World Anti-Doping Agency External Quality Assessment Scheme (EQAS) for WADA Anti-Doping Laboratories

1.0 Overview of Organization

World-Anti-Doping Agency (WADA)'s mission is to lead a collaborative worldwide movement for doping-free sport.

WADA was established in 1999 as an international independent agency composed and funded equally by the sport movement and governments of the world. Its key activities include the harmonization of anti-doping rules worldwide, the promotion and support of anti-doping scientific research, education, the conduct of investigations and intelligence gathering, the development of global anti-doping capacities, the accreditation or approval of anti-doping laboratories, and the monitoring of compliance with the World Anti-Doping Code (Code) – the document harmonizing anti-doping policies in all sports and all countries.

The Agency's executive (Executive Committee) and governing bodies (Foundation Board) consist of equal representatives from the Olympic Movement and public authorities.

WADA has established its headquarters in Montreal, Canada, with regional offices located in Lausanne (Switzerland), Tokyo (Japan), Cape Town (South Africa), and Montevideo (Uruguay).

Additional information on WADA can be found at www.wada-ama.org.

2.0 Key Priorities

One of WADA's main tasks is to coordinate a comprehensive anti-doping program at the international level using the highest quality standards for doping control. Therefore, the coordination of an effective laboratory accreditation system worldwide, including the implementation of an ongoing worldwide laboratory Proficiency Testing Program (PTP) through its External Quality Assessment Scheme (EQAS), constitutes an important priority for WADA. This is of particular importance for an effective worldwide anti-doping testing of athletes. The WADA EQAS program, including its Management System, is compliant with the ISO/IEC 17043:2023 (Conformity assessment — General Requirements for the Competence of Proficiency Testing Providers) [1].

3.0 Request for Tender

WADA, as a Proficiency Testing provider, invites tenders ("Tenders") to this Request for Tenders ("RFT") from service providers ("Tenderers") to enter into a contractual agreement to serve as a Proficiency Testing Sample Provider, for the purpose of preparation, characterization, packaging and distribution of biological samples* to WADA anti-doping laboratories worldwide as part of the WADA EQAS. For consideration, the characterization analysis of these samples must be conducted employing analytical procedures in strict accordance with ISO/IEC 17025:2017 (General Requirements for the Competence of Testing and Calibration Laboratories) [2] requirements.

4.0 WADA Proficiency Testing Program

The WADA EQAS is a comprehensive program that includes three (3) types of EQAS¹:

- Regular Blind EQAS: consists of at least ten (10) EQAS samples distributed over at least two

 rounds annually to each anti-doping laboratory with approximately 30-35 laboratories worldwide (including WADA-accredited laboratories as well as laboratories in the probationary phase of WADA accreditation). Please refer to WADA's website for the list of WADA-accredited laboratories.
- Double-Blind EQAS: consists of at least six (6) EQAS samples distributed over at least two (2) rounds annually to Anti-Doping Organizations (ADOs), selected by WADA, for shipment to each WADA-accredited laboratory ² (probationary-phase laboratories do not receive double-blind EQAS samples).
- 3. <u>Educational EQAS</u>: consists of at least two (2) samples annually. The participating laboratories may vary according to the specific purposes of the EQAS round (*e.g.*, for evaluation of Laboratory performance of non-mandatory Analytical Methods and/or analysis of non-mandatory matrices).

The WADA EQAS Samples may be constituted of:

- a) Blank samples, which are samples (urine, blood or Dried Blood Spot (DBS) matrix) confirmed to be free of any Prohibited Substance or Prohibited Method (according to the effective version of the WADA Prohibited List).
- b) Samples that are deliberately adulterated (for example, but not limited to, by the addition of Non-Prohibited Substances that may share common Metabolite(s) with Prohibited Substances or which may affect the interpretation of analytical results confounding factors).
- c) Samples containing one or more Analytes (parent compounds, Metabolites, Markers or degradation products) of Prohibited Substances or Prohibited Methods, which are representative of doping practices.

Key features of an effective laboratory PTP are that it delivers, within established timelines, fit-forpurpose homogeneous and stable biological samples containing well-defined concentrations of Analytes of Prohibited Substances or Prohibited Methods. Satisfactory laboratory performance in the WADA EQAS is key to obtaining and maintaining WADA accreditation by anti-doping laboratories. This PTP is also a critical element in the harmonization of analytical procedures between the anti-doping laboratories.

Listed below are the main features and responsibilities for the PTP:

Additional EQAS samples may be distributed to anti-doping laboratories on an Ad-hoc basis related to WADA accreditation procedures or laboratory monitoring activities.

² The WADA-accredited laboratory shall be operational for receiving double-blind EQAS samples, *i.e.*, the Laboratory shall not be under Suspension nor subject to an Analytical Testing Restriction (ATR).

4.1 WADA will:

4.1.1 Decide upon the nature (content and concentrations) of the Analytes to be contained in the biological samples among a pre-established list of substances, which is based on the WADA's Prohibited List.

Provide the EQAS Sample Provider (successful Tenderer) with detailed information related to when, where, and to whom EQAS samples shall be delivered including a list of the participating laboratories (for blind and educational EQAS) and participating ADOs (for double-blind EQAS) and their shipping addresses.

- 4.1.2 Inform the EQAS Sample Provider, in advance, of the timelines for preparation and distribution of the EQAS sample sets and their labeling format.
- 4.1.3 Provide scientific support to the EQAS Sample Provider to:
 - a) Prepare EQAS samples,
 - b) Establish validated, fit-for-purpose test methods for the evaluation of the EQAS samples in compliance with ISO/IEC 17025:2017 [2] requirements,
 - c) Determine the criteria for sample suitability,
 - d) Be properly informed of fit-for-purpose storage conditions, and
 - e) Improve the EQAS program.
- 4.1.4 Establish connections between the successful Tenderer and doping control laboratories and any other relevant facilities to support the preparation and/or evaluation of EQAS samples (e.g., to facilitate testing of blank samples to determine whether they are fit-for-purpose or to conduct other specialized testing, such as Gas Chromatography/Combustion/Isotope Ratio Mass Spectrometry (GC/C/IRMS) to characterize an EQAS sample before its release in the EQAS).
- 4.1.5 Provide support through the sharing of knowledge with the EQAS Sample Provider for maintaining compliance with the relevant technical requirements of ISO/IEC 17043:2023 [1] that apply to the WADA EQAS activities that are subcontracted.
- 4.1.6 Conduct in person and/or remote audits of activities, documentation and services of the Sample Provider related to the Agreement in order to assess the Sample Provider's compliance with all EQAS procedures accredited under ISO/IEC 17025:2017 [2], as well as with the relevant technical requirements of ISO/IEC 17043:2023 [1] that apply to the WADA EQAS activities that are subcontracted. 3
- 4.1.7 Evaluate the EQAS Participants' performance, including the communication of EQAS results and preparation of related reports.

WADA, as the Proficiency Testing Provider, is responsible for the externally provided products and services for the WADA EQAS, as stipulated in ISO/IEC 17043:2023 Art.6.4.6. In addition, it is WADA's responsibility, in accordance with ISO/IEC 17043:2023 Art. 6.4.2, to ensure that providers of external products and services comply with the relevant clauses of the standard. Therefore, WADA will conduct surveillance assessments of externally provided services for the WADA EQAS in accordance with ISO/IEC 17043:2023 Art. 7.5.3.

5.0 Tenderer Qualifications and Requirements

- 5.1.1 Be ISO/IEC 17025:2017 [2] accredited or equivalent for the analytical methods applied to the characterization of EQAS samples, including the determination of sample homogeneity and stability in accordance with WADA-established protocols and criteria of acceptance. 4
- 5.1.2 Be compliant with relevant technical requirements of ISO/IEC 17043:2023 [1] that are applicable to the subcontracted EQAS activities (e.g., production, characterization, handling, storage, packaging, labelling, and distribution of WADA EQAS samples).
- 5.1.3 Ensure that appropriate measures are implemented to minimize the risk of samples transmitting communicable diseases (*e.g.* hepatitis, HIV, SARS-Cov-2, etc).
- 5.1.4 Be able to prepare and characterize EQAS samples in at least one (1) of the following three (3) matrices (urine, blood ⁵, or DBS).
- 5.1.5 Maintain the capability to perform administration studies in human subjects to collect post-administration samples representative of the metabolic profile(s) of Prohibited Substances.
- 5.1.6 Be able to prepare and characterize different types of samples, at WADA's direction:
 - a) Blank (for all prohibited substances and prohibited methods) samples;
 - b) Samples "spiked" with synthetic compounds or metabolite(s) (e.g. glucuronides, sulfates) normally found in anti-doping testing.
 - c) Samples collected after controlled administration studies of relevant substances or after using relevant prohibited methods in human subjects.

EQAS samples should be, as much as possible, representative of athlete samples regularly tested by the anti-doping Laboratories. WADA will communicate to the Sample Provider which target analytes shall be present in each EQAS sample, and their expected concentrations and corresponding acceptable target concentration ranges. In particular, double-blind EQAS samples containing Analytes of Prohibited Substances or Prohibited Method(s) should, to the extent possible (in consideration, for example, of technical or ethical constraints, availability of the pharmaceutical grade substance, etc.) be prepared from controlled administration studies performed in human subjects. However, if this is not possible, then the double-blind EQAS sample(s) may be prepared by spiking expected target analyte(s) in the sample matrix in consideration of the representative metabolic profile(s).

5.1.7 Ensure minimum batch sizes of 90 bottles or DBS collection devices for each EQAS Sample prepared to permit re-testing, if required, and re-use of the samples in the future. Smaller batch sizes could be prepared upon WADA's approval.

For urine samples, the individual samples within a batch for distribution to each laboratory shall contain at least 60 mL per bottle (except for "double-blind" EQAS

⁴ It is desirable that the Tenderer holds ISO/IEC 17034 ^[3] accreditation or equivalent for the EQAS related activities. While this accreditation is not mandatory, possession of ISO/IEC 17034 or equivalent accreditation will be considered favorably during the evaluation process and may be regarded as an added value in the assessment of the tender.

⁵ Including whole blood, plasma and serum.

- samples; 95 mL/bottle). For blood, blood components (e.g. serum or plasma) and DBS samples, the sample volumes will be specified by WADA.
- 5.1.8 Conduct analysis of blank samples before spiking or administration to ensure that the pool is free of unintended Prohibited Substances or of any significant matrix or drug interferences. This activity may be subcontracted in some cases upon WADA's approval.
- 5.1.9 Conduct analysis of fractions collected after administration of a substance to ensure that the fractions contain the relevant target analyte(s) and are not contaminated by the unintended presence of other Prohibited Substances.
 - [Comment to 3.2.6: Fulfillment of provisions 3.2.4 and 3.2.6 will require that the Tenderer has the analytical capacity to test for Prohibited Substances and Prohibited Methods, at least at initial testing procedure level, in accordance with WADA technical requirements for anti-doping laboratories. In the absence of appropriate analytical capacity, this analysis may be subcontracted upon WADA's approval]
- 5.1.10 The successful Tenderer shall follow the criteria established in WADA protocols for Analyte target concentrations and corresponding acceptable concentration ranges for each sample in each EQAS round.
- 5.1.11 Perform homogeneity and stability studies on prepared EQAS samples in compliance with WADA protocols.
 - a) Due to the fact that the WADA anti-doping laboratories may analyze samples using different in-house developed methods, including *e.g.* immunoassays, gel electrophoretic methods, GC-MSⁿ, LC-MSⁿ and HRMS, it is mandatory that the sample be characterized using methods that are fit-for-purpose. In case the EQAS Sample Provider does not have the capability to conduct a specific analysis, it may be subcontracted to WADA-accredited laboratories upon WADA's approval.
 - b) The analytical method(s) used to quantify the concentration of the defined list of Threshold Substances ⁶ may be selected by the successful Tenderer. However, the quantitative procedure shall be validated as fit-for-purpose in compliance with the method performance requirements specified in the applicable WADA Technical Document(s), Technical Letter(s) or Laboratory Guidelines.
 - c) The analytical method(s) used to quantify the concentration of Non-threshold Substances may be selected by the successful Tenderer. However, the procedure shall be validated as fit-for-purpose in consideration of the applicable Minimum Required Performance Level (MRPL) and/or Minimum Reporting Level (MRL) [4].
- 5.1.12 Produce analytical reports, including description of sample preparation protocols and results of homogeneity and stability testing, at least one month prior to sample distribution for WADA's approval.
- 5.1.13 Ensure that samples that will be re-distributed after storage are re-analyzed to ensure proper homogeneity and stability. A report of the re-analysis shall be issued to WADA before sample release.

⁶ A Prohibited Substance for which there is a pre-established threshold and Decision Limit (DL) and which, therefore, requires the quantitative determination of a property value (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by WADA) in excess of the DL for determination of an Adverse Analytical Finding (AAF).

- 5.1.14 Ensure appropriate codification of batches in agreement with WADA.
- 5.1.15 Ensure appropriate labeling of individual sample containers (note: format to be provided by WADA).
- 5.1.16 Ensure appropriate frozen storage capacity to store prepared EQAS samples until release and to store extra EQAS samples for future use (for a period to be determined by WADA).
- 5.1.17 Distribute simultaneously EQAS samples (and associated documentation, if necessary) worldwide to all the laboratories identified by WADA. The successful Tenderer shall be able to distribute samples compliant with global legal requirements in the various host countries of the laboratories.
- 5.1.18 Maintain the capability to rapidly re-analyze EQAS samples upon WADA's request.
- 5.1.19 Provide EQAS sample(s) at least two (2) times a year to a defined list of ADOs in order to include the double-blind EQAS samples in their routine doping control sample collection procedures.
- 5.1.20 If and when requested by WADA, prepare and distribute EQAS samples for educational purposes. Such undertakings shall include the steps defined herein, as applicable.
- 5.1.21 If and when requested by WADA, prepare and distribute additional EQAS samples on an Ad-Hoc basis to selected laboratories seeking WADA accreditation (candidate and probationary laboratories, Major Event laboratories) or as otherwise determined by WADA for laboratory monitoring purposes (e.g., as part of WADA laboratory on-site assessment).
- 5.1.22 Maintain operations continuously except weekends, national holidays, and end-of-year holidays.
- 5.1.23 Demonstrate compliance with the WADA Code of Ethics for laboratories.

6.0 Timeframe for Proficiency Testing Samples

The initiation of this Tender starts with the first set of five (5) blind EQAS samples to be prepared and delivered by the successful Tenderer to each laboratory in January 2027.

- a) For the blind EQAS, starting in 2027, a minimum of of five (5) samples/round will be prepared and delivered to the laboratories over two rounds.
- b) Double-blind samples will consist of a total of at least six (6) samples distributed to ADOs over at least two rounds per year..

7.0 Timeline for Tender

Tenders must be submitted by email to WADA by close of business (17:00h EST, Montreal time), on **16 January 2026** ("Closing Date and Time"). Late Tenders will not be considered.

8.0 Ownership of the Product

In the event a contract is awarded, WADA will own all rights to any and all product(s) associated with this contract.

9.0 Tender Requirements

Tender should be submitted to WADA by interested Tenderers. This shall include:

- 9.1 A description of the service to be provided (including a description of the Tenderer as a company or organization and a copy of their annual report if available).
- 9.2 A summary of relevant experience.
- 9.3 The following cost categories:
 - 9.3.1 WADA asks interested companies to provide details of laboratory costs regarding the proficiency program that meets WADA's requirements.

The contract will be initially established for a period of five (5) years.

Costs should include a breakdown by year for each year of the contract, as follows:

- a) Two (2) sets of five (5) blind samples for 30-35 WADA-accredited and probationary phase laboratories.
- b) Six (6) "double-blind" samples for 30-35 WADA-accredited laboratories, to be delivered through ADOs.
- c) Two (2) educational samples for 30-35 WADA-accredited and probationary phase laboratories.
- 9.3.2 A proposed schedule of payments.
- 9.3.3 Tenders should be submitted in US dollars, including the total amount for 5 years and any anticipated extra costs.
- 9.3.4 Evidence of the service provider's financial and economic standing, including a statement from the Tenderer's financial institution(s) and details of turnover within the service areas covered by this specification for the past three (3) financial years.
- 9.3.5 Evidence that the Tenderer is not bankrupt or in bankruptcy proceedings, has not been convicted of any offences or professional misconduct, and has fulfilled social security and taxation obligations.
- 9.3.6 Details of the service provider's professional indemnity insurance coverage (minimum of 1 million US dollars).
- 9.3.7 The educational and professional qualifications of the service provider's managerial staff dedicated to the Tender.
- 9.3.8 Evidence that the Tenderer is ISO/IEC 17025:2017 [2] accredited or equivalent.
- 9.3.9 If applicable, evidence that the Tenderer is compliant with the ISO/IEC 17043:2023 [1] requirements that apply to the WADA EQAS activities to be subcontracted.

- 9.3.10 Evidence of enrolment, as prescribed in the service provider's country of establishment, in the relevant professional or trade register or provision of the relevant declaration or certificate.
- 9.3.11 A list of references concerning the Tenderer's services.
- 9.3.12 A formal written acceptance of Swiss Law to govern the terms and conditions of the Tenderer's offer.
- 9.3.13 A formal written acceptance of the Arbitration clause as stated under 9.5 hereafter.

10.0 Tender Instructions

Tenders shall be sent in PDF format by email (not fax) by the Closing Date and Time: <u>16 January</u> <u>2026 by 17:00h EST</u> (Montreal time), to the following contact ("Official Contact"), to the attention of Dr. Osquel Barroso, Senior Associate Director Science & Medicine, Laboratories:

e-mail: elizabeth.adams@wada-ama.org

11.0 Evaluation criteria for award of contract

The criteria to be used in making the awards (not necessarily in order of importance) will be:

- 11.1 Overall quality of the offer.
- 11.2 Adequacy of proposed response.
- 11.3 Quality standards of service.

Note: references from other contracting authorities as specified by Tenderer may be sought.

- 11.4 Experience, expertise and quality of staff (status, qualifications, general experience).
- 11.5 The most economically advantageous Tender. WADA shall not, however, be bound to accept the lowest cost Tender.

12.0 Terms and Conditions

- 12.1 WADA undertakes to use its best endeavours to hold confidential, any information provided by Tenderers. Should Tenderer wish that any of the information supplied in their Tender not be disclosed because of its sensitivity, such information should be identified as confidential.
- 12.2 WADA does not bind itself to accept either the lowest cost Tender or any Tender submitted. WADA shall decide at its sole discretion to accept any offer.
- 12.3 Tenderer may revise or withdraw its Tender before the Closing Date and Time by providing written notice to the Official Contact above. Notwithstanding the "Tender Irrevocability" clause below, upon the Closing Date and Time, all Tenders become irrevocable.
- 12.5 Tenders will be open for acceptance and irrevocable for at least 60 days after the Closing Date and Time. Any statements made about the performance and specifications of the

- proposed product or services will be considered to be true and will be incorporated into the final contract with WADA.
- 12.6 WADA may exclude a Tenderer from the Tender process if at any point during the Tender process there is supporting evidence of Tenderer's: bankruptcy, misrepresentations or false declarations, professional misconduct or final judgments in respect to serious offenses, or failure to pay taxes.
- 12.7 The Tenderers must identify any third-party services that are a part of its Tender. WADA reserves the right to approve/disapprove, or recommend other third-party contractors.
- 12.8 By submitting a Tender, the Tenderer confirms that the current or past employment or other interests or relationships of Tenderer (including Tenderer's subcontractors) do not create or lead to any actual, potential or perceived conflict of interest, unfair advantage, bias or reasonable apprehension of bias that would favor the Tenderer (including Tenderer's subcontractors) with respect to the procurement process.
- 12.9 WADA will not be liable for any costs or expenses incurred in the preparation of a Tender.
- 12.10 By submitting a Tender, Tenderer agrees that it will not make claims for and otherwise irrevocably waives any claims whatsoever, whether arising under contract law, tort law or otherwise, for compensation, costs, damages, expenses, losses, and loss of profits, relating to the RFT or with respect to the RFT process, including claims for costs, expenses and loss of profits if no contract is made with Tenderer.
- 12.11 If requested by WADA, Tenderers will make themselves available for any interviews considered necessary during the selection process. WADA also reserves the right to visit and assess the Tenderer's facilities and meet the relevant staff before awarding the contract.
- 12.12 By submitting a Tender, the Tenderer agrees that, if selected, it will enter into a contract with WADA on the same terms and conditions set out in its Tender, together with such other terms and conditions as may be agreed upon and finalized by the Parties (e.g. limitation of liability, security and privacy safeguards, etc.). If a contract cannot be finalized between the Parties within 45 days of notification of the successful Tenderer, WADA may, at its sole discretion at any time, thereafter, terminate discussions with that Tenderer and either terminate the RFT process or commence finalizations of a contract with the next qualified Tenderer.
- 12.13 In addition to any other reservation of rights in this RFT, WADA reserves the right, in its sole discretion to: (a) to reject any or all Tender at any time; (b) modify the terms of the RFT prior to Closing Date and Time; (c) terminate the RFT at any time without award and obtain the services described in the RFT by other means.
- 12.14 All terms and conditions of the Proficiency Testing Tender are governed by Swiss law. Any disputes arising from or related to the Proficiency Testing Tender will be submitted exclusively to the relevant courts in Switzerland and theses courts shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with the Tender or its subject matter.
- 12.15 The Tenderer, if chosen, shall undertake to indemnify WADA against claims and litigation (including legal fees) related to/arising from the quality or distribution of biological samples prepared by the Tenderer.

- 12.16 The Tenderer, if chosen, shall undertake to maintain strict confidentiality on all matters relating to the service being provided to WADA and understands a breach of confidentiality may result in possible legal action against the Tenderer and the immediate cancellation of this Tender.
- 12.17 The Tenderer is responsible for ensuring that all procedures for preparation, handling and shipping of biological material are strictly followed.
- 12.18 The contract, to be signed between WADA and the selected Tenderer, will be initially established for a period of five (5) years with the possibility to prolong the contract by mutual written agreement between WADA and the selected Tenderer.

13.0 Official Contact

From the time this RFT is issued until a service provider is selected, the Tenderer should not communicate with any WADA staff regarding this Tender other than the person listed below ("Official Contact"); unauthorized communication may disqualify the Tenderer from further consideration. Any communication (questions, inquiries, clarifications) from the Tenderer concerning this RFT must be submitted in writing to designated Official Contact. Questions should clearly reference the section and item in question. Questions received after the Closing Date and Time will not be considered.

WADA's point of contact for all matters arising from this RFT shall be:

Elizabeth Adams
Assistant, Science and Medicine Suite 1700, 800 Rue de Square-Victoria
Montreal, QC, H3C 0B4
elizabeth.adams@wada-ama.org

14.0 References

- [1] ISO/IEC 17043:2023 Conformity assessment General Requirements for the Competence of Proficiency Testing Providers.
- [2] ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories.
- [3] ISO 17034:2016 General Requirements for the Competence of Reference Material Producers.
- [4] WADA Technical Document TD2022MRPL Version 1.1 Minimum Required Performance Levels and Applicable Minimum Reporting Levels for Non-Threshold Substances Analyzed by Chromatographic Mass Spectrometric Analytical Methods