

**Accreditation criteria for anti-doping laboratories
seeking accreditation or are already accredited
by the World Anti-Doping Agency (WADA)**

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Scope:

These additional criteria apply to the accreditation of testing laboratories seeking accreditation or are already accredited by the World Anti-Doping Agency.

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1 Scope

These additional criteria apply to the accreditation of testing laboratories seeking accreditation or are already accredited by the World Anti-Doping Agency.

2 Terms and definitions

The definitions apply as set out in DIN EN ISO/IEC 17025, DIN EN ISO/IEC 17000 as well as in the WADA ISL.

3 Description

3.1 General

Before being granted accreditation by WADA, anti-doping laboratories shall be accredited against ISO/IEC 17025 by an accreditation body that is a Full Member of ILAC. The cooperation between accreditation bodies and WADA is specified in the Second ILAC Communication based on the ILAC WADA MoU. General obligation for assessments is that accreditation bodies include the requirements of the WADA ISL and in addition those of the Technical Documents of WADA. The specific requirements are set out below in greater detail.

3.2 Additional requirements for anti-doping laboratories

3.2.1 Requirements from WADA documents

According to the Second ILAC Communication, all relevant WADA Technical Documents in their current versions as well as the following sections of the WADA ISL shall also apply for WADA anti-doping laboratories:

- Section 4.0: Process and Requirements for WADA accreditation:
Subsections 4.2.1, 4.2.2, 4.4.1, 4.4.2, 4.4.9, 4.4.10, 4.5.
- Section 5.0: Application of ISO/IEC 17025 to the Analysis of Urine Doping Control Samples
- Section 6.0: Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples
- Annex B: Laboratory Code of Ethics
Subsections 1.0, 3.1, 3.2, 4.1, 4.2, 4.3, 5

In addition, the WADA Guidelines, e. g. WADA T/E ratio Guideline, WADA Guideline for test reports and WADA hGH Guidelines shall be taken into consideration.

3.2.2 Requirements from DAkkS documents

With respect to their analytics, anti-doping laboratories must be able to react flexibly to new doping substances and methods. Section 4.4.11 of the WADA ISL therefore proposes a flexible accreditation for anti-doping laboratories, which permits adding new analytes to accredited test methods modifying existing test methods and developing new test methods within the scope already accredited and having these new methods accredited without the need of an on-site assessment. This corresponds to a flexibility category II of the scope accreditation. If this type of accreditation is requested, the requirements of the policy document 71 SD 0 002 "Flexibility of the scope of accreditation of testing laboratories and medical laboratories" apply.

The introduction of completely new test methods that have not yet been approved by WADA, is excluded from the flexibility of the scope of accreditation.

3.3 Assessment

When assessing anti-doping laboratories, the requirements of the Second ILAC Communication shall apply. According to these requirements, a so-called „WADA ISL-Trained Assessor“ shall be used in each assessment. Furthermore, the requirements of the current versions of the WADA International Standard for Laboratories, of "The Prohibited List" as well as of the Technical Documents of WADA shall be considered during the assessment. The WADA Guidelines as well as "The Code" shall also be taken into account in an appropriate manner.

In particular, the implementation of the current versions of the WADA documents has to be ensured by the laboratory by the time the documents are enforced. During each assessment, the "Internal Chain of Custody" (TD20xxLCOC) (traceability) has to be evaluated and a „Document Package" (TD20xxLDOC) has to be included in the assessment.

With respect to the system requirements and technical requirements, the activities of mobile laboratory units, e. g. in haematological tests, must be assessed during the initial and re-accreditation as well as at least in one on-site surveillance.

When assessing the WADA EQAS (External Quality Assessment Scheme), the comments of WADA must be involved in the assessment of individual laboratories. To this end, the comments may be requested prior to the assessment and in addition to the list of proficiency tests.

3.4 Documentation of assessment results

The compliance with the requirements has to be documented in the assessment report on the DIN EN ISO/IEC 17025 and in the event of a flexible scope of accreditation also in the form 75 FB 002.1_A "Checklist on the Flexible Scope of Accreditation".

In addition to the DAkkS assessment reports, a Summary Assessment Report shall be prepared in English language to inform the WADA by the WADA ISL Trained Assessor after the closure of all

non-conformities and implementation of the corrective actions. The content of the report shall cover at a minimum the topics mentioned in the ILAC Second Communication and the report form 72 FB 021 must be used for this. Before this report is forwarded to WADA, it will be sent to the laboratory for information.

3.5 Design of certificates

The scope described on the certificate may be divided into four areas based on the test methods used:

- Chromatographic/mass spectrometric or spectrometric or mass spectrometric test methods
- Bioanalytical methods
- Haematological methods/flow cytometry
- Physico-chemical methods

The scope on the certificate can be presented for example as follows:

Tests in the following fields:

Chromatography/spectrometric or mass spectrometric and bioanalytical tests for detecting doping relevant substances and their metabolites in human urine, blood and blood components; haematological tests on blood and blood components; physico-chemical analysis of urine.

The individual test methods are then presented under detailed headings.

4 Related documents

ILAC WADA MoU	Memorandum of Understanding (MoU) between the World Anti-Doping Agency (WADA) and the International Laboratory Accreditation Cooperation (ILAC) ¹
Second ILAC Communication	Second ILAC Communication – Joint DOCUMENT – Cooperation between WADA and ILAC for the attention of all accreditation bodies of laboratories also accredited by the World Anti-Doping Agency (WADA)
The Code	World Anti-Doping Code ²
WADA ISL	WADA International Standard for Laboratories
WADA Technical Documents	WADA Technical Documents according to the Index of the technical documents (TD20xx INDEX)
WADA hGH Guidelines	Guidelines - hGH isoform differential immunoassays for anti-doping analyses
WADA Guideline for test reports	Guideline for laboratory test reports
WADA T/E ratio Guideline	Guidelines for the reporting and management of elevated T/E ratios and endogenous steroids
The Prohibited List	The 20xx Prohibited List (changed annually)
TD20xxLCOC	Laboratory Internal Chain of Custody (current version)
TD20xxLDOC	Laboratory Documentation Packages (current version)
71 SD 0 002	Flexibility of the scope of accreditation of testing laboratories and medical laboratories
75 FB 002.1_A	Checklist on the Flexible Scope of Accreditation
75 FB 022_e	Assessment Summary Report for WADA - ISO/IEC 17025 and WADA Requirements

¹ The ILAC WADA documents are published on the ILAC Website <https://www.ilac.org/partnerships.html>

² The WADA documents are published on the WADA Websites <http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/International-Standards/Laboratories/>