



IFHA REFERENCE LABORATORY

WHITE MANUAL

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August 2017	5	<ul style="list-style-type: none"> • First Release 	Reference Laboratory Technical Committee
9 October 2018	6	<ul style="list-style-type: none"> • Add in new Section 6.1 and Criteria 14 of Annexure A • Change in Section 5.1.1: (All documentation must be delivered to <u>the Secretariat of the RLAC by email...dated by Head of Laboratory</u>) and (<u>The RLAC shall confirm receipt of a completed application (and administration fee: see 5.1.2) in writing within one calendar month.</u>) • Section 5.1.2 (The application shall be accompanied by the administrative fee <u>of US\$1,000</u>, set by the RLAC, which is payable to the IFHA.) 	Reference Laboratory Technical Committee
23 May 2019	7	<ul style="list-style-type: none"> • Change in Section 5.1.4 (from “<u>3</u>” weeks to “<u>4</u>” weeks) • Change in Criteria 3 of 	Reference Laboratory Technical Committee

		<p>Annexure A (add in “<u>preferably from external racing authorities</u>”)</p> <ul style="list-style-type: none"> • Change in Criteria 5 of Annexure A (add in testing the relevant range of drugs in <u>hair</u> in addition to blood and urine) 	
25 June 2020	8	<ul style="list-style-type: none"> • Addition in Section 4 – Composition of RLTC and Appointment of RLTC members • Update clause 5.1.4: To state that it is the assessor of an application who selects the substances for the proficiency testing for Reference Laboratory applicants. • Update clause 5.1.5: To reflect the introduction of the IFHA Reference Laboratory Proficiency Testing Protocol, and replace the reference to the AORC Proficiency Testing SOP 	Reference Laboratory Technical Committee
9 February 2021	9	<ul style="list-style-type: none"> • Update clauses 5.15-5.18, with consequential changes to clauses 5.2-5.5 & Annexure D: To allow for a “Remote Assessment” of a candidate laboratory, and if successful to be provisionally appointed as an IFHA Reference Laboratory • Update clause 5.2: To include further guidance on what may constitute a material change in operations which would require a laboratory to provide a disclosure to the RLAC 	Reference Laboratory Appointment Committee
19 May 2021	10	<ul style="list-style-type: none"> • Update of Annexure C to include more Major Doping Agents. 	Reference Laboratory Technical Committee

5 July 2022	11	<ul style="list-style-type: none"> • Update of Annexure C to include more Major Doping Agents. 	Reference Laboratory Technical Committee
9 June 2023	12	<ul style="list-style-type: none"> • Update of Section 5.2 for an IFHA Reference Laboratory to cover the costs of on-site reassessment or ad-hoc assessment/inspection; • Minor editorial changes 	Reference Laboratory Appointment Committee
24 May 2024	13	<ul style="list-style-type: none"> • Minor editorial changes in Annexures A, C and D 	Reference Laboratory Technical Committee
5 October 2025	14	<ul style="list-style-type: none"> • Clarify Annexure A Points 6 and 15; • Revise Annexures B and D and insert the RLAC-endorsed reassessment guide as Annexure E to clarify the assessment and re-assessment processes; • Clarify in the plasma on-site assessment section of Annexure C regarding the analytes that can be detected for TB-500 • Minor editorial clarification in Clauses 5.1.6 and 5.2 	Reference Laboratory Technical Committee

Distribution List

All IFHA Reference Laboratories and Reference Laboratory Applicants

1. IFHA Reference Laboratory White Manual

This White Manual sets out the process which the International Federation of Horseracing Authorities (IFHA) has established for reviewing applications for laboratories wishing to be appointed as an IFHA Reference Laboratory and for the maintenance, suspension or revocation of an appointment.

2. Preamble

Objectives of the IFHA Reference Laboratory Program

At present each racing jurisdiction has access to one or more analytical laboratories as the key infrastructure in their anti-doping controls. However, these laboratories vary in many ways, including but not limited to: scale of the laboratory, funding, equipment, staff expertise, volume of testing, number of operating years, and their capability to detect the use of prohibited substances as defined by the IFHA, especially the Major Doping Agents (MDA) such as those substances listed in the Article 6E of the International Agreement on Breeding, Racing and Wagering, which are not to be administered to racehorses at any time in their careers.

The central purpose of the IFHA Reference Laboratory program is to foster an environment in which all races that are significant to the IFHA rankings of horses, races and jockeys are supported by analytical laboratories which the IFHA has reviewed and have been assessed by it to have certain characteristics considered important by the IFHA. These characteristics include but are not limited to the scale of operations, resourcing (floor space, equipment, staffing, funding), laboratory accreditation, research activity and capability to detect the use of prohibited substances including in particular the MDA.

It should be noted that it is not intended that all racing analytical laboratories would become IFHA Reference Laboratories, and the fact that a racing analytical laboratory has not been appointed as an IFHA Reference Laboratory is not a reflection on the general competency of that organisation.

Pre-existing landscape

It may be noted that there is an existing framework within which racing analytical laboratories operate.

Broadly described these are the elements of this framework:

(i) Laboratory accreditation

A number of jurisdictions have relied on national or recognised accreditation bodies. These bodies assess the facility's performance based on the relevant international standard. For racing analytical laboratories this is, in most cases, ISO/IEC 17025. The review process examines a range of matters including: the qualifications, training, knowledge and experience of staff; correct equipment that is properly calibrated and maintained; adequate quality assurance procedures; appropriate testing procedures and so on. However, the scope of accreditation and the performance specification are not

standardised for horseracing laboratories, and these can be defined by the applicant laboratory.

The International Standards Organisation (ISO) is a non-governmental international organisation which develops market relevant International Standards which are voluntary and consensus-based. The ISO has published ISO/IEC 17025 “*General Requirements for the Competence of Testing and Calibration Laboratories*”. This standard specifies the general requirements for the competence to carry out tests and/or calibration. It covers testing and calibration performed using standard methods, non-standard methods and laboratory-developed methods. The standard is intended for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognising the competence of laboratories.

(ii) ILAC – G7

International Laboratory Accreditation Cooperation (ILAC) is the international authority on laboratory and inspection body accreditation, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world. Its core purpose is to promote international acceptance of the equivalence of calibration, test and inspection reports produced by accredited facilities.

ILAC has published ILAC – G7 “*Accreditation Requirements and Operating Criteria for Horseracing Laboratories*”. The purpose of ILAC – G7 is to **amplify** the general requirements laid down in ISO/IEC 17025 as they apply to the particular circumstances of horseracing laboratories. Specifically, ILAC – G7 consists of three parts:

- Part A** provides interpretation of some of the requirements of ISO/IEC 17025 for horseracing laboratories. It consists of a compilation of test-method-related requirements for horseracing laboratories that accreditation bodies have put forward.
- Part B** contains recommendations for establishing the presence of prohibited substances that have been agreed within the horseracing industry.
- Part C** contains the following recommendations: (i) compliance with an appropriate performance specification as required by the relevant authority; and (ii) adoption of harmonised definitions for terms commonly used by racing chemists.

(iii) Association of Official Racing Chemists

The Association of Official Racing Chemists (AORC) consists of individuals, not laboratories. It has almost 200 members concerned with the detection of drugs in racing animals.

The AORC has developed a series of guidelines and recommendations for use by racing chemists:

- AORC Guidelines for the Minimum Criteria for Identification by Chromatography and Mass Spectrometry;
- AORC Guidelines for Referee Analysis;
- AORC Proficiency Testing Urine Drug List and the AORC Proficiency Testing Plasma Drug List (current versions);
- AORC Guidelines for Controlling the Application of Screening Limits;
- AORC Guidelines: Recommendations for the Screening and Confirmatory Analysis of Animal Hair Samples;
- AORC Guidelines for the Minimum Criteria for Identification of Transgenes or Vectors by Polymerase Chain Reaction (PCR) Analysis;
- AORC Guidelines for Deriving Thresholds; and
- A Glossary of Terms Commonly Used in Racing Chemistry.

(iv) Article 6 of IFHA International Agreement on Breeding, Racing and Wagering

Article 6 of the International Agreement on Breeding, Racing and Wagering (IABRW) stipulates that the aim of signatory countries is that their laboratories should:

- be accredited according to ISO/IEC 17025, and to the supplementary document ILAC-G7;
- conform with the Guide for establishing the presence of prohibited substances (Part B of ILAC-G7);
- meet the Performance specification of the International Federation of Horseracing Authorities;
- take part in inter-laboratory comparisons;
- adopt international thresholds for substances endogenous to the horse and those arising from plants traditionally grazed or harvested as equine feed (Clause 16 of Article 6A);
- control the detection of legitimate therapeutic substances through the application of harmonised International Screening Limits (ISLs) in urine and plasma which have been recommended by the IFHA's Advisory Council on Equine Prohibited Substances and Practices and selectively adopted by the relevant signatory countries; and
- control the detection of certain environmental substances through the application of harmonised International Residue Limits (IRLs) which have been

recommended by the IFHA's Advisory Council on Equine Prohibited Substances and Practices and selectively adopted by the relevant signatory countries.

3. Reference Laboratory Appointment Committee

- a. The Reference Laboratory Appointment Committee (RLAC) is an agency of IFHA.
- b. The IFHA Executive Director shall be the Chairman of the RLAC and other members may be appointed by the Executive Council from time to time.
- c. The purpose of the RLAC is to decide on the appointment, suspension and revocation of appointment as an IFHA Reference Laboratory.
- d. In considering an application for appointment or determining whether to suspend or revoke an appointment the RLAC may inform itself by any means it considers useful.
- e. Amongst other things the RLAC may appoint assessors to carry out "on site", virtual or hybrid assessment, review documentation, and may arrange Proficiency Testing (PT) to be conducted.
- f. The RLAC administers a PT Program and a Negative Samples Exchange Program for the IFHA Reference Laboratories (including provisionally-appointed IFHA Reference Laboratories).

4. Reference Laboratory Technical Committee

- a. The Reference Laboratory Technical Committee (RLTC) is an agency of the IFHA.
- b. The RLTC is composed of a representative nominated by each of the following founding IFHA Reference Laboratories:
 - Racing Analytical Services Limited
 - Laboratoire Des Courses Hippiques
 - The Hong Kong Jockey Club Racing Laboratory
 - LGC Group, Sport & Specialised Analytical Services
 - Kenneth L. Maddy Equine Analytical Chemistry Laboratory
- c. It is noted that all appointments to the RLTC are to be approved by the IFHA Executive Council.
- d. The purposes of the RLTC are to:
 - Train assessors appointed by the RLAC
 - Act as a source of advice to assessors on individual assessments

- Act as a source of advice to the RLAC on individual assessments
- Act as a source of advice to the RLAC on revisions to the White Manual
- Carry out such other functions as the RLAC or the Executive Council may give to it from time to time

5. Process and Requirements for IFHA Reference Laboratory Appointment

This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining appointment as an IFHA Reference Laboratory.

5.1 Applying for IFHA Reference Laboratory appointment

The application to be appointed as an IFHA Reference Laboratory must have received the support of and be presented by a racing authority, regional association, or national association that is a member of the IFHA.

5.1.1 Submit application

The laboratory shall complete an application form approved by the RLAC (Annexure A).

Note: The RLAC may require an update of this information during the process of assessment.

All documentation must be delivered to the Secretariat of the RLAC by email in order for the applicant to be considered for appointment. An attachments checklist (Annexure B) may be used to assist the submission of relevant documentation. The completed application shall be signed and dated by the Head of the Laboratory.

The RLAC shall confirm receipt of a completed application (and administration fee: see 5.1.2) in writing within one calendar month.

5.1.2 Assessment fees & charges

The application shall be accompanied by the administrative fee of US\$1,000, set by the RLAC, which is payable to the IFHA.

If the preliminary assessment by the RLAC is satisfactory, the applicant will be considered as a candidate laboratory, which will then be responsible for meeting the costs of proficiency testing and either on-site or hybrid assessment.

5.1.3 Initial assessment

The RLAC will carry out an initial assessment of the application. If the RLAC is satisfied on the basis of the documentation provided, that the candidate may satisfy the threshold criteria for appointment as set out in Annexure A then proficiency testing will be arranged and an assessment team (comprising one or more assessors) will be appointed to carry out an on-site or

hybrid inspection. If the RLAC determines on the basis of the documentation provided that the applicant has not met the threshold criteria, then it may at its absolute discretion reject the application.

5.1.4 Proficiency Testing (PT)

A set of approximately 5 PT samples consisting of equine urine, plasma and hair will be prepared and dispatched to the candidate laboratory. The RLAC-appointed assessor(s) will be responsible for selecting the substances contained in each PT sample. Each PT sample will contain one unknown substance at or above the concentration as outlined in Annexure C.

The candidate laboratory shall successfully identify, and if relevant quantify, the substances detected. It shall provide a report within 4 weeks from receipt of the PT samples.

All analytical data must be kept by the candidate laboratory, to be reviewed by the assessor and possibly by the RLAC.

An appeal against the results of the proficiency testing shall be dealt with according to the procedures set out in the IFHA Reference Laboratory Proficiency Testing Protocol (including section 4.10). The IFHA Executive Council will be informed of the appeal, investigation outcome, decision and recommendation. Any appeal against the results of the proficiency testing that cannot be resolved between the appellant and the RLAC may be referred to the IFHA Executive Council.

5.1.5 Site-Visit, Hybrid or Remote Assessment

i. Site Visit

The RLAC-appointed assessor(s) will carry out an on-site or hybrid assessment after the reported results of the PT samples have been agreed by the RLAC as being satisfactory (i.e., all unknown substances identified and no false positive reported).

ii. Remote assessment:

- a. If, for any reason, it is not possible for an on-site or hybrid assessment to be conducted by an RLAC-appointed assessor, the RLAC may authorise a remote assessment to be conducted.
- b. The process for a remote assessment is to be determined by the RLAC in the particular circumstances. That process may include an RLAC-appointed assessor conducting part or all of the assessment remotely via video conference or similar facilities.
- c. Where a remote assessment occurs, the applicant laboratory is eligible for provisional appointment as an IFHA Reference Laboratory, pending the completion of a full on-site or hybrid assessment in accordance with 5.1.5(i) (see further, 5.1.6 and 5.1.7 below).

5.1.6 Report

Within approximately one month after the site visit or the remote assessment, the assessment team will submit a combined confidential report to the RLAC. In preparing the report, the assessor(s) may have regard to the matters set out in Annexure D and to any other matters which in his, her or their judgment are relevant.

Report following On-Site Assessment: Where an on-site or hybrid assessment has been conducted, the assessment team may make a recommendation on whether an appointment should be made or, if this is not the case, may identify deficiencies to be corrected or needed improvements in order to be considered for appointment.

Report following Remote Assessment: Where a remote assessment has been conducted, the assessment team may make a recommendation on whether a provisional appointment should be made or, if this is not the case, may identify deficiencies to be corrected or needed improvements in order to be considered for provisional or formal appointment.

The RLAC may at its absolute discretion copy the assessment team's confidential report or provide a summary of the report to the candidate laboratory.

5.1.7 RLAC's decision

Following receipt of a recommendation by the relevant RLAC-appointed assessor or assessment team, the RLAC may decide to:

- a. appoint the candidate laboratory as an IFHA Reference Laboratory on a formal basis. Where such an appointment occurs, that laboratory will be required to participate in all IFHA Reference Laboratory compliance and quality assurance-related programmes;
- b. appoint the candidate laboratory as an IFHA Reference Laboratory on a provisional basis on terms determined by the RLAC in its discretion (including, but not limited to, that the provisional appointment be made subject to a full on-site or hybrid assessment of the laboratory by an RLAC-appointed assessor to the satisfaction of the RLAC). Where such an appointment occurs, the laboratory will be classified as a provisionally-appointed IFHA Reference Laboratory and be required to participate in all IFHA Reference Laboratory compliance and quality assurance-related programmes;
- c. reject the candidate laboratory's application. Where the RLAC decides to reject an application, that decision is subject to review by the IFHA Executive Council on an application by the head of the candidate laboratory. If the RLAC determines that the candidate laboratory has failed its application:
 - i. *following an onsite or hybrid assessment:* it cannot re-apply for appointment within 12 months from the date of notification;
 - ii. *following a remote assessment:* it is eligible to undertake a further remote assessment (or an on-site/hybrid assessment if that is possible) at a time to be arranged with the RLAC.

5.1.8 Issue and publication of award of appointment

Upon recommendation by the RLAC that an applicant laboratory be appointed (or provisionally appointed) as an IFHA Reference Laboratory, a document signed by the Chairman of the IFHA or his nominated delegate shall be issued in recognition of such appointment or provisional appointment (as applicable). A list of IFHA Reference Laboratories will be available on the IFHA's website.

Where a laboratory is granted provisional appointment, that provisional appointment, unless suspended or revoked (in accordance with, respectively, 5.3 or 5.4), shall remain until such time as a successful on-site or hybrid assessment is undertaken and is considered satisfactory by the RLAC. In that case, a document signed by the Chairman of the IFHA or his nominated delegate shall be issued in recognition of the appointment.

5.2 Maintaining appointment as an IFHA Reference Laboratory

The IFHA Reference Laboratories (including a provisionally-appointed IFHA Reference Laboratory) shall successfully participate in the RLAC PT Scheme and the Negative Sample Exchange Program. In the normal course, an on-site reassessment will take place every 3 to 4 years. A guide for the reassessment can be found in Annexure E. In addition, the RLAC reserves the right to assess and inspect an IFHA Reference Laboratory at any time. The notice of any reassessment or assessment/inspection will be made in writing to the Head of the IFHA Reference Laboratory. Unless otherwise provided by the RLAC, each IFHA Reference Laboratory will be responsible for meeting the costs of any reassessment or *ad hoc* assessment/inspection.

An IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) shall continually comply with the criteria set out in Annexure A.

Obligation of ongoing disclosure: Where an IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) experiences a material change to its operations, including a change (for example, a major renovation, a major change in laboratory instrumentation, or a departure of key staff) with the potential to put the laboratory in a position of non-compliance with the criteria set out in Annexure A, the Head of the Laboratory (or his or her delegate) must inform the RLAC of such material change within 28 days of it occurring. Following receipt of the notification by the RLAC, the RLAC may, in its discretion, request additional information in writing or from visual inspection to ensure compliance with the provisions of this White Manual. A failure to comply with this obligation of ongoing disclosure may result in suspension or revocation of appointment.

Annual Declaration: An IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) must, on an annual basis at the direction of the RLAC, submit a formally executed declaration (in a form provided by the RLAC) to confirm that the laboratory was in compliance with the criteria set out in Annexure A for that previous year.

The RLAC may at its absolute discretion request documentation from an IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) relevant to the criteria set out in Annexure A.

Failure of an IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) to provide timely information requested by the specified date shall be considered a refusal to cooperate and may result in suspension or revocation of appointment.

5.3 Suspension of appointment

Whenever the RLAC has substantive reason to believe that suspension of appointment (or provisional appointment) may be required and that immediate action is necessary the RLAC may immediately suspend a laboratory's appointment.

The period and terms of suspension shall be proportionate to the seriousness of the non-compliance(s) or lack of performance. A period of suspension shall be up to 12 months, during which time any non-compliance or identified deficiency must be corrected, documented and reported to the RLAC at least six (6) weeks before the end of the suspension period. Delay in submitting the proper corrective and preventive action reports may lead to an extension of the suspension period. If any non-compliance or identified deficiency is not corrected during the suspension period, the Reference Laboratory appointment will be revoked, unless a one-time only extension of the suspension period, not to exceed two (2) months, is granted by the RLAC.

A decision by the RLAC to suspend an appointment (including a provisional appointment) is reviewable by the IFHA Executive Council on application by the relevant laboratory within 5 working days of being notified.

5.4 Revocation of appointment

The RLAC may revoke the appointment (or provisional appointment) of a laboratory. A decision by the RLAC to revoke an appointment (or provisional appointment) is reviewable by the IFHA Executive Council on application by the relevant laboratory within 5 working days of being notified.

If a laboratory, whose appointment (or provisional appointment) has been revoked, should seek a new appointment at a time agreed by the RLAC, it shall begin the process as a new applicant laboratory as described in Section 5.1.

5.5 Notification

5.5.1 Written notice

When a laboratory's appointment (or provisional appointment) is suspended or revoked, the RLAC shall immediately serve the laboratory with written notice of the suspension or revocation. This notice shall state the following:

- 1) The reason for suspension or revocation;
- 2) The terms of the suspension or revocation; and
- 3) The period of suspension.

5.5.2 Effective date

Subject to any application to the IFHA Executive Council for review of the RLAC decision, a suspension is immediately effective. A revocation is effective sixty (60) calendar days after the date of the written notice or, if a review is requested, upon the Executive Council's decision to uphold the proposed revocation. A Reference Laboratory that has received notice that its appointment (or provisional appointment) is in the process of being revoked shall be immediately suspended until the revocation is made final or is rescinded by the IFHA Executive Council.

6.1 Documents and Communications to be in English

Unless otherwise expressly agreed by the RLAC:

- 1) all documentation provided to, and communications with, the RLAC in support of, or in any way related to, an application to become an IFHA Reference Laboratory, must be in English. This includes all documents or communications related to an application made in accordance with section 5.1 of this White Manual. To the extent that any document or part of a document is not in English, the RLAC (including any assessor) may require the document to be translated. The costs incurred in the translation (if any) of document submitted as part of an application, including any delays caused by the failure of an applicant to translate a document, are to be met by the applicant;
- 2) an applicant must ensure that relevant personnel required for any site visit or any verbal communication are proficient in English, and that adequate real-time interpretation services are available (where required) for the site visit, and related communications. The costs of translation services are to be met by the applicant; and
- 3) once appointed, an IFHA Reference Laboratory must ensure that all documents submitted to, and communications with, RLAC are in English. This includes, but is not limited to, any matter related to section 5.2-5.5 above.

IFHA Reference Laboratory Appointment**IFHA Reference Laboratory Threshold Criteria**

	Criteria	Criteria met (Yes/No)	Information
1	Major provider of testing services to racing authority(ies)		List authorities being served:
2	Minimum of 5 years' experience of doping control testing		Years of relevant experience:
3	Analysed at least 20 B-samples in the last 5 years, preferably from external racing authorities		No. of B-samples analysed:
4	At least two Professional Members of the AORC		Names of AORC Professional or Fellow members:
5	ISO/IEC 17025 accreditation for testing a comprehensive range of drugs in equine urine, blood and hair, including representatives of all classes in Article 6E of the IABRW of the IFHA		Provide copies of the scope of accreditation and the last assessment report:
6	Operating in accordance with ILAC-G7 and the applicable AORC/IFHA guidelines listed therein, including the AORC guidelines on hair analysis, MS criteria, referee analysis, and applying screening limits; the IFHA Performance Specification; and unless otherwise specified by the client authority the IFHA Guideline on Lab Documentation Package		
7	Demonstrated capability to meet the IFHA Performance Specification and the latest version of the AORC PT drug lists in horse urine and horse plasma		Provide a list of Limits of Detection for these substances:
8	<ul style="list-style-type: none"> ♦ No false positive and no more than two (2) false negative results in total in the AORC PT Program (both urine and plasma) plus, for maintaining appointment, in the RLAC's PT and Negative Samples Exchange Programs in the last three years ♦ No false positive result from any other PT or samples exchange programs for at least 3 years 		Provide copies of the reports from all PT and samples exchange programs participated in the past 3 years:

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9	Evidence of contributions to the advancement of racing chemistry: at least 2 peer-reviewed publications on racing chemistry in the past 5 years or at least 2 papers or presentations in the last three ICRAVs		List relevant publications or presentations:
10	Minimum of 5000 horseracing regulatory samples analysed per year, with no false positive result for the last 3 years		List the no. of horseracing regulatory samples analysed in the past 3 years, drugs reported, and any false positive reported:
11	Capability to identify the prohibited substances referred to in Annexure C at the required concentrations in the relevant medium		Provide a list of the Limits of Detection for these substances:
12	Control the detection of legitimate therapeutic substances through the application of IFHA/ARF Screening Limits (or RMTC/ARCI reporting limits)		Provide a list of the Limits of Detection (or Limits of Quantification) and the applicable limits for these substances:
13	Control the detection of environmental substances through the application of residue limits where inadvertent exposure is a relevant risk in the jurisdiction		Provide a list of the Limits of Detection (or Limits of Quantification) and the applicable limits for these substances:
14	At least two professional members of staff with demonstrated proficiency in written and oral English		Name and Title of Laboratory Staff, and details of English proficiency
15	If requested by the relevant horseracing authority, test reports and laboratory documentation packages (compliant with the relevant IFHA Guideline or with the authority's requirements) must either be in English or be translated into English		Provide written confirmation of capacity and agreement to comply with this criterion.

Additional supporting documentation to be provided:

- Laboratory organizational chart;
- List of technical, administrative, and research staff members and their qualifications;
- Schematic representation of the laboratory facilities, including square footage, describing functional areas (e.g., sample reception area, GC-MS and LC-MS instrument rooms, sample storage area, etc.), and identifying secure entrances and exits. Photographs and floor plans may be included.

 Date and Signature of the Head of the Laboratory

Attachments Checklist for IFHA Reference Laboratory Appointment

List of documents to be submitted for initial assessment:

- Laboratory organisation chart
- List of technical, administrative, and research staff members and their qualifications
- Schematic representation of the laboratory facilities, including square footage, describing functional areas, and identifying secure entrances and exits.
- Documents from the major client(s) or racing authority(ies) supporting the applicant laboratory
- Scope of accreditation
- Last assessment report from the accreditation body
- Limits of Detection for the substances in the IFHA Performance Specification and latest version of the AORC PT drug lists
- Summary of all Proficiency Test (PT) and negative samples exchange results for the past 3 years
- Publications in the past 5 years and/or papers or presentations in the last 3 ICRAV meetings
- No. of horseracing regulatory samples tested in the past 3 years and record of any false positive
- List of drugs reported in the past 3 years
- Number of reference standards and a list of MDAs (shown in Annexure C) available in the applicant laboratory
- Test procedures, summaries of validation reports and limits of detection for the MDA listed in Annexure C
- Limits of Detection (or Limits of Quantification) and the applicable limits for controlling the use of legitimate therapeutic substances and inadvertent exposure to environmental substances
- A representative Laboratory Document Package submitted for a positive A-sample
- Other documents (please specify)

Note: (1) This list is not exhaustive. The laboratory should cover other substances under the same class, typified from the analytes in this Prohibited Substances List.

Proficiency Testing			On Site Assessment		
Matrix	Analyte	Concentration	Matrix	Analyte	Concentration
Urine	16β-hydroxy-stanozolol (metabolite of stanozolol)	100 pg/mL	Urine	Brombuterol	500 pg/mL
	16β-hydroxy-furazabol	5 ng/mL		Buserelin	500 pg/mL
	4-hydroxy-testosterone (metabolite of formestane)	5 ng/mL		Capromorelin	1 ng/mL
	5α-estrane-3β,17α-diol (metabolite of nandrolone)	2 ng/mL		Dermorphin (H-Tyr-D-Ala-Phe-Gly-Tyr-Pro-Ser-NH2)	500 pg/mL
	6α-hydroxy-androst-4-ene-3,17-dione (metabolite of 6-OXO)	50 ng/mL		Deslorelin	500 pg/mL
	Acetylfentanyl	200 pg/mL		GHRP-1 (Ala-His-D-2Nal-Ala-Trp-D-Phe-Lys-NH2)	250 pg/mL
	AICAR	400 ng/mL		GHRP2 (D-Ala-D-β-Nal-Ala-Trp-D-Phe-LysNH2)	100 pg/mL
	Andarine (S4)	50 pg/mL		GHRP6 (His-D-Trp-Ala-Trp-D-Phe-Lys-NH2)	100 pg/mL
	Clenbuterol	100 pg/mL		Goserelin	500 pg/mL
	Clenpenterol	500 pg/mL		Hexarelin	500 pg/mL
	Cobalt	100 ng/mL (threshold, quantitation required)		Histrelin	500 pg/mL
	Efaproxiral (RSR 13)	2 ng/mL		Ibutamoren	500 pg/mL
	Epitrenbolone (17α-trenbolone)	250 pg/mL		Ipamorelin	500 pg/mL
	FG2216 (IOX-3)	20 ng/mL		Leuprorelin	500 pg/mL
	FG4592	100 pg/mL		Ractopamine	1 ng/mL
	Furanylfentanyl	200 pg/mL		rHuEPOs (in either urine or plasma)	100 pg/mL
	GW0742	1 ng/mL		Salbutamol (albuterol)	500 pg/mL
	GW1516	100 pg/mL		Terbutaline	200 pg/mL
	IOX-2	2 ng/mL		Triptorelin	500 pg/mL
	ITPP (myo-Inositol TrisPyroPhosphate)	10 ng/mL			
	LGD2226	2 ng/mL			
	Ligandrol (LGD-4033)	5 ng/mL			
	Metenolone	5 ng/mL			
	Molidustat	5 ng/mL			
	Norbuprenorphine	1 ng/mL			
	Norethandrolone	2 ng/mL			
	Norfentanyl	500 pg/mL			
	Ostarine (S22)	50 pg/mL			
	Pirbuterol	5 ng/mL			
	RAD140	2 ng/mL			
	Tamoxifen	1 ng/mL			
	Testosterone (in fillies and mares)	55 ng/mL (threshold, quantitation required)			
Testosterone (in geldings)	20 ng/mL (threshold, quantitation required)				
Tetrahydrogestrinone	2 ng/mL				
Trendione	250 pg/mL				
Tulobuterol	500 pg/mL				
Zilpaterol	500 pg/mL				

Proficiency Testing			On Site Assessment		
Matrix	Analyte	Concentration	Matrix	Analyte	Concentration
Plasma	1,4,6-Androstatriene-3,17-dione (ATD)	200 pg/mL	Plasma	Boldenone undecylenate	50 pg/mL
	1-Androstenedione	500 pg/mL		Cimbuterol	200 pg/mL
	1-Testosterone	300 pg/mL		Dermorphin (Tyr-D-Ala-Phe-Gly-Tyr-Pro-Ser-NH ₂)	250 pg/mL
	4-Androstene-3,6,17-trione (6-OXO)	250 pg/mL		GHRP2 (D-Ala-D-b-Nal-Ala-Trp-D-Phe-Lys-NH ₂)	100 pg/mL
	Andarine (S4)	200 pg/mL		GHRP6 (His-D-Trp-Ala-Trp-D-Phe-Lys-NH ₂)	100 pg/mL
	Brombuterol	200 pg/mL		IGF-1	screening only
	Buprenorphine	500 pg/mL		Minimum of three different rGHs (e.g., reGH, rpGH, rbGH, roGH, rhGH...)	50 ng/mL
	Clenbuterol	20 pg/mL		rHuEPOs (in either urine or plasma)	100 pg/mL
	Clodronic acid	1 ng/mL		Salbutamol	100 pg/mL
	Clomifene	300 pg/mL		TB500 (N-Acetylated Leu-Lys-Lys-Thr-Glu-Thr-Gln) or N-Acetylated Leu-Lys (TB500 metabolite)	250 pg/mL
	Clostebol	100 pg/mL		Terbutaline	200 pg/mL
	Cobalt	25 ng/mL (threshold, quantitation required)		Testosterone decanoate	50 pg/mL
	Danazol	100 pg/mL		Testosterone propionate	50 pg/mL
	Drostanolone	200 pg/mL		Testosterone undecanoate	50 pg/mL
	Formestane	250 pg/mL		Zilpaterol	200 pg/mL
	GW0742	500 pg/mL			
	GW1516	100 pg/mL			
	Ligandrol (LGD-4033)	500 pg/mL			
	Methyltestosterone	100 pg/mL			
	Nandrolone	100 pg/mL			
	Norethandrolone	100 pg/mL			
	Ostarine (S22)	200 pg/mL			
	Stanozolol	50 pg/mL			
	Testosterone	100 pg/mL (threshold, quantitation required)			
	Tiludronic Acid	200 pg/mL			
	Trenbolone	100 pg/mL			
	Trendione	100 pg/mL			
	Turinabol	100 pg/mL			
Zoledronic acid	5 ng/mL				

Proficiency Testing			Proficiency Testing		
Matrix	Analyte	Concentration	Matrix	Analyte	Concentration
Hair	Andarine	10 pg/mg	Hair	Salbutamol	50 pg/mg
	Bambuterol	5 pg/mg		Salmeterol	50 pg/mg
	Boldenone undecylenate	10 pg/mg		Stanozolol	10 pg/mg
	Clenbuterol	10 pg/mg		Testosterone cypionate	20 pg/mg
	Clostebol	10 pg/mg		Testosterone decanoate	10 pg/mg
	FG4592	50 pg/mg		Testosterone propionate	10 pg/mg
	Formoterol	10 pg/mg		Testosterone undecanoate	10 pg/mg
	GW1516	20 pg/mg		Trenbolone acetate	10 pg/mg
	Nandrolone phenylpropionate	10 pg/mg		Turinabol	20 pg/mg
	Norethandrolone	50 pg/mg		Zilpaterol	10 pg/mg

IFHA Reference Laboratory Initial Appointment Assessment Guide

The scope of the on-site assessment for initial appointment is at the discretion of the assessor(s) and may include the items listed below, which would ensure compliance with the requirements of the White Manual, ISO/IEC 17025 and ILAC-G7.

Reference can also be made to Appendix B of Annexure E for certain recommended on-site activities, including the preparation of a sample containing a substance taken from the On-site Assessment tables of Annexure C for processing by the candidate laboratory.

1. GENERAL

ISO ACCREDITATION SCOPE

- Last assessment/reassessment results
- Confirm if accreditation is for a flexible scope
- Confirm if all matrices of horse urine, blood and hair are covered by accreditation (could be covered by flexibility or not in some countries)

QUALITY ASSURANCE

- Confirm if compliance with ILAC-G7 and applicable AORC/IFHA Guidelines
- Performance in PT and Samples Exchange programs
- Internal audit records
- Last annual system review record/report

SAMPLES

- Number of samples analysed per year
- Substances reported
- Reporting/turnaround time
- Experience in B-sample analyses

EQUIPMENT, METHODOLOGY, AND LABORATORY FLOOR AREA

- Limits of detection
- Confirm compliance with IFHA Performance Specifications and AORC PT Drug Lists
- Confirm compliance with Annexure C

STAFF

- Number (Full Time Equivalent), qualifications and experience
- Staff dedicated to screening and confirmation (including quantification)

ACCESS TO REFERENCE MATERIALS

- MDA including those listed in Annexure C
- Others

ANNEXURE D

RESEARCH

- Staff (number and qualifications) dedicated to research and method development
- Brief descriptions of ongoing and recently completed R&D projects
- Recent publications and presentations

2. RESULTS of RLAC's PROFICIENCY TESTING

- Documentation and data provided

3. ON SITE, HYBRID OR REMOTE_ASSESSMENT (particularly for_unstable drugs)

- Confirm procedures are in place
- Vertical audit of a reported case
- Validation of relevant analytical methods (routine or dedicated analytical line)

IFHA Reference Laboratory Reassessment Guide

General comments:

In the normal course, an on-site reassessment will take place every 3 to 4 years. The notice of the assessment/inspection will be made in writing to the Head of the IFHA Reference Laboratory. Unless otherwise provided by the RLAC, each IFHA Reference Laboratory will be responsible for meeting the costs of any reassessment.

An IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) shall continually comply with the criteria set out in Annexure A. The RLAC may at its absolute discretion request documentation from an IFHA Reference Laboratory (including a provisionally-appointed IFHA Reference Laboratory) relevant to the criteria set out in Annexure A.

Guide for the Reassessment of an IFHA Reference Laboratory:

1. The reassessment will normally involve two RLAC-appointed assessors, one preferably independent of the current IFHA Reference Laboratories, and the other may be a staff of another IFHA Reference Laboratory. The involvement of the latter will require the consent the Reference Laboratory being reassessed.
2. Normally, the reassessment will comprise a paper review by both assessors, as well as a one-day on-site visit by one of the assessors (preferably the independent one).
3. At least 10 calendar days prior to the agreed date of on-site visit, the Reference Laboratory being reassessed will have to submit relevant documentation (see **Appendix A** below) for the two assessors to review. Any questions arising from this paper review can be dealt with either before or during the on-site visit.
4. The scope of the on-site reassessment is at the discretion of the assessor and may be with reference to Annexure D of the White Manual, which would ensure compliance with the requirements of the White Manual, ISO/IEC 17025 and ILAC-G7. However, **Appendix B** below lists the recommended scope of activities.

Appendix A (documents in English to be submitted before the on-site re-assessment):

1. Current laboratory organization chart.
2. List of technical, administrative, and research staff members and their qualifications (and AORC membership if any). A summary of the number of staff in each category and their qualifications would suffice if staff names are already indicated in the clause above.
3. Schematic representation of the laboratory facilities, including square footage, describing functional areas, and identifying secure entrances and exits (photographs and floor plans may be included).
4. Current scope of accreditation to ISO/IEC 17025 requirements (covering horse urine, blood and hair).
5. Latest assessment report from the accreditation body.
6. Summary of all results of Proficiency Testing (PT) and Negative Sample Exchanges participated in the past 3 years.
7. Latest annual system review report (sensitive financial information, such as the operating

budget or costs per sample, may be redacted).

8. Number of annual horseracing regulatory samples analysed in the past 3 years and record of any false positive.
9. A list of external B-samples analysed in the past 3 years.
10. Limits of Detection (and Limits of Quantification if relevant) for all substances listed in Annexure C of the IFHA Reference Laboratory White Manual.
11. A representative Laboratory Document Package (LDP) submitted for a positive A-sample.
12. A representative Method Validation report for a substance listed in Annexure C of the IFHA Reference Laboratory White Manual (the substance and matrix involved are different from those provided for the LDP).

Appendix B (recommended scope of activities for an IFHA Reference Laboratory on-site re-assessment):

1. Opening meeting.
2. The assessor selects a substance from the On-site Assessment tables of Annexure C of the IFHA Reference Laboratory White Manual and witness the spiking of a blank matrix to the specified concentration by a laboratory staff. Both screening and confirmation are then conducted on the identified spiked sample in accordance with the laboratory relevant SOP. The procedures of sample preparation, instrumental analysis and data processing will be witnessed by the assessor from time to time. The analytical data and results obtained are to be discussed with the assessor before the end of the day. For a lengthy procedure, any interim data and results may be supplemented with a final report provided as soon as possible and not more than 3 days from the date of visit.
3. General laboratory tour, including assessment of laboratory security and inspection of sample receipt and storage and other facilities. The assessor may take the opportunity to verify that the forensic integrity of regulatory samples is maintained.
4. The assessor selects to inspect a different ongoing screening or confirmatory method involving Annexure C substance(s) being performed, preferably in a matrix different from Clause 2 above.
5. Reviewing selected test procedures/SOPs involving other Annexure C substance(s) and in a different matrix (discussion with the staff involved, including assessing their understanding/application of the ILAC-G7 and relevant AORC Guidelines).
6. Reviewing Method Validation reports for other selected substances listed in Annexure C of the IFHA Reference Laboratory White Manual (discussion with the professional staff involved).
7. The assessor selects a reported A-sample positive case (preferably involving an Annexure C substance) which is different from the one with its Laboratory Document Package already submitted to perform a vertical audit.
8. Discuss with laboratory staff any questions/issues related to compliance with requirements of the IFHA Reference Laboratory White Manual (particularly Annexure A, ISO/IEC 17025 and ILAC-G7) or arisen from the submitted documents.
9. Closing meeting and any agreed follow-up actions.
10. Prepare the final report (in consultation with the other assessor) in a format similar to the one used in the initial assessment of the Reference Laboratories.