WADA Technical Document – TD2023LDOC

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Written by:	*WADA* Science	Approved by:	*WADA* Executive Committee
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LABORATORY DOCUMENTATION PACKAGE

1.0 Introduction

This *Technical Document* (*TD*) and its annexes outline the requirements for the production of Laboratory Documentation Packages by Laboratories and *ABP* Laboratories, as applicable.

This *TD* includes instructions for producing Laboratory Documentation Packages by Laboratories for analytical results obtained by the application of qualitative Test Methods (applied to Non-Threshold Substances) and quantitative Test Methods, such as those applied to the determination of Threshold Substances (*e.g.*, see Art. 3.3.3 and Annex C), the *Markers* of the steroid profile (see Annex E) or the GC/C/IRMS analysis (see Annex A), for example.

In addition, this *TD* also includes instructions for producing *Athlete Biological Passport* (*ABP*) Laboratory Documentation Packages and *ABP* Laboratory Certificates of Analysis (see Annexes D, E and F of this *TD*, as well as Annex C of the *International Standard* for *Results Management* (ISRM) [1] and the *Technical Document* for Athlete Passport Management Unit Requirements and Procedures (TD APMU) [2].

This *TD* includes the following Annexes, which list the documentation required for specific analyses:

- Annex A: GC/C/IRMS (applicable to analyses by Gas Chromatography/Combustion/Isotope Ratio Mass Spectrometry);
- Annex B: ERA (applicable to the analysis of EPO and other Agents Affecting Erythropoiesis using electrophoretic Analytical Methods);
- Annex C: hGH (applicable to the human Growth Hormone Isoforms Differential Immunoassays and/or the hGH Biomarkers Test)
- Annex D: Hematological *ABP* Laboratory Documentation Package;
- Annex E: Steroidal *ABP* Laboratory Documentation Package;
- Annex F: Endocrine *ABP* Laboratory Documentation Package.

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1.1 Production of Laboratory Documentation Packages by Laboratories [a]

If requested by the *Testing* Authority (TA), *Results Management* Authority (RMA) or *WADA*, Laboratory Documentation Packages shall be provided by the Laboratory that reported the results to support an *Adverse Analytical Finding* (*AAF*) or *Atypical Finding (ATF)*.

[Comment: Athletes or Athlete representatives may only request a Laboratory Documentation Package through the relevant TA or RMA.

An APMU or Passport Custodian may request a Laboratory Documentation Package on behalf of the TA or RMA. In such cases, the APMU or Passport Custodian shall copy the relevant TA or RMA, as applicable, on all requests to the Laboratory for Laboratory Documentation Packages.]

Laboratories are not required to produce a Laboratory Documentation Package for a *Sample* reported as a Negative Finding, unless requested by a hearing body or disciplinary panel as part of a *Results Management* process or Laboratory disciplinary proceedings to address a specific concern.

Laboratory Documentation Packages may be requested for "A" and/or "B" *Samples,* including all relevant split subsets of the *Sample*. However, Laboratory documents applicable to both "A" and "B" *Samples* (*e.g., Doping Control* Form (DCF), *Sample* receipt documentation, etc.) need only be provided once in the Laboratory Documentation Package.

A Laboratory Documentation Package should be provided to the TA, RMA, APMU, Passport Custodian or *WADA*, as applicable, within the timelines stipulated in the *International Standard* for Laboratories (ISL) [3].

This *TD* sets forth formal requirements. Deviations from the requirements set forth herein shall not invalidate the associated *AAF* or *ATF*.

1.2 Production of *ABP* Laboratory Documentation Packages or *ABP* Laboratory Certificates of Analysis by Laboratories and *ABP* Laboratories.

If requested by the TA, RMA, Passport Custodian, APMU or *WADA, ABP* Laboratory Documentation Packages or *ABP* Laboratory Certificates of Analysis shall be provided by the Laboratory or *ABP* Laboratory to support the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM [1] and the TD APMU. [2]).

[a] Articles 2 and 3 in this *TD* define the general requirements for production of Laboratory Documentation Packages by Laboratories. For the specific requirements to produce *ABP* Laboratory Documentation Packages and *ABP* Laboratory Certificates of Analysis by Laboratories or *ABP* Laboratories for the different modules of the *ABP* (hematological, steroidal and endocrine), refer to the corresponding Annexes D, E and F of this *TD*.

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[Comment: Athletes or Athlete representatives may only request an ABP Laboratory Documentation Package and/or ABP Laboratory Certificates of Analysis through the relevant TA or RMA.

An APMU or Passport Custodian (where the Passport Custodian is not the TA or RMA for the Sample) may request an ABP Laboratory Documentation Package and/or ABP Laboratory Certificates of Analysis on behalf of the TA or RMA. In such cases, the APMU or Passport Custodian shall copy the relevant TA or RMA, as applicable, on all requests to the Laboratory or ABP Laboratory for ABP Laboratory Documentation Packages and/or ABP Laboratory Certificates of Analysis.]

ABP Laboratory Documentation Packages and/or *ABP* Laboratory Certificates of Analysis should be provided to the TA, RMA, APMU, Passport Custodian, or *WADA*, as applicable, within the timelines stipulated in the ISL [3].

Annexes D, E and F of this *TD* set forth formal requirements for the preparation of *ABP* Laboratory Documentation Packages and/or *ABP* Laboratory Certificates of Analysis for the Hematological, Steroidal and Endocrine Modules, respectively. Deviations from the requirements set forth herein shall not invalidate the associated *Adverse Passport Finding (APF)*.

1.3 Scope of Content of a Laboratory Documentation Package, *ABP* Laboratory Documentation Package and *ABP* Laboratory Certificates of Analysis

A Laboratory Documentation Package, *ABP* Laboratory Documentation Package and *ABP* Laboratory Certificates of Analysis shall be comprised of the information outlined below to support the result of the Laboratory's analysis of the relevant *Sample*. Laboratory working documents, computer printouts, and similar documents may be in the native language of the Laboratory. The table of contents, summaries and any flowcharts explaining the sequence of steps in the process and any other explanatory information shall be provided at least in English.

The items outlined in this *TD* shall be the only information included in a Laboratory Documentation Package, *ABP* Laboratory Documentation Package or *ABP* Laboratory Certificates of Analysis for the relevant analyses. Therefore, a Laboratory is not required to provide any additional documentation, such as Standard Operating Procedures (SOP), general quality management documents (*e.g.*, ISO compliance documents), validation or External Quality Assessment Scheme (EQAS) data or any other data or document, in hardcopy or electronic format, not specifically outlined by this *TD*.

2.0 Formatting Requirements

Laboratory Documentation Packages shall meet the following formatting requirements:

- A Table of Contents;
- Sequentially numbered pages;

- Presentation in a format that will allow proper review of the documents, such as clearly scanned documents, descriptors, etc. (annotations may be included by the Laboratory to assist interpretation);
- Information that appears on data and forms that refers to other *Samples* should be redacted by the Laboratory;
- Any adjustments to the records in the Laboratory Documentation Package shall be conducted as forensic corrections in accordance with ISO/IEC 17025;
- Data, charts, graphs, etc. shall be clearly described and presented.

  [Comment: Descriptions may be provided in the Table of Contents, page headers, titles, etc.; data and chart details shall be legible.]

3.0 Documentation Requirements

Laboratory Documentation Packages shall contain the following information:

3.1 Cover Page

- Identification of the Laboratory preparing the Laboratory Documentation Package, including the relevant *Sample* code and whether it is an "A" or a "B" *Sample*;
- A signed statement by the Laboratory Director or authorized delegate certifying that the Laboratory Documentation Package contains authentic copies of original data and forms;
- A declaration specifying that the Laboratory Documentation Package shall be handled as confidential information, shall not be disclosed to third parties or be reproduced or forwarded unless written approval is obtained from the Laboratory;
- A statement certifying that the *Sample* was analyzed according to the relevant *WADA* rules in force (*e.g.*, ISL, *TD*s);
- Any relevant comments.

3.2 Chain of Custody

- List of Laboratory staff involved in the analysis of the *Sample*, including signatures and/or initials and position title(s);

  [Comment: Each individual's complete signature/initials/name shall be provided to assist in the interpretation of the Laboratory Internal Chain of Custody documents.]

- The Laboratory version of the DCF related to the *Sample*. The *Sample's* external chain of custody form shall also be included if provided by the TA;

- The Laboratory's documentation of receipt of the *Sample*, including a declaration about any condition observed upon *Sample* receipt that may adversely impact the integrity of the *Sample* (in accordance with the ISL [3]*);*
- Documentation linking the relevant *Sample* code (container or kit code) to the Laboratory identification code (if available);
- Laboratory Internal Chain of Custody documentation of the relevant "A" and/or "B" *Sample* (see TD LCOC [4]);
- Summary of the chain of custody which is supported by the Laboratory Internal Chain of Custody documentation provided.

3.3 Analytical Data

3.3.1 Confirmation Procedure (CP) Data

CP method details to be provided within the documentation:

- SOP title or identification code of the CP method applied;
- Instrument type/identification code;
- Description of the composition of each Quality Control (QC) sample(s) analyzed in the same batch;
- The monitored ions/transitions in the method for identification of the target Analyte(s) (for GC-MS^n and/or LC-MS^n procedures);
- "A" and/or "B" *Sample* Laboratory Internal Chain of Custody documentation for the CP relevant to the storage and handling of the *Sample* container (if not provided under 3.2 above);
- CP Aliquot Laboratory Internal Chain of Custody documentation [4];
- CP analytical instrument sequence file;

  [Comment: A copy of the original file (preferably generated by the analytical instrument software), which demonstrates the identification and order of analysis of each Sample analyzed in the CP.]

- CP chromatographic and spectral data (for GC-MS^n and/or LC-MS^n procedures):
  - Positive QC sample(s);
  - Negative QC sample(s); and
  - Aliquot(s) analyzed to conclude the *AAF(s) or ATF(s)*.

[Comment: The Laboratory shall demonstrate that the CP data is traceable to the Laboratory Internal Chain of Custody documentation. CP data shall be copies of the original data which was evaluated by the Laboratory to support the conclusion of an AAF or ATF.]

- For GC-MS^n and/or LC-MS^n procedures, identification data demonstrating compliance with the TD IDCR [5] including:
  - A summary table with relative abundances (RAs) of diagnostic ions, retention time (RT) data and relevant calculation results;

    [Comment: The Laboratory is not required to quantify or estimate a concentration for a Non-Threshold Substance not subject to a Minimum Reporting Level (MRL) [3].]
  - The applicable criteria utilized to identify the target Analyte(s) and report an *AAF or ATF*;
  - Signed or initialed statements, traceable via hard copies or electronic records, that the results meet the applicable criteria.

    [Comment: For example, "Pass/Fail" as a statement of compliance with the relevant criteria.]
- Statement if there was a deviation from the CP SOP.

  [Comment: If a deviation exists (e.g., a change in the split ratio or a dilution of the derivatized Sample due to Sample overload in the instrument; application of an additional cleanup step; or an explanation for the re-analysis of the Sample with a new Aliquot) then documentation of the deviation(s) from the written CPs shall be provided with a statement detailing whether the deviation had an impact on the result.]
- A signed and dated statement of acceptable performance based on the evaluation of the analytical instrumentation which was used to generate the *Sample*'s CP data.

  [Comment: For example: "Instrument [identification] performance was evaluated according to the instrument tune report, system suitability test and positive and negative QC results and considered valid throughout the analytical sequence". This statement shall be signed (or initialed) and dated by the operator performing the evaluation.]

3.3.2 Additional Documentation for Non-Threshold Substances with an *MRL* only

A summary of the Analytical Method used to establish whether the concentration levels of the target Analyte(s) of Non-Threshold Substances with an *MRL* have exceeded the *MRL* during the "A" CP (see TD MRPL [14]).

[Comment: It is not required to perform a quantification to determine the concentration level(s) of the target Analyte(s) of Non-Threshold Substances with an MRL. In such cases, the analytical signal (relative to that of the internal standard) for the Analyte in the Sample shall exceed the analytical signal corresponding to the 1.2 · MRL

level for the Laboratory to conclude that the concentration level of the Analyte in the Sample exceeds the MRL (see also the TD MRPL [14]).

The estimation of the concentration level for Non-Threshold Substances with an MRL shall only be conducted in the "A" CP in order to report an AAF (or an ATF, when applicable). This is not required for the "B" CP, where only the identification (i.e., presence) of the Non-Threshold Substance and/or its Metabolite(s), Marker(s) or degradation products is enough to confirm the AAF or ATF, as applicable.]

- The confirmed Specific Gravity (SG) of the urine *Sample*. If an adjustment for SG is necessary (for SG > 1.018), then the resulting adjusted *MRL* shall be provided (see TD MRPL[14]);
- The "A" *Sample* CP data of the target Analyte(s) used to determine whether the concentration level of the target Analyte(s) has exceeded the 1.2 · *MRL* limit (or 1.2 · MRL_{adj}, if applicable) for:
  - The single-point calibrator (SPC) (chromatographic data);
  - The independent QC sample (chromatographic and mass spectrometric data); and
  - The *Sample* Aliquot (chromatographic and mass spectrometric data).

3.3.3 Additional Documentation for Quantitative CP Methods only (Threshold Substances)

A summary of the quantitative data for the Threshold Substance(s) (see TD DL [6] or applicable *TD* [5, 7-9] or Laboratory Guidelines [8]), including:

[Comment:

- *For those Threshold Substances of exogenous origin, which are analyzed by chromatography-based Analytical Methods, reporting requirements are specified in the TD DL [6]. For the "B" Sample confirmation of exogenous Threshold Substances [4], a quantitative CP is not necessary [3]. In such cases, the Laboratory shall only establish the presence (i.e., the identity) of the Threshold Substance or its Metabolite(s) or Marker(s) in the "B" Sample in accordance with the TD IDCR [5].*
- *For endogenous Threshold Substances (human Growth Hormone - hGH, human Chorionic Gonadotropin - hCG), these requirements are included in specific TDs or Laboratory Guidelines (TD GH [7], Laboratory Guidelines on hGH Biomarkers Test [8] and Annex C of this TD for hGH [7]; TD CG/LH [9] for hCG). For the "B" Sample confirmation of endogenous Threshold Substances, the quantitative CP shall establish that the identified Threshold Substance or its Metabolite(s) or Marker(s) is present in the "B" Sample at a concentration and/or ratio and/or score of measured analytical values greater than (>): the Threshold,*

and/or that the Threshold Substance or its Metabolite(s) or Marker(s) is of exogenous origin [b].

- *For other quantitative CPs, such as GC-MS^n for the Markers of the urinary steroid profile or GC/C/IRMS analysis, details are provided in the TD EAAS [10] and TD IRMS [11] and in Annexes E and C, respectively, of this TD.]*

- The calibration curve or SPC;
- The mean concentration (or ratio or score) from triplicate (3x) determinations as well as the individual concentrations determined for all the *Sample* Aliquots determined with appropriate units (as applicable);
- The nominal and measured concentrations of the QC sample(s) in addition to the Laboratory acceptance criteria with a statement that the QC(s) test results pass the Laboratory acceptance criteria;
- The Laboratory result for the Threshold Substance in the *Sample* (units), as the mean value from triplicate determinations;
- The confirmed urine SG. If an adjustment for SG is necessary (for SG > 1.018), then the resulting adjusted *Decision Limit* (DL_{adj}) [6] shall be provided;
- The Measurement Uncertainty (MU) details:
  - A statement that the relative u_c (%) for results at levels close to the Threshold does not exceed the maximum permissible relative u_{c_Max}(%) in Table 1 of the TD DL [6] or applicable *TD* [5, 7-9] or Laboratory Guidelines [8].

    [Comment: The summary table provided shall compile the necessary data and applicable criteria utilized to evaluate the quantitative results obtained for the target Analyte(s) in order to report an AAF or ATF.]

3.4 Laboratory Test Report(s)

Laboratory Documentation Packages shall include the Laboratory (*ADAMS*) Test Report(s) including, when applicable, the relevant Laboratory Test Report(s) from the Laboratory(-ies) that performed subcontracted analyses.

[Comment: In the case of quantitative CPs, the ADAMS Test Report shall include details in compliance with the TD DL [6] or applicable TD [5, 7-9] or Laboratory Guidelines [8].]

[b] For endogenous Threshold Substances, the Threshold values have been established based on reference population statistics, and already incorporate the Measurement Uncertainty. Therefore, the Threshold constitutes the *DL*.

3.5 Repeated CP

When a Laboratory repeats a CP, the Laboratory Documentation Packages shall provide a short explanation regarding the failed CP(s) (*e.g.*, date and/or analytical run number) including the reason(s) for why the CP was repeated.

3.6 Subcontracted Analysis

If a Laboratory Documentation Package includes a subcontracted analysis in another Laboratory, then the subcontracted Laboratory shall provide the documentation (as described in this *TD*) to the Laboratory (which subcontracted the analysis and reported the result into *ADAMS*) for the preparation of the Laboratory Documentation Package for the TA, RMA or *WADA*. The Laboratory Documentation Package shall clearly describe the steps conducted by each Laboratory.

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ANNEX A

LABORATORY DOCUMENTATION PACKAGE FOR GC/C/IRMS ANALYSIS

This Annex of the TD2023LDOC includes instructions for producing Laboratory Documentation Packages for confirmatory analysis results supporting an *Adverse Analytical Finding* (*AAF*) or *Atypical Finding (ATF)* based on the application of Gas Chromatography/Combustion/Isotope Ratio Mass Spectrometry (GC/C/IRMS), or during the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM and the TD APMU).

1.0 Formatting Requirements

A GC/C/IRMS Laboratory Documentation Package shall meet the formatting requirements detailed in Article 2.0 of this *Technical Document*.

2.0 Documentation Requirements

2.1 Chain of Custody

The chain of custody documentation shall meet the requirements detailed in Article 3.2 of this *Technical Document* and the TD LCOC [4].

2.2 Confirmation Procedure Analytical Data

- If an adjustment for urinary Specific Gravity (SG) is necessary (for SG > 1.018) [9, 10], then the SG of the *Sample* and the resulting adjusted concentration of the Target Compound (TC) shall be provided;
- Analysis description (*e.g.,* scheme/sequence of key analysis steps);
- *Sample* preparation:
  - Documentation demonstrating the order of HPLC sequence injection;
  - Statement on the verification of retention time (RT) stability and completeness of fraction collection;
- GC/C/IRMS analysis:
  - Data on CO_2 pulses stability test and statement on when the linearity signal was checked last;
  - CP analytical instrument sequence file;

[Comment: A copy of the file (preferably generated by the analytical instrument software) which demonstrates the order of analysis of each Sample in the CP.]

- GC/C/IRMS Test Results for relevant Target Compounds (TCs) (which produced the *AAF* or *ATF*) and Endogenous Reference Compounds (ERCs), including:
  - Chromatograms with the integration and annotation of the peaks;
  - $\delta^{13}C$ values (before and after correction for acetylation, if applicable); and
  - $|\Delta\delta^{13}C|$ values.

These results shall be produced for:

- The Reference Material (RM);
  - The Laboratory acceptance criteria for the $\delta^{13}C$ determinations of the TCs and ERCs in the RM shall be provided;
  - It shall be stated whether the RM test results pass the Laboratory acceptance criteria.
- The Negative (QCN) and Positive (QCP) QC Samples;
  - The Laboratory acceptance criteria for the $\delta^{13}C$ determinations of the TCs and ERC in the QC samples shall be provided;
  - It shall be stated whether the QC test results pass the Laboratory acceptance criteria.
- The *Sample*
  - Summary of results: Worksheet with $\delta^{13}C$ values, associated u_c (expressed in ‰) and $|\Delta\delta^{13}C|$ values for the relevant TCs and ERCs.
- GC-MS Analysis
  - Mass spectrum of each relevant TC and ERC (as per the TD IDCR) in the *Sample* and a comparison with mass spectrum obtained from a reference preparation;
  - Proof of identification of the peaks of the relevant TC(s) and ERCs in accordance with TD IDCR [5] requirements;
    - A summary table with the Relative Abundances (RAs) of diagnostic ions, Retention Time (RT) data and relevant calculation results;
    - The applicable criteria utilized to identify the target Analyte(s);
    - Signed or initialed statements, traceable via hard copies or electronic records, that the results meet the applicable criteria.

      [Comment: For example, "Pass/Fail" as a statement of compliance with the relevant criteria.]

- A statement on the criteria that were fulfilled, as per the TD IRMS [11], to report an *AAF*.

  [Comment: the TD IRMS criteria to report an AAF may be found in the ADAMS Test Report.]

- Second Opinion (if requested).

2.3 Laboratory Test Report(s)

Test Report documentation as detailed in Article 3.4 of this *Technical Document* and the TD IRMS [11].

2.4 Subcontracted Analysis

A subcontracted analysis shall meet the requirements detailed in Article 3.6 of this *Technical Document*.

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ANNEX B

LABORATORY DOCUMENTATION PACKAGE FOR ERYTHROPOIETIN RECEPTOR AGONISTS (ERAs) ANALYSIS BY ELECTROPHORETIC ANALYTICAL METHODS

This Annex of the TD2023LDOC includes instructions for producing Laboratory Documentation Packages for results supporting an *Adverse Analytical Finding* (*AAF*) or *Atypical Finding (ATF)* reported for erythropoietin (EPO) and other erythropoietin receptor agonists (ERAs) when using polyacrylamide gel electrophoretic (PAGE) Analytical Methods, or during the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM and the TD APMU).

[Comment: Erythropoietin Receptor Agonists (ERAs), as defined in the Prohibited List, include erythropoietin and its analogs and mimetics (previously known as Erythropoiesis Stimulating Agents). Their analysis is covered in the TD EPO [12].]

1.0 Formatting Requirements

An ERA Laboratory Documentation Package shall meet the formatting requirements as detailed in Article 2.0 of the TD2023LDOC.

2.0 Documentation Requirements

2.1 Chain of Custody

The chain of custody shall meet the requirements detailed in Article 3.2 of the TD2023LDOC and the TD LCOC [4].

2.2 Analytical Data

2.2.1 Confirmation Procedure (CP)

- Test Description

  [Comment: For example, description of the key steps in the SAR-PAGE procedure, including method used for immunopurification.]

- *Sample* sequence description (content and lane position on the gel);
- Confirmation results including gel images and report (*e.g.,* GASepo Analysis Report) on:
  - Negative control sample (QCN);
  - Positive control sample(s) (QCP);
  - Reference standard solution(s) used to define basic, acidic and endogenous areas in IEF-PAGE or apparent molecular mass in SDS-PAGE and SAR-PAGE;
  - Test sensitivity control(s) (if applicable); and
  - *Sample* Aliquot.
- Conclusion from CP.

  [Comment: For example, "The band in Sample x shows a faint, diffuse area above the corresponding band for endogenous EPO on the SAR-PAGE gel; therefore, the presence of recombinant EPO is confirmed according with the WADA TD EPO [12]. Consequently, a second opinion for this Sample shall be requested".]
- Second Opinion (signed by a member of the *WADA* EPO Working Group (see TD EPO [12]).

2.2.2 Additional Analyses to Assess rEPO Findings

2.2.2.1 Analysis on Blood *Samples* for VAR-EPO [12]

When there is a finding for rEPO in urine or blood *Samples* requiring further investigation under Annex B of the TD EPO and other blood *Samples* from the *Athlete* are analyzed to establish whether the *Athlete* is a carrier of the *EPO* c.577del variant (see TD EPO [12]), the Laboratory shall include *WADA*'s written instructions on how to report the results of the *Sample* under investigation (based on the blood test results) in the Laboratory Documentation Package.

2.2.2.2 DNA Analysis

If necessary, a DNA analysis targeting the *EPO* gene (exon 5 or region encompassing c.577) in blood *Samples* shall be conducted (as described in the TD EPO [12]) and the test results included in the Laboratory Documentation Package, including:

- DNA Analysis Test Description

  [Comment: For example, description of the DNA sequencing platform (e.g., Sanger) and the key steps in the DNA Analysis procedure.]
- Description of the *Sample* subjected to DNA analysis (*Sample* code, *Testing* Authority, Date of Collection, matrix *e.g.,* whole blood/serum/plasma) if different from the *Sample* under

investigation;

- DNA sequencing analysis images and results (or copy of DNA test report):
  - Quality Control sample(s);
  - *Sample* Aliquot.
- DNA Analysis Test Report with conclusion.

  The DNA Analysis Test Report shall conclude on whether the blood *Sample* tested indicates that the associated *Athlete* is a carrier of the *EPO* c.577del variant.

  [Comment: For example, "The EPO sequencing results conclude that the Athlete that provided the blood Sample tested is a carrier of the EPO c.577del variant" or "The EPO sequencing results conclude that the Athlete that provided the blood Sample tested is not a carrier of the EPO c.577del variant".]
- *WADA*'s written instructions on how to report the finding under investigation (based on the results of the DNA analysis).

2.3 Laboratory Test Report(s)

The Test Report documentation as detailed in Article 3.4 of the TD2023LDOC and the TD EPO [12].

2.4 Subcontracted Analysis

A subcontracted analysis shall meet the requirements detailed in Article 3.6 of this *Technical Document*.

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ANNEX C

LABORATORY DOCUMENTATION PACKAGE FOR hGH ISOFORMS DIFFERENTIAL IMMUNOASSAYS AND/OR hGH BIOMARKERS TEST ANALYSIS

This Annex of the TD2023LDOC includes instructions for producing Laboratory Documentation Packages for Confirmation Procedure (CP) results supporting an *Adverse Analytical Finding* (*AAF*) or *Atypical Finding (ATF)* reported for human Growth Hormone (hGH) following the application of the hGH Isoforms differential immunoassays or the hGH Biomarkers Test, or during the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM and the TD APMU).

1.0 Formatting Requirements

An hGH Laboratory Documentation Package shall meet the formatting requirements as detailed in Article 2.0 of this *Technical Document*.

2.0 Documentation Requirements

2.1 Chain of Custody

The chain of custody shall meet the requirements detailed in Article 3.2 of this *Technical Document* and the TD LCOC [4].

2.2 CP Analytical Data

- Summary test description, including:
  - Scheme/sequence of key analysis steps;
  - Kit lot numbers if applying the Isoforms Test;
  - IGF-I and P-III-NP assay pairs and kit lot numbers (as applicable) if applying the Biomarkers Test.
- Statement of acceptable performance based on the evaluation of the analytical instrument, which was used to generate the *Sample*'s CP data.

  [Comment: For example: "Instrument [identification] meets performance criteria based on the Laboratory SOP and QC data". This statement shall be signed and dated by the analyst performing the evaluation.]

- Assays' calibration curve;
- Sequence of analysis;
- Test data for negative (QCN) and positive (QCP) QC sample(s) and *Sample,* including:
  - Isoforms Test [7]
    - The REC and PIT concentrations, expressed to three (3) decimal places, for each *Sample* Aliquot analyzed using kit-1 and kit-2;
    - The mean concentrations from the determinations expressed to three (3) decimal places;
    - The Relative Standard Deviation (RSD, %) of the determinations;
    - The resulting REC/PIT ratios (ratio-1; ratio-2), expressed to two (2) decimal places, calculated from the corresponding mean REC and PIT concentrations from the determinations;
    - The applicable (kit, gender of the *Athlete*) *Decision Limit*(s) (*DL*); and
    - The u_c (%) at values close to the *DL* as determined by the Laboratory during method validation.
  - Biomarkers Test [8]
    - The IGF-I and P-III-NP concentrations (truncated to the nearest integer for IGF-I and two (2) decimal places for P-III-NP) for each *Sample* Aliquot analyzed with two (2) different IGF-I / P-III-NP assay pair combinations;
    - The mean concentrations from the determinations (expressed to the nearest integer for IGF-I and two decimal places for P-III-NP);

      [Comment: When the bottom-up LC-MS/MS or LC-HRMS method is used for IGF-I quantification during the CP, the Laboratory shall report the IGF-I concentrations (individual determinations, mean concentration) determined from the quantification of T1 and T2 peptides, as well as the calculated difference between these mean (T1, T2) concentrations. The Laboratory shall also report the average (overall) IGF-I concentration determined from the quantification of T1 and T2 [8].]

    - The GH-2000 scores, expressed to two (2) decimal places, calculated from the natural logarithms (ln) of the mean concentrations (ng/mL) of IGF-I and P-III-NP;

      [Comment: When the bottom-up LC-MS/MS or LC-HRMS method is used for IGF-I quantification during the CP, the GH-2000 score is calculated from the natural logarithm (ln) of the average (overall) concentration (ng/mL) of IGF-I determined from the quantification of T1 and T2 [8].]

    - The *applicable DL*(s) (assay pair, gender of the *Athlete*); and
    - The u_c at values close to the *DL* as determined by the Laboratory during method validation.
- The Laboratory acceptance criteria for the concentrations and ratios/scores of each QC sample, and a

statement on whether the QC test results passed the Laboratory acceptance criteria.

2.3 Laboratory Test Report(s)

- Laboratory Test Report from *ADAMS,* including the conclusion from the CP;

  Example Isoforms Test [7]:

  "The analysis of the *Sample* using the hGH differential immunoassays has produced the following analytical values of assay ratios: 2.52 for kit "1" and 2.40 for kit "2", which are greater than the corresponding *DL*s of 1.84 and 1.91, respectively. The relative combined standard uncertainty (u_c, %) estimated by the Laboratory at levels close to the *DL* is 15% for kit "1" and 17% for kit "2". This constitutes an *Adverse Analytical Finding* for hGH".

  Example Biomarkers Test [8]:

  "The analysis of the *Sample* with the hGH Biomarkers Test has produced the following GH-2000 scores: 10.90 for assay pair '1' [IDS IGF-I + Centaur P-III-NP] and 9.90 for assay pair '2' [LC-MS/MS IGF-I + Orion P-III-NP], which are greater than the corresponding male-specific *DL*s of 10.61 and 9.70, respectively. The combined standard uncertainty (u_c) estimated by the Laboratory at levels close to the *DL* is 0.40 for assay pair '1' and 0.35 for assay pair '2'. This constitutes an *Adverse Analytical Finding* for hGH".

- Relevant Laboratory Test Report(s) from subcontracted analyses, if any.

2.4 Subcontracted Analysis

A subcontracted analysis shall meet the requirements detailed in Article 3.5 of this *Technical Document*.

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ANNEX D
HEMATOLOGICAL *ABP*
LABORATORY DOCUMENTATION PACKAGE

The requirements of this Annex of the TD2023LDOC are relevant to the analysis of blood *Athlete Biological Passport (ABP) Samples* (whole blood) by a Laboratory or *ABP* Laboratory in support of the Hematological Module of the *ABP*.

This *TD* Annex outlines the requirements for the production of a hematological *ABP* Laboratory Documentation Package or a hematological *ABP* Laboratory Certificate of Analysis by a Laboratory or *ABP* Laboratory for the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM and the TD APMU) [2]).

1.0 Formatting Requirements

A hematological *ABP* Laboratory Documentation Package shall meet the formatting requirements as detailed in Article 2.0 of this *Technical Document*.

2.0 Documentation Requirements

2.1 Cover Page

The cover page shall meet the requirements detailed in Article 3.1 of this *Technical Document*.

2.2 Temperature Data Logger Report

The hematological *ABP* Laboratory Documentation Package shall include a copy of the blood *ABP Sample*'s temperature data logger report.

2.3 Chain of Custody

The chain of custody documentation shall meet the requirements detailed in Article 3.2 of this *Technical Document* and the TD LCOC [4].

2.4 Analytical Data

- Original Sysmex full blood count and scattergram printouts, which include:

- The Blood *ABP Sample* code;
- The analysis date and time; and
- The instrument identification.

- The evaluation record of the Blood *ABP Sample* and associated XN-check (levels 1, 2 and 3) quality control (QC) results, including:
  - Results of all blood *ABP Sample* analyses (minimum two per *ABP Sample*);
  - All XN-check QC levels from the same batch as the blood *ABP Sample*;
  - Acceptance criteria; and
  - Statement(s) of acceptance.

  [Comment: The evaluation shall include the necessary data and applicable criteria as per the TD BAR [13].]
- XN-CHECK manufacturer assay sheets for each QC level; and
- *ADAMS* record printout (Test Report) which contains:
  - Date of submission of the results into *ADAMS*;
  - Date and time of blood *ABP Sample* reception;
  - Date and time of blood *ABP Sample* analysis;
  - Sport/discipline;
  - *Testing* Authority (TA), *Results Management* Authority (RMA), *Sample* Collection Authority (SCA); and
  - Reported test results for the *Markers* of the blood *ABP Sample*.

3.0 Hematological *ABP* Laboratory Certificate of Analysis Requirements

A hematological *ABP* Laboratory Certificate of Analysis shall only contain the following information:

3.1 Cover Page

A signed and dated document by the Laboratory Director or the Director of the *ABP* Laboratory or authorized delegate including:

- Identification of the Laboratory or the *ABP* Laboratory preparing the hematological *ABP* Laboratory Certificate of Analysis;
- The relevant blood *ABP Sample* code;
- A statement certifying that the hematological *ABP* Laboratory Certificate of Analysis contains authentic

copies of original data and forms;

- A statement specifying that the hematological *ABP* Laboratory Certificate of Analysis shall be handled as confidential information which shall not be disclosed to third parties and shall not be reproduced or forwarded unless written approval is obtained from the Laboratory or the *ABP* Laboratory;
- A declaration certifying that the blood *ABP Sample* was analyzed according to the relevant *WADA* rules in force (*e.g.*, ISL, *TD*s); and
- Any relevant comments.

3.2 Analytical Data

The full blood count and scattergram printout of the accepted and reported blood *ABP Sample* analysis, including:

- The Blood *ABP Sample* code;
- The analysis date and time; and
- The instrument identification and serial number.

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ANNEX E

STEROIDAL *ABP*

LABORATORY DOCUMENTATION PACKAGE

The requirements of this Annex of the TD2023LDOC are relevant to Laboratories analyzing urine and/or blood (serum) *Samples* in support of the Steroidal Module of the *Athlete Biological Passport (ABP)*.

This *TD* Annex outlines the requirements for the production of a steroidal *ABP* Laboratory Documentation Package or a steroidal *ABP* Laboratory Certificate of Analysis by a Laboratory for the quantification of the *Markers* of the urinary or blood steroid profile, respectively, during the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM [1] and the TD APMU) [2].

1.0 Formatting Requirements

A steroidal *ABP* Laboratory Documentation Package shall meet the formatting requirements as detailed in Article 2.0 of this *Technical Document*.

2.0 Documentation Requirements

2.1 Cover Page

The cover page shall meet the requirements detailed in Article 3.1 of this *Technical Document*.

2.2 Chain of Custody

The chain of custody documentation shall meet the requirements detailed in Article 3.2 of this *Technical Document* and the TD LCOC [4].

3.0 Steroidal *ABP* Laboratory Documentation Package Requirements

A steroidal Passport includes data from multiple *Samples*, which could either originate from an ITP or a CP in the case of a urine *Sample*, or a primary quantification or confirmatory quantification in the case of a blood *Sample*. For urine *Samples*, whenever a CP for the *Markers* of the steroid profile has been performed on the *Sample*, the steroidal *ABP* Laboratory Documentation Package shall only include the CP analytical data. For blood *Samples*, whenever a confirmatory quantification for the *Markers* of the steroid profile has been performed

on the *Sample*, the steroidal *ABP* Laboratory Documentation Package shall include both primary and confirmatory analytical data.

A steroidal *ABP* Laboratory Documentation Package shall contain the following information:

GC-MS^n Analytical Data of the Urinary Steroid Profile or LC-MS^n Analytical Data of the Blood Steroid Profile

- A general description of the Analytical Method *(e.g.,* scheme/sequence of key analysis steps*)*, including:
  - Standard Operating Procedure (SOP) title or identification code of the Analytical Method applied;
  - Instrument type/Identification code;
  - Description of the QC sample(s) analyzed in the same batch;
  - The monitored ions/transitions in the method for identification of the target Analyte(s).
- A statement on whether the efficiency of hydrolysis and derivatization passed the Laboratory acceptance criteria for the *Sample*.
- Analytical instrument sequence file;

  [Comment: A copy of the original sequence file (preferably generated by the analytical instrument software), which demonstrates the identification and order of analysis of each Sample analyzed.]
- GC-MS^n (urine) or LC MS^n (blood) chromatographic and spectral data:

  [Comment: data shall be copies of the original data which were evaluated by the Laboratory]
  - Calibration curve or concentrations of the calibration standards for all *Markers* of the urinary steroid profile;
  - Assigned chromatograms for the relevant *Markers* of the steroid profile and their respective Internal Standards;
  - For a confirmed *Sample*, identification data of the chromatographic peaks of the relevant *Markers* demonstrating compliance with the TD IDCR [5], including:
    - QC sample(s);
    - *Sample*;
    - A summary table with relative abundances (RAs) of diagnostic ions, retention time (RT) data and relevant calculation results;
    - The applicable criteria utilized to identify the target *Marker*(s);

      [Comment: It is not necessary to perform the GC-MS^n confirmatory identification of the urinary steroid Markers twice, both during the initial GC-MS^n confirmation and during the subsequent GC/C/IRMS

analysis. However, the identification of the urinary steroid Markers (i.e., target compounds) is still mandatory prior to reporting an Adverse Analytical Finding (AAF) or an Atypical Finding (ATF) based on GC/C/IRMS results (see TD EAAS [10] and TD IRMS [11]).

- Signed and initialed statements, traceable via hard copies or electronic records, that the results meet the applicable criteria.

  [Comment: For example, "Pass/Fail" as a statement of compliance with relevant criteria.]

- Initial or confirmed SG of the urine *Sample*;
- Initial or confirmed, as applicable, values of the *Markers* of the steroid profile for:
  - QC sample(s); and
  - *Sample*;

  [Comment: An ADAMS printout of the Sample record containing this information may be provided to address this requirement.

  In addition, the Laboratory acceptance criteria for the concentrations of the Markers in the QC(s) shall be provided with a statement that the QC(s) test results pass the Laboratory acceptance criteria.]
- The associated absolute u_c for all the *Markers* of the steroid profile;
- Statement that the associated relative u_c (%) for the *Markers* of the steroid profile does not exceed the maximum allowed relative u_{c_Max} (%) specified in the TD EAAS (urine) [10] or in the Guidelines for the Quantification of Endogenous Steroids in Blood;
- For the urinary steroid profile, initial or confirmed, as applicable, values of:
  - 5α-androstanedione (5αAND) concentration; and/or
  - 5β-androstanedione (5βAND) concentration, and
  - ratio of 5αAND/Androsterone (A); and/or
  - ratio of 5βAND/Etiocholanolone (Etio);
  - CP ratio of T_{free}/T_{total}

  [Comment: the steroid ratios specified above shall be as determined from the respective steroid concentrations (and not as an intensity ratio (height or area) of the two peaks)]
- Results regarding the presence/absence, as well as estimated concentration where available, of factor(s) impacting the urinary steroid profile as described in TD EAAS.

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4.0 Steroidal *ABP* Laboratory Certificate of Analysis Requirements

A steroidal *ABP* Laboratory Certificate of Analysis shall contain the following information:

4.1 Cover Page

A signed and dated document by the Laboratory Director or authorized delegate including:

- Identification of the Laboratory preparing the steroidal *ABP* Laboratory Certificate of Analysis, including the relevant *Sample* code;
- A statement certifying that the steroidal *ABP* Laboratory Certificate of Analysis contains authentic copies of original data and forms;
- A statement specifying that the steroidal *ABP* Laboratory Certificate of Analysis shall be handled as confidential information, which shall not be disclosed to third parties and shall not be reproduced or forwarded unless written approval is obtained from the Laboratory;
- A statement certifying that the *Sample* was analyzed according to the relevant *WADA* rules in force (*e.g.*, ISL, *TD*s);
- Any relevant comments.

4.2 GC-MS^n or LC-MS^n Data

The GC-MS^n (urine) or LC-MS^n (blood) analysis of the *Sample*, including:

- Chromatographic printout for all relevant *Markers*;
- Initial or confirmed, if available, SG of the urine *Sample*
- The measured values of the relevant *Markers*;
- The associated u_c expressed in units;
- *Sample* code;
- Analysis date and time;
- Instrument identification code;
- The Laboratory acceptance criteria for the concentrations of each QC sample, and a statement on whether the QC test results passed the Laboratory acceptance criteria.

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ANNEX F

ENDOCRINE *ABP*

LABORATORY DOCUMENTATION PACKAGE

The requirements of this Annex of the TD2023LDOC are relevant to Laboratories analyzing blood (serum) *Samples* in support of the Endocrine Module of the *Athlete Biological Passport (ABP)*.

This *TD* Annex outlines the requirements for the production of an endocrine *ABP* Laboratory Documentation Package or an endocrine *ABP* Laboratory Certificate of Analysis by a Laboratory for the quantification of the *Markers* of the Endocrine Module of the *ABP* during the compilation of an *ABP* Documentation Package (as described in Annex C of the ISRM [1] and the TD APMU [2]).

1.0 Formatting Requirements

An endocrine *ABP* Laboratory Documentation Package shall meet the formatting requirements as detailed in Article 2.0 of the TD2023LDOC.

2.0 Documentation Requirements

2.1 Cover Page

The cover page shall meet the requirements detailed in Article 3.1 of this *Technical Document*.

2.2 Chain of Custody

The chain of custody documentation shall meet the requirements detailed in Article 3.2 of this *Technical Document* and the TD LCOC [4].

3.0 Endocrine *ABP* Laboratory Documentation Package Requirements

An endocrine Passport includes data from multiple *Samples* which could either originate from a primary quantification and, in some cases, also from a confirmatory quantification if a *Sample* has been flagged by the Adaptive Model as an ATPF or based on an APMU request. Whenever a confirmatory quantification has been performed on the *Sample*, the endocrine *ABP* Laboratory Document Package shall include both primary and confirmatory quantification data.

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An endocrine *ABP* Laboratory Documentation Package shall contain the following information for each S*ample*.

3.1 Quantification of IGF-I by Top-down LC-MS^n

- A general description of the Analytical Method *(e.g.,* scheme/sequence of key analysis steps*)*, including:
  - Standard Operating Procedure (SOP) title or identification code of the Analytical Method applied;
  - Instrument type/Identification code;
  - Description of QC sample(s) analyzed in the same batch;
  - The monitored ions/transitions in the method for identification of the target Analyte.
- Analytical instrument sequence file;

  [Comment: A copy of the original sequence file (preferably generated by the analytical instrument software), which demonstrates the identification and order of analysis of each Sample analyzed in the Analytical Method run.]
- LC-MS^n data:

  [Comment: the data shall be copies of the original data which were evaluated by the Laboratory]
  - Calibration curve or concentrations of the calibration standard(s) for IGF-I;
  - Clearly integrated chromatograms for IGF-I and its respective (deuterated) Internal Standard;
  - For a confirmed *Sample*, identification data of the chromatographic peak of IGF-I demonstrating compliance with the TD IDCR [5], including:
    - QC sample(s);
    - *Sample*;
    - A summary table with relative abundances (RAs) of diagnostic ions, retention time (RT) data and relevant calculation results;
    - The applicable criteria utilized to identify the target *Marker*(s);
    - The summary table shall include signed/initialed statements (or electronic signature/validated LIMS record) that the results meet the applicable criteria.

      [Comment: For example, "Pass/Fail" as a statement of compliance with relevant criteria.]
  - Analytical data for QC and *Sample*, including:
    - IGF-I concentration measured for the two (2) *Sample* Aliquots;
    - The mean concentration of IGF-I from the duplicate determinations (truncated to the nearest);

- The associated absolute u_c.

  [Comment: An ADAMS printout of the Sample record containing this information may be provided to address this requirement.

  In addition, the Laboratory acceptance criteria for the concentrations of the Markers in the QC(s) shall be provided with a statement that the QC(s) test results pass the Laboratory acceptance criteria.]

- Statement that the associated relative u_c (%) for IGF-I does not exceed the maximum allowed relative u_{c_Max} (%) specified in the Guidelines for the hGH Biomarkers [8].

3.2 Quantification of P-III-NP with Centaur (Siemens) Assay

- Summary test description, including:
  - Scheme/sequence of key analysis steps;
  - Kit lot number;
- Statement of acceptable performance based on the evaluation of the analytical instrument, which was used to generate the *Sample*'s data.

  [Comment: For example: "Instrument [identification] meets performance criteria based on the Laboratory SOP and QC data". This statement shall be signed and dated by the analyst performing the evaluation.]
- Assays' calibration curve;
- Sequence of analysis;
- Test data for QC sample(s) and *Sample,* including:
  - The P-III-NP concentrations measured for the two (2) *Sample* Aliquots;
  - The mean concentration from the duplicate determinations (truncated to the two (2) decimal places);
  - The absolute u_c at values close to the LOQ as determined by the Laboratory during method validation.
- The Laboratory acceptance criteria for the concentrations of each QC sample, and a statement on whether the QC test results passed the Laboratory acceptance criteria.

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4.0 Endocrine *ABP* Laboratory Certificate of Analysis Requirements

An endocrine *ABP* Laboratory Certificate of Analysis shall contain the following information:

4.1 Cover page

A signed and dated document by the Laboratory Director, or authorized delegate, including:

- Identification of the Laboratory preparing the endocrine *ABP* Laboratory Certificate of Analysis, including the relevant *Sample* code;
- A statement certifying that the endocrine *ABP* Laboratory Certificate of Analysis contains authentic copies of original data and forms;
- A statement specifying that the endocrine *ABP* Laboratory Certificate of Analysis shall be handled as confidential information, which shall not be disclosed to third parties and shall not be reproduced or forwarded unless written approval is obtained from the Laboratory;
- A statement certifying that the *Sample* was analyzed according to the relevant *WADA* rules in force (*e.g.*, ISL, *TD*s);
- Any relevant comments.

4.2 IGF-I LC-MS^n Analytical Data

The LC-MS^n analysis of the *Sample*, including:

- Copy of the original chromatographic printout(s) for IGF-I;
- The IGF-I concentrations measured for the two (2) *Sample* Aliquots;
- The mean concentration of IGF-I from the duplicate determinations (truncated to the nearest integer);
- The absolute u_c at values close to the LOQ as determined by the Laboratory during method validation;
- *Sample* code;
- Analysis date and time;
- Instrument identification code;
- The Laboratory acceptance criteria for the concentrations of each QC sample and a statement on whether the QC test results passed the Laboratory acceptance criteria.

4.3 P-III-NP Analytical Data

- The P-III-NP concentrations measured for the two (2) *Sample* Aliquots;

- The mean concentration of P-III-NP from the duplicate determinations (truncated to the two (2) decimal places);
- The absolute u_c at values close to the LOQ as determined by the Laboratory during method validation;
- *Sample* code;
- Analysis date and time;
- Instrument identification code;
- The Laboratory acceptance criteria for the concentrations of each QC sample and a statement on whether the QC test results passed the Laboratory acceptance criteria.

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References

[1] The World Anti-Doping *Code the International Standard for Results Management (ISRM).*

[2] *WADA Technical Document* TD APMU : Athlete Passport Management Unit Requirements and Procedures.

[3] The World Anti-Doping *Code International Standard* for Laboratories (ISL).

[4] *WADA Technical Document* TD LCOC: Laboratory Internal Chain of Custody.

[5] *WADA Technical Document* TD IDCR: Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for *Doping Control* Purposes.

[6] *WADA Technical Document* TD DL: *Decision Limits* for the Confirmatory Quantification of Exogenous Threshold Substances by Chromatography-based Analytical Methods.

[7] *WADA Technical Document* TD GH: Human Growth Hormone (hGH) Isoform Differential Immunoassays for *Doping Control* Analyses.

[8] *WADA* Laboratory Guidelines on human Growth Hormone Biomarkers Test for *Doping Control* Analyses.

[9] *WADA Technical Document* TD CG/LH: Reporting and Management of Urinary Chorionic Gonadotrophin (hCG) and Luteinizing Hormone (LH) Findings in Male *Athletes*.

[10] *WADA Technical Document* TD EAAS: Measurement and Reporting of Endogenous Anabolic Androgenic Steroid (EAAS) *Markers* of the Urinary Steroid Profile.

[11] *WADA Technical Document* TD IRMS: Detection of Synthetic Forms of *Prohibited Substances* by GC/C/IRMS.

[12] *WADA Technical Document* TD EPO: Harmonization of Analysis and Reporting of EPO and other Erythropoietin Receptor Agonists (ERAs) by Polyacrilamide Gel Electrophoretic (PAGE) Analytical Methods.

[13] *WADA Technical Document* TD BAR: Blood Analytical Requirements *Athlete Biological Passport* Operating Guidelines & Compilation of Required Elements.

[14] *WADA Technical Document* TD MRPL: Minimum Required Performance Levels and Applicable *Minimum Reporting Levels* for Non-Threshold Substances Analyzed by Chromatographic - Mass Spectrometric Analytical Methods.

[Current versions of WADA ISL, Technical Documents and Laboratory Guidelines may be found at https://www.wada-ama.org/en/anti-doping-partners/laboratories]