

R203 – SPECIFIC REQUIREMENTS: ANIMAL DRUG TESTING LABORATORY ACCREDITATION PROGRAM

September 2005

1.0 INTRODUCTION

These accreditation requirements are applicable to the special animal drug testing laboratory accreditation program designed to meet the requirements of any of the following testing providers: The Association of Official Racing Chemists (AORC), The Iowa State University's International Interlaboratory Testing Program (IITP), Cornell University's Interstate Drug testing Alliance (IDTA) and the Testing Integrity Program administered by the University of California- Davis.). All of these testing providers cover tests under the A2LA Chemical Field of Testing.

Internationally accepted accreditation criteria and individual user requirements such as those of the Association of Official Racing Chemists (AORC) form the basis for the requirements of this program.

One of the major objectives of this program is to provide those responsible for using or approving animal drug testing laboratories with an effective alternative to their own action of evaluating and recognizing qualified laboratories. A thorough and balanced assessment is provided, as individual requirements are coordinated with A2LA requirements in other areas to provide overall accreditation of a laboratory with a minimum disruption to laboratory operations. A2LA is committed to working with government and non-government users and racing authorities to provide accreditation over an appropriate scope to realize this objective.

The scope of this program covers screening and confirmatory methodologies, including immunoassay, chromatographic and spectrometric techniques, for the qualitative and quantitative detection and identification of prohibited substances and their metabolites and artifacts under state or regulatory authorities. The sample collection and laboratory analyses shall include, but not be limited to, the matrices of animal fluids, tissue, and other materials and associated pharmaceutical preparations and paraphernalia. Applications for accreditation may be made for one or more specific testing technologies, matrices and substances.

2.0 DEFINITIONS

- 2.1 Animal Drug Testing Laboratory (herein known as laboratory): A facility that performs tests on body fluids, tissue, and other materials from an animal, or associated pharmaceutical preparations and paraphernalia for the detection and identification of drug-related analytes.
- 2.2 Drug: A substance, which may prevent or cure disease or otherwise enhance the physical or mental welfare and/or performance of the tested animal.
- 2.3 Test: An analytical process carried out according to a specified procedure that allows for the detection and/or identification of one or more analytes of interest on a sample.
- 2.4 Foreign Substance: All substances except those which exist naturally in the untreated animal at normal physiological levels; and substances or metabolites thereof which are contained in animal feeds or feed supplements and/or chemotherapeutic agents; or pharmaceutical aids.
- 2.5 Prohibited substance: Any substance defined as prohibited by the client.
- 2.6 AORC: Association of Official Racing Chemists.
- 2.7 IITP: Iowa State University's International Interlaboratory Testing Program.

- 2.8 IDTA: Cornell University's Interstate Drug Testing Alliance.
- 2.9 TIP: Testing Integrity Program, administered by University of California- Davis.
- 2.10 Quality Manual: A manual that describes a laboratory's quality system, including its policies and practices for quality assurance and quality control. Detailed procedures may be contained in other documentation cited by the quality manual.
- 2.11 Quality Assurance: A system by which a laboratory monitors technical and non-technical functions to ensure the quality of testing.
- 2.12 Quality Control: Mechanisms designed to ensure that any test result produced by a test method or instrument is valid and acceptable.
- 2.13 Reference Material: A chemical available from a commercial source or a synthetic sample which has chromatographic and spectral characteristics in conformity with non-controversial published data or which has been validated by comparison with a certified reference material. This material may also be an isolate from an authenticated drug-administered urine or blood, providing the analytical data available is sufficient to fully justify its identity as a metabolite of the drug in question.
- 2.14 Certified Reference Material: A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (such national or international institutes or certifying bodies of an equivalent status (such as U.S. Pharmacopoeia, British Pharmacopoeia, World Health Organization and other pharmaceutical authorities) and are acceptable after a simple identity check.
- 2.15 Traceability: A property of a result of a determination that can be related to appropriate standards through an unbroken chain of comparisons.
- 2.16 Proficiency Testing: Determination of the laboratory testing performance by means of interlaboratory comparisons.
- 2.17 Client: Individuals or groups requiring services from an animal drug testing laboratory, such as but not limited to equine practitioners, racing commissions, show associations, fair associations, regulatory agencies and trainers.
- 2.18 ISO: International Organization for Standardization.
- 2.19 IEC: International Electrotechnical Commission.
- 2.20 Blind sample testing: A system for periodically sending laboratories for testing a set of samples whose values for the concentrations and/or presence of analytes are known to the program administrator but not known in advance of testing to the participating laboratories.

3.0 GENERAL AND SPECIFIC CRITERIA

The general criteria for accreditation are contained in ISO/IEC 17025-2005, "General requirements for the competence of calibration and testing laboratories". All provisions of the general criteria, and the additions noted below shall apply under this program.

Specific criteria are an elaboration on or interpretation of the general criteria plus those requirements of accreditation applicable to a certain field of testing, testing technology, type of test, or specific test. These specific criteria normally come from other standards or documents that apply to special areas

and that have been recommended for inclusion in specific programs by appropriate technical committees.¹ Additional specific requirements for this program approved by the A2LA Board of Directors is described below. The numbering system for each section below corresponds to the major sections of ISO/IEC 17025-2005.

4 Management requirements

4.1 – 4.15 No additions.

5 Technical requirements

5.1 General No additions.

5.2 Personnel No additions.

5.3 Accommodation and environmental conditions No additions.

5.4 Test and calibration methods and method validation

5.4 A.1 The laboratory shall employ documented instructions on the handling and preparation of samples for testing, performance of all test procedures, and the use and operation of all relevant equipment and instruments. All instructions, manuals and reference data relevant to the work of the laboratory shall be maintained current and be readily available to the staff and shall include:

5.4 A.1.1 clear, unambiguous instructions for equipment or instrument operation and method performance;

5.4 A.1.2 dates of adoption of instructions and dates of technical changes;

5.4 A.1.3 data on repeatability and reproducibility of methods as appropriate; and

5.4 A.1.4 identification of any known limitations of methods, such as applicable concentration ranges and possible interferences as appropriate.

5.4 A.2 The laboratory shall:

5.4 A.2.1 have an initial screening procedure for prohibited substances that specifies the minimum schedule of tests for samples before they can be reported as negative;

5.4 A.2.2 document for each screening test how it decides which samples to follow up;

5.4 A.2.3 determine and document the limit of detection for representative analytes for each method used; and

5.4 A.2.4 check all data including those for negative results.

5.5 Equipment

5.5 A.1 The laboratory shall comply with local regulations covering the storage and handling of controlled substances.

5.6 Measurement traceability No additions.

5.7 Sampling No additions.

¹. Chemists Advisory Committee of the Association of Racing Commissioners International Quality Assurance Committee.

5.8 Handling of test and calibration items No additions.

5.9 Assuring the quality of tests and calibration results

5.9 A.1 The laboratory shall have measures to ensure that incidences of "false-negative" and "false-positive" results are kept to a minimum including:

5.9 A.1.1 blind submission of spiked samples or known positive and negative samples into the analytical system;

5.9 A.1.2 participation in proficiency and blind sample testing from any of the following testing programs: The Association of Official Racing Chemists (AORC), The Iowa State University's International Interlaboratory Testing Program (IITP), Cornell University's Interstate Drug testing Alliance (IDTA) and the Testing Integrity Program, administered by the University of California-Davis.

5.10 Reporting the results

5.10 A.1 Each report shall contain at least the information required in the following clauses, including that which is required by the client: 5.10.2 a), b), d), f), g), i), j).

5.10 A.2 In addition, each report shall contain the following information:

5.10 A.2.1 Unique identification of every included page of the report (e.g., page 1 of 2, page 2 of 2);

5.10 A.2.2 Sample identification or client number;

5.10 A.2.3 Along with the signature of person authorized to issue the report, the date of authorization.

PROFICIENCY AND BLIND SAMPLE TESTING

Applicants under this program are required to participate in the proficiency and blind sample testing from any of the following testing programs:

The Association of Official Racing Chemists (AORC), Executive Director: Sharon McLellan, P.O. Box 296, Pte. Claire, Qc., Canada, H9R 4N9; Phone 514 697 7578; Fax 514 694 7421.

Iowa State University's International Interlaboratory Testing Program (IITP), Administrator: Walter Hyde, Ph.D., Iowa State University, Department of Racing Chemistry, College of Veterinary Medicine, Ames, Iowa 50011.

Cornell University's Interstate Drug testing Alliance (IDTA), Administrator: George Maylin, Ph.D. D.V.M., Cornell University, 925 Waven Drive, Ithaca, New York 14850; Phone 607 255 6555.

Testing Integrity Program (TIP), Administrator: Scott Stanley, Ph.D. Veterinary Drug Laboratory, University of California-Davis, P.O. Box 1990, Davis, California 95617; Phone 916 752 6253.

The laboratory shall provide the proficiency testing provider with written permission to release the laboratory's results under this program directly to A2LA for the sole purpose of its use in monitoring the laboratory's performance and compliance with accreditation requirements.

If a laboratory's results are deemed outliers or unacceptable, then the laboratory shall investigate and determine the cause(s) for such unacceptable results, correct any problems identified, and report to A2LA the outcome of such investigations.

Document Revision History

Date	Description
June 29, 2001	General Criteria updated to reference ISO/IEC 17025. Specific Criteria numbering and order changed to match ISO/IEC 17025. Document Revision History section added. No other changes made.
September 13, 2005	Updated to reference ISO 17025:2005

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