WADA Technical Document – ISL TD2027PERF

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Laboratory Performance Evaluation

1.0 Introduction

This *Technical Document* (*TD*), which constitutes an integral part of the *International Standard* for Laboratories [1] (ISL [1]), outlines the *WADA* requirements for the evaluation of Laboratory performance within the framework of the *WADA* External Quality Assessment Scheme (EQAS) and during routine Analytical *Testing*.

The Laboratory Expert Advisory Group (Lab EAG) [2] evaluates Laboratory performance and oversees the accreditation of Laboratories and the approval of *ABP* Laboratories.

2.0 Laboratory EQAS Program

The *WADA* system of Laboratory EQAS and routine Analytical *Testing* performance evaluation (see Points Scale Table in Article 3.8 below) has been developed with the objective of setting a transparent and balanced procedure for evaluation of Laboratory operations. It is based on the principle of proportionality and is focused on improving and harmonizing Laboratory Analytical *Testing* capabilities. It is ultimately aimed at supporting Laboratory quality management and maintaining the confidence in and strengthening the anti-doping Laboratory system.

Satisfactory EQAS performance in single-blind and double-blind EQAS rounds, as well as over a consecutive twelve (12)-month period [3] is necessary for maintaining *WADA* accreditation.

[Comment 1 to Article 2.0: An EQAS Round is a distribution of EQAS sample(s) to the Laboratories for Analytical Testing as defined by WADA.]

Laboratory performance in the educational EQAS is not evaluated according to the Points Scale Table; however, unsatisfactory performance in an educational EQAS shall trigger and investigation and/or the implementation of corrective actions by the Laboratory, as applicable. Where the unsatisfactory educational EQAS performance relates to a new or *WADA*-specific Analytical *Testing* Procedure (ATP), this may prevent the Laboratory from seeking an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation [3] for the affected ATP and thereby preclude its application in routine Analytical *Testing*

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[1] To facilitate the comprehension and interpretation of ISL provisions, including ISL *TDs* and ISL *Technical Letters* (*TLs*), when requirements apply to both Laboratories and *ABP* Laboratories, both shall be referred to as "Laboratory(-ies)". If, instead, provisions apply exclusively to either Laboratories or *ABP* Laboratories, the specific definition is used as applicable. When the term "laboratory" is used, it implies laboratories that are neither *WADA*-accredited nor -*ABP*-approved.

[2] Laboratory Expert Advisory Group, Terms of Reference; https://www.wada-ama.org/en/resources/governance/laboratory-expert-advisory-group-terms-reference.

[3] The twelve (12)-month period, used to assess the total number of points accumulated by a Laboratory according to the Points Scale Table (Article 3.8), is defined as the most recent consecutive twelve (12)-month interval starting from the date that the Laboratory is informed by *WADA*, in writing, of the final number of points assigned in respect to a Laboratory nonconformity. Any assigned points will expire after a twelve (12)-month period; however, the total number of points accumulated within any consecutive twelve (12)-month period shall not reach the maximum allowed number of points established in the Points Scale Table.

(see the ISL Article 4.1.4.2.4 [1] and ISL *TD* ATP [2]). In such circumstances, the Laboratory may only apply the newly *WADA*-approved ATP for routine *Sample* analysis when it properly corrects the deficiencies identified in the educational EQAS (as determined by *WADA*) and the Test Method is included in the Laboratory's Scope of ISO/IEC 17025 Accreditation [3].

[Comment 2 to Article 2.0: Some ATPs are not eligible for a Flexible Scope of ISO/IEC 17025 Accreditation and require an extension of the Scope of ISO/IEC 17025 Accreditation before the Laboratory can apply the procedure to the analysis of Samples. WADA-specific ATPs, and the process to be followed for their implementation, are described in the ISL TD ATP [2]]

2.1. EQAS Samples Analyzed with Qualitative Procedures (Non-Threshold Substances)

When a Non-Threshold Substance has been reported, the Laboratory result will be evaluated based on the expected test result for the EQAS sample, *e.g., Adverse Analytical Finding* (*AAF*), *Atypical Finding* (*ATF*), or Negative Finding.

a) Non-Threshold Substances (NTS) without *Minimum Reporting Levels* (*MRLs*) [4]

i. EQAS samples containing an NTS at a concentration greater than or equal to (≥) the Minimum Required Performance Level (MRPL) [4]

The Laboratory shall report the EQAS sample results as an *AAF*. EQAS results shall be evaluated as per the Points Scale Table.

ii. EQAS samples containing an NTS at a concentration below (<) the MRPL

EQAS results shall not be evaluated using the Points Scale Table. However, the Laboratory should report the presence of a NTS without an *MRL* at an estimated concentration below (<) the MRPL if an Analyte of the NTS is identified in the *Sample* in accordance with the ISL *TD* IDCR [5] and/or other applicable ISL *TD* or ISL *TL*. *WADA* may require the Laboratory to conduct an internal investigation and report to *WADA* if such *Samples* are not reported as an *AAF*.

b) Non-Threshold Substance with an *MRL* [6]:

i. EQAS samples at a concentration greater than (>) 150% of the *MRL*

The Laboratory shall report the EQAS sample results as an *AAF*. EQAS results shall be evaluated as per the Points Scale Table.

ii. EQAS samples at concentrations less than or equal to (≤) 150% of the *MRL*

[4] For an EQAS sample to be considered suitable for Laboratory performance evaluation (*i.e.*, evaluation of Laboratory capacity to detect and report the presence of a *Prohibited Substance,* a *Prohibited Method* or a confounding factor in the sample), criteria have been established to ensure that the concentration of the target Analyte(s) in the EQAS sample, as determined by the EQAS Sample Provider, meet the applicable substance detection (MRPL) and/or reporting [*MRL*, *Decision Limit* (*DL*)] criteria.

The Laboratory should report the EQAS sample results as a Negative Finding, except for those *Prohibited Substances* for which the result shall be reported as *ATF* or in those specific circumstances where the result shall be reported as *AAF* (see ISL *TD MRL* [6]). EQAS results shall be evaluated using the Points Scale Table if it is determined that the Laboratory did not follow the applicable reporting requirements.

2.2. EQAS Samples Analyzed with Quantitative Procedures [5]

a) The quantitative determinations in EQAS samples of Threshold Substances at levels greater than (>) 50% of the Threshold, the *Markers* of the of the Steroidal and Endocrine Modules of the *Athlete Biological Passport* (*ABP*), the urinary SG, and the carbon isotopic ratios of Target Compounds (TCs) and Endogenous Reference Compounds (ERCs) by GC/C/IRMS will be statistically evaluated (*e.g.*, *z*-score [6], degree of equivalence analysis) to determine the compatibility of the reported result with the assigned value (reference, nominal or consensus value, as applicable).

In addition, the Bias (*B*) and Measurement Uncertainty (MU) of the determination will also be statistically evaluated for compliance with the criteria indicated in the effective version of the ISL *TD DL* [7] or other relevant ISL *TD*, ISL *TL* or Laboratory Guidelines (LGs).

b) A Laboratory shall achieve a satisfactory statistical evaluation of their reported quantitative results. Nonconforming results shall be evaluated as per the Points Scale Table.

[Comment to Article 2.2 b): For Laboratory harmonization, the main criterion applied for the evaluation of EQAS quantitative results is the compatibility of the reported Laboratory result with the assigned value for proficiency assessment. Therefore, the incorrect reporting, for example, of an EQAS sample containing a Threshold Substance as a Negative Finding or as an AAF, as applicable, is not considered as a False Negative Finding or False AAF, respectively, if the absolute z-score for the Laboratory's quantitative result is < 3.0 [6].]

i. Unsatisfactory Quantitative Result (absolute *z*-score ≥ 3.0)

– *WADA* shall request the Laboratory to provide a Corrective Action Report (CAR) for unsatisfactory quantitative result occurrences in accordance with the Points Scale Table. The CAR shall be submitted within thirty (30) days of receiving a written notification about the unsatisfactory result(s) from *WADA* (unless the nonconformity led to the

[5] Applicable to the measurement of concentrations of Threshold Substances and the *Markers* of the Steroidal and Endocrine Modules of the *ABP*, as well as urinary Specific Gravity (SG) and Gas Chromatography / Combustion / Isotope Ratio Mass Spectrometry (GC/C/IRMS) determinations.

[6] The *z*–score is calculated for the quantitative results reported by each Laboratory according to Eq. 1, and is expressed truncated to one (1) decimal place:

$$(\text{Eq.1}) \quad z = \frac{x_i - x_{pt}}{\sigma_{pt}}$$

Where: x_i is the mean value of the Laboratory's measurements; x_{pt} is the assigned value for proficiency assessment (reference, nominal or consensus value, as applicable); σ_{pt} is the standard deviation for proficiency assessment (*i.e.*., the maximum allowed combined standard uncertainty - u_{c_Max} - or the robust Reproducibility - s_R - of results from all participant Laboratories). The u_{c_Max} is adopted as σ_{pt} unless a u_{c_Max} has not yet been established by *WADA*, in which case the s_R will be used as σ_{pt}.

reporting of a False *AAF* or a False Negative Finding, in which case the CAR shall be provided in accordance with Articles 3.2 and 3.3 below, respectively).

- Failure to submit a satisfactory CAR (as per Article 3.5) or the non-approved late submission of the CAR without prior approval by *WADA* shall result in the imposition of further points in accordance with the Points Scale Table.

ii. Questionable Quantitative Result (absolute *z*-score > 2.0 and < 3.0)

WADA shall request the Laboratory to perform an internal investigation to determine the root cause(s) of the questionable result and implement appropriate corrective measures to resolve them. It is not necessary to provide a CAR to *WADA*.

3.0 Evaluation of Laboratory EQAS and Routine Analytical *Testing* Performance

3.1. Application of Analytical *Testing* Procedures (ATPs)

a) Any *Sample* test result reported during routine Analytical *Testing* or in an EQAS shall be based on the application of validated ATPs, in accordance with the ISL *TD* VAL [8].

b) The inclusion of an ATP within the Laboratory's Scope of ISO/IEC 17025 Accreditation establishes the presumption that the ATP has been validated as Fit-for-Purpose [1], [3].

3.2. False *AAF*

The reporting of a False *AAF* is not acceptable for any blind or double-blind EQAS sample or during routine Analytical *Testing* conducted by a Laboratory.

a) False *Adverse Analytical Finding* during routine Analytical *Testing*

i. The Laboratory shall inform the *Testing* Authority (TA) (or *Results Management* Authority (RMA), if different) and *WADA* immediately if the Laboratory discovers that it reported a False *AAF* during routine Analytical *Testing*.

ii. *WADA* shall inform the Laboratory immediately if a routine Analytical *Testing* False *AAF* is identified by *WADA,* based on information received from a TA, an RMA, through *WADA*'s *Results Management* activities or through any other means.

b) False *Adverse Analytical Finding* in EQAS

i. If a False *AAF* is reported during the (blind- or double-blind) EQAS, *WADA* shall immediately start an investigation to establish if the incorrect result was caused by the EQAS Sample Provider (blind and double-blind EQAS) or the TA / *Delegated Third Party* (*DTP*) / *Major Event Organization* (*MEO*) that delivered the *Sample* to the Laboratory (only for double-blind EQAS).

ii. If the *WADA* investigation indicates that the False *AAF* result was caused by an error made by the EQAS Sample Provider or the TA / *DTP* / *MEO*, *WADA* shall inform the Laboratory, and no further action shall be required from the Laboratory.

iii. If it is established that the False *AAF* was caused by an error made by the Laboratory during the Analytical *Testing* of the EQAS sample(s), *WADA* shall inform the Laboratory as soon as possible.

c) Cessation of Affected Analytical *Testing* Activities

i. When a False *AAF* is reported, the Laboratory shall cease all affected ATP(s) and/or Laboratory process(es) (*e.g.,* ITP(s) and/or CP(s) as applicable, *Sample* aliquoting, reporting of results) as soon as it becomes aware that a False *AAF* has been reported, to prevent further nonconformities and to prioritize the conduct of a Root Cause Analysis (RCA) and the planning of corrective actions.

ii. The Laboratory shall inform its customers of the cessation of the affected ATP(s) and/or Laboratory process(es) if it affects the results reporting timelines.

d) *WADA* Laboratory Assessment

The reporting of any False *AAF* result, irrespective of whether it relates to routine Analytical *Testing* or the EQAS, or whether it results in the imposition of an Analytical *Testing* Restriction (ATR) or the Suspension of the Laboratory's *WADA* accreditation, may trigger a *WADA* Laboratory Assessment and the requirement that additional EQAS samples be analyzed by the Laboratory. All costs associated with the preparation, characterization and shipment of the EQAS samples, as well as the conduct of the Laboratory Assessment, shall be at the Laboratory's expense.

3.2.1 False *Adverse Analytical Finding* Reported during Routine Analytical *Testing* with *Consequences* [7] for the *Athlete*.

a) If the reporting of the False *AAF* has resulted in *Consequences* imposed against an *Athlete*, the Laboratory shall initially receive twenty (20) points in accordance with the Points Scale Table, irrespective of the nature of the error (technical/methodological or clerical/administrative) that led to the reporting of the False *AAF*.

b) Voluntary Self-reporting

If the Laboratory first informs *WADA* of their investigation and discovery of a False *AAF*, then the Laboratory shall have five (5) points deducted from the twenty (20) points initially assigned.

[7] Defined in the *Code* [9] as resulting in one or more of the following consequences for the *Athlete*: *Disqualification*, *Ineligibility*, *Provisional Suspension, Financial Consequences* and/or *Public Disclosure*.

c) Root Cause Analysis and Plan of Corrective Action(s)

The Laboratory shall provide *WADA* with a Root Cause Analysis (RCA) and a plan of corrective action(s) for rectification of the nonconformity within five (5) days of informing *WADA* or being informed by *WADA* of the False *AAF*, as applicable.

For Major *Events*, this period shall be substantially shorter (within twenty-four (24) hours of notification of the False *AAF*; see also ISL Article 7.7 [1]). In exceptional cases, the timeline may be extended by *WADA.*

d) Lab EAG Review

The Lab EAG shall review the Laboratory's RCA and plan of corrective actions within five (5) days, or within a timeline otherwise defined by *WADA*, and determine:

i. RCA: Whether the Laboratory's RCA investigation has correctly identified the root cause(s) of the nonconformity.

ii. Plan of Corrective and Preventive Actions Plan: whether the Laboratory's plan for corrective and preventive actions is adequate to rectify and minimize the risk of recurrence of the nonconformity (see also Article 3.5).

e) Submission of Corrective Action Report

Following the Lab EAG's approval of the Laboratory's RCA and corrective actions plan, the Laboratory shall provide *WADA* with a CAR including evidence of implementation of the corrective and preventive actions within five (5) days, or within a timeline otherwise determined by *WADA* (for example, within forty-eight (48) hours during Major *Events*; see also ISL Article 7.7 [1]).

f) Satisfactory and Timely Corrective Action Report: Resumption of Analytical *Testing*

i. If the nonconformity is satisfactorily resolved within the timelines established in this Article 3.2.1, as determined by the Lab EAG, the Laboratory shall have five (5) points deducted, in accordance with the Points Scale Table.

ii. The Laboratory shall be informed by *WADA*, in writing, of the final number of points assigned in connection with the reporting of the False *AAF* [8].

iii. Nevertheless, *WADA* reserves the right to send extra EQAS samples or perform an On-site Assessment of the Laboratory, at *WADA*'s discretion and at the Laboratory's expense.

[8] *WADA* shall inform a Laboratory in writing about the assignment of points, as decided by the Lab EAG and in accordance with the Points Scale Table (Article 3.8). If the final decision regarding the number of points to be imposed is conditional on the evaluation of implemented corrective actions or other follow-up measures (*e.g.,* analysis of further EQAS samples) that have been requested by the Lab EAG, *WADA* will only inform the Laboratory about the final number of points imposed at the end of the evaluation process.

iv. The Laboratory may resume Analytical *Testing* following written notification by *WADA*, provided that the total number of accumulated points by the Laboratory for a twelve (12)-month [3] period has not reached thirty (30) points.

g) Unsatisfactory Corrective Action Report: Suspension or Analytical *Testing* Restriction

If the nonconformity is not satisfactorily resolved within the timelines in accordance with this Article 3.2.1, as determined by the Lab EAG, then the Laboratory shall be assigned an additional ten (10) points and the Lab EAG shall recommend the ATR or Suspension of the Laboratory, as applicable (see ISL Article 7.1.1.2 [1]) [9].

h) Additional Analyses

i. *WADA* may request the Laboratory to analyze additional EQAS samples (at the Laboratory's expense) and/or perform a retrospective review of the relevant analytical results. In addition, *WADA* may request the Laboratory to re-analyze any relevant *Samples* stored in the Laboratory that were previously reported as *AAF* based on the application of the ATP(s) for which the noncompliance occurred during the preceding twelve (12)-months (or during a period otherwise determined by *WADA*) [3, 10, 11].

ii. Depending on the root cause(s) of the error that led to the reporting of the False *AAF*, this re-analysis may be limited to one Analyte, a class of *Prohibited Substances* or *Prohibited Methods*, or may include any *Prohibited Substance* or *Prohibited Method*.

iii. The Laboratory shall report the results of the re-analysis to *WADA*.

iv. The Laboratory shall inform all its customers whose Analytical *Testing* results may have been affected.

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[9] During the period of ATR or Suspension, the Laboratory shall follow the instructions provided in ISL Articles 7.2.1 and 7.2.2 [1], respectively, regarding *Samples* in the Laboratory's possession. *WADA* shall conduct an Assessment (preferably on-site) of the Laboratory, including the analysis of additional EQAS samples. The ATR or Suspension of the Laboratory shall be lifted only once the required conditions have been satisfactorily met, and the Laboratory provides sufficient evidence, as determined by *WADA*, that appropriate steps have been taken to remedy the issue(s) that resulted in the ATR or Suspension.

[10] The retrospective review of the analytical results and re-analysis of previous relevant *Samples* reported as *AAF* shall be performed with the objective of determining whether any other related [*i.e.*, produced by the same root cause(s)] False *AAF*(s) have been reported by the Laboratory. The discovery of additional False *AAF*(s) shall lead to the implementation of corrective measures and shall be communicated to the responsible TA (or RMA, if different) and to *WADA*. However, the additional False *AAF*(s) will not lead to the accumulation of additional points if produced by the same root cause(s), as determined by *WADA*.

[11] The Laboratory may not re-analyze *Sample*(s) previously reported as *AAFs* if the responsible *Anti-Doping Organization* (*ADO*) has charged the *Athlete* with *a Code* Article 2.1 [9] anti-doping rule violation resulting from the analysis of the *Sample*, without the consent of the *Athlete* or approval from a hearing body. However, in connection with its monitoring of a Laboratory, *WADA* may direct the Further Analysis of a *Sample*, which has resulted in a *Code* Article 2.1 anti-doping rule violation charge, without the consent of the *Athlete* or approval from a hearing body, provided that the resulting analytical result is not used against the *Athlete* [for example, re-analyzing *Sample*(s) which the Laboratory has reported as *AAF* when other *Sample*(s) analyzed by the Laboratory using the same ATP has been discovered to be a False *AAF*(s)].

3.2.2 False *Adverse Analytical Finding* reported during routine Analytical *Testing* with No *Consequences* for an *Athlete* or False *Adverse Analytical Finding* reported for an EQAS Sample

a) Root Cause Analysis and Plan of Corrective Action(s)

The Laboratory shall provide *WADA* with an RCA and a plan of corrective action(s) for rectification of the nonconformity within five (5) days of informing *WADA* or being informed by *WADA* of the False *AAF*, as applicable.

b) Lab EAG Review

The Lab EAG shall review the Laboratory's RCA and plan of corrective actions within five (5) days, or within a timeline otherwise determined by *WADA* and determine:

i. RCA: Whether the Laboratory's RCA investigation has correctly identified the root cause(s) of the nonconformity as either a technical/methodological error or a clerical/administrative error.

ii. Plan of Corrective and Preventive Action(s): whether the Laboratory's plan for corrective action(s) is adequate to rectify and minimize the risk of recurrence of the nonconformity (see also Article 3.5).

c) Classification of Error

The Lab EAG, taking into consideration the RCA investigation performed by the Laboratory, shall determine whether the error shall be classified as technical/methodological or clerical/administrative.

i. Technical/Methodological Error

The Laboratory shall be initially assigned twenty (20) points in accordance with the Points Scale Table.

ii. Clerical/Administrative Error [12]

The Laboratory shall be initially assigned fifteen (15) points in accordance with the Points Scale Table.

[12] For the purpose of Laboratory performance evaluation, clerical/administrative errors are defined as those incidental, non-systematic errors of no technical or methodological origin (*e.g.*, a typographical error when manually recording an analytical result). The Laboratory shall bear no responsibility for clerical/administrative errors reflected in the Laboratory documentation, which were made, for example, by the *Sample* Collection Authority (SCA) or the TA.

d) Voluntary Self-reporting

If the Laboratory first informs *WADA* of their investigation and discovery of a *False AAF*, then the Laboratory shall have five (5) points deducted from the number of points initially assigned.

e) Submission of Corrective Action Report

Following approval of the Laboratory's RCA and corrective actions plan by the Lab EAG, the Laboratory shall provide *WADA* with a CAR including evidence of implemented corrective and preventive actions within five (5) days, or within a timeline otherwise determined by *WADA*.

f) Additional Analyses

i. The Laboratory may be required by *WADA* to analyze additional EQAS samples (at the Laboratory's expense) and/or perform a retrospective review of the relevant analytical results. In addition, *WADA* may request the Laboratory to re-analyze any relevant *Samples* stored in the Laboratory that were previously reported as *AAF* based on the application of the ATP(s) for which the noncompliance occurred during the preceding twelve (12)-months (or during a period otherwise determined by *WADA*) [3, 8, 9].

ii. Depending on the root cause(s) of the error that led to the reporting of the False *AAF*, this re-analysis may be limited to one Analyte, a class of *Prohibited Substances* or *Prohibited Methods*, or may include any *Prohibited Substance* or *Prohibited Method*.

iii. The Laboratory shall report the results of the re-analysis to *WADA*.

iv. The Laboratory shall be required to inform all its customers whose Analytical *Testing* results may have been affected.

g) Satisfactory and Timely Corrective Action Report: Resumption of Analytical *Testing*

i. If the Laboratory can remedy the technical or methodological error through the implementation of satisfactory corrective action(s) (as per Article 3.5) according to the procedure and within the timelines established in this Article 3.2.2, as determined by the Lab EAG, the Laboratory shall have ten (10) points deducted, in accordance with the Points Scale Table.

ii. The Laboratory will be informed by *WADA*, in writing, of the final number of assigned points assigned in connection with the reporting of the False *AAF* [10].

iii. The Laboratory may resume Analytical *Testing* following written notification by *WADA*, provided that the total number of accumulated points by the Laboratory for a twelve (12)-month [3] period has not reached thirty (30) points.

h) Unsatisfactory Corrective Action Report

i. If the submitted Laboratory's CAR is considered unsatisfactory by the Lab EAG, the Laboratory shall be provided with feedback and the opportunity to submit a revised CAR within seven (7) days (unless informed otherwise by *WADA*).

ii. If the Laboratory submits a satisfactory revised CAR (as per Article 3.5) in a timely manner, as determined by the Lab EAG, the Laboratory shall have five (5) points deducted, in accordance with the Points Scale Table.

- The Laboratory shall be informed by *WADA*, in writing, of the final number of points assigned in connection with the reporting of the False *AAF* [10].
- The Laboratory shall be able to resume Analytical *Testing* following written notification by *WADA*, provided that the total points accumulated by the Laboratory for a twelve (12)-month [3] period has not reached thirty (30) points.

iii. If the Laboratory is unable to resubmit a satisfactory CAR in a timely manner, as determined by the Lab EAG, the Laboratory shall receive an additional ten (10) points [10].

iv. The Lab EAG shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an ATR against the Laboratory for a particular ATP or for the analysis of a particular class of *Prohibited Substances* or *Prohibited Methods*, as applicable [11].

3.2.3 False *Adverse Analytical Finding* during a Major *Event* (see ISL Article 7.7 **[1]**)

a) If a False *AAF* is reported during a Major *Event*, the Laboratory shall immediately cease the application of the relevant ATP(s) and inform the responsible RMA (*i.e.*, the *MEO* or *DTP* delegated to undertake *Results Management* responsibilities for the Major *Event*) and *WADA*.

b) The Laboratory shall investigate the root cause of the nonconformity within twenty-four (24) hours and provide a CAR to *WADA* within forty-eight (48) hours of notification of the False *AAF*, unless otherwise agreed in writing.

c) All *Samples* stored in the Laboratory, which were analyzed prior to the reporting of the False *AAF* and reported as *AAF* based on the application of the ATP(s) for which the noncompliance occurred, shall be re-analyzed [8, 9]. The results of the investigation and

analysis shall be presented to *WADA* within forty-eight (48) hours, unless otherwise agreed in writing.

d) Satisfactory and Timely Corrective Action Report: Resumption of Analytical *Testing*

If the Laboratory can remedy the nonconformity through the implementation of satisfactory and timely corrective and preventive actions (as per Article 3.5), the Laboratory may resume the affected Analytical *Testing* activities during the Major *Event* following written notification by *WADA*. The Laboratory shall inform the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) of *WADA*'s decision.

e) Unsatisfactory Corrective Action Report

i. If the Laboratory is unable to submit a satisfactory CAR in a timely manner, as determined by *WADA*, the Laboratory shall be notified by *WADA* that it may not resume the affected Analytical *Testing* activities during the Major *Event*, which shall be subcontracted, in consultation with the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*), to other Laboratory(-ies).

ii. The Laboratory shall inform the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) of *WADA*'s decision.

iii. In addition, the Lab EAG shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an ATR against the Laboratory for a particular ATP or for the analysis of a particular class of *Prohibited Substances* or *Prohibited Methods*, as applicable [10].

3.3. False Negative Finding

3.3.1 False Negative Finding during routine Analytical *Testing* or EQAS

Laboratories failing to identify and/or report an Analyte(s) of *Prohibited Substance*(s) and/or *Prohibited Method*(s) in a blind or double-blind EQAS sample or during routine Analytical *Testing* shall be informed of the False Negative Finding as soon as possible by *WADA*.

a) *WADA* shall immediately start an investigation to establish whether the False Negative Finding was the result of the Laboratory's Analytical *Testing* process.

b) If *WADA*'s investigation determines that the False Negative Finding occurred due to mistake(s) related to the Laboratory's Analytical *Testing* process, the Laboratory shall be initially imposed ten (10) points in accordance with the Points Scale Table.

The reporting of False Negative Finding(s) caused by Laboratory errors, irrespective of whether it relates to routine Analytical *Testing* or the EQAS, or whether it results in an ATR or the Suspension of a Laboratory's *WADA* accreditation, may trigger a *WADA* Laboratory Assessment and the requirement that additional EQAS samples be analyzed by the Laboratory, as determined by *WADA*. All costs associated with the preparation, characterization and shipment of the EQAS samples, as well as the conduct of the Laboratory assessment, shall be at the Laboratory's expense.

c) Voluntary Self-reporting

If the False Negative Finding is related to the analysis of a routine *Sample* or a double-blind EQAS sample and the Laboratory first informs *WADA* of their investigation and discovery of a False Negative Finding, then the Laboratory shall have five (5) points deducted from the ten (10) points initially assigned.

d) Root Cause Analysis and Plan of Corrective and Preventive Action(s)

The Laboratory shall provide *WADA* with an RCA and a plan of corrective action(s) for rectification of the nonconformity within five (5) days of informing *WADA* or being informed by *WADA* of the False Negative Finding, as applicable.

The plan of corrective and preventive action(s) shall include the re-evaluation of *Sample* data and/or the re-analysis of an appropriate number of *Samples* reported, as determined by *WADA*, as a Negative Finding based on the application of the ATP(s) for which the noncompliance occurred [8, 9].

e) Lab EAG Review

The Lab EAG shall review the Laboratory's RCA and plan of corrective and preventive actions within five (5) days, or within a timeline otherwise determined by *WADA* (for example, for Major *Events*), and determine:

i. RCA: whether the Laboratory's RCA investigation has correctly identified the root cause(s) of the nonconformity.

ii. Plan for Corrective and Preventive Actions: whether the Laboratory's plan for corrective and preventive actions is adequate to rectify and minimize the risk of recurrence of the nonconformity (see also Article 3.5).

f) Submission of Corrective Action Report

Following approval of the Laboratory's RCA and corrective actions plan by the Lab EAG, the Laboratory shall provide *WADA* with a CAR including evidence of implementation of the corrective actions plan within five (5) days, or within a timeline otherwise determined by *WADA*.

g) Satisfactory and Timely Corrective Action Report

If the Laboratory can remedy the issue(s) that led to the reporting of the False Negative Finding, through the implementation of satisfactory corrective action(s) (as per Article 3.5) and within the timelines established in this Article 3.3, as determined by the Lab EAG, five (5) points initially imposed shall be deducted, in accordance with the Points Scale Table. Consequently, the Laboratory shall be informed by *WADA*, in writing, of the final number of points assigned in connection with the reporting of the False Negative Finding [10].

h) Unsatisfactory Corrective Action Report

If the Laboratory's CAR is considered unsatisfactory by the Lab EAG, the Laboratory shall be provided with feedback and the opportunity to submit a revised CAR within seven (7) days (unless informed otherwise by *WADA*).

i. If the Laboratory is able to resubmit a satisfactory CAR in a timely manner, as determined by the Lab EAG, the Laboratory shall have five (5) points deducted, in accordance with the Points Scale Table.

ii. If the Laboratory is unable to resubmit a satisfactory revised CAR in a timely manner, as determined by the Lab EAG, an additional five (5) points shall be assigned to the Laboratory in accordance with the Points Scale Table.

iii. Additional Analyses

- *WADA* shall request the Laboratory to analyze additional (blind and/or double-blind) EQAS sample(s) (at the Laboratory's expense). Depending on the root cause(s) of the False Negative Finding, this additional analysis may be limited to one Analyte, a class of *Prohibited Substances* or *Prohibited Methods*, or may include any *Prohibited Substance* or *Prohibited Method*.
- The Laboratory shall report correct results for the analysis of all EQAS samples. In addition, the Laboratory shall implement satisfactory corrective action(s) (as determined by the Lab EAG), which ensures that the cause(s) of the nonconformity is rectified, thus avoiding repetition of the mistake in the future.
- Failure by the Laboratory to report correct results for the additional EQAS sample(s) or to implement satisfactory corrective action(s) shall incur the assignment of additional points to the Laboratory in accordance with the Points Scale Table.

iv. The Lab EAG, considering the root cause(s) of the False Negative Finding, may make a recommendation to the Chair of the *WADA* Executive Committee to impose an ATR against the Laboratory or to suspend the Laboratory's *WADA* accreditation, as applicable.

3.3.2 False Negative Finding during a Major *Event* (see also ISL Article 7.7 [1])

a) The Laboratory shall be required to investigate the root cause(s) and apply corrective action(s) within forty-eight (48) hours of notification of the False Negative Finding, unless otherwise agreed in writing.

b) The Laboratory shall reanalyze an appropriate number of stored *Samples* (as determined by *WADA*) that were reported as a Negative Finding based on the application of the ATP(s) for which the noncompliance occurred [8, 9].

c) Satisfactory and Timely CAR: Resumption of Analytical *Testing*

If the Laboratory can remedy the nonconformity through the implementation of satisfactory and timely corrective actions (as per Article 3.5), the Laboratory shall be notified by *WADA*, and no further action shall be required.

d) Unsatisfactory Corrective Action Report

i. If the Laboratory is unable to submit a satisfactory CAR in a timely manner, as determined by *WADA*, the Lab EAG shall make a recommendation to the Chair of the *WADA* Executive Committee to impose an ATR against the Laboratory for a particular ATP or for the analysis of a particular class of *Prohibited Substances* or *Prohibited Methods*, as applicable.

ii. The Laboratory shall inform the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) of *WADA*'s decision.

iii. Affected ATP(s) shall be subcontracted, in consultation with the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*), to other Laboratory(-ies).

3.4 Reporting EQAS Results

3.4.1 Reporting Blind EQAS Results

The results of the blind EQAS shall be submitted to *WADA* on or before the specified reporting date unless an extension is requested by the Laboratory and granted by *WADA* for valid reasons.

a) A Laboratory failing to report results of blind EQAS samples by the established deadline, without prior approval by *WADA* or without justified grounds, as determined by *WADA*, shall be assigned two (2) points.

b) An additional two (2) points shall be assigned for reporting eight (8) to fourteen (14) days beyond the applicable deadline (refer to the Points Scale Table in Article 3.8).

c) A Laboratory failing to report blind EQAS results within fifteen (15) days beyond the *WADA*-established or *WADA*-approved deadline (based on valid justification, as determined by *WADA*) shall result in the evaluation of the corresponding EQAS sample(s) as False Negative Finding(s) (for those findings produced by different and unrelated root causes) and the assignment of points in accordance with the Points Scale Table in Article 3.8. In such cases, no points shall be accumulated for late reporting, in addition to those assigned for the False Negative Finding(s).

3.4.2 Reporting Double-Blind EQAS Results

a) The deadline for reporting double-blind EQAS results by the Laboratory is twenty (20) days [13] from receipt of the double-blind EQAS sample(s), unless any of the following conditions is met:

i. An extension has been agreed with the TA after the Laboratory has provided the TA with a valid reason for the delay in the reporting of the results (see also ISL Article 5.2.6.4 [1]).

[Comment to Article 3.4.2 a): Any agreed extension to the reporting deadline for the double-blind EQAS samples should not surpass forty-five (45) days from the date of reception of the double-blind EQAS samples by the Laboratory, unless otherwise approved by WADA upon confidential consultation with the TA.]

ii. A postponement has been established or approved by *WADA* based on justified grounds (*e.g.* double-blind EQAS samples for which a second opinion may be required before reporting an *AAF*; the double-blind EQAS round coincides with national statutory holidays).

iii. The Laboratory is unable to perform the analysis due to a temporary analytical incapacity (*e.g.*, instrument breakdown, need for method revalidation). In this case, the Laboratory shall inform the TA and *WADA* (if applicable).

b) A Laboratory failing to report double-blind EQAS results within twenty (20) days of receipt of the EQAS samples (or twenty (25) days, if GC/C/IRMS analysis has been requested [13]) shall be assigned two (2) points if any of the following conditions is met:

i. The Laboratory did not inform the TA about the delay, or

ii. The Laboratory did not provide a valid reason for the delay (as determined by *WADA*), or

iii. The Laboratory did not inform the TA of further delays beyond the extended reporting deadline that had been accepted by the TA (based on justified grounds).

[13] As per ISL Article 5.3.6.4 [1] if GC/C/IRMS analysis has been requested as part of the initial Analytical *Testing* menu, the "A" *Sample* results should be reported in *ADAMS* within twenty-five (25) days of *Sample* receipt.

c) The failure by a Laboratory to report the EQAS results within fifteen (15) days beyond the reporting deadline [13], or otherwise within fifteen (15) days beyond the TA-agreed deadline, as applicable, shall result in the evaluation of the corresponding EQAS sample(s) as False Negative Finding(s) (for those findings produced by different and unrelated root causes) and the assignment of points in accordance with the Points Scale Table in Article 3.8. In such cases, no points shall be accumulated for late reporting, in addition to those assigned for the False Negative Finding(s).

[Comment to Article 3.4.2 c): If the Laboratory determines that it cannot analyze the double-blind EQAS samples and report results within fifteen (15) days after the agreed extended deadline, it shall inform the TA as soon as possible. If the Laboratory cannot report results within a maximum sixty (60) days deadline after reception of the double-blind EQAS samples (for valid reasons, as determined by WADA), and has informed the TA accordingly, the Laboratory shall not be evaluated for the analysis of the affected EQAS sample(s) within the double-blind EQAS round. See also point e) below.]

d) The double-blind EQAS round shall be closed at the earliest of the two (2) following scenarios:

i. When all participating Laboratories have reported their double-blind EQAS results in *ADAMS*, or

ii. Sixty (60) days from the date when the double-blind EQAS sample(s) have been delivered to all participating Laboratories.

e) Reason(s) provided by a Laboratory for not reporting results within sixty (60) days of receipt of the double-blind EQAS samples shall be considered and evaluated by *WADA*:

i. A Laboratory that provides valid reasons, as determined by *WADA*, shall not be evaluated for the analysis of the affected EQAS sample(s). Consequently, *WADA* shall arrange for the delivery of the same number of replacement double-blind EQAS sample(s) to the Laboratory, at the Laboratory's expense, to account for the analysis of the required minimum number of annual double-blind EQAS samples.

ii. A Laboratory that provides reasons that are determined to be not valid by *WADA*, or a Laboratory that has failed to inform the TA about its incapacity to meet the agreed reporting timelines, shall be evaluated as per points b) and c) above.

3.5 Corrective Action Report Evaluation

A CAR shall be considered satisfactory when it meets each of the following criteria, as determined by *WADA*:

a) Comprehensively identifies the root cause(s) of the nonconformity, following an appropriate investigation into all the factors that may have caused the problem (RCA).

b) Leads to the documented implementation of effective corrective action(s) to solve the problem, and

c) Leads to the documented implementation of appropriate preventive actions, if applicable, to minimize the risk of recurrence of the nonconformity.

A satisfactory CAR shall include only the necessary supporting documentation [*e.g.,* raw analytical data, data review files, evidence of procurement of Reference Material(s)], which demonstrates the implemented action(s) described in the CAR. Emphasis is also put on the timely delivery of the CAR within the given timeframe.

3.6 Further Procedural Evaluations [14]

a) If the Lab EAG considers that a CAR is unsatisfactory, and the Laboratory does not provide a satisfactory revised CAR within a reasonable time frame after receiving feedback from the Lab EAG, the Laboratory shall receive two (2) points, as determined by the Lab EAG.

b) CARs related, for example, to nonconformities detected during *WADA* Laboratory Assessments, or to procedural or reporting nonconformities with the ISL, ISL *TDs* or ISL *TLs*, or unsatisfactory performance in the analysis of EQAS samples (not related to a False *AAF* or False Negative Finding), shall be submitted to *WADA* within thirty (30) days of *WADA*'s notification to the Laboratory. Under certain circumstances, this period may be shorter (for matters considered critical for Laboratory operations) or longer (*e.g.*, for remedial actions not necessarily within the hands of the Laboratory, such as building, institutional, or policy changes), as determined by *WADA*.

c) If the Laboratory's CAR is considered unsatisfactory by the Lab EAG, the Laboratory shall be provided with feedback and the opportunity to submit a revised CAR within seven (7) days (unless informed otherwise by *WADA*).

d) Late submission of CARs, as determined by the Lab EAG, shall result in the imposition of one (1) additional point per seven (7) days beyond the applicable deadline, unless the Laboratory provides valid reason(s) for the delay, as determined by the Lab EAG. After five (5) weeks beyond the applicable deadline, in the absence of valid reason(s), the Lab EAG may recommend imposing a sanction to the Laboratory.

[14] Article 3.6 does not apply to the evaluation of CARs for False *AAFs* or False Negative Findings, which are covered in Articles 3.2 and 3.3, respectively.

e) Unless informed otherwise by *WADA*, the corrective and preventive action(s) reported to and approved by *WADA* shall be implemented in the routine operations of the Laboratory immediately.

f) *WADA* reserves the right to send additional (blind or double-blind) EQAS samples and/or perform a Laboratory Assessment to verify the efficacy of implemented corrective and preventive action(s), at any time and at the Laboratory's expense.

3.7 Overall Laboratory Evaluation

WADA shall evaluate Laboratory EQAS performance for each EQAS round, as well as Laboratory performance in routine Analytical *Testing* and assign points for nonconformities or failures to perform as indicated in the Points Scale Table.

a) The accumulation of the maximum allowed number of points for the EQAS and/or routine Analytical *Testing*, as determined in the Points Scale Table below, shall prompt the Lab EAG to make a recommendation to the Chair of the *WADA* Executive Committee to impose an ATR against the Laboratory or to impose a Suspension of the Laboratory's *WADA* accreditation, as applicable.

b) When a Laboratory's *WADA* accreditation is suspended:

i. If a Laboratory under Suspension accumulates the maximum allowed number of points in the EQAS during Suspension:

- If the Laboratory is not capable of correcting the issue(s) before the end of the Suspension period, the Lab EAG shall make a recommendation to the Chair of the *WADA* Executive Committee to extend the Laboratory's Suspension for up to an additional six (6) months.
- If the Laboratory is not capable of correcting the issue(s) before the end of the extended Suspension period, then the Lab EAG shall make a recommendation to the *WADA* Executive Committee to revoke the Laboratory's accreditation.

ii. Any accrued points leading up to the Suspension or further accumulated through the Laboratory's participation in the blind EQAS program during the Suspension period, are reset to zero (0) upon reinstatement of its *WADA* accreditation.

c) When a Laboratory is subject to an Analytical *Testing* Restriction:

i. Laboratories under an ATR remain operational (except for the activity(-ies) under the ATR) and, therefore, are evaluated during the ATR as any other, fully operational Laboratory.

ii. Any points not related to the ATR, which were accumulated up to the imposition of the ATR or further accumulated during the ATR period (within a twelve (12)-month period [3]), are carried over after the lifting of the ATR.

iii. Any points accrued in relation to the ATR are annulled after the lifting of the ATR.

3.8 Points Scale Table for Laboratory and Probationary laboratory Performance

Conditions	Nonconformity	Type of Error	Points	Actions and Sanctions
Routine Analytical *Testing*	**False *AAF* + *Consequence* for the *Athlete*** (Art. 3.2.1)	**Any type of error**	**20**	**Cease affected Analytical *Testing* activities**
		Self-reporting	**- 5**	
		Satisfactory and timely CAR	**- 5**	**Resume Analytical Testing** [15]
		Unsatisfactory CAR	**+ 10**	**ATR / Suspension** [11]
Routine Analytical *Testing* Or **EQAS**	**False *AAF* + No *Consequence* for the *Athlete*** (Art. 3.2.2)	**Technical/Methodological error**	**20**	**Cease affected Analytical *Testing* activities**
		Self-reporting [16]	**- 5**	
		Satisfactory and timely CAR	**- 10**	**Resume Analytical *Testing*** [15]
		Unsatisfactory CAR		
		• Satisfactory revised CAR	**-5**	**Resume Analytical *Testing*** [15]
		• Unsatisfactory revised CAR	**+ 10**	**ATR / Suspension** [11]
		Clerical/Administrative error	**15**	**Cease affected Analytical *Testing* activities**
		Self-reporting [16]	**- 5**	
		Satisfactory and timely CAR	**- 10**	**Resume Analytical *Testing*** [15]
		Unsatisfactory CAR		
		• Satisfactory revised CAR	**- 5**	**Resume Analytical *Testing*** [15]
		• Unsatisfactory revised CAR	**+ 10**	**ATR / Suspension** [11]
Routine Analytical *Testing* Or **EQAS**	**False Negative Finding** (Art. 3.3)	**False Negative Finding**	**10**	**Additional EQAS samples** [17]
		Self-reporting [16]	**- 5**	
		Satisfactory and timely CAR	**- 5**	
		Unsatisfactory CAR		
		• Satisfactory revised CAR	**- 5**	
		• Unsatisfactory revised CAR	**+ 5**	
Routine Analytical *Testing* Or **EQAS**	**Documentation** [18] **or technical Issue**	**ISL, ISL *TD* or ISL *TL* Nonconformity** [19]		
		Unsatisfactory CAR	**2**	**n/a**
		Late Submission of CAR	**1**	

[15] *WADA* reserves the right to send extra EQAS samples or perform an assessment of the Laboratory, at *WADA*'s discretion.

[16] Voluntary self-reporting is not applicable to blind EQAS samples.

[17] The results of the analysis of the additional EQAS samples will be evaluated in accordance with this Points Scale Table.

[18] Documentation includes, but is not limited to, Laboratory Documentation Packages (LDOCs), CARs and Test Reports.

[19] When an ISL / *TD* / *TL* nonconformity leads to the misreporting of a False *AAF* or a False Negative Finding, then points will be assigned in accordance with Articles 3.2 and 3.3, respectively.

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EQAS Evaluation	Result		Points
Urinary *Markers* of the Steroidal Module of the *ABP* |*z*-score| ≥ 3.0 (Occurrences*)	**|*z*-score| ≥ 3.0 and CAR**		
	4-7	Unsatisfactory CAR	**2**
		Satisfactory and timely CAR	1
	8-12	Unsatisfactory CAR	**4**
		Satisfactory and timely CAR	2
	13-18	Unsatisfactory CAR	**6**
		Satisfactory and timely CAR	3
	> 18	Unsatisfactory CAR	**8**
		Satisfactory and timely CAR	4
• **GC/C/IRMS $\delta^{13}C$** (≥ 2 occurrences**) • **Threshold Substances** (per occurrence) • **Blood *Markers* of the Steroidal Module of the *ABP*** (per occurrence) *** • **Blood *Markers* of the Endocrine Module of the *ABP*** (per occurrence) ****	**2.0 < |z-score| < 3.0** Internal Investigation		**0**
	|*z*-score| ≥ 3.0 [20] Unsatisfactory CAR		**5**
	|*z*-score| ≥ 3.0 [20] Satisfactory and timely CAR		**0**
SG determination (per occurrence)	**|*z*-score| ≥ 3.0** Unsatisfactory CAR		**1**
Late reporting of blind [21] **or double-blind** [22] **EQAS results**	Late reporting Late reporting >15 days beyond the deadline		**2** **False Negative Finding**

Evaluation	Points	Sanction
Point Total for single EQAS round (blind or double-blind ***)**	**≥ 20**	**ATR** **Or** **Suspension** [11]
Point Total for double-blind EQAS *** for 12-month period** [3]		
Point Total for routine Analytical *Testing* *** for 12-month period** [3]		
Point Total (blind and double-blind EQAS and routine Analytical *Testing* ***) for 12-month period** [3]	**≥ 30**	

* Based on a total of six (6) determinations per urine EQAS sample: Androsterone (A), Etiocholanolone (Etio), Testosterone (T), Epitestosterone (E), 5α-androstane-3α,17β-diol (5αAdiol) and 5β-androstane-3α,17β-diol (5βAdiol).

** Per EQAS sample subjected to GC/C/IRMS analysis.

*** Based on a total of two (2) determinations per blood EQAS sample: Testosterone (T) and Androstenedione (A4).

**** Based on a total of two (2) determinations per blood EQAS sample: Insulin-like Growth Factor I (IGF-I) and N-terminal pro-peptide of type III collagen (P-III-NP).

***** Candidate laboratories and Probationary laboratories are exempt from the double-blind EQAS program and routine Analytical *Testing*.

[20] When an unsatisfactory (|*z*-score| ≥ 3.0) quantification result leads to the misreporting of the EQAS sample as a False *AAF* or as a False Negative Finding, then points will be assigned in accordance with Articles 3.2 and 3.3, respectively.

[21] See Article 3.4.1

[22] See Article 3.4.2

4.0 Evaluation of Candidate laboratory Performance

The Pre-Probationary Test (PPT) is a part of *WADA*'s evaluation of a Candidate laboratory to enter the probationary phase of *WADA* accreditation. Successful participation in the PPT EQAS [23] and satisfactory outcomes of *WADA*'s laboratory on-site assessment are required before a Candidate laboratory becomes eligible to continue into the subsequent, probationary phase of *WADA* accreditation.

Once a Candidate laboratory satisfactorily addresses any PPT EQAS performance issues and any nonconformities identified during the *WADA* on-site assessment and is granted access to the probationary phase of *WADA* accreditation, the points accumulated during the PPT are annulled and are not carried forward into the probationary phase.

4.1. False *Adverse Analytical Finding*

A Candidate laboratory shall automatically fail the PPT if a False *AAF* (technical/methodological or clerical/administrative error) is reported in the PPT EQAS.

a) *WADA* shall inform the Candidate laboratory of a False *AAF* reported in the PPT EQAS as soon as possible.

b) The Candidate laboratory shall implement and report to *WADA* satisfactory corrective and preventive action(s), as determined by the Lab EAG, within thirty (30) days of *WADA*'s request (unless informed otherwise by *WADA*). The CAR, if approved by *WADA*, shall be implemented in the operations of the Candidate laboratory as soon as possible.

c) The Candidate laboratory shall only be eligible for re-instatement into the *WADA* accreditation process upon providing documentation to *WADA* that appropriate corrective and preventive action(s) have been implemented, as determined by the Lab EAG, to satisfactorily address the issue and prevent recurrence in the future.

d) *WADA* may decide to send an additional set of PPT EQAS samples and/or perform a further assessment (virtual or on-site) of the Candidate laboratory, at the Candidate laboratory's expense, prior to considering whether the Candidate laboratory may continue in the *WADA* accreditation process.

e) Failure by the Candidate laboratory to implement satisfactory corrective action(s) within a reasonable timeframe, as determined by the Lab EAG, shall lead to the Revocation of the Candidate laboratory status.

[23] In contrast to the EQAS for Laboratories and Probationary laboratories in the latest stages of the probationary period, EQAS sample composition for the PPT only includes those *Prohibited Substances* and *Prohibited Methods* that are to be analyzed with those ATPs that are determined by *WADA* to be mandatory for a laboratory at this early stage of the accreditation process (for example, not including analyses such a human growth hormone (hGH), Erythropoietin Receptor Agonists (ERAs), or GC/C/IRMS).

4.2. False Negative Finding

a) *WADA* shall inform the Candidate laboratory of a False Negative Finding reported in the PPT EQAS as soon as possible.

b) Reporting of a False Negative Finding by a Candidate laboratory in the PPT EQAS is not necessarily evaluated as failing the PPT (unless the Candidate laboratory accumulates twenty (20) or more points for the PPT EQAS round due to multiple independent occurrences). However, the Candidate laboratory shall implement and report to *WADA* satisfactory corrective and preventive action(s), as determined by the Lab EAG, within thirty (30) days of *WADA*'s request (unless informed otherwise by *WADA*). The CAR, if approved by *WADA*, shall be implemented in the operations of the Candidate laboratory as soon as possible.

c) *WADA* may decide to send an additional set of PPT EQAS samples and/or perform a further assessment (virtual or presential) of the Candidate laboratory, at the Candidate laboratory's expense, prior to considering whether the Candidate laboratory may continue in the *WADA* accreditation process.

d) Failure by the Candidate laboratory to implement satisfactory corrective actions (as per Article 3.5) within a reasonable timeframe, as determined by the Lab EAG, may lead to the Revocation of the Candidate laboratory status.

4.3. Overall Candidate laboratory Evaluation

WADA shall evaluate a Candidate laboratory's PPT EQAS performance and assign points for each noncompliance or failure to perform in accordance with the Points Scale Table, except for the criteria applied to double-blind EQAS and routine Analytical *Testing* evaluation, which are not applicable to Candidate laboratories.

5.0 Evaluation of Probationary laboratory Performance

Probationary laboratories participate in the regular blind EQAS for Laboratories, and their EQAS performance is assessed, similarly to Laboratories, in accordance with the Points Scale Table (see also ISL *TD* EQAS). In addition, *WADA* distributes blind EQAS samples to Probationary laboratories as part of the Final Accreditation Test (FAT). Composition of the probationary EQAS and FAT EQAS samples follows the criteria described in the ISL *TD* EQAS [24].

WADA may also provide, upon request and at the expense of the Probationary laboratory, samples from past EQAS rounds to allow the Probationary laboratory an opportunity to evaluate its performance against the recorded performance of Laboratories.

[24] However, Probationary laboratories are not evaluated for their performance of some specific ATPs (for example, hGH, ERAs, or GC/C/IRMS) until the latest stages of the probationary EQAS and/or during the FAT EQAS.

5.1. False *Adverse Analytical Finding*

WADA shall inform the Probationary laboratory of any False *AAF* reported in a probationary EQAS round or FAT EQAS as soon as possible.

5.1.1 False *Adverse Analytical Finding* during a Probationary EQAS Round

a) The reporting of any False *AAF* (technical/methodological or clerical/administrative error) by a Probationary laboratory during a probationary EQAS round shall be considered as a failed EQAS round participation.

b) A probationary EQAS round failure shall result in the extension of the probationary phase by at least one (1) additional EQAS round before the Probationary laboratory becomes eligible to undergo the FAT.

c) The Probationary laboratory shall implement and report to *WADA* satisfactory corrective and preventive action(s), as determined by the Lab EAG, within thirty (30) days of *WADA*'s request (unless informed otherwise by *WADA*). The CAR, if approved by *WADA*, shall be implemented in the operations of the Probationary laboratory as soon as possible.

d) The Probationary laboratory shall only be eligible to continue its participation in the *WADA* probationary EQAS upon providing documentation to *WADA* that appropriate corrective and preventive action(s) have been implemented, as determined by the Lab EAG, to satisfactorily address this issue and prevent recurrence in the future.

e) *WADA* may decide to send additional EQAS samples and/or perform a mid-probationary assessment (virtual or presential) of the Probationary laboratory, at the Probationary laboratory's expense, prior to considering whether the Probationary laboratory may continue in the *WADA* accreditation process.

f) Failure by the Probationary laboratory to implement satisfactory corrective actions within a reasonable timeframe, as determined by the Lab EAG, shall lead to the Revocation of its Probationary laboratory status.

5.1.2 False *Adverse Analytical Finding* during the Final Accreditation Test EQAS

a) A Probationary laboratory shall automatically fail the FAT if a False *AAF* (technical/methodological or clerical/administrative error) is reported in the FAT EQAS.

b) The Probationary laboratory shall implement and report to *WADA* satisfactory corrective and preventive action(s), as determined by the Lab EAG, within thirty (30) days of *WADA*'s request (unless informed otherwise by *WADA*). The CAR, if approved by *WADA*, shall be implemented in the operations of the Probationary laboratory as soon as possible.

c) The Probationary laboratory shall only be eligible for *WADA* accreditation:

i. Upon providing documentation to *WADA* that appropriate corrective and preventive action(s) have been implemented, as determined by the Lab EAG, to satisfactorily address this issue and prevent recurrence in the future.

ii. The laboratory participates in an additional probationary EQAS round with satisfactory results.

d) *WADA* may decide to send an additional set of FAT EQAS samples and/or perform a further assessment (virtual or presential) of the Probationary laboratory, at the Probationary laboratory's expense, prior to considering whether the Probationary laboratory may be granted *WADA* accreditation.

e) Failure by the Probationary laboratory to implement satisfactory corrective actions (as per Article 3.5) within a reasonable timeframe, as determined by the Lab EAG, shall lead to the Revocation of the Probationary laboratory status.

5.2. False Negative Finding

a) *WADA* shall inform the Probationary laboratory of any False Negative Finding reported in a probationary EQAS round or the FAT EQAS as soon as possible.

b) Reporting of a False Negative Finding by a Probationary laboratory in a probationary EQAS round or the FAT EQAS is not necessarily evaluated as failing the EQAS (unless the Probationary laboratory accumulates twenty (20) or more points for the EQAS round). However, the Probationary laboratory shall implement and report to *WADA* satisfactory corrective and preventive action(s), as determined by the Lab EAG, within thirty (30) days of *WADA*'s request (unless informed otherwise by *WADA*). The CAR, if approved by *WADA*, shall be implemented in the operations of the Probationary laboratory as soon as possible.

c) If the Probationary laboratory reports a False Negative Finding during the FAT EQAS, *WADA* may decide to send an additional set of FAT EQAS samples and/or perform a further assessment (virtual or presential) of the Probationary laboratory, at the Probationary laboratory's expense, prior to considering whether the Probationary laboratory may be granted *WADA* accreditation.

d) Failure by the Probationary laboratory to implement satisfactory corrective actions (as per Article 3.5) within a reasonable timeframe, as determined by the Lab EAG, may lead to the Revocation of its Probationary laboratory status.

5.3. Reporting Blind EQAS Results

The results of the blind EQAS shall be submitted to *WADA* on or before the specified reporting date unless an extension is granted by *WADA* for valid reason(s).

a) A Probationary laboratory failing to report results of blind EQAS samples by the established deadline, without prior approval by *WADA* or without justified grounds, as determined by *WADA*, shall receive two (2) points, and an additional two (2) points for reporting eight (8) to fourteen (14) days beyond the applicable deadline (refer to the Points Scale Table in Article 3.8).

b) A Probationary laboratory failing to report blind EQAS results within fifteen (15) days beyond the *WADA*-established or *WADA*-approved deadline (based on valid justification, as determined by *WADA*) shall result in the evaluation of the corresponding EQAS sample(s) as False Negative Finding(s) (for those findings produced by different and unrelated root causes) and the assignment of points in accordance with the Points Scale Table in Article 3.8. In such cases, no points shall be accumulated for late reporting, in addition to those assigned for the False Negative Finding(s).

5.4. Overall Probationary laboratory Evaluation

a) Successful participation in the probationary EQAS, as well as in the FAT EQAS and associated *WADA* on-site laboratory assessment, are required before a Probationary laboratory is eligible to be considered for *WADA* accreditation.

b) At *WADA*'s discretion, the FAT EQAS and on-site assessment may be conducted separately or at the same time.

c) Once a Probationary laboratory is granted *WADA* accreditation, points accumulated during the probationary period are annulled and are not carried forward onto the accredited phase.

d) A laboratory failing the probationary phase of accreditation shall be considered, at the laboratory's request, as a Candidate laboratory. The laboratory shall be required to repay the initial accreditation fee to *WADA* (see ISL Article 4.1.2.1 [1]) and retake the PPT, at the laboratory's expense, to re-enter the probationary phase (see ISL Article 4.1.2.7 [1]).

5.4.1 Participation in the Probationary EQAS

a) *WADA* shall evaluate the Probationary laboratory's EQAS performance for each probationary EQAS round and assign points for each noncompliance or failure to perform in accordance with the Points Scale Table, except for the criteria applied to double-blind EQAS and routine Analytical *Testing* evaluation, which are not applicable to Probationary laboratories.

b) Any Suspension period of a Probationary laboratory's participation in the probationary EQAS shall be determined by *WADA*.

c) *WADA* may decide to extend the probationary period of accreditation based on its evaluation of the overall performance of the Probationary laboratory in the probationary EQAS, even if the Probationary laboratory has not reached the maximum number of points based on the Points Scale Table.

d) Serious and repeated issues in the probationary EQAS shall result in the Revocation of the laboratory's status as a Probationary laboratory.

e) Successful participation in the *WADA* probationary EQAS for at least three (3) rounds is required before the Probationary laboratory can proceed to the FAT.

5.4.2 Participation in the Final Accreditation Test

a) Successful participation in the FAT EQAS and associated *WADA* on-site laboratory assessment, are required before a Probationary laboratory is eligible to be considered for *WADA* accreditation.

b) *WADA* may decide to extend the probationary period of accreditation based on its evaluation of the overall performance of the Probationary laboratory in the FAT, even if the Probationary laboratory did not reach the maximum number of points based on the Points Scale Table.

6.0 Laboratory Performance Evaluation in *WADA* Laboratory Assessments

WADA Laboratory Assessments are conducted in relation to Laboratory Accreditation or *ABP* Approval procedures and as part of *WADA*'s regular Laboratory or *ABP* Laboratory monitoring activities (see ISL Article 6.1.2 [1]).

WADA Laboratory Assessments may also be performed if nonconformities identified during routine operations carry the potential risk of a *WADA* Laboratory Accreditation withdrawal (ATR or Suspension) or *ABP* Laboratory Suspension, as determined by the Lab EAG. Such Assessment shall be conducted, at the Laboratory's expense, with the aim of determining whether the identified nonconformity(-ies) have been addressed satisfactorily by the Laboratory (as determined by *WADA*) and to evaluate Laboratory operations in compliance with the ISL, and applicable ISL *TD*s and ISL *TL*s.

a) Nonconformities identified in a *WADA* Assessment shall be addressed by the Laboratory and evaluated by the Lab EAG.

b) CARs related to nonconformities detected during *WADA* assessments shall be submitted to *WADA* within thirty (30) days of *WADA*'s release of the Assessment Report to the Laboratory. Under certain circumstances, this period may be shorter (for matters considered critical for Laboratory operations) or longer (*e.g.*, for remedial actions not necessarily within the hands of the Laboratory, such as building, institutional, or policy changes), as determined by *WADA*.

c) The non-resolution of nonconformities identified in a *WADA* Laboratory Assessment in a satisfactory and timely manner, as determined by *WADA*, may result in a Lab EAG's recommendation to the Chair

of the *WADA* Executive Committee to impose an ATR or the Suspension of the Laboratory, or to suspend the approval of the *ABP* Laboratory, as applicable. In grave circumstances (see ISL Article 7.1.2 [1]), or upon repeated failures in the EQAS or during routine Analytical *Testing* in addition to continuous unresolved nonconformities after the conduct of a *WADA* Laboratory Assessment, the Lab EAG may recommend to the *WADA* Executive Committee to revoke the accreditation of the Laboratory or the approval of the *ABP* Laboratory, as applicable.

7.0 Evaluation of Laboratory Performance in *WADA* EQAS for the *Markers* of the Hematological Module of the *Athlete Biological Passport*

WADA shall assess the performance of Laboratories and *ABP* Laboratories for the analysis of the *Markers* of the Hematological Module of the *ABP.* Satisfactory EQAS performance over a consecutive twelve (12)-month period [3] is necessary for maintaining *WADA* accreditation or approval for this analysis.

a) The Laboratory shall achieve a satisfactory statistical evaluation of their reported results. Nonconforming results shall be evaluated as described below.

   i. Nonconforming results in two (2) EQAS rounds in the most recent twelve (12)-months [3] for each of the following *Markers*:

      - Reticulocytes Percentage (RET%).
      - Haemoglobin (HGB).

   ii. Nonconforming results in three (3) EQAS rounds in the most recent twelve (12)-months [3] for each of the following *Markers*:

      - Red Blood Cell (Erythrocyte) Count (RBC).
      - Mean Corpuscular Volume (MCV).
      - Haematocrit (HCT).
      - Mean Corpuscular Haemoglobin (MCH).
      - Mean Corpuscular Haemoglobin Concentration (MCHC).
      - White Blood Cell (Leukocyte) Count (WBC).
      - Platelet (Thrombocyte) Count (PLT).

b) A Laboratory with unsatisfactory results (as per the criteria above) shall provide *WADA* with a CAR within fifteen (15) days of receiving a written notification about the unsatisfactory result(s) from *WADA*.

   i. The Laboratory shall verify its performance through a statistical evaluation of the relevant reported results for the analysis of the manufacturer's internal quality controls (QCs) to assess systematic or random errors (related to those *Markers* with nonconforming results in the EQAS).

   ii. The non-resolution of the identified nonconformities which are demonstrated to be due to Laboratory performance issues (*WADA* EQAS and internal QC results), as determined by *WADA*, may result in a Lab EAG's recommendation to the Chair of the *WADA* Executive Committee to

impose an ATR on the Laboratory for the analysis of the *Markers* of the Hematological Module of the *ABP*, or to suspend the approval of the *ABP* Laboratory, as applicable.

[Comment to Article 7.0 b): Lab EAG recommendations for imposition of an ATR or Suspension of a Laboratory's performance of the analysis of the Markers of the Hematological Module of the ABP are made in consideration of the unresolved nonconformities reported by the Laboratory in the WADA EQAS, irrespective of the total number of points accumulated by the Laboratory during this period.]

iii. Failure to submit a satisfactory CAR or the late submission of the CAR without prior approval by *WADA* shall result in the imposition of points in accordance with the Points Scale Table; however, the points associated with the *WADA* EQAS for the *Markers* of the Hematological Module of the *ABP* are not included in the overall points system of the Points Scale Table.

8.0 Classification of Laboratory Nonconformities

WADA classifies Laboratory nonconformities as major (MC) or minor (mNC), based on their impact on Laboratory operations, and may provide guidance as Recommendations (REC) as defined below:

8.1. Major Nonconformity

A nonconformity caused by a critical failure to comply with a requirement of the ISO/IEC 17025 (or ISO/IEC 15189, if applicable, for an *ABP* Laboratory), the ISL, or its associated ISL *TD*s and ISL *TL*s.

[Comment to Article 8.1: An issue classified as a NC would either i) compromise the Laboratory quality management system, ii) jeopardize or has the potential to jeopardize the reliability of the analytical results (whether the issue is random or systemic), iii) represent a threat to the credibility of the anti-doping system, iv) infringe the ISL Code of Ethics or v) derive from a repeated failure to effectively resolve a previous NC or mNC. A response is required to address NCs by issuing a CAR that includes a RCA, action(s) taken, and supporting documentation. A NC shall lead to consequences imposed on the Laboratory if not resolved satisfactorily or in a timely manner.]

8.2. Minor Nonconformity

A non-critical nonconformity caused by the insufficient fulfillment of a requirement of the ISO/IEC 17025 (or ISO 15189, if applicable for an *ABP* Laboratory), the ISL, or its associated ISL *TD*s and ISL *TL*s.

[Comment to Article 8.2: An issue classified as a mNC is i) determined as random or infrequent, or ii) not directly or immediately impactful on the quality of the Laboratory's performance and results or the credibility of the anti-doping system. A response is required to address mNCs by issuing an Action Report. Supporting documentation may be required (at the discretion of assessor/WADA). An RCA shall not be required; however, the Laboratory may decide to open its own internal CAR procedure to manage the mNC. A repeated failure to satisfactorily resolve an mNC in a timely manner shall be treated as a NC.]

8.3. Recommendation

Observations provided as opportunities for improvement and guidance for best practice aiming to improve documents and/or operations and to prevent failures to meet requirements.

[Comment to Article 8.3: This category also includes deviations from guidance provided in Technical Notes (TNs). A response is requested to determine whether the recommendation was accepted and implemented by the Laboratory.]

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9.0 References

[1] *WADA International Standard* for Laboratories (ISL) 2027.

[2] *WADA Technical Document* ISL *TD* ATP: Analytical *Testing* Procedures.

[3] ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories.

[4] *WADA Technical Document* ISL *TD* MRPL: Minimum Required Performance Levels for Non-Threshold Substances.

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

[6] *WADA Technical Document* ISL *TD MRL*: *Minimum Reporting Levels* Applied in *Doping Control*.

[7] *WADA Technical Document* ISL *TD DL*: *Decision Limits* for the Confirmatory Quantification of Exogenous Threshold Substances.

[8] *WADA Technical Document* ISL *TD* VAL: Minimum Requirements for Validation of Analytical *Testing* Procedures for *Doping Control.*

[9] The World Anti-Doping *Code* 2027.

[Current versions of WADA's ISL and Technical Documents may be found at https://www.wada-ama.org/en/what-we-do/international-standards]