



CNAS-CL01-SL03

Accreditation Scheme for Anti-Doping Laboratory

China National Accreditation Service for Conformity Assessment

Foreword

To strengthen the cooperation in accrediting anti-doping laboratories, the International Laboratory Accreditation Cooperation (ILAC) and the World Anti-Doping Agency (WADA) signed Joint Communications to make clear the responsibilities and duties regarding accreditation of anti-doping laboratories. This accreditation scheme was formulated by China National Accreditation Service for Conformity Assessment (CNAS) with a view to fulfilling the responsibilities specified in the Joint Communications, and ensuring the accreditations granted by CNAS were reliable and effective, and recognized and accepted by WADA.

A normative annex is included.

CNAS-CL-SL03:2019 replaces the former CNAS-CL-SL03:2018.

Accreditation Scheme for Anti-Doping Laboratory

1 Scope

This scheme is applicable to the accreditation of the anti-doping laboratories designated by General Administration of Sport, China.

2 Normative references

CNAS-CL01: Accreditation Criteria for the Competence of Testing and Calibration Laboratories (IDT, ISO/IEC 17025)

CNAS-CL10: Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Chemical Testing

WADA: International Standard for Laboratories (ISL)

3 Requirements

3.1 Anti-doping laboratories shall meet the requirements of CNAS-CL01 Accreditation Criteria for the Competence of Testing and Calibration Laboratories and other accreditation requirements set out by CNAS, as well as International Standard for Laboratories (ISLs) and other technical requirements issued by WADA.

Note: The relevant technical requirements of WADA please refer to the website of WADA (<http://www.wada-ama.org>).

3.2 The laboratories shall implement the latest versions of the technical requirements issued by WADA as required.

3.3 The laboratories shall incorporate the requirements of CNAS and WADA into quality management system documentation and the corresponding testing procedures.

3.4 The laboratories shall formulate the Standard Operating Procedures (SOPs) for each testing method, and set out the quality control requirements in SOPs. Each SOP shall be validated, and include the revision history, such as version changes and approval dates.

3.5 The accreditation scope of anti-doping laboratories will be described in flexible ways. In the accreditation scope, the test objects are divided according to the types of doping in the “Prohibited Substances List” published by WADA, and the

description of test methods should including: analyte type, matrix, instrument, purpose of method, sample preparation principles etc.

3.6 The laboratory shall establish a list of prohibited substances and corresponding test methods that can be inspected and keep the updated records. When CNAS or other interested parties require such list, the laboratory shall be able to provide it at as requested. The list includes at least the followings:

- The names of prohibited substances;
- Purpose of the method(ITP,CP,QP)
- Matrix(blood, urine, plasma, saliva, hair etc)
- The code, title, implementation date and version of SOP;
- The type of technology (immunoassays ,LC,GC etc)
- Sample preparation principles(Chemical hydrolysis, Derivatization, Enzymatic digestion, LLE, immunopurification etc)
- The revision history of the list, including the revision date and revised contents.

3.7 Method validation shall be undertaken when the prohibited substances or test methods in the list are adjusted, and validation records shall be retained. If the test technologies were not included in the accreditation scope, the laboratories shall apply to CNAS for expanding the new test techniques into the accreditation scope, and try to participate the external quality assessment scheme(EQAS).

4 Proficiency Testing

The laboratories are required to participate in the EQAS organized by WADA each year, and shall provide the relevant records to CNAS in the integral manner. In the meantime, CNAS encourages the laboratories to participate in the relevant proficiency testing activities organized by other bodies.

5 Application for accreditation

When applying for accreditation or reassessment, the laboratories shall submit the ISL conformity checklist and accreditation scope as well as the list of prohibited substances and the corresponding test methods.

6 Change of accreditation status

CNAS will inform WADA about the changes of accreditation status (i.e. suspension, termination of accreditation, etc) of the laboratories. When WADA suspends or terminates the accreditation of the anti-doping laboratories, the laboratories shall report to CNAS immediately. CNAS will analyze and decide

whether the same decision is to be made.

Annex A (normative):

The Assessment and Report Requirements of Anti-doping Laboratories

A1 The management and implementation of CNAS assessment shall meet the requirements of ISL, and the initial assessment and reassessment team shall include at least one ISL-trained technical assessor.

A2 The assessment team shall confirm all the key testing technologies in the initial assessment and reassessment, or confirm part of testing technologies in the supervisor assessment, and submit the ISL checklist to CNAS when the requirements of the related application covered by the ISL and related technique documents .

A3 The assessment team shall draft the summary report in English after the assessment report is completed, and submit the summary report to CNAS once confirmed by the laboratories. The summary report shall include the followings:

- The type and scope of assessment;
- The name of assessors (indicating whether the assessors have been registered by WADA and theirs responsibilities in the assessment);
- The general conclusions of assessment, including the nonconformities;
- Whether the nonconformities have been corrected, and whether the laboratories have taken the corrective actions;
- The recommendation of accreditation, including scope of accreditation;
- The results of EQAS of anti-doping laboratories. Whether the laboratories have taken the corrective actions for the unsatisfactory results of EQAS;
- The date of the next assessment.

A4 If the problems affecting the test results seriously are found during the assessment, the assessment team shall inform CNAS immediately. After confirming the findings, CNAS will take the appropriate measures according to relevant requirements, and inform WADA accordingly.