

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

1.0 Request for Tender

The World-Anti-Doping Agency (WADA), as a proficiency testing provider, is seeking a tenderer 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 External Quality Assessment Scheme (EQAS).*

** Mainly human urine samples but may have human blood on separate occasions during contract period.*

About WADA

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

The World Anti-Doping Agency (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 scientific research, education, investigations and intelligence, development of anti-doping capacities, and monitoring of compliance with the World Anti-Doping Code (Code) – the document harmonizing anti-doping policies in all sports and all countries.

The Agency consists 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. This is of particular importance for effective worldwide anti-doping testing of athletes. WADA's comprehensive approach involves the development of standards and harmonization of rules; health, medical and research activities; ethics and education; intelligence and investigation; and legal matters.

3.0 WADA Proficiency Testing Program

An important priority for WADA is the coordination of an effective laboratory accreditation system worldwide, including the implementation of an ongoing worldwide proficiency testing program through its EQAS.

The WADA EQAS is a comprehensive program that includes 3 types of EQAS:

- Blind EQAS;
- Double-blind EQAS, and
- Educational EQAS.

The Blind EQAS consists of at least 15 urine samples delivered annually to each anti-doping laboratory (including WADA-accredited laboratories as well as laboratories in the probationary phase of WADA accreditation), including blank samples and samples containing one or more doping substances and/or their metabolites, and/or markers of the use of prohibited substances or prohibited methods. The blind EQAS samples are shipped in fit-for-purpose vials to the participant laboratories as one set of 5 samples per round, with at least 3 rounds per year. The Double-Blind EQAS program consists of at least 5 EQAS samples per accredited laboratory annually (probationary-phase laboratories do not receive double-blind EQAS samples) and the Educational (Open) EQAS program consists of approximately 2 sets of 2-3 samples per laboratory annually.

Key features of an effective laboratory proficiency testing program are that it delivers, within established timelines, fit-for-purpose homogeneous and stable biological samples containing well-defined concentrations of doping substances and/or metabolites and/or markers. Satisfactory laboratory performance in the WADA EQAS is key to the obtaining and maintenance of WADA accreditation by anti-doping laboratories. This proficiency testing program 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 Proficiency Testing program:

3.1 WADA will:

- 3.1.1 Decide upon the nature (content and concentration) of the doping substances or metabolites or markers to be contained in the biological samples among an established list of substances/target analyte(s).
- 3.1.2 Supply the successful tenderer with the list and addresses of participating laboratories (approximately 30-40 laboratories worldwide; please refer to WADA's website).
- 3.1.3 Inform the successful tenderer, in advance, of the timelines for distribution of the sample sets.

- 3.1.4 Supply the successful tenderer with the labeling format for the EQAS samples.
- 3.1.5 Be responsible for receiving, evaluating, and reporting on the EQAS results.
- 3.2 The successful tenderer shall:
- 3.2.1 Be ISO/IEC 17025 accredited or equivalent for the preparation and characterization of EQAS samples, including the determination of sample homogeneity and stability in accordance with WADA-established protocols and criteria of acceptance (INST-206_HOMO/STAB).
- 3.2.2 Prepare three types of samples in accordance with WADA's direction:
1. Blank (for all drug classes) samples (urine, blood or blood component matrix);
 2. Samples (urine, blood or blood component matrix) "spiked" with synthetic compounds or metabolite(s) (e.g. glucuronides, sulfates) normally found in anti-doping testing;
 3. Samples (urine, blood or blood component matrix) collected after controlled administration studies of relevant substances in human subjects.
- The target analytes will be chosen by WADA from the relevant annual version of the List of Prohibited Substances and Methods. Criteria for target concentrations, both for threshold and non-threshold substances, will be specified for each EQAS round according to WADA protocols.
- 3.2.3 Conduct analysis of blank samples before spiking to ensure that the pool is free of unintended prohibited substances or of any significant matrix or drug interferences.
- 3.2.4 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: Fulfillment of provisions 3.2.3 and 3.2.4 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].*
- 3.2.5 Ensure that appropriate measures are implemented to minimize the risk of samples transmitting communicable diseases (e.g. hepatitis, HIV, SARS-Cov-2, etc).
- 3.2.6 Ensure batch sizes of a minimum 90 bottles to permit re-testing, if required, and to use the samples in the future. Smaller batch sizes could be prepared upon WADA's approval.

3.2.7 Arrange for and ensure that the quality control of the samples is performed before EQAS samples are declared fit-for-purpose and shipped to the participants, with the following guidelines:

- i) EQAS samples should be, as much as possible, representative of doping control samples. WADA will communicate to the sample provider which target analytes shall be present in each EQAS sample, and their expected concentrations. In particular, double-blind EQAS samples containing prohibited substance(s) and/or metabolite(s) of prohibited substance(s) and/or marker(s) of prohibited substance(s) 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).
- ii) Due to the fact that the WADA anti-doping laboratories may analyze samples using different in-house developed methods, including e.g. immunoassays, electrophoretic methods, GC/MSⁿ, LC/MSⁿ and HRMS, it is mandatory that the sample be characterized using methods that are fit-for-purpose so that the sample is suitable. The provider shall not subcontract these analyses to any of the WADA-accredited laboratories unless specifically approved by WADA.
- iii) The analytical method(s) used to quantify the concentration of the defined list of threshold substances may be selected by the successful tenderer. However, the procedure shall be validated as fit-for-purpose in compliance with the method characteristics specified in the applicable WADA Technical Document(s), Technical Letter(s) or Laboratory Guidelines. The repeatability of the quantitative procedure shall not be higher than (\leq) 50%* of the corresponding maximum allowed combined standard uncertainty (U_{c_Max}) as detailed in the Technical Document for the decision limits for the confirmatory quantification of threshold substances (TD DL), unless otherwise directed by WADA, and the estimated uncertainty of the method (U_c) shall not be higher than (\leq) the U_{c_Max} .
- iv) 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). The method repeatability shall not be higher than (\leq) 7.5%*.

*These criteria for the repeatability of the measuring procedure are established to ensure that the method's repeatability is sufficiently small to detect any sample inhomogeneity.

- 3.2.8 Samples that will be re-distributed after storage will be re-analyzed for the target substance and the target concentration to ensure proper homogeneity and stability.
- 3.2.9 A report of the re-analysis will be issued to WADA before sample release. Ensure distribution methods of at least 60 mL quantities in appropriate bottles for urine (exception for “double-blind” EQAS; 95 mL) per laboratory. For blood and blood components (e.g. serum or plasma) samples, the sample volumes will be specified by WADA.
- 3.2.10 Ensure labeling of vials (note: format to be provided by WADA).
- 3.2.11 Ensure codification of batches in agreement with WADA.
- 3.2.12 Produce analytical reports, including details of analytical quality control procedures (homogeneity, stability) and qualitative and quantitative (if applicable) results to be sent to WADA for approval and acceptance at least one month prior to distribution.
- 3.2.13 Simultaneously distribute EQAS samples (and associated documentation, if necessary) worldwide to all the approximately 30-40 laboratories identified by WADA (see [list](#) on WADA’s website). The successful tenderer shall be able to distribute samples compliant with global legal requirements in the various host countries of the laboratories.
- 3.2.14 Ensure proper methods are utilized to prevent degradation of finished EQAS Samples and have the capability of appropriate long-term storage (frozen) of remaining fractions for possible future use.
- 3.2.15 Perform homogeneity and stability studies on prepared EQAS samples and comply with WADA document INST-206_HOMO/STAB.
- 3.2.16 Maintain the capability to rapidly re-analyze samples upon WADA’s request when/if analytical issues arise.
- 3.2.17 Maintain the capability to perform administration studies in human subjects to collect post-administration samples representative of the metabolic profile(s) of doping substances.
- 3.2.18 In order to comply with the “double-blind” EQAS as described in the WADA International Standard for Laboratories (ISL), the successful tenderer will be requested to provide urine sample(s) at least five times a year to a defined list of anti-doping organizations in order to include the EQAS samples in their routine doping control sample collection procedures. WADA will provide the information of when, where and to whom such samples shall be delivered, and the successful tenderer shall ensure delivery according to WADA specifications.
- 3.2.19 If and when requested by WADA, prepare and distribute “open” EQAS samples for educational purposes. Such undertakings shall include the steps defined herein, as applicable.

- 3.2.20 If and when requested by WADA, prepare and distribute additional EQAS samples for laboratories seeking WADA accreditation (candidate and probationary laboratories) as well as WADA laboratory on-site assessments, or as otherwise requested by WADA, to selected laboratories during the year (approximately 6 laboratories per year).
- 3.2.21 Maintain operations continuously except weekends, national holidays and end of the year holidays (24 December to 2 January).
- 3.2.22 Demonstrate compliance with the WADA Code of Ethics for laboratories (2021 International Standard for Laboratories – Annex A).

4.0 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 the laboratories in January 2022.

For the blind EQAS, starting in 2022, a set of five (5) samples will be prepared and delivered to the laboratories for each round typically held in January, April and September.

Double-blind samples will consist of at least five (5) samples per laboratory per year. Unless explicitly requested by WADA, double-blind samples will consist of samples containing at least one prohibited substance dispensed into a fit-for-purpose bottle at a minimum volume of 95 mL.

5.0 Timeframe for Tender

Proposals must be mailed to WADA and must reach WADA's office by close of business (16:30h, Montreal time), on 15 January 2021. Late submissions may not be considered.

6.0 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.

7.0 Submissions

A written proposal should be submitted to WADA by interested tenderers. This should include:

- 7.1 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).
- 7.2 A summary of relevant experience.

7.3 The following cost categories:

7.3.1 WADA asks interested companies to provide details of laboratory costs regarding the proficiency program that meets WADA's requirements.

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

- 3 sets of 5 blind samples to 30-40 WADA-accredited and probationary phase laboratories;
- 5 "double-blind" samples to 30-35 WADA-accredited laboratories, to be delivered through anti-doping organizations;
- 2 educational samples to 30-40 WADA-accredited and probationary phase laboratories.

It would be helpful if the tenderer could provide costing per set of 5 samples on the basis of blank samples, spiked samples, and post-administration samples.

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

7.3.2 A proposed schedule of payments.

7.3.3 Tenders should be submitted in US dollars, including the total amount for 5 years and any anticipated extra costs.

7.3.4 Evidence of the service provider's financial and economic standing, including a statement from the candidate's bankers and details of turnover within the service areas covered by this specification for the past three (3) financial years.

7.3.5 Evidence that the candidate 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.

7.3.6 Details of the service provider's professional indemnity insurance coverage (minimum of 1 million US dollars).

7.3.7 The educational and professional qualifications of the service provider's managerial staff dedicated to the tender.

7.3.8 Evidence that the tenderer is ISO/IEC 17025 accredited or equivalent.

7.3.9 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.

7.3.10 A list of references concerning the tenderer's services.

7.3.11 A formal written acceptance of Swiss Law to govern the terms and conditions of the tenderer's offer.

7.3.12 A formal written acceptance of the Arbitration clause as stated under 9.5 hereafter.

8.0 Evaluation criteria for award of contract

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

8.1 Overall quality of the offer and of the EQAS samples;

8.2 Adequacy of proposed response;

8.3 Quality standards of service;

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

8.4 Experience, expertise and quality of staff (status, qualifications, general experience);

8.5 The most economically advantageous tender. WADA shall not, however, be bound to accept the lowest cost tender.

9.0 Terms and Conditions

9.1 WADA undertakes to use its best endeavours to hold confidential any information provided by tenderers. Should tenderers wish that any of the information supplied in their tender not be disclosed because of its sensitivity, such information should be identified as confidential.

9.2 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.

9.3 WADA will not be liable for any costs or expenses incurred in the preparation of a tender.

9.4 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.

9.5 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 these courts shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with the tender or its subject matter.

- 9.6 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.
- 9.7 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.
- 9.8 The tenderer is responsible for ensuring that all procedures for preparation, handling and shipping of biological material are strictly followed.
- 9.9 The contract, to be signed between WADA and the selected tenderer, will be initially established for a period of five (5) years with possibility to prolong the contract by mutual written agreement between WADA and the selected tenderer.

Proposals should be sent by e-mail (not fax) by 15 January 2021, to the following contact, to the attention of Dr. Osquel Barroso, Senior Deputy Director Science, Laboratories:

e-mail: Hai-Yen.Huynh@wada-ama.org

10.0 Contact

For further information, please contact:

Dr. Osquel Barroso, Senior Deputy Director Science, Laboratories

c/o Mrs Hai-Yen Huynh, Executive Assistant, Sciences and International Partnerships

Telephone: +1 514-904-8814

e-mail: Hai-Yen.Huynh@wada-ama.org