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KENYA
ACCREDITATION
SERVICE

ACC-CD-44

Criteria for the Accreditation of Anti-Doping Laboratories

Table of Contents

1 Background Information

1.1 Process Overview

This guidance document specifies the accreditation criteria for testing laboratories undertaking Anti-Doping laboratory testing and seeking accreditation from KENAS. The content of this document will be reviewed and revised every four years or as needed. All referenced documents shall be considered in their most current versions.

ISO/IEC 17025 accreditation for a laboratory is a prerequisite for WADA accreditation. The requirements for accreditation are laid down in ISO/IEC 17025 for testing and calibration laboratories and International Standard for Laboratories (ISL).

1.2 Purpose

This document was developed by the Technical Working Group on Anti-Doping Laboratory Accreditation and approved for adoption by KENAS. It supplements the ISO/IEC 17025 and ISL standards, providing specific guidance for KENAS assessors and for laboratories seeking to obtain or maintain accreditation for anti-doping testing.

1.3 Scope

This document covers the application of ISO/IEC 17025 for the accreditation of an Anti-Doping laboratory. The document will be applied in conjunction with the Assessor Guide and Terms of Reference ACC-CD-02, procedure for Management and Reporting of Assessments ACC-PR-07, Sampling during Assessment and Internal Audits ACC-PR-03, Policy for Management of Extraordinary Events PL-13, and the Policy for dealing with objection of assessors/experts PL-30. Accreditation shall be based on demonstrated competence of the Anti-Doping laboratory testing in accordance with ISO/IEC 17025 and ISL requirements.

1.4 Role(s) and Responsibility:

The roles and responsibilities outlined below relate to the implementation of this document in KENAS by the Testing Laboratories Accreditation Scheme.

Role	Responsibility
Manager Testing Laboratories	Process owner
Principal Accreditation Officer Testing Laboratories	Reviewer
Chief Manager Laboratories	Recommender
Chief Executive Officer	Approval
Anti-Doping Testing Laboratories	Compliance

2 Terms and Definitions

For the purpose of this guidance document, the following terms and definitions shall apply in addition to those specified in the ISL, ISO/IEC 17000 and the Kenya Accreditation Service Act Cap 496A Laws of Kenya.

2.1 Definition of Terms

2.1.1 Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.1.2 Athlete

Any Person who competes in a legitimate sport at local, national and international level (as defined by each International Federation) or the national level (as defined by each National Anti-Doping Organization).

2.1.3 Athlete Biological Passport (ABP)

The program and methods of gathering and collating data as described in the International Standard for Laboratories (ISL) and Investigations and International Standard for Testing Laboratories (ISTI).

2.1.4 ABP Laboratory

A laboratory not otherwise accredited by WADA, which is approved by WADA to apply Analytical Methods and processes in support of the haematological module of the ABP program and in accordance with the criteria for approval of non-accredited laboratories for the ABP.

2.1.5 ADAMS

The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their Anti-Doping operations in conjunction with data protection legislation.

2.1.6 Anti-Doping Laboratory Testing:

Analytical testing that refers to parts of the Doping Control process which includes sample handling, analysis and reporting of results. It is the process of acquisitioning and storing, together, with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data.

2.1.7 Anti-Doping Organization

WADA or a Signatory that is responsible for adopting rules for initiating, implementing or enforcing any part of the Doping Control process.

2.1.8 Aliquot

A portion of the Sample of biological fluid (e.g. urine, blood) obtained from the Athlete used in the analytical process.

2.1.9 Analyte

A substance, compound or measurand, which is analysed and/or determined in a biological matrix using an Analytical Testing Procedure performed under controlled analytical and laboratory conditions.

2.1.10 Athlete Passport Management Unit (APMU)

A unit composed of a Person or Persons that is responsible for the timely management of Athlete Biological Passports in ADAMS on behalf of the Passport Custodian.

2.1.11 Competence

Ability to apply knowledge, experience, and skills to achieve intended results.

2.1.12 2.1.12 In-Competition

The period commencing at 11: 59 pm on the day before a Competition in which the Athlete is scheduled to participate through the end of such Competition and the Sample collection process related to such Competition.

2.1.13 Laboratory Internal Chain of Custody

Documentation maintained within the Laboratory to record the chronological traceability of custody (by Person(s) or upon storage) and actions performed on the Sample and any Aliquot of the Sample taken for Analytical Testing.

2.1.14 Metabolite

A metabolite is a substance produced when the body breaks down (metabolizes) a drug or compound. When an athlete consumes a substance, their body processes it, resulting in metabolites that can be detected in urine and blood samples.

2.1.15 Mutatis Mutandis

(used when comparing two or more cases or situations) Making necessary alterations while not affecting the main point at issue.

2.1.16 Out-of-Competition

Any period which is not In-Competition.

2.1.17 Prohibited Method

Refers to any method that is listed on WADA's Prohibited List as one that is prohibited in sports.

2.1.18 Prohibited Substance

Any substance, or class of substances, so described on the Prohibited List.

2.1.19 Scope of accreditation

The specific conformity assessment services for which accreditation is sought or has been granted.

2.1.20 Technical Document

A document adopted and published by WADA from time to time containing mandatory technical requirements on specific Anti-Doping topics as set forth in an International Standard.

2.1.21 Major event:

A series of individual international competitions conducted together under an international multi-sport organisation functioning as a ruling body (e.g. the Olympic Games, Pan American Games)

2.1.22 Technical letter:

Mandatory technical requirements provided by WADA from time to time(ad-hoc) to address particular issues on the analysis, interpretation and reporting of specific prohibited substances(s) and /or prohibited method(s) or on the application of specific Laboratory or ABP Laboratory procedure.

2.1.23 Laboratory guidelines:

Recommendations of laboratory best practice provided by WADA to address specific Laboratory operations or to provide technical requirements and guidance on interpretation and reporting of results for the analysis of specific laboratory procedures.

2.1.24 Laboratory documentation package:

The material produced by a laboratory upon the request by the Testing Authority, Results Management authority or WADA, as set forth in the Technical Document on Laboratory Documentation Packages, to support an analytical result such as an Adverse analytical finding or an atypical finding.

2.1.25 Anti-Doping Laboratory testing

The scientific analysis of biological samples (such as urine or blood) to detect prohibited substances and methods used for performance enhancement in sports. It is conducted by laboratories accredited to ISO/IEC 17025 and accredited by World Anti-Doping Agency (WADA).

2.1.26 Analytical testing:

Analytical testing refers to the process of using scientific techniques and methodologies to examine the composition, structure, and properties of substances or materials.

2.1.27 Threshold substance:

Exogenous or endogenous Prohibited Substance, Metabolite or Marker of a Prohibited Substance for which the identification and quantitative determination (e.g. concentration, ratio, score) more than a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an Adverse Analytical Finding.

2.1.28 Measurement Uncertainty:

Parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result

2.1.29 Minimum reporting level:

The lowest concentration of a substance that a laboratory is required to report as a quantifiable result with acceptable accuracy and precision. It is typically set above the method detection limit (MDL) to ensure reliable and reproducible measurements.

2.1.30 Decision limit:

Is the lowest concentration or value of an analyte that can be detected with a specified probability while minimizing the risk of false positives

2.1.31 WADA

World Anti-Doping Agency: is an international organization established in 1999 to promote, coordinate, and monitor the fight against doping in sports. It is responsible for developing and enforcing the World Anti-Doping Code (WADC), which sets global standards for anti-doping policies, testing procedures, and penalties for violations.

2.1.32 Prohibited list

The World Anti-Doping Agency (WADA) publishes an annual Prohibited List that identifies substances and methods banned in sports. This list is a component of the World Anti-Doping Code and is updated yearly to reflect new scientific research and doping trends. The list is available on the WADA website

2.1.33 Security officer

Is responsible for ensuring the integrity, confidentiality, and protection of the laboratory’s operations, data, and physical environment.

2.1.34 Management system

Is a structured framework of policies, processes, and procedures that an organization implements to achieve its objectives effectively and efficiently. It provides a systematic approach to managing various aspects of an organization, such as quality, safety, environment, security, or compliance with regulatory requirements.

2.1.35 Results management authority

The organization or body responsible for receiving, reviewing, and managing the results of doping control analyses conducted by WADA-accredited laboratories.

2.1.36 WADA accreditation:

The official recognition granted by the World Anti-Doping Agency (WADA) to laboratories that meet the highest standards for conducting anti-doping testing and analysis. WADA-accredited laboratories are authorized to analyze samples from athletes and detect the presence of Prohibited Substances and Prohibited Methods, ensuring compliance with the World Anti-Doping Code and International Standard for Laboratories (ISL).

2.1.37 Atypical Finding:

A report from a WADA-accredited laboratory or other WADA-approved laboratory which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an Adverse

2.1.38 Passport Finding:

A report described as an Atypical Passport Finding as described in the applicable International Standards

2.2 Acronyms and Abbreviations

Term	Definition
CAB	Conformity Assessment Body
DCF	Doping Control Forms
EPO	Erythropoietin
EQAS	External Quality Assessment Scheme
ISTI	International Standard for Testing and Investigations
ISL	International Standard for Laboratories
KENAS	Kenya Accreditation Service
MU	Measure of Uncertainty
QC	Quality Control
TD LDOC	Technical Document on Laboratory Documentation Packages
WADA	World Anti-Doping Agency

3 Criteria

3.1 General Requirements

3.1.1 All KENAS assessments are done in accordance with ISO/IEC 17025 and the relevant KENAS policies and procedures. KENAS documents are available on the KENAS Website (https://www.kenas.go.ke/).

3.1.2 The Laboratory is responsible to define the scope of Anti-Doping testing but at a minimum shall implement all mandatory analytical testing procedures and sample retention times as determined by WADA.

3.1.3 An accredited laboratory shall undertake antidoping analytical testing as per the WADA Code of Ethics for Laboratories as in the Annexure A of ISL.

3.2 Structural and Resource Requirements

3.2.1 General

The general structure and resource requirements shall comply with the requirements of ISO/IEC 17025 and WADA guidelines as outlined in the ISL document. The Laboratory shall have the necessary personnel, facilities, equipment, systems and support services to manage and perform its activities effectively.

3.2.2 Laboratory Personnel

ISO/IEC 17025 Clause 6.2 and ISL Clause 5.2.2 requirements shall apply for laboratory personnel. Applicable regulatory requirements for personnel shall be met by the laboratory.

3.2.3 Laboratory Facilities and Environmental Conditions

ISO/IEC 17025 clause 6.3 and ISL Clause 5.2.3.1 & 5.2.3.2 requirements shall apply for laboratory facilities and environmental conditions.

3.2.3.1 The Laboratory shall have a dedicated and restricted area within the Controlled Zone for Sample receipt and Aliquot acquisition and preparation;

3.2.3.2 ISO/IEC 17025 Clause 6.3 and ISL Clause 5.2.3.3 requirements shall apply for environmental control in the laboratory;

3.2.3.3 The Laboratory's storage and handling of controlled substances shall comply with applicable national legislation;

3.2.3.4 To minimize any attempts of fraud or counterfeiting, the Laboratory shall implement a policy to ensure that the discarded urine and blood Sample containers, as well as the seals and rings, cannot be collected by unauthorized persons or recovered after disposal (for example, bottles should be destroyed, or trash containers should be properly secured).

3.2.4 Control and Security of Electronic Data and Information

ISO/IEC 17025 clause 4.2 & 7.11 and ISL Clause 5.2.3.5 requirements shall apply for confidentiality of data, information and operations in the laboratory. The laboratory shall comply with relevant data protection act and demonstrate control over registration and processing of data or equivalent in respective geographical jurisdictions.

3.2.5 Laboratory Equipment

ISO/IEC 17025 Clause 6.4 and ISL Clause 5.2.4 requirements shall apply for equipment

3.2.6 Metrological traceability

ISO/IEC 17025 clause 6.5 and ISL Clause 5.2.5 requirements shall apply for metrological traceability.

3.2.7 Subcontracting of analysis

ISO/IEC 17025 clause 6.6 and ISL Clause 5.2.6 requirements shall apply for subcontracting of analysis in the laboratory.

3.2.8 Purchasing of Services and Supplies

ISO/IEC 17025 clause 6.6 and ISL Clause 5.2.7 requirements shall apply for subcontracting of analysis in the laboratory.

3.3 Process Requirements

ISO/IEC 17025 Clause 7.0 and ISL Clause 5.3, Clause 6.0 and Clause7.0 requirements shall apply for process requirements in the laboratory.

3.3.1 Urine samples shall be frozen immediately after aliquots are taken for the initial testing procedure(s) to minimize risks of sample microbial degradation. Retained urine samples shall be stored frozen after reception until analysis, if applicable.

3.3.2 Secondary use of Samples and Aliquots for Research and Quality Assurance

Samples and aliquots shall be anonymized to ensure that any subsequent results cannot be traced back to a particular athlete. Only after anonymization, may a sample or aliquot be used for the following purposes:

a) Anti-doping research, if the athlete consented to the use of his or her sample for research the consent for research, as declared in the Doping Control Form (DCF) or as obtained by other means, shall be recorded in the laboratory's records for reference.
b) Quality assurance and method development: Without requiring athlete consent anonymised samples and aliquots may be used for:
    i. Quality assurance and improvement of existing test methods
    ii. Development or evaluation of analytical testing procedures for prohibited substances or Prohibited Methods listed on the prohibited list at the time of Sample collection
    iii. Establishing reference population ranges or thresholds or other statistical analyses.

3.4 Proficiency Testing Scheme

3.4.1 Testing laboratories shall participate in the relevant Proficiency Testing Schemes and present the record of results at the time of application for accreditation to KENAS.

3.4.2 Accredited testing laboratories shall participate in WADA EQAS as scheduled as part of the requirements to maintain accreditation.

3.5 Management System Requirements

ISO/IEC 17025 clause 8.0 requirements shall apply for management system requirements

3.6 Use of KENAS accreditation symbol on examination reports

The rules for the use of the KENAS symbol are set in the document PL-54 Policy on the Use of KENAS Marks, Combined Marks and Reference.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
2.	ISL	International Standard for Laboratories.
3.	TD LCOC	Technical Document for Laboratory Chain of Custody
4.	WADA Code of Ethics	WADA Code of Ethics
5.	ISO 9001	Quality Management Systems Requirements

5 Revision/Amendment Records

Date	Ver	Revised By	Reason For Revision
28/06/2025	01	SDE	Newly developed