or frozen until analysis. In all circumstances, the Laboratory shall take the appropriate steps to maintain the integrity of the Sample.  “A” Sample serum or plasma Aliquots used for “A” Confirmation Procedures shall be analyzed as soon as possible after thawing.  The “B” Sample serum or plasma fractions shall be immediately stored frozen in the collection tube according to established protocols until analysis, if applicable\*.  b) Samples for which Analytical Testing will be performed on the cellular fraction of whole blood.  Whole blood Samples shall be maintained refrigerated and shall be analyzed according to established protocols. After Aliquots have been taken for analysis, Samples shall be returned to refrigerated storage. Whole blood Samples shall not be frozen. In all circumstances, appropriate steps to ensure the integrity of the Sample(s) shall be taken by the Laboratory.  If, after completion of analyses on the cellular components of whole blood, the Sample is centrifuged to obtain the plasma fraction for additional analyses (e.g. EPO), then the plasma Sample shall be stored as described above.  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines. |  |  |
| **5.3.5 Selection and Validation of Analytical Testing Procedures** | |  |  |
|  | Standard methods are generally not available for Doping Control analyses. The Laboratory shall select, validate and document Analytical Testing Procedures, which are Fit-for-Purpose for the analysis of representative target Analytes of Prohibited Substances and Prohibited Methods.  Validation results for Analytical Testing Procedures shall be summarized in a Validation Report and supported by the necessary documentation and analytical data. The Validation Report shall indicate whether the Analytical Testing Procedure is Fit-  for-Purpose and shall be approved at least by the Laboratory Director and the Laboratory Quality Manager, or other qualified senior Laboratory staff, e.g. the Deputy Scientific Director, as designated by the Laboratory Director.  The Laboratory shall define and document the conditions that would trigger the revalidation of an Analytical Testing Procedure (e.g. change of internal standard, modified extraction procedure or chromatographic methodology, change in detection technique) or a partial re-assessment of the validation process (e.g. replacement or upgrade of instrument, addition of new Analyte to the Analytical Method).  This Article applies only to the validation of Analytical Testing Procedures, and not to the review of the analytical results for any Sample(s). |  |  |
| **5.3.5.1 Validation of Analytical Testing Procedures for Non-Threshold Substances** | The Laboratory shall develop, as part of the method validation process, appropriate standard solutions for detection and/or identification and estimation of the concentration of Non-Threshold Substances using Reference Materials. In the absence of suitable Reference Materials, Reference Collections may be used for detection and identification.  a) Validation of Initial Testing Procedures for Non-Threshold Substances  The Laboratory shall validate the Selectivity, carryover, reliability of detection at the MRPL and Limit of Detection (LOD) for the Initial Testing Procedure from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis. For chromatographic-mass spectrometric Analytical Methods, the Initial Testing Procedure shall allow the detection of each Non-Threshold Substance or its representative Metabolite(s) or Marker(s) at 50% or less of the Minimum Required Performance Levels (MRPL) (see the Technical Document on Minimum Required Performance Levels, TD MRPL).  For Non-Threshold Substances with Minimum Reporting Levels (MRL), the Laboratory shall validate and document the concentration levels that will require a Confirmation Procedure.  If there is no available Reference Material, an estimate of the detection capability of the Initial Testing Procedure (i.e. the LOD) for the Non-Threshold Substance or its representative Metabolite(s) or Marker(s) may be provided by assessing a representative substance from the same class of Prohibited Substances with a similar chemical structure.  b) Validation of Confirmation Procedures for Non-Threshold Substances  Factors to be investigated in the method validation procedure to demonstrate that a Confirmation Procedure for Non-Threshold Substances is Fit-for-Purpose include, but are not limited to:  - Selectivity: The ability of the Confirmation Procedure to detect and identify the Analyte of interest, taking into account interference(s) from the matrix or from other substance(s) present in the Sample. Selectivity shall be determined and documented from the analysis of an adequate number of representative samples prepared in the matrix of Sample analysis, in compliance with the Technical Document on chromatographic-mass spectrometric identification criteria (TD IDCR) or other applicable Technical Document, Technical Letter or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between Analytes of closely related structures;  - Limit of Identification (LOI): When the analyses of Non-Threshold Substances are based on chromatographic-mass spectrometric techniques, the Laboratory shall determine the lowest concentration at which each Non-Threshold Substance or its representative Metabolite(s) or Marker(s), for which a Reference Material is available, is identified at no more than 5% false negative rate (in compliance with the TD IDCR or other applicable Technical Document, Technical Letter or Laboratory Guidelines). The LOI shall be lower than the applicable MRPL;  [Comment: The TD MRPL requirement that the LOD, estimated during method validation, shall be equal to or less than (≤) 50% of the MRPL, is applicable to the Initial Testing Procedures and not to the Confirmation Procedures. This ensures the detection of the Non-Threshold Substance (or its representative Metabolite or characteristic Marker, as applicable) at the MRPL at all times, which then triggers the subsequent performance of a Confirmation Procedure.  Due to inherent differences between the procedures (e.g. Sample preparation) and identification requirements (e.g. number of diagnostic ions or precursor-product ion transitions) applicable to Initial Testing Procedures and Confirmation Procedures, their detection capabilities may differ. Therefore, it may occur that a Sample is reported as an Adverse Analytical Finding for a Non-Threshold Substance at concentrations lower than the estimated LOD of the Initial Testing Procedure. Furthermore, since LOD values are estimations based on method validation with a limited number of representative samples, a Laboratory may be able to effectively confirm the presence of a target Non-Threshold Substance (or its representative Metabolite or characteristic Marker) in a given Sample at levels below the validated LOD (e.g. in a Sample with low background or less matrix interferences).  A Confirmation Procedure for a Non-Threshold Substance shall allow the unequivocal identification of the Non-Threshold Substance (or its representative Metabolite(s) or characteristic Marker(s)) in compliance with the TD IDCR. If successfully identified, a Non-Threshold Substance can be reported at a concentration below the estimated LOD of the Initial Testing Procedure or the LOI of the Confirmation Procedure.]  - Robustness: The Confirmation Procedure shall be demonstrated to produce similar results with respect to minor variations in analytical conditions, which may affect the results of the analysis. Those conditions that are critical to ensuring reproducible results shall be considered;  - Carryover: The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis;  [Comment: Elimination of ‘injection memory’ effect is demonstrated by injecting a blank control sample for the Analyte in question, prepared in the Sample matrix, immediately prior to the Sample of interest.] |  |  |
| **5.3.5.2 Validation of Analytical Testing Procedures for Threshold Substances** | As part of the validation process for chromatography-mass spectrometric Analytical Methods applied to the analysis of Threshold Substances, the Laboratory shall develop acceptable standard solutions for identification of Threshold Substances using Reference Materials. For Confirmation Procedures, Certified Reference Materials should be used for quantification, if available.  For the application of affinity-binding assays to the analysis of Threshold Substances, the Laboratory shall follow the applicable Technical Document (e.g. Technical Document on human Growth Hormone, TD GH) or Laboratory Guidelines.  a) Validation of Initial Testing Procedures for Threshold Substances  The Laboratory shall validate Initial Testing Procedures that are Fit-for-Purpose, in accordance with relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines.  For chromatographic-mass spectrometric Initial Testing Procedures, the Laboratory shall validate the Selectivity, LOD and dynamic range from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis\*.  The Laboratory shall validate and document the concentration levels which will require quantitative Confirmation Procedure(s)\*.  [Comment: In order to account for a possible underestimation of concentrations of Threshold Substances during non-quantitative Initial Testing Procedures, the Laboratory shall establish, and document in the Test Method’s SOP, criteria (e.g. concentration levels), determined during the Initial Testing Procedure method validation, to evaluate initial results as Presumptive Adverse Analytical Findings and ensure that all potentially positive Samples are subjected to quantitative Confirmation Procedures.  Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines, the Laboratory may also choose to forward all Samples containing an exogenous Threshold Substance to confirmation analysis, in order to ensure that all potential Presumptive Adverse Analytical Findings are subjected to Confirmation Procedure(s).]  The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial Testing Procedures\*.  b) Validation of Confirmation Procedures for Threshold Substances  Factors to be investigated during the method validation to demonstrate that a quantitative Confirmation Procedure for a Threshold Substance is Fit-for-Purpose include but are not limited to:  - Selectivity, LOI, Robustness, Carryover (see Article 5.3.5.1);  - Limit of Quantification (LOQ): The Laboratory shall demonstrate that a quantitative Confirmation Procedure has an established LOQ of no more than 50% of the Threshold value or in accordance with the LOQ values required in relevant Technical Document(s) or Laboratory Guidelines;  - Dynamic Range: The range of the quantitative Confirmation Procedure shall be documented from at least 50% to 200% of the Threshold value;  - Repeatability (sr): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results over a short time, using a single operator, item of equipment, etc. Repeatability at levels close to the Threshold shall be determined;  - Intermediate Precision (sw): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results at different times and with different operators and instruments, if applicable, performing the assay. Intermediate Precision at levels close to the Threshold shall be determined;  - Bias (b): The Bias of the measurement procedure shall be evaluated either using Certified Reference Materials or traceable Reference Materials, if available, or from comparison with a reference method or with the consensus values obtained from an inter-Laboratory comparison study or EQAS participation. Bias at the levels close to the Threshold shall be determined;  - Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with the Technical Document on Decision Limits (TD DL) or other applicable Technical Document (e.g. TD GH), Technical Letter or Laboratory Guidelines. At least, MU at levels close to the Threshold shall be addressed during the validation of the quantitative Confirmation Procedure.  Confirmation Procedure method validation data (including the estimation of MU) is evaluated during the assessment process for inclusion of the quantitative Confirmation Procedure within the Laboratory’s Scope of ISO/IEC 17025 Accreditation. Therefore, for those Confirmation Procedures that are included within the Laboratory’s Scope of ISO/IEC 17025 Accreditation, the Laboratory is not required to produce method validation data or other evidence of method validation in any legal proceeding.  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines. |  |  |
| **5.3.6 Sample Analysis** | |  |  |
|  | Laboratories shall analyze Samples collected by Anti-Doping Organizations using In-Competition or Out-of-Competition Analytical Testing menus to detect the presence of Prohibited Substances or Prohibited Methods only (as defined in the Prohibited List). In addition, Laboratories may analyze Samples for the following, in which case the results of the analysis shall not be reported as an Atypical Finding or an Adverse Analytical Finding:  - Non-prohibited substances or methods that are included in the WADA Monitoring Program (see Code Article 4.5);  - Non-prohibited substances for results interpretation purposes (e.g. confounding factors of the “steroid profile”, non-prohibited substances that share Metabolite(s) or degradation products with Prohibited Substances), if applicable;  - Non-prohibited substances or methods requested as part of a Results Management process by the Results Management Authority, a hearing body or WADA;  - Non-prohibited substances or methods requested by the Testing Authority as part of its safety code, code of conduct or other regulations (see comments to Code Articles 5.1 and 23.2.2); or  - Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated in Article 5.3.12.  [Comment: An Anti-Doping Organization has the discretion to apply anti-doping rules to an Athlete who is neither an International-Level Athlete nor a National-Level Athlete and may elect to request that Samples collected from these Athletes are analyzed for less than the full menu of Prohibited Substances and Prohibited Methods. The Anti-Doping Organization is responsible for providing the Laboratory with the appropriate written justification for a reduced Testing menu.]  At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures, as determined by WADA in specific Technical Document(s), Technical Letter(s) or Laboratory Guidelines. Laboratories may implement additional methods for the analysis of particular Prohibited Substances or Prohibited Methods.  [Comment: Mandatory Analytical Testing Procedures are those Analytical Methods for which all Laboratories shall have available analytical capacity, in compliance with relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines, and therefore should have the Analytical Method included in their Scope of ISO/IEC 17025 Accreditation. However, based on an In-Competition or Out-of-Competition Analytical Testing menu, a mandatory Analytical Testing Procedure is not necessarily applied to all Samples. For some Samples, Testing Authorities may decide to request Analytical Testing for specific Prohibited Substances or Prohibited Methods only. These requests shall be detailed in the Sample chain of custody. On occasion, however, certain Analytical Testing Procedures (e.g. gene doping) or the analysis of certain Prohibited Substances (e.g. some large peptides) or Prohibited Methods (e.g. homologous blood transfusion) with a given Analytical Testing Procedure may not be mandatory for all Laboratories. WADA will maintain the list of mandatory Analytical Methods for reference by the Anti-Doping Organizations.]  Analytical Testing Procedure(s) included in the Laboratory’s Scope of ISO/IEC 17025 Accreditation shall be considered as Fit-for-Purpose and therefore the Laboratory shall not be required to provide method validation documentation or EQAS performance data in support of an Adverse Analytical Finding.  However, if the Analytical Testing Procedure has not been included yet in the Laboratory’s Scope of ISO/IEC 17025 Accreditation, the Laboratory shall validate the procedure in compliance with the ISL and the applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines prior to its application to the analysis of Samples. In such cases, the Laboratory may be required to provide method validation documentation or EQAS performance data in support of an Adverse Analytical Finding (see Article 4.4.2.2).  Laboratories may, on their own initiative and prior to reporting a test result, apply additional Analytical Testing Procedures to analyze Samples for Prohibited Substances or Prohibited Methods not included in the standard Analytical Testing menu or in the Technical Document for sport-specific analysis (TD SSA), provided that the additional work is conducted at the Laboratory’s expense and does not significantly affect the possibility to submit the Sample, as identified by the Testing Authority or WADA, to Further Analysis. Results from any such analysis shall be reported in ADAMS and have the same validity and Consequences as any other analytical result. |  |  |
| **5.3.6.1 Application of Initial Testing Procedures** | The objective of the Initial Testing Procedure is to obtain information about the potential presence of Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method. Results from Initial Testing Procedure(s) can be included as part of longitudinal studies (e.g. endogenous steroid or hematological profiles), provided that the method is Fit-for-Purpose.  The Initial Testing Procedure(s) shall fulfil the following requirements:  - The Initial Testing Procedure shall be Fit-for-Purpose;  - The Initial Testing Procedure shall be performed on Aliquot(s) taken from the container identified as the “A” Sample;  [Comment: In cases when the “A” Sample cannot be used for the Initial Testing Procedure(s), the Initial Testing Procedure may be performed on an Aliquot of the first bottle of the split “B” Sample, which is to be used as the “A” Sample (see Article 5.3.3.2).]  - The Initial Testing Procedure shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;  - All batches undergoing an Initial Testing Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis\*;  - The Initial Testing Procedures for Non-Threshold Substances shall include appropriate controls of representative substance(s) at or below the MRPL;  - The Initial Testing Procedures for Threshold Substances shall include appropriate controls close to the Threshold\*\*;  - Results from Initial Testing Procedures are not required to consider the associated MU\*\*;  - The Laboratory shall establish criteria, based on its method validation and in accordance with its SOP, to evaluate results from an Initial Testing Procedure as a Presumptive Adverse Analytical Finding, which would trigger confirmation analyses.  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines.  \*\* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines |  |  |
| **5.3.6.2 Application of Confirmation Procedures** | The objective of the Confirmation Procedure is to obtain a result, which supports or does not support the reporting of an Adverse Analytical Finding or Atypical Finding.  A Confirmation Procedure for a Non-Threshold Substance with a Minimum Reporting Level may also be performed if the result estimated from the Initial Testing Procedure is lower than the applicable Minimum Reporting Level, as determined by the Laboratory in accordance with the method’s validation results.  A result obtained in the Initial Testing Procedure for a Threshold Substance higher than the Threshold requires a Confirmation Procedure, even if this result is below the relevant Decision Limit 14. A Confirmation Procedure may also be performed if the result obtained in the Initial Testing Procedure is lower than the Threshold, as determined by the Laboratory or as specifically required by the Testing Authority (or Results Management Authority, if different) or WADA.  Irregularities in the Initial Testing Procedure(s) shall not invalidate an Adverse Analytical Finding, which is adequately established by a Confirmation Procedure.  The Confirmation Procedure(s) shall fulfil the following requirements:  - The Confirmation Procedure(s) shall be Fit-for-Purpose, including the estimation of the MU associated with a quantitative Confirmation Procedure;  - The Confirmation Procedure(s) shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;  - The Confirmation Procedure shall have equal or greater Selectivity than the Initial Testing Procedure and shall provide accurate quantification results (applicable to Threshold Substances). The Confirmation Procedure should incorporate, when possible and adequate, a different Sample extraction protocol and/or a different analytical methodology\*;  - All batches undergoing a Confirmation Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis.  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines |  |  |
| **5.3.6.2.1 Confirmation Procedure Methods** | Mass spectrometry (MS) coupled to chromatographic separation (e.g. gas or liquid chromatography) is the analytical technique of choice for confirmation of most Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method. These are acceptable methods for both the Initial Testing Procedure and the Confirmation Procedure.  Affinity-binding assays (e.g. Immunoassays), electrophoretic methods and other Analytical Methods are also routinely used for detection of macromolecules in Samples.  [Affinity-binding assays applied for the Initial Testing Procedure(s) and Confirmation Procedure(s) shall use affinity reagents (e.g. antibodies) recognizing different epitopes of the macromolecule analyzed, unless a purification (e.g. immunopurification) or separation method (e.g. electrophoresis, chromatography) is used prior to the application of the affinity-binding assay to eliminate the potential of cross-reactivity. The Laboratory shall document, as part of the method validation, that any such purification or separation method is Fit-for-Purpose.  In affinity-binding assays which include multiple affinity reagents (such as sandwich immunoassays), at least one (1) of the affinity reagents (either applied for capture or detection of the target Analyte) used in the affinity-binding assays applied for the Initial Testing Procedure(s) and Confirmation Procedure(s) must differ. The other affinity reagent may be used in both affinity-binding assays.  For Analytes that are too small to have two (2) independent antigenic epitopes, two (2) different purification methods or two (2) different Analytical Methods shall be applied. Multiplexed affinity-binding assays, protein chips, and similar simultaneous multi-Analyte testing approaches may be used.  Antibodies may also be used for specific labelling of cell components and other cellular characteristics. When the purpose of the test is to identify populations of blood constituents, the detection of multiple Markers on the cells as the criteria for an Adverse Analytical Finding replaces the requirement for two (2) antibodies recognizing different antigenic epitopes. An example is the detection of surface Markers on red blood cells (RBCs) using flow cytometry. The flow cytometer is set up to selectively recognize RBCs. The presence on the RBCs of more than one surface Marker (as determined by antibody labelling) as a criterion for an Adverse Analytical Finding may be used as an alternative to multiple antibodies to the same Marker.] |  |  |
| **5.3.6.2.2 “A” Confirmation Procedure:** | - Aliquots  The “A” Confirmation Procedure shall be performed using new Aliquot(s) taken from the container identified as the “A” Sample. At this point, the link between the Sample external code as shown in the Sample container and the Laboratory internal Sample code shall be verified.  [Comment: In cases when the “A” Sample cannot be used, the “A” Confirmation Procedure may be performed on an Aliquot of the split “B” Sample (see Article 5.3.3.2).]  - Target Analyte(s)  If the presence of more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is detected by the Initial Testing Procedure(s), the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as reasonably possible (such decision should take into account the volumes available in the “A” and “B” Samples). The confirmation(s) shall prioritize the identification and/or quantification of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The decision shall be made in consultation with the Testing Authority (or Results Management Authority, if different) and documented.  - Existence of approved Therapeutic Use Exemption (TUE)  When there is a Presumptive Adverse Analytical Finding for hCG, hGH (Biomarkers Test), Beta-2 Agonists, Diuretics, Amfetamine, Methylphenidate, Glucocorticoids or Beta-blockers, the Laboratory may contact the Testing Authority (or Results Management Authority, if different) to enquire whether an approved Therapeutic Use Exemption (TUE) exists for the Prohibited Substance(s) detected.  [Comment: Unless there is a prior agreement between the Testing Authority (or Results Management Authority, if different) and the Laboratory, contacting the Testing Authority (or Results Management Authority, if different) in such cases is not a requirement for the Laboratory. The Laboratory may proceed, at its discretion, to confirm the Presumptive Adverse Analytical Finding for hCG, hGH (Biomarkers Test), Beta-2 Agonists, Diuretics, Amfetamine, Methylphenidate, Glucocorticoids or Beta-blockers and report an Adverse Analytical Finding in ADAMS according to the confirmation results obtained.]  [Comment: In principle, the enquiry by Laboratories regarding the existence of an approved TUE for a Beta-2 Agonist may be applied not only to those Beta-2 Agonists which are prohibited under any condition, but also to those which are permitted up to a maximum dose by inhalation only, as specified in the Prohibited List. In such cases, the Laboratory may enquire about the existence of an approved TUE for the Use of a prohibited route of administration or a supra-therapeutic inhalation dose.]  When possible, the Laboratory should provide an estimated concentration of the Analyte(s) from the Initial Testing Procedure. Any such contact with the Testing Authority (or Results Management Authority, if different) shall be confirmed in writing (for further guidance, refer to the Laboratory Guidelines on TUE enquiries).  The instruction by the Testing Authority (or Results Management Authority, if different) on whether the Laboratory shall proceed or not with the confirmation based on an approved TUE shall be provided to the Laboratory in writing. If not proceeding with the confirmation, then the Testing Authority (or Results Management Authority, if different) shall provide WADA with a copy of the approved TUE or the associated TUE number if the TUE has been submitted into ADAMS.  - Repetition of the “A” Confirmation Procedure  The Laboratory may repeat the Confirmation Procedure for an “A” Sample, if appropriate, (e.g. quality control failure, chromatographic peak interferences, inconclusive “A” confirmation results). In that case, the previous test result shall be nullified. Each repeat confirmation shall be performed using (a) new Aliquot(s) taken from the “A” Sample container and shall be recorded.  - “A” Confirmation Procedure for Non-Threshold Substances  For Non-Threshold Substances without Minimum Reporting Levels, Adverse Analytical Finding or Atypical Finding decisions for the “A” Sample shall be based on the identification of the Non-Threshold Substance or its characteristic Metabolite(s) or Marker(s), as applicable, in compliance with the TD IDCR and/or other relevant Technical Document (e.g. TD MRPL), Technical Letter or Laboratory Guidelines.  For Non-Threshold Substances with Minimum Reporting Levels as specified in the TD MRPL, Adverse Analytical Finding decisions for the “A” Sample should be based on the identification of the Non-Threshold Substance or its characteristic Metabolite(s) or Marker(s), in compliance with the TD IDCR, at an estimated concentration greater than the Minimum Reporting Level, unless there is justification for reporting the finding at levels below the Minimum Reporting Level (e.g. if the analysis forms part of an ongoing investigation).  - “A” Confirmation Procedure for Threshold Substances  For Threshold Substances, Adverse Analytical Finding or Atypical Finding decisions for the “A” Sample shall be based on the confirmed identification (in accordance with the TD IDCR, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance and/or its Metabolite(s) or Marker(s) and their quantitative determination in the Sample at a level exceeding the value of the relevant Decision Limit, which is specified in the TD DL or other applicable Technical Document(s) (e.g. TD GH) or Laboratory Guidelines.  Quantitative Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (e.g. concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) “A” Sample Aliquots\*. If there is not enough Sample volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.  By determining that the test result exceeds the Decision Limit, the quantitative Confirmation Procedure establishes that the Threshold Substance or its Metabolite(s) or Marker(s) is present in the Sample at a level greater than the Threshold, with a statistical confidence of at least 95% (for more information, refer to the TD DL).  For endogenous Threshold Substances, Markers of the “steroid profile”, or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions for the “A” Sample may also be based on the application of any Fit-for-Purpose Confirmation Procedure that establishes the exogenous origin of the Prohibited Substance or its Metabolite(s) or Marker(s) (e.g. GC/C/IRMS). Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).  For some exogenous Threshold Substances, which are identified as such in the Prohibited List and the TD DL, Adverse Analytical Finding decisions for the “A” Sample do not require a quantification procedure if detected in the presence of any Prohibited Substance classified under S5. “Diuretics and Masking Agents” of the Prohibited List. In such cases, the identification (in accordance to the TD IDCR) of the Threshold Substance and/or its Metabolite(s) in the Sample is sufficient to conclude an Adverse Analytical Finding.  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines. |  |  |
| **5.3.6.2.3 “B” Confirmation Procedure** | - Testing Laboratory  The “B” Confirmation Procedure shall be performed in the same Laboratory as the “A” Confirmation Procedure, unless there are exceptional circumstances, as determined by WADA and with WADA’s prior written approval, which prevent the “B” Confirmation Procedure from being performed in the same Laboratory.  - Notification and Timing of “B” Confirmation Procedure  The “B” Confirmation Procedure shall only be performed by the Laboratory upon request by either the Athlete or the Testing Authority or Results Management Authority (if different).  The Testing Authority or Results Management Authority, as applicable, should inform the Laboratory, in writing, within fifteen (15) days following the reporting of an “A” Sample Adverse Analytical Finding by the Laboratory, whether the “B” Confirmation Procedure shall be conducted. This includes situations when the Athlete does not request the “B” Sample analysis or expressly or implicitly waives his/her right to the analysis of the “B” Sample, but the Testing Authority or Results Management Authority decides that the “B” Confirmation Procedure shall still be performed.  If the “B” Confirmation Procedure is to be performed, either upon the request of the Athlete or the Testing Authority or Results Management Authority, it should be performed as soon as possible after the Testing Authority or Results Management Authority, as applicable, has provided such notice to the Laboratory.  The timing of the “B” Confirmation Procedure may be strictly fixed within a very short period of time and without any possible postponement, if circumstances so justify it. This can notably and without limitation be the case when a postponement of the “B” Sample analysis could significantly increase the risk of Sample degradation and/or inadequately delay the decision-making process in the given circumstances (e.g. and without limitation, during or in view of a Major Event requiring rapid completion of the Sample analysis).  If the Athlete declines to be present in person and/or through a representative, or does not indicate whether he or she requests the “B” Sample analysis, or if the Athlete will not attend (in person and/or through a representative) once a date and time for the analysis has been proposed or if the Athlete or the Athlete’s representative claims not to be available on the date or at the time of the opening of the “B” Sample, despite reasonable attempts to find an alternative date and time convenient both to the Athlete and to the Laboratory, the Testing Authority or Results Management Authority or WADA, as applicable, shall instruct the Laboratory to proceed regardless. The Laboratory, in consultation with the Testing Authority, the Results Management Authority or WADA, as applicable, shall appoint an Independent Witness to verify that the “B” Sample container shows no signs of Tampering and that the identifying numbers match that on the Sample collection documentation. An Independent Witness may be appointed even if the Athlete has indicated that he/she will be present and/or represented.  - Authorization of non-Laboratory Persons to attend the “B” Confirmation Procedure  The following non-Laboratory Persons shall be authorized to attend the “B” Confirmation Procedure:  o The Athlete and/or representative(s) of the Athlete or, in the absence of the Athlete and/or representative(s), an Independent Witness:  • The Athlete and a maximum of two (2) representatives, and/or the Independent Witness, have the right to attend the “B” Sample opening, aliquoting and resealing procedures;  • The Athlete and/or one (1) representative may also have reasonable opportunity to observe other steps of the “B” Confirmation Procedure, as long as their presence in the Laboratory does not interfere with the Laboratory’s routine operations or Laboratory safety or security requirements.  [Comment: An Independent Witness may also attend even if the Athlete is present and/or represented.]  o A translator (if applicable);  o A representative of the Testing Authority or the Results Management Authority (if requested by the Testing Authority or the Results Management Authority, respectively);  o A representative of the National Olympic Committee and/or National Sport Federation and/or International Federation, as applicable, may also attend the “B” Sample opening procedure, upon request and with prior approval of the Laboratory Director.  The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations. Persons attending shall not interfere with the “B” Sample opening or the “B” Confirmation Procedure process in any way at any time and shall strictly follow the instructions of the Laboratory. The Laboratory may have any Person removed, including the Athlete or Athlete’s representative, if they are not following the instructions, disturbing or interfering with the “B” Sample opening or the Analytical Testing process. Any behavior resulting in removal shall be reported to the Testing Authority and/or Results Management Authority, as applicable. Interference may further be constitutive of an anti-doping rule violation in accordance with Code Article 2.5, “Tampering, or Attempted Tampering with any part of Doping Control by an Athlete or other Person”.  - Opening, Aliquoting and Resealing of “B” Sample  The “B” Confirmation Procedure shall be performed using Aliquot(s) taken from the container defined as the “B” Sample.  [Comment: In cases when the “B” Sample cannot be used for Analytical Testing, the unopened, sealed “A” Sample may be split (see Article 5.3.3.2) and the “B” Confirmation Procedure(s), if needed, may be performed on an Aliquot taken from the split, resealed “A” Sample fraction designated as the “B” Sample.]  The Athlete and/or his/her representative(s) or the Independent Witness shall verify that the “B” Sample container is properly sealed and shows no signs of Tampering, and that the identifying numbers match that on the Sample collection documentation. At a minimum, the Laboratory Director or representative and the Athlete or their representative(s) and/or the Independent Witness shall sign the Laboratory documentation attesting that the “B” Sample container was properly sealed and showed no signs of Tampering, and that the identifying numbers matched those on the Sample collection documentation.  If the Athlete, and/or their representative(s), or the Independent Witness refuse to sign the Laboratory documentation because they consider that the “B” Sample container was not properly sealed and/or showed signs of Tampering, or if the identifying numbers did not match those on the Sample collection documentation, the Laboratory shall not proceed with the “B” Confirmation Procedure and will inform the Testing Authority or Results Management Authority (if different) immediately to obtain instructions. In such cases, the “B” Confirmation Procedure may have to be re-scheduled.  If, on the other hand, the Athlete and/or their representative(s), or the Independent Witness refuse to sign the Laboratory documentation for any other reason, the Laboratory shall proceed with the “B” Confirmation Procedure. At the same time, the Laboratory shall inform the Testing Authority or Results Management Authority (if different) immediately. The reasons for the refusal shall be documented and included as a comment in the Test Report in ADAMS.  The Laboratory shall then ensure that the “B” Sample container is opened and Aliquots for the “B” Confirmation Procedure are taken in the presence of the Athlete or his/her representative(s) or the Independent Witness.  The Laboratory shall also ensure that, after opening and taking Aliquots for the “B” Confirmation Procedure, the “B” Sample is properly resealed in the presence of the Athlete and/or his/her representative(s) or the Independent Witness, who should be offered the opportunity to select the resealing equipment for the “B” Sample container from several identical/sealed items, if available.  At a minimum, the Laboratory Director or representative and the Athlete and/or their representative(s) and/or the Independent Witness shall sign another part of the Laboratory documentation attesting that they have witnessed the “B” Sample opening and aliquoting procedures and that the “B” Sample was properly resealed. If the Athlete and/or their representative or the Independent Witness refuse to sign this part of the Laboratory documentation, the reasons for the refusal shall be documented and included as a comment in the Test Report in ADAMS. In either case, the Laboratory shall continue with the “B” Confirmation Procedure.  - Target Analyte(s)  If more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method has been confirmed in the “A” Confirmation Procedure, the Laboratory shall confirm as many of the Adverse Analytical Findings as possible given the “B” Sample volume available. The decision on the prioritization for the confirmation(s) shall be made to prioritize the analysis of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The decision should be made in consultation with the Testing Authority (or Results Management Authority, if different) and documented.  - Repetition of the “B” Confirmation Procedure  The Laboratory may repeat the Confirmation Procedure for a “B” Sample, if appropriate, (e.g. quality control failure, chromatographic peak interferences, inconclusive “B” confirmation results). In that case, the previous test result shall be nullified. The Laboratory may repeat the “B” Confirmation Procedure using the remaining volume of the same Aliquot initially taken from the “B” Sample container. However, if there is not enough volume left of the initial Aliquot, then the Laboratory shall use a new Aliquot(s) taken from the re-sealed B” Sample container. In such cases, the re-opening, aliquoting and re-sealing of the B” Sample container shall be performed in the presence of the Athlete and/or Athlete’s representative(s) and/or Independent Witness, as per the procedure described above. Each Aliquot used shall be documented.  - “B” Confirmation with Negative Results  If the final “B” confirmation results are negative, the Analytical Testing result shall be considered a Negative Finding. The Laboratory shall notify the Testing Authority (or Results Management Authority, if different) and WADA immediately. The Laboratory shall conduct an internal investigation of the causes of the discrepancy between the “A” and “B” Sample results and should report its outcomes to the Results Management Authority and WADA within seven (7) days.  [Comment: Target Analytes [e.g. parent compound, Metabolite(s), Maker(s)] used to conclude the presence of a given Prohibited Substance or Use of a Prohibited Method may differ between the “A” and “B” Confirmation Procedures. This does not mean that the “B” confirmation results are negative, as long as the Analyte(s) targeted allows the unequivocal and conclusive identification of the Prohibited Substance or Prohibited Method in the “B” Sample.]  - “B” Confirmation Procedure for Non-Threshold Substances and exogenous Threshold Substances  For Non-Threshold Substances (including those with Minimum Reporting Levels as specified in the TD MRPL) and exogenous Threshold Substances, the “B” Sample results shall only confirm the presence of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) identified in the “A” Sample (in compliance with the TD IDCR) for the Adverse Analytical Finding to be valid\*. No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) is necessary.  - “B” Confirmation Procedure for endogenous Threshold Substances  For endogenous Threshold Substances, Adverse Analytical Finding decisions for the “B” Sample results shall be based on the confirmed identification (in accordance with the TD IDCR, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance or its Metabolite(s) or Marker(s) and their quantitative determination in the Sample at a level exceeding the value of the relevant Threshold as specified in the TD DL or other applicable Technical Document(s) or Laboratory Guidelines. Comparison of the measured value of the “B” Sample to the measured value of the “A” Sample is not necessary to establish “B” Sample confirmation. The “B” Sample value is only required to exceed the applicable Threshold.  Quantitative “B” Confirmation Procedures for endogenous Threshold Substances shall be based on the determination of the mean of measured analytical values (e.g. concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) “B” Sample Aliquots\*. If there is not enough Sample volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.  For endogenous Threshold Substances, Markers of the “steroid profile”, or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions for the “B” Sample results may also be based on the application of any Fit-for-Purpose Analytical Testing Procedure that establishes the exogenous origin of the Prohibited Substance and/or its Metabolite(s) or Marker(s) (e.g. GC/C/IRMS). Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines. |  |  |
| **5.3.6.3 Further Analysis** | Further Analysis of stored Samples shall, as a matter of principle, be aimed at detecting all the Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method included in the Prohibited List in force at the time of the collection of the Sample(s).  - Selection of Samples and Laboratories for Further Analysis  Stored Samples may be selected for Further Analysis at the discretion of the Testing Authority. WADA may also direct the Further Analysis of Samples at its own expense (see Code Article 6.6). In cases where WADA takes physical possession of a Sample(s), it shall notify the Testing Authority (see Code Article 6.8), which shall retain ownership of the Sample(s) pursuant to the ISTI Article 10.1, unless ownership of the Sample(s) has been transferred pursuant to ISTI Article 10.2.  The choice of which Laboratory will conduct the Further Analysis will be made by the Testing Authority or WADA, as applicable. Requests to the Laboratory for Further Analysis shall be made in writing and be recorded as part of the Sample’s documentation.  When a Sample has been reported as a Negative Finding or Atypical Finding, there is no limitation on the Testing Authority or WADA or others authorized by either of them to conduct Further Analysis on the Sample.  Further Analysis may also be performed on stored Samples, which were previously reported as Adverse Analytical Findings where such report did not result in an anti-doping rule violation charge under Code Article 2.1. Any Prohibited Substance or Prohibited Method detected, which was prohibited at the time of Sample collection, shall be reported.  However, pursuant to Code Article 6.5, Further Analysis may not be applied on a Sample after the responsible Anti-Doping Organization has charged the Athlete with a Code Article 2.1 anti-doping rule violation resulting from the analysis of the Sample, without the consent of the Athlete or approval from a hearing body.  Previously acquired Initial Testing Procedure data may also be re-evaluated for the presence of Prohibited Substances or their Metabolite(s) or Marker(s) of Prohibited Substances or Prohibited Methods, at the initiative of the Testing Authority, the Results Management Authority, WADA or the Laboratory itself. The results of such re-evaluation, if suspicious, shall be communicated to the Testing Authority, the Results Management Authority or WADA, as applicable, and may lead to Further Analysis.  - Analytical Testing Procedures for Further Analysis of Stored Samples  Further Analysis of stored Samples shall be performed under the ISL, Technical Documents, Technical Letters and Laboratory Guidelines in effect at the time the Further Analysis is performed.  Further Analysis of stored Samples includes, notably, but without limitation, the application of newly developed or more sensitive Analytical Testing Procedures and/or the analysis of new target Analytes of Prohibited Substance(s) or Prohibited Method(s) [e.g. Metabolite(s) and/or Marker(s)], which were not known or not included in the initial Analytical Testing of the Sample.  Depending on the circumstances, and to ensure an effective and targeted use of the available Sample volume, priorities may be set, and/or the scope of the Further Analysis restricted to specific analyses (in particular, but without limitation, to analyses based on new or improved Analytical Testing Procedures).  - Further Analysis of Stored Samples Process  a) Use of the “A” Sample  The Testing Authority or WADA may instruct the Laboratory to use the “A” Sample for both the Initial Testing Procedure(s) and the “A” Confirmation Procedure(s), to use it only for the Initial Testing Procedure(s) or not to use the “A” Sample for Further Analysis at all.  If the Laboratory has been instructed to perform only Initial Testing Procedure(s) on the “A” Sample, any suspicious analytical result obtained from the “A” Sample shall be considered as a Presumptive Adverse Analytical Finding, irrespective of the Analytical Testing Procedure applied, and shall be confirmed using the split “B” Sample (see below).  When a Confirmation Procedure is performed on the “A” Sample and an Adverse Analytical Finding is reported on this basis, the “B” Confirmation Procedure shall be applicable (as per Article 5.3.6.2.3).  b) Use of the split “B” Sample  When the “A” Sample is used only for the Initial Testing Procedure(s) or is not used at all during Further Analysis, the “B” Sample shall be split and used for analysis. The “B” Sample shall be split into two fractions, in accordance with Article 5.3.3.2. The Athlete and/or a representative of the Athlete should be invited to witness the splitting procedure. At a minimum, the splitting process shall be conducted in the presence of an appointed Independent Witness.  Even if present during the splitting procedure, the Athlete and/or his/her representative has no right to attend the Analytical Testing Procedures to be performed on the first split fraction of the “B” Sample, which shall be deemed as the “A” Sample. In the event an Adverse Analytical Finding is notified based on the results of a Confirmation Procedure of the first fraction of the “B” Sample, the second split fraction of the “B” Sample shall be deemed as the “B” Sample. If applicable, a “B” confirmation shall be decided and performed in accordance with Article 5.3.6.2.3.  [Comment: Since the first split fraction of the “B” Sample is considered as an “A” Sample, analysis of Aliquots taken from this Sample may include the performance of Initial Testing Procedure(s) and “A” Confirmation Procedures or “A” Confirmation Procedures only (if the Initial Testing Procedure(s) was/were already performed using the “A” Sample).] |  |  |
| **5.3.6.4 Alternative Biological Matrices** | Any negative Analytical Testing results obtained from hair, nails, oral fluid or other biological material shall not be used to counter Adverse Analytical Findings or Atypical Findings from urine or blood (including whole blood, plasma or serum). |  |  |
| **5.3.7 Assuring the Validity of Analytical Results** | |  |  |
|  | The Laboratory shall monitor its analytical performance and the validity of test results by operating quality control schemes, which are appropriate to the type and frequency of Analytical Testing performed by the Laboratory. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.  All quality control procedures shall be documented by the Laboratory. The range of quality control activities include, but are not limited to:  - Use of appropriate quality control samples (QCs)  [Comment: Appropriate positive and negative QCs shall be included in every analytical run both for the Initial Testing Procedure(s) and Confirmation Procedure(s)\*.  Appropriate internal standard(s) shall be used for chromatographic methods.  For Threshold Substances, quality control charts (QC-charts) referring to appropriate control limits depending on the Analytical Testing Procedure employed (e.g. +/- 2SD; +/- 3SD; +/- U95%), shall be regularly used to monitor method performance and inter-batch variability (when applicable).]  - Implementation of an Internal Quality Assurance Scheme (iQAS)  [Comment: The Laboratory shall establish a functional and robust iQAS program, in accordance with the requirements of ISO/IEC 17025, which challenges the entire scope of the Analytical Testing process (i.e. from Sample accessioning through result reporting). The Laboratory shall implement a procedure that prevents the submission of iQAS results into ADAMS.  The iQAS plan shall include and evaluate as many Laboratory procedures as possible, including the submission of a sufficient number of test samples on a regular basis (e.g. monthly) and shall incorporate as many categories of Prohibited Substances and Prohibited Methods as possible.  The Laboratory shall have a dedicated SOP for the iQAS program, which incorporates a detailed procedure for the planning, preparation, (blind and/or double-blind) introduction of the iQAS samples and management of the iQAS results (reviewing and follow-up of nonconformities).]  - Mandatory participation in the WADA EQAS (see Section 6.0).  - Implementation of Internal Audits  [Comment: Internal audits shall be conducted in accordance with the requirements of ISO/IEC 17025, and shall have a dedicated SOP incorporating a detailed procedure for the planning and performance of the audits, the training and selection of internal auditors, specification of their auditing activities, as well as for management of the internal audit conclusions (reviewing and follow-up of nonconformities).  Internal audit responsibilities may be shared amongst personnel provided that any Laboratory staff member does not audit his/her own area.  Internal audits shall be carried out by qualified Laboratory staff members. In addition, qualified members of the Laboratory's host organization (e.g., university, institute, company) may also be included in the internal auditing teams.]  - Implementation of External Audits  [Comment: Laboratories may also consider having their procedures and systems audited by other Laboratory Directors or external auditors. However, this shall not replace the performance of internal audits by the Laboratory.]  \* Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines. |  |  |
| **5.3.8 Results Management** | |  |  |
| **5.3.8.1 Review of Results** | The Laboratory shall conduct a minimum of two (2) independent reviews of all Initial Testing Procedure raw data and results. The review process shall be recorded.  A minimum of two (2) Certifying Scientists shall conduct an independent review of all Adverse Analytical Findings and Atypical Findings before a test result is reported. Evidence of the review and approval of the analytical run/batch shall be recorded.  - Second Opinion  The Laboratory may request a second opinion from other Laboratory(-ies) before reporting an Adverse Analytical Finding or Atypical Finding. Such requests for second opinions may be required by specific Technical Document(s), Technical Letters or Laboratory Guidelines, required by WADA from certain Laboratory(-ies) for all or for specific Analytical Testing Procedures under certain conditions (e.g. following the recent obtaining of WADA accreditation or after a period of Suspension or Analytical Testing Restriction), or requested at the discretion of the Laboratory (e.g. for firstly detected Analytes or for difficult to interpret findings). In any case, the request for a second opinion shall be made in writing and the second opinion received shall be recorded as part of the Sample’s documentation. Any transfer of data and information necessary for the second opinion shall be made securely and respecting the confidentiality of the analytical data and any other information.  The Laboratory that performed the analysis is responsible for the result and for issuing the final Test Report.  - Laboratory Review of Adverse Analytical Findings and Atypical Findings  At a minimum, the review of Adverse Analytical Findings and Atypical Findings shall include:  o Documentation linking the Sample external code (as specified in the DCF) to the Laboratory internal Sample code;  o Laboratory Internal Chain of Custody documentation;  o Initial Testing Procedure(s) and Confirmation Procedure(s) analytical data and calculations;  o Quality control data;  o Completeness of technical and analytical documentation supporting the reported findings;  o Compliance of test data with the Analytical Testing Procedure’s validation results (e.g. MU);  o Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings;  [Comment: The Laboratory should consider the prevailing scientific knowledge regarding, for example, the possibility of Sample or Aliquot contamination, the presence of analytical artifacts, the possible natural occurrence of the Analyte at low concentrations, microbial or chemical degradation, the detection of Metabolites which may be common to non-prohibited substances or the absence of characteristic Phase-I or Phase-II Metabolites.]  - When the Confirmation Procedure result(s) are rejected as Adverse Analytical Finding(s) or Atypical Finding(s) based on the results review, the reason(s) for the rejection shall be recorded. |  |  |
| **5.3.8.2 Traceability of Results and Documentation** | The Laboratory shall have documented procedures to ensure that it maintains a record related to each Sample analyzed. In the case of an Adverse Analytical Finding or Atypical Finding, the record shall include the data necessary to support the conclusions reported as set forth in and limited by the TD LDOC.  - Each step of Analytical Testing shall be traceable to the staff member who performed that step;  - Significant deviation from a written SOP shall be recorded;  - Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record;  - Requests for information by the Testing Authority, Results Management Authority or WADA to a Laboratory shall be made in writing;  - Laboratory Documentation Packages and Certificates of Analysis shall be in compliance with the TD LDOC. Laboratories are not required to produce a Laboratory Documentation Package for a Sample in which no Prohibited Substance or Prohibited Method or their Metabolite(s) or Marker(s) was detected, unless requested by a hearing body or disciplinary panel as part of a Results Management process or Laboratory disciplinary proceedings. |  |  |
| **5.3.8.3 Confidentiality of the Analytical Data and Athlete’s Identity** | Confidentiality of the analytical data and Athlete’s identity shall be observed by all parties (e.g. Laboratory, Testing Authority, Results Management Authority, WADA, other parties informed including, where different, International Federations, National Olympic Committees, National Federations). The Laboratory shall not make any attempt to identify an Athlete that has provided a Sample.  Information sent by a facsimile is acceptable provided that the correct facsimile number is verified prior to transmission and the receipt is verified after the facsimile has been transmitted.  Encrypted emails or documents shall be used for reporting or discussion of Adverse Analytical Findings or Atypical Findings if the Athlete can be identified or if any information regarding the identity of the Athlete is included. Whenever the Laboratory handles analytical data or information where an Athlete is identified or identifiable, the Laboratory shall treat such data in accordance with the requirements of the International Standard for the Protection of Privacy and Personal Information (ISPPPI). |  |  |
| **5.3.8.4 Reporting Test Results** | A Laboratory shall not conduct any additional Analytical Testing on a Sample for which the Athlete has been charged with a Code Article 2.1 anti-doping rule violation unless consent from the Athlete or approval from a hearing body is obtained by the Testing Authority or Results Management Authority (if different) – see also Article 5.3.6.3.  Unless specifically requested to make a partial submission of test results by the Testing Authority or Results Management Authority (if different), a Laboratory shall not report analytical results for any Sample until all analyses detailed in the Analytical Testing menu of the relevant DCF have been completed (e.g. ongoing analysis for EPO). Therefore:  a) If a Laboratory is requested to report an Adverse Analytical Finding(s) for a Sample(s) before all analyses on that Sample have been completed, then the Laboratory shall advise the Testing Authority or Results Management Authority (if different) that Sample analysis has not been completed and, in addition, that if the Athlete is charged with a Code Article 2.1 anti-doping rule violation before the additional analyses on the Sample have been completed, then the additional analyses cannot be conducted until consent from the Athlete or approval from a hearing body is obtained;  b) If the Laboratory receives a request to conduct Confirmation Procedures for an atypical or suspicious steroid profile of a Sample, which are triggered by ADAMS notifications after the “A” Sample has already been reported as an Adverse Analytical Finding, then the Laboratory shall advise the Testing Authority or Results Management Authority (if different) that if the Athlete is charged with a Code Article 2.1 anti-doping rule violation, the additional Confirmation Procedures cannot be performed until consent from the Athlete or approval from a hearing body is obtained.  - Reporting Times  Reporting of “A” Sample results should occur in ADAMS within twenty (20) days of receipt of the Sample. The reporting time required for specific occasions (e.g. for Major Events, see Annex B) may be substantially less than twenty (20) days. The reporting time may be altered by agreement between the Laboratory and the Testing Authority. The Testing Authority should be informed of any delay in the reporting of “A” Sample results.  The Laboratory Documentation Packages and/or Certificates of Analysis should be provided by the Laboratory only to the relevant Results Management Authority or WADA upon request and should be provided within fifteen (15) days of the request, unless a different deadline is agreed upon with the Results Management Authority or WADA, respectively.  - Reporting Requirements  The Laboratory shall record the test result for each individual Sample from Signatories or WADA in ADAMS.  [Comment: Test results for samples from non-Signatories, except WADA, shall not be reported in ADAMS].  When reporting test results in ADAMS, the Laboratory shall include, in addition to the mandatory information stipulated in ADAMS, in the relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines, and in the ISO/IEC 17025 standard, the following:  - The SG of the Sample (Initial Testing Procedure and “A” and “B” Confirmation Procedures);  - The name of the Results Management Authority, if provided;  - Relevant comments, if necessary, for proper interpretation of the test result or recommendations to the Testing Authority (for example, for Target Testing of the Athlete);  [Comment: The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the ADAMS Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented. An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, whether the observed results may suggest the need for additional investigations regarding potential environmental contamination causes and/or Further Analysis and whether an observed result is consistent with a set of reported conditions.]  - Specific tests performed, in addition to the Laboratory routine Analytical Testing menu (e.g. EPO GC/C/IRMS, hGH, blood transfusions, DNA, genomic profiling, etc.);  - Any irregularities noted on Samples;  - Any refusal by the Athlete and/or his/her representative(s) or the Independent Witness, as applicable, to sign the Laboratory documentation for the “B” Sample opening, aliquoting or re-sealing procedures (see Article 5.3.6.2.3).  The Laboratory is not required to provide any additional Test Report, either in hard-copy or digital format, other than the submission of test results in ADAMS. All Anti-Doping Organizations shall access the Test Reports of their Samples in ADAMS. Upon request by WADA, the Laboratory shall report a summary of the results of analyses performed in a format specified by WADA. In addition, the Laboratory shall also provide any information requested by WADA in relation to the Monitoring Program (Code Article 4.5).  The Laboratory shall qualify the result(s) of the analysis in the ADAMS Test Report as:  a) Adverse Analytical Finding; or  b) Atypical Finding; or  c) Negative Finding; or  [Comment: In cases when the Testing Authority confirms to the Laboratory the existence of an approved TUE for the Prohibited Substance, which is consistent with the Presumptive Adverse Analytical Finding results obtained in the Initial Testing Procedure (see Art 5.3.6.2.2), the Laboratory shall report the result as a Negative Finding as instructed by the Testing Authority.]  d) Not Analyzed  [Comment: Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed by or agreed with the Testing Authority) such as Sample irregularities, intermediate Samples of a Sample Collection Session, etc. (see Article 5.3.3).]  - Test Report for Non-Threshold Substances  a) “A” Sample Test Report  The Laboratory is not required to report concentrations for Non-Threshold Substances. The Laboratory shall report the actual Prohibited Substance(s) and/or its Metabolite(s), or Marker(s) of the Use of Prohibited Substance(s) or Prohibited Method(s) present (i.e. identified, as per the TD IDCR) in the Sample and in accordance with the reporting requirements established in the TD MRPL.  [Comment: When applicable, the Laboratory shall record in the ADAMS Test Report the specific Metabolite(s) or Marker(s) of the Non-Threshold Substance that were identified in the Sample.]  However, the Laboratory should provide estimated concentrations when possible and for information purposes only, upon request by the Testing Authority, Results Management Authority or WADA, if the detected level of the Non-Threshold Substance(s), its Metabolite(s), or Marker(s) may be relevant to the Results Management of an anti-doping case. In such instances, the Laboratory should indicate the estimated concentration while making it clear to the Testing Authority, Results Management Authority or WADA that the concentration was obtained by an Analytical Testing Procedure, which has not been validated for quantitative purposes.  b) “B” Sample Test Report  For Non-Threshold Substances, irrespective of whether or not they have a Minimum Reporting Level, the Laboratory result for the “B” Sample shall only establish the presence (i.e. the identity) of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) in accordance with the TD IDCR or other applicable Technical Document(s). The Laboratory is not required to quantify or estimate the concentration of such Prohibited Substance, or its Metabolite(s) or Marker(s).  - Test Report for Threshold Substances  a) “A” Sample Test Report  For Threshold Substances, the Laboratory Test Report for the “A” Sample shall establish that the identified Prohibited Substance(s) or its Metabolite(s) or Marker(s) is present at a concentration and/or ratio and/or score of measured analytical values greater than the Decision Limit, and/or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.  In the event that the Threshold Substance(s), which are identified as such in the Prohibited List and the TD DL, is (are) detected in the presence of (a) diuretic(s) or masking agent(s), the Laboratory shall establish the presence (i.e. the identity) of the Prohibited Substance(s) and/or its Metabolite(s) in accordance with the TD IDCR and the TD DL and report it as an Adverse Analytical Finding, in addition to the reporting of the diuretic(s) or masking agent(s). In such cases, the Laboratory should report the estimated concentration of the Threshold Substance(s), indicating that the levels detected may have been impacted by the presence of the diuretic(s) or masking agent(s).  b) “B” Sample Test Report  For exogenous Threshold Substances, the Laboratory Test Report for the “B” Sample shall only establish the presence (i.e. the identity) of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) in accordance with the TD IDCR.  For endogenous Threshold Substances, the Laboratory Test Report for the “B” Sample shall establish that the identified Prohibited Substance(s) or its Metabolite(s) or Marker(s) is present at a concentration and/or ratio and/or score of measured analytical values greater than the Threshold, and/or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.  In the event that the Threshold Substance(s), which are identified as such in the Prohibited List and the TD DL, is (are) detected in the presence of (a) diuretic(s) or masking agent(s), the Laboratory shall establish the presence (i.e. the identity) of the Prohibited Substance(s) and/or its Metabolite(s) in accordance with the TD IDCR and the TD DL and report it as an Adverse Analytical Finding, in addition to the reporting of the masking agent(s). In such cases, the Laboratory shall report the estimated concentration of the Threshold Substance(s), indicating that the levels detected may have been impacted by the presence of the diuretic(s) or masking agent(s). |  |  |
| **5.3.9 Control of Nonconformities in Analytical Testing** | |  |  |
|  | The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical Testing does not comply with set requirements.  Any nonconformities in Analytical Testing shall be recorded and kept as part of the documentation of the Sample(s) involved.  - Risk Minimization  Laboratories shall take corrective actions in accordance with ISO/IEC 17025 and WADA Laboratory Guidelines for Corrective Action Investigation and Reporting.  When conducting a corrective action investigation, the Laboratory shall perform and record a thorough Root Cause Analysis of the nonconformity.  - Improvement  The Laboratory shall maintain, and when appropriate improve, the effectiveness of its Management System in accordance with ISO/IEC 17025. |  |  |
| **5.3.10 Complaints** | |  |  |
| **5.3.10** | Complaints shall be handled in accordance with ISO/IEC 17025. | DIN EN ISO IEC 17025 |  |
| **5.3.11 Storage of Samples** | |  |  |
| **5.3.11.1 Storage of Urine Samples\*** | All urine Samples retained for storage in the Laboratory shall be stored frozen in a secure location under continuous chain of custody. The Laboratory shall keep all chain of custody and other records (either as hard-copy or in digital format) pertaining to those Samples.  a) Urine Sample(s) without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the “A” and “B” urine Sample(s) without an Adverse Analytical Finding or Atypical Finding for a minimum of three (3) months after reporting the final analytical result in ADAMS, or for a maximum of ten (10) years after the Sample collection date, if the long-term storage of the Sample(s) has been requested, in writing, by the relevant Testing Authority or WADA\*\*.  b) Urine Samples with Irregularities: The Laboratory shall retain the “A” and “B” urine Sample(s) with irregularities for a minimum of three (3) months after reporting in ADAMS, or for a longer period as determined by the Testing Authority, Results Management Authority or WADA\*\*.  c) Urine Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the “A” and “B” urine Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of six (6) months after reporting the final analytical result (for the “A” or the “B” Sample, as applicable) in ADAMS \*\*\*, \*\*\*\*, or for a longer period as informed to the or WADA\*\*.  d) Urine Samples under challenge, dispute or investigation: If the Laboratory has been informed by the Testing Authority, the Results Management Authority or WADA (in writing and within the applicable storage period as defined in this Article 5.3.11.1) that the analysis of a urine Sample is challenged, disputed or under investigation, the Laboratory shall retain both the “A” and “B” Samples until further notice by the Testing Authority, the Results Management Authority or WADA, as applicable\*\*.  \* This refers to “A” and “B” Samples stored in Sample collection containers (urine collection bottles, blood collection tubes) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical Testing Procedures. However, minimum and maximum retention times apply to any Aliquot(s) of a Sample that remains after completion of the Analytical Testing.  \*\* The Laboratory may charge storage costs to the Testing Authority or WADA, as applicable, for the storage of Samples for periods longer than the stated minimum storage times. However, the Laboratory may store Samples beyond the applicable minimum storage times at their own discretion and expense. In such cases, the Laboratory shall inform the responsible Testing Authority. Any Further Analysis on these Samples will require the approval of the Testing Authority or WADA.  \*\*\* If the “B” Sample Confirmation Procedure is not performed, the Laboratory may dispose of both the “A” and “B” Samples six (6) months after reporting the “A” Sample analytical result. However, if the “B” Sample Confirmation Procedure is performed, then the Laboratory shall retain both the “A” and “B” urine or plasma/serum Sample(s) for a minimum of six (6) months after reporting the “B” Sample analytical result.  \*\*\*\* Nevertheless, the Laboratory shall contact and inform the relevant Testing Authority and WADA before disposing of any Samples with Adverse Analytical Findings for which the Testing Authority or Results Management Authority Laboratory, in writing, by the relevant Testing Authority, Results Management Authority |  |  |
| **5.3.11.2 Storage of Blood Samples** | A. Samples for which Analytical Testing has been performed on blood serum/plasma fraction only (not on cellular components):  All serum or plasma Samples retained for storage in the Laboratory shall be stored frozen according to established protocols in a secure location under continuous chain of custody. The Laboratory shall keep all chain of custody and other records (either as hard-copy or in digital format) pertaining to those Samples.  a) Serum/plasma “A” and “B” Samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the serum/plasma “A” and “B” Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of three (3) months after reporting the final analytical result in ADAMS, or for a maximum of ten (10) years after the Sample collection date, if the long-term storage of the Sample(s) has been requested by the relevant Testing Authority or WADA\*.  b) Serum/plasma Samples with irregularities: The Laboratory shall retain the serum/plasma Samples with irregularities for a minimum of three (3) months after reporting the final analytical result in ADAMS, or for a longer period as determined by the Testing Authority, Results Management Authority or WADA\*.  c) Plasma/serum “A” and “B” Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain “A” and “B” plasma/serum Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of six (6) months after reporting the final analytical result (for the “A” or the “B” Sample, as applicable)  (if different) has not provided instructions about the performance or not of the “B” Confirmation Procedure (see Article 5.3.6.2.3). in ADAMS \*\*, \*\*\* or for a longer period as informed to the Laboratory, in writing, by the relevant Testing Authority, Results Management Authority or WADA\*.  d) Plasma/serum “A” and “B” Sample(s) under challenge, dispute or investigation: If the Laboratory has been informed by the Testing Authority, the Results Management Authority or WADA (in writing and within the applicable storage period as defined in this Article 5.3.11.2) that the analysis of a serum/plasma Sample is challenged, disputed or under investigation, the Laboratory shall retain both the “A” and “B” Samples until further notice by the Testing Authority the Results Management Authority or WADA, as applicable\*.  B. Samples for which Analytical Testing has been performed on cellular fractions of whole blood.  a) Whole blood “A” and “B” Samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the whole blood Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of one (1) month after reporting the final analytical result in ADAMS\*.  b) Whole blood Samples with irregularities: The Laboratory shall retain the whole blood Samples with irregularities for a minimum of one (1) month after reporting the final analytical result in ADAMS, or for a longer period as determined by the Testing Authority, Results Management Authority or WADA\*.  c) Whole blood “A” and “B” Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain “A” and “B” whole blood Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of three (3) months after reporting the final analytical result (for the “A” or the “B” Sample, as applicable) in ADAMS \*\*\*, \*\*\*\* or for a longer period as informed to the Laboratory, in writing, by the relevant Testing Authority, Results Management Authority or WADA\*.  d) Whole blood “A” and “B” Sample(s) under challenge, dispute or investigation: If the Laboratory has been informed by the Testing Authority, the Results Management Authority or WADA (in writing and within the applicable storage period as defined in this Article 5.3.11.2) that the analysis of a whole blood Sample is challenged, disputed or under investigation, the Laboratory shall retain both the “A” and “B” Samples until further notice by the Testing Authority, the Results Management Authority or WADA, as applicable\*.  \* The Laboratory may charge storage costs to the Testing Authority or WADA, as applicable, for the storage of Samples for periods longer than the stated minimum storage times. However, the Laboratory may store Samples beyond the applicable minimum storage times at their own discretion and expense. In such cases, the Laboratory shall inform the responsible Testing Authority. Any Further Analysis on these Samples will require the approval of the Testing Authority or WADA.  \*\* If the “B” Sample Confirmation Procedure is not performed, the Laboratory may dispose of both the “A” and “B” Samples six (6) months after reporting the “A” Sample analytical result. However, if the “B” Sample Confirmation Procedure is performed, then the Laboratory shall retain both the “A” and “B” urine or plasma/serum Sample(s) for a minimum of six (6) months after reporting the “B” Sample analytical result.  \*\*\* Nevertheless, the Laboratory shall contact and inform the relevant Testing Authority and WADA before disposing of any Samples with Adverse Analytical Findings for which the Testing Authority or Results Management Authority Laboratory, in writing, by the relevant Testing Authority, Results Management Authority  \*\*\*\* If the “B” Sample Confirmation Procedure is not performed, the Laboratory may dispose of both the “A” and “B” whole blood Samples three (3) months after reporting the “A” Sample analytical result. However, if the “B” Sample Confirmation Procedure is performed, then the Laboratory shall retain both the “A” and “B” whole blood Sample(s) for a minimum of three (3) months after reporting the “B” Sample analytical result. |  |  |
| **5.3.11.3 Long-term Storage of Samples** | At the direction of the Testing Authority or WADA, any urine or serum/plasma Sample may be stored in long-term storage for up to ten (10) years after the Sample collection date for the purpose of Further Analysis, subject to the conditions set out in Articles 5.3.6.3, 5.3.11.1 and 5.3.11.2.  Sample(s) may be stored in long-term storage under the custody of either a Laboratory or another Fit-for-Purpose facility under the responsibility of the Testing Authority, which has ownership of the Sample(s) pursuant to Article 10.1 of the ISTI. The Testing Authority shall retain the Sample collection records pertaining to all stored Samples for the duration of Sample storage.  - Laboratories as Sample Custodians  The Laboratory shall ensure that Samples are stored according to established protocols in a secure location in the Laboratory’s permanent controlled zone and under continuous chain of custody. The written request from the Testing Authority or WADA for long-term storage of Samples shall be properly documented.  Samples may also be transported for long-term storage to a specialized, secure Sample storage facility, which is located outside the Laboratory’s permanent controlled zone and is under the responsibility of the Laboratory or may be transported to another Laboratory. If the external Sample storage facility is not covered by the Laboratory’s ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall be Fit-for Purpose and have its own ISO accreditation or certification (e.g. 17025, 20387, 9001). The transfer of the Samples to the external long-term storage facility or Laboratory shall be recorded.  If Sample(s) are to be transported for storage at a location outside the secured area of the Laboratory that first analyzed the Sample(s), the Laboratory shall secure the “A” Sample(s) to be shipped either by re-sealing individual “A” Sample container(s) with a tamper-evident sealing system, which has similar capabilities for security and integrity as the original sealing system, or by sealing the box in which the Sample(s) are shipped in a manner that maintains Sample integrity and chain of custody. Neither the Athlete nor his or her representative nor an Independent Witness is required to be present for this procedure.  [Comment: For example, Sample(s) may be resealed with new resealing systems (e.g. new bottlecaps) produced by the manufacturer of an appropriate Sample collection equipment that replicates the security and tamper-evident functionality of the original seal. The resealing system of shipped “A” Sample(s) shall be tamper evident.]  “B” Sample(s) to be shipped shall be individually sealed, either in the original, sealed “B” Sample container(s) or, if previously opened, by re-sealing the individual “B” Sample container(s) with a tamper-evident sealing system, which has similar capabilities for security and integrity as the original sealing system. The resealing of the “B” Sample(s), if necessary, shall be witnessed by either the Athlete or his/her representative or by an appointed Independent Witness.  During transport and long-term storage, Sample(s) shall be stored at a temperature appropriate to maintain the integrity of the Sample(s). In any anti-doping rule violation case, the issue of the Sample’s transportation or storage temperature shall be considered where failure to maintain an appropriate temperature could have caused the Adverse Analytical Finding or other result upon which the anti-doping rule violation is based.  The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to a stored Sample for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) (e.g. full-scan mass spectrometry data) as detailed in Article 5.3.6.3.  If Sample(s) are transported to another Laboratory for long-term storage, the Sample’s external chain of custody and other non-analytical records (e.g. DCF), available to the transferring Laboratory, shall also be transferred, immediately or upon later request, to the Laboratory storing the Samples or to the Testing Authority, either as originals or copies.  - Testing Authorities as Sample Custodians  Sample(s) may also be transported for long-term storage to a Fit-for-Purpose, secure Sample storage facility, which is under the responsibility of the Testing Authority that has ownership over the Samples. In such cases, the external storage facility shall have its own ISO accreditation or certification (e.g. 17025, 20387, 9001) and shall maintain security requirements comparable to those applicable to a Laboratory. The Testing Authority shall ensure that Samples are stored according to established protocols in a secure location under continuous chain of custody.  The written request from the Testing Authority for the transfer of the Sample(s) to long-term storage shall be properly documented. The transfer of the Samples to the external long-term storage facility shall also be recorded. The Laboratory shall secure the Sample(s) for transportation to the long-term storage facility as described above.  The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to all Samples transferred for long-term storage for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data. The Laboratory shall transfer the Sample’s external chain of custody and other non-analytical records to the Testing Authority, either as originals or copies, immediately or upon request. |  |  |
| **5.3.12 Secondary Use or Disposal of Samples and Aliquots** | |  |  |
|  | The Laboratory shall maintain SOP(s) pertaining to the secondary use of Samples or Aliquots for research or quality assurance, as well as for the disposal of Samples and Aliquots. The requirements of this Article 5.3.12 apply mutatis mutandis to an Anti-Doping Organization that takes custody of Samples for long-term storage.  When the minimum applicable Sample storage period has expired (see Articles 5.3.11.1 and 5.3.11.2), and neither the Testing Authority, the Results Management Authority nor WADA have requested the long-term storage of the Sample for the purpose of Further Analysis or have informed the Laboratory that a challenge, dispute, or longitudinal study is pending, or if the Laboratory has not made its own decision to keep the Samples for long-term storage, the Laboratory shall do one of the following with the Sample(s) and Aliquots as soon as practicable: |  |  |
| **5.3.12.1 Disposal of the Sample(s) and Aliquots** | Disposal of Samples and Aliquots shall be recorded under the Laboratory Internal Chain of Custody. |  |  |
| **5.3.12.2 Secondary use of Samples and Aliquots for Research and Quality Assurance** | Samples and Aliquots shall be anonymized to ensure that any subsequent results cannot be traced back to a particular Athlete (see Code Article 6.3). Only after anonymization, may a Sample or Aliquot be used for:  a) Anti-doping research, if the Athlete consented to the use of his or her Sample for research; or  [Comment: Athlete consent for research, as declared in the DCF or as obtained by other means, shall be recorded in the Laboratory’s documentation for reference.]  b) Quality assurance, quality improvement of existing Test Methods, development or evaluation of Analytical Testing Procedures for Prohibited Substances or Prohibited Methods included in the Prohibited List at the time of Sample collection, or to establish reference population ranges or Thresholds or other statistical purposes. Athlete’s consent is not required for these purposes.  The use of Samples and Aliquots for the purposes of this Article 5.3.12.2 is subject to the following conditions:  a) The Laboratory must respect Code Article 19 and the ISL Code of Ethics requirements related to research, types of permitted research, and respect of ethical standards for research or quality assurance studies involving human subjects;  b) The Laboratory must not make any attempt to re-identify an Athlete from Samples or Aliquots used for the purposes of this Article 5.3.12.2 or data arising from any research or quality assurance analysis;  c) The Laboratory must consult the applicable national regulations, guidance, or authorities to determine whether a study should be considered as falling under 5.3.12.2 a) or 5.3.12.2 b);  [Comment: If the Laboratory is unsure whether a study can proceed without Athlete consent after consulting the foregoing sources, the Laboratory shall consult with WADA].  d) In the event the Laboratory wishes to transfer Sample(s) or Aliquots to be used for the purposes of this Article 5.3.12.2 to another Laboratory or a third-party research institution or group, or wishes to partner with another Laboratory or research institution or group for the purpose of an Article 5.3.12.2 study, the Laboratory shall subject the receiving party to the conditions described in this Article 5.3.12.2 by way of a written agreement and shall prohibit the receiving party from further transferring any Sample(s) or Aliquots or related data to another party. |  |  |
| **5.4 Management Requirements** | |  |  |
| **5.4.1 Organization** | |  |  |
|  | Within the framework of ISO/IEC 17025, the Laboratory shall be considered as a testing laboratory. | DIN EN ISO IEC 17025 |  |
| **5.4.2 Management Reviews** | |  |  |
|  | Management reviews will be conducted to meet the requirements of ISO/IEC 17025. | DIN EN ISO IEC 17025 |  |
| **5.4.3 Document Control** | |  |  |
|  | The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025. The Laboratory Director (or designee) shall approve the Management System documentation and all other documents used by Laboratory staff members involved in Analytical Testing.  The Laboratory shall implement a procedure in its Management System to ensure that the contents of ISL, Technical Documents, Technical Letters and Laboratory Guidelines are incorporated into the Laboratory’s SOPs by the applicable effective date and that implementation is completed, recorded and assessed for compliance. If this is not possible, the Laboratory shall send a written request for an extension beyond the applicable effective date for consideration by WADA. Any failure by the Laboratory to implement mandatory requirements by the established effective date, without a prior approval by WADA, shall be considered a noncompliance and may affect the Laboratory accreditation status. |  |  |
| **5.4.4 Control and Storage of Technical Records** | |  |  |
|  | The Laboratory shall keep a copy of all Sample records to the extent needed to produce Laboratory Documentation Packages or Certificates of Analysis, in accordance with the TD LDOC, in a secure storage until Sample disposal or anonymization (see Article 5.3.12).  In addition, this information shall be stored for ten (10) years from collection date for all Sample data and chain-of-custody information related to the Athlete Biological Passport (e.g. hematological and steroid profile Markers) |  |  |
| **5.4.5 Cooperation with Customers and with WADA** | |  |  |
|  | Cooperation with customers shall be handled in accordance with ISO/IEC 17025.  - Ensuring Responsiveness to WADA  The Laboratory Director or his/her designee shall:  - Ensure adequate communication with WADA in a timely manner;  - Provide complete, appropriate and timely explanatory information as requested by WADA;  - Report to WADA any unusual circumstances or information with regard to Analytical Testing, patterns of irregularities in Samples, or potential Use of new substances;  - Provide documentation to WADA [e.g. Management System documentation, SOPs, contracts (not including commercial or financial information) with Signatories, or with Sample Collection Authorities or Delegated Third Parties working on behalf of Signatories] upon request to ensure conformity with the rules established under the Code as part of the maintenance of WADA accreditation. This information shall be treated in a confidential manner.  - Ensuring Responsiveness to Testing Authority and/or Results Management Authority  The Laboratory Director shall be familiar with the Testing Authority rules and the Prohibited List.  The Laboratory Director shall interact with the Testing Authority and/or Results Management Authority in regard to specific timing, report information, or other support needs. These interactions should occur in a timely manner and should include, but are not limited to, the following:  - Communicating with the Testing Authority and/or Results Management Authority concerning any significant question of Analytical Testing needs or any unusual circumstance in the Analytical Testing process (including delays in reporting);  - Providing complete, timely and unbiased explanations to the Testing Authority and/or Results Management Authority when requested or when there is a potential for misunderstanding of any aspect of the Analytical Testing process, Laboratory Test Report, Certificate of Analysis or Laboratory Documentation Package;  - If requested by the Testing Authority, the Laboratory shall provide advice and/or opinion to the Testing Authority regarding the Prohibited Substances and Prohibited Methods included in the Analytical Testing Procedures;  - Providing evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings. The requests from such expert testimonies shall originate, in writing, from the Testing Authority, Results Management Authority, WADA or hearing bodies as part of the Results Management process. The Laboratory shall not provide expert testimony to Athletes or Athletes’ representatives, including their legal counsels;  - Responding to any complaint submitted by a Testing Authority or Results Management Authority concerning the Laboratory and its operation.  As required by ISO/IEC 17025, the Laboratory shall actively monitor the quality of the services provided to the relevant Anti-Doping Organizations, including the introduction of an annual questionnaire to clients to assess their satisfaction (or otherwise) with the performance of the Laboratory. There should be documentation that the Testing Authority or Results Management Authority concerns have been incorporated into the Laboratory’s Management System where appropriate. |  |  |

| **ISL ANNEX A - Code of ethics for laboratories and ABP laboratories** | | **Referenzdokument / Erläuterungen** | **B** |
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| **1.0 Confidentiality** |  |  |  |
|  | Directors of Laboratories and ABP Laboratories, their delegates and all Laboratory staff shall respect and comply with ISL Article 5.3.8.3 and Code Article 14.3.6. |  |  |
| **2.0 Research in Support of Doping Control** | |  |  |
|  | Laboratories shall participate in research programs, provided that the Laboratory Director is satisfied with their bona fide nature and the program(s) have received proper ethical approval, if applicable. The Laboratory shall not engage in any research activity that undermines or is detrimental to the World Anti-Doping Program.  The Laboratories are expected to develop a research and development program to support and expand the scientific foundation of Doping Control. This research may consist of the development of new methods or technologies, the pharmacological characterization of a new doping agent, the characterization of a masking agent or method, and other topics relevant to the field of Doping Control. |  |  |
| **2.1 Research on Human Subjects** | |  |  |
|  | The Laboratories and ABP Laboratories shall follow the Helsinki Declaration and any applicable national standards as they relate to the involvement of human subjects in research. Voluntary informed consent shall also be obtained from human subjects in any drug administration studies for the purpose of development of a Reference Collection or proficiency testing materials.  Athletes who may undergo Doping Control Testing by Anti-Doping Organizations shall not be the subjects of drug administration studies that include Prohibited Substances or Prohibited Methods. |  |  |
| **2.2 Controlled Substances** | |  |  |
|  | The Laboratories are expected to comply with the relevant and applicable national laws regarding the handling, storage and discarding of controlled (illegal) substances. |  |  |
| **3.0 Analysis** |  |  |  |
|  | The Laboratory or ABP Laboratory shall not engage in any analysis or activity that undermines or is detrimental to the World Anti-Doping Program.  *[Comment: The World Anti-Doping Program comprises the anti-doping programs of WADA and all Signatories, including International Federations, National Anti-Doping Organizations, Regional Anti-Doping Organizations, Major Event Organizations, the International Olympic Committee (IOC) or the International Paralympic Committee (IPC).]* |  |  |
| **3.1 Analytical Testing for Anti-Doping Organizations (Signatories or WADA)** | |  |  |
|  | The Laboratories and ABP Laboratories shall accept Samples for Analytical Testing from Anti-Doping Organizations only if all of the following conditions have been met:  - The Sample matrix is of the proper type (e.g. blood, urine) for the requested analyses;  - The Samples have been collected, sealed and transported to the Laboratory or ABP Laboratory in accordance with the ISTI; and  - The collection is a part of a legitimate anti-doping program, as determined by WADA, or satisfies any of the conditions for Sample analysis indicated in ISL Article 5.3.6. |  |  |
| **3.2 Analytical Testing for non-Signatories** | |  |  |
|  | Laboratories and ABP Laboratories shall not accept Samples directly from individual Athletes or from individuals or organizations acting on their behalf.  Laboratories or ABP Laboratories may accept samples from non-Signatories for analysis; however, any such analysis shall not be conducted under the Laboratory’s WADA accreditation or under the ABP Laboratory’s WADA approval and test results shall not be reported in ADAMS. In addition, such analyses shall not negatively affect the Analytical Testing of Samples from Anti-Doping Organizations, concerning, in particular, the allocation of resources (e.g. human, financial, instrumental resources) and the reporting of results in a reliable and timely manner.  *[Comment: A Laboratory or ABP Laboratory shall only refer to its WADA accreditation or approval status, as applicable, for an activity that falls under its Analytical Testing activities for Anti-Doping Organizations. For the avoidance of doubt, laboratory test reports or other documentation or correspondence related to samples from non-Signatories shall not declare or represent that any such testing is covered under the laboratory’s WADA-accredited or -approved status].* |  |  |
| **3.3 Clinical or Forensic Analysis** | |  |  |
|  | Occasionally the Laboratory may be requested to analyze a sample for a banned drug or endogenous substance coming from a hospitalized or ill Person in order to assist a physician in the diagnostic process. In such circumstances, the Laboratory Director shall agree to analyze the sample only if the organization making the request provides a letter explaining the medical reason for the test and explicitly certifying that the requested analysis is for medical diagnostic or therapeutic purposes.  The Laboratory may conduct work to aid a forensic and/or legal investigation, but due diligence should be exercised to ensure that the work is requested by an appropriate agency or organization. The Laboratory should not engage in analytical activities or expert testimony that would intentionally question the integrity of an individual or the scientific validity of work performed in the anti-doping program. |  |  |
| **3.4 Other Analytical Activities** | |  |  |
|  | The Laboratory or ABP Laboratory shall not provide analytical services in a Doping Control adjudication, unless specifically requested by the responsible Testing Authority or Results Management Authority (if different), WADA or a hearing body.  The Laboratory shall not engage in analysing commercial material or preparations (e.g. dietary or herbal supplements), unless:  - Specifically requested by an Anti-Doping Organization or a hearing body as part of a Results Management or adjudication process; or  - If done as part of a legitimate anti-doping research program, as determined by WADA; or  - If a request is made by an Athlete, the Laboratory may conduct the analysis if agreed by the Anti-Doping Organization, which may also specify conditions that must be followed prior to or during the analysis (e.g. verification of original sealed packages, product batch number).  The Laboratory shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.  Analytical activities performed under Articles 3.3 and 3.4 of Annex A will not fall under the WADA-accredited or -approved status of the laboratory and shall not negatively affect the Analytical Testing of Samples from Anti-Doping Organizations.  *[Comment: For the avoidance of doubt, laboratory test reports or other documentation or correspondence related to these other analytical activities shall not declare or represent that any such testing is covered under the laboratory’s WADA-accredited or -approved status.]* |  |  |
| **3.5 Sharing of Knowledge** | |  |  |
|  | When information on new doping substance(s), method(s), or practice(s) is known to the Laboratory, such information shall be shared with WADA within sixty (60) days. When possible, the Laboratories shall share information with WADA regarding the detection of potentially new or rarely detected doping agents as soon as possible. Immediately after having been notified of the Use of a new substance or method as a doping agent, WADA will inform all Laboratories.  The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of Analytical Testing in the WADA-accredited laboratory system.  *[Comment: Sharing of knowledge can occur in various ways, including but not limited to directly communicating with WADA, participating in scientific meetings, publishing results of research, sharing of specific details of Analytical Methods, working with WADA to produce and/or distribute new Reference Material(s) or Reference Collection(s) or disseminating information regarding the chromatographic behaviour and mass spectra of the Analytes.]* |  |  |
| **4.0 Duty to Preserve the Integrity of the World Anti-Doping Program and to Avoid any Detrimental Conduct** | |  |  |
|  | The personnel of Laboratories and ABP Laboratories shall not engage in conduct or activities that undermine or are detrimental to the World Anti-Doping Program. Such conduct could include, but is not limited to, fraud, embezzlement, perjury, etc. that would cast doubt on the integrity of the anti-doping program.  ISL – January 2021 Page 148 of 160  All employees of Laboratories and ABP Laboratories shall strictly respect the confidentiality of Analytical Testing results, as well as of all other Laboratory or Testing Authority information, including information provided by WADA under confidentiality.  No employee or consultant of Laboratories and ABP Laboratories shall provide counsel, advice or information to Athletes or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a Prohibited Substance or its Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method in order to avoid an Adverse Analytical Finding.  No employee or consultant of Laboratories and ABP Laboratories shall provide information about a Test Method to an Athlete or Athlete Support Personnel, which could be used to avoid the detection of doping.  No staff of Laboratories and ABP Laboratories shall assist an Athlete in avoiding collection of a representative Sample (e.g. advice on masking strategies or detection windows).  [This does not prohibit the publication and/or presentation of scientific research results, general presentations to educate Athletes, students, or others concerning anti-doping programs and Prohibited Substances or Prohibited Methods.]  If a staff member of a Laboratory or ABP Laboratory is requested to provide evidence in anti-doping proceedings, they are expected to provide independent, scientifically valid expert testimony.  The Laboratory or ABP Laboratory shall not issue any statements related to its analytical processes or findings, unless otherwise provided in Code Article 14.3.6. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the responsible Anti-Doping Organization(s). |  |  |

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| **Die Anforderungen des WADA ISL wurden stichprobenartig begutachtet:**[[3]](#endnote-2)) | | | **Ja** | **Nein** | |
| Ort: |  | Datum: | Bitte wählen | gez*. Name Begutachter:* [[4]](#endnote-3) |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Berichtsprüfung durch den Verfahrensmanager:** | | |  | | |
| Ort: |  | Datum: | Bitte wählen | gez. *Name VM:* |  |

Hinweis: Mit diesem Bericht bestätigt der Begutachter nicht die vollständige Richtigkeit der angegebenen Referenzdokumente der Konformitätsbewertungsstelle.

1. Unter Begutachtungstyp ist die Art der Begutachtung/die Begutachtungstechnik anzugeben, wobei mehrere Begutachtungstypen im Rahmen einer Begutachtung zum Tragen kommen können. Bitte wählen Sie aus den folgenden Möglichkeiten das zutreffende Element bzw. die zutreffende Kombination von Elementen für die Angabe des Begutachtungstyps aus:

   Vor-Ort-Begutachtung / Fernbegutachtung / Witness-Audit (Vor-Ort) / Witness-Audit (Fernbegutachtung) / Witness-Prüfung / Dokumentenprüfung / Sonstige Begutachtungstätigkeit (bitte ggf. präzisieren) [↑](#footnote-ref-1)
2. Status im Begutachterteam: LB=Leitender Begutachter; SB=Systembegutachter; FB=Fachbegutachter; FE=Fachexperte; H=Hospitant [↑](#endnote-ref-1)
3. Das vorläufige Ergebnis der Begutachtung wurde dem Antragsteller im Abschlussgespräch mitgeteilt und ggf. vorhandene Abweichungsberichte übergeben. [↑](#endnote-ref-2)
4. Dieser Bericht wurde persönlich von am Bitte wählen erstellt und ist ohne Unterschrift gültig. [↑](#endnote-ref-3)