RMTC
Racing Medication & Testing Consortium

LABORATORY ACCREDITATION REQUIREMENTS AND CODE OF STANDARDS

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** refer to the most current version for ISO/IEC 17025 requirements and Attachments A, B, C & D*

1.0 Terms and definitions

Adverse Analytical Finding: A report from a Laboratory or other approved Testing entity that identifies in a Sample the presence of a Prohibited Substance or its Metabolites or Markers (including elevated quantities of Endogenous or Threshold Substances) or evidence of the Use of a Prohibited Practice.

Aliquot: A portion of the Sample of biological fluid or tissue *(e.g.,* urine, blood, etc.) obtained from the horse and used in the analytical testing process.

Analytical Testing: The parts of the Drug and Medication Control process involving Sample handling, analysis, and reporting following receipt in the Laboratory.

Anti-doping and Medication Control Program (ADMC): The anti-doping and medication program established under section 6(a) of the Horseracing Integrity and Safety Act of 2020.

Atypical Finding: A report from a Laboratory that requires further investigation before determination of an Adverse Analytical Finding.

Batch: A set of samples processed as a group.

Case Sample: A set of biological samples derived from a single horse that may include blood, urine, hair or other.

Certified Reference Material: Reference Material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate of analysis that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Competition: A horse race. The distinction between a Competition and an Event will be provided in the rules of the applicable organization.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or concentration of one or more specific Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance, Threshold Substance, or Prohibited Practice in a Sample. A Confirmation Procedure may also indicate in a Sample a concentration of Threshold Substance greater than a threshold concentration plus the expanded measurement uncertainty.

Coverage factor k: The coverage factor k is a numerical value from statistical tables or computation that is used to compute the expanded measurement uncertainty associated with a method. For example, a coverage factor of 3 confers a certain level of statistical certainty for the measurement uncertainty value. Larger values of the "coverage factor k" increase the certainty of the measurement uncertainty estimate.

Decision Limit - The Decision Limit is the Regulatory Threshold (*q.v.*) plus the Expanded Measurement Uncertainty (q.v.) and is therefore the highest concentration of a regulated substance that may be present in a sample without the laboratory issuing an Adverse Analytical Finding for the substance.

Designated Special Event: A series of individual national Competitions conducted together under an organizing body *(e.g.,* TOBA Graded Stakes Committee, Triple Crown Productions, Breeders' Cup Limited) and for which a significant increase of resources and sample testing capacity may be required to conduct Drug and Medication Control for the Event as determined by the RMTC.

Drug and Medication Control: The process including test distribution planning, sample collection and handling, laboratory analysis, results management, hearings and appeals.

Endogenous Substance - Any substance that is natural to the untreated horse.

Event: A series of individual Competitions *(e.g.,* Breeders' Cup races) conducted under the supervision of one organizing body.

Expanded Measurement Uncertainty - The expanded measurement uncertainty is calculated by multiplying the Coverage Factor (q.v.) by the Measurement Uncertainty (*q*.v.).

Fit for Purpose: Suitability of a test to meet testing objectives.

Horse: For purposes of Drug and Medication Control, any horse entered in an officially recognized competition conducted under the rules of racing of a Horse Racing Authority.

Horse Racing Authority: The entity(ies) designated by state or federal statute as possessing the primary authority and responsibility to adopt and implement Drug and Medication Control rules, direct the collection of Samples, manage test results, and conduct of hearings.

Horseracing Integrity and Safety Authority (HISA): The authority at the national level recognized for purposes of developing and implementing a horseracing anti-doping and medication control program and a racetrack safety program for covered horses, covered persons, and covered horseraces**.**

Horseracing Integrity and Welfare Unit (HIWU): The independent enforcement agency of the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control (ADMC) Program

In-Competition: For purposes of differentiating between In-competition and Out- of-Competition Testing, unless provided otherwise in the rules of a relevant Horse Racing Authority, an In-Competition test is a test wherein a horse is selected for Testing in the period immediately before or after completion of a Competition.

Initial Testing Procedure (Screening Procedure): An analytical test procedure whose purpose is to identify those Samples which may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Practice or the quantity of a Threshold Substance, Metabolite(s) of a Threshold Substance, or Marker(s) of the Use of a Threshold Substance or Prohibited Practice in excess of a defined threshold.

Interim Accreditation: Accreditation status awarded to laboratories that have satisfactorily completed the application requirements but which have not yet received full accreditation.

Intermediate Precision, si: Variation, expressed as a standard deviation or relative standard deviation, in test results observed when one or more factors, such as time, equipment, and operator are varied within a Laboratory.

International Standard: A standard adopted by the RMTC in support of the Code. Compliance with a National Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the National Standard were performed properly.

Laboratory: An accredited laboratory applying test methods and processes to provide evidentiary data for the detection and, if applicable, quantification of a substance in urine, blood, and other biological or non-biological Samples.

Laboratory Documentation Package: The physical or electronic records produced by the Laboratory to support the issuance of an Adverse Analytical Finding *(q.v.)* as set forth in the RMTC Technical Document 'for Laboratory Documentation Packages (Appendix C).

Laboratory Internal Chain of Custody: Documentation of the sequence of Persons in possession of the Sample and any Aliquot of the Sample taken for Testing. [Comment: Laboratory Internal Chain of Custody is generally documented by a written record of the date, location, action taken, and the individual performing an action with a Sample or Aliquot.]

Marker: A substance, group of substances, or biological measurements that indicate the Use of a Prohibited Substance or a Prohibited Practice.

Measurement Uncertainty: The Measurement Uncertainty (MU) is a parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the concentration of the analyte. The MU is different from the error *(i.e.,* bias) associated with the measurement since the error or bias is the difference between the measured value and the true value whereas the measurement uncertainty is a range of values that could reasonably be attributed to the measured concentration.

Metabolite: Any substance produced by a biotransformation process.

Minimum Required Performance Level (MRPL): concentration of a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Practice that a Laboratory is expected to reliably detect and confirm in the routine daily operation of the Laboratory. See Attachment B— AGSC Testing Protocol (Current version).

National Standard for Laboratories (NSL): The National Standard applicable to Laboratories as set forth herein.

Non-Biological Sample/Specimen - Any material other than blood and urine that is collected for the purposes of Drug and Medication Control. Examples of non- biological material include aqueous, semi-solid, and solid substances, unknown solutions, powders, tablets, swabs, syringes, animal feed or other materials officially collected for the purposes of Drug and Medication Control.

Non-Threshold Substance: A substance for which the documentable detection of that substance at any concentration is considered a Drug and Medication Control rule violation.

Out-of-Competition: Any Drug and Medication Control procedures so described under RCI Model Rules, Section ARCI-025-022.

Person: A natural person or an organization or other entity.

Presumptive Analytical Finding: The status of a Sample test result for which there is a suspicious result in the Initial Testing Procedure, but for which a confirmation test has not yet been completed.

Prohibited Practice: Any method or practice so described under RCI Model Rules, Section ARCI-011-015.

Prohibited Substance: Any substance not specifically permitted by state statute or by the rules promulgated by the Horse Racing Authority as a Regulated Therapeutic Substance or Endogenous Substance. .

Publicly Disclose or Publicly Report: To disseminate or distribute information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with Article 14.

Quality Manual: The Quality Manual is a document that describes the Laboratory's quality system. The Quality Manual shall include an Introduction, statement of the Scope, a section on Definitions and Terminology, a section on Management Requirements, and a section on Technical Requirements. The Management Requirements shall include sections on Organization, the Management System, Document control, Review of Contracts, Subcontracting, Purchasing, Service to the customer, Complaints, Control of Non-Conforming Work, Improvement, Corrective Actions, Preventive Actions, Control of Quality Records, Internal Audits, and Management Review. The Technical Requirements shall include sections on Personnel and Personnel Training, Accommodations, Test

Methods and Validation, Equipment, Measurement Traceability, Sampling, Handing of Test Items, Quality Control, and Reports and Calibration Certificates.

Reference Collection: A collection of samples of known origin that may be used in the determination of the identity of an unknown substance. For example, a well characterized sample obtained from a verified administration study in which scientific documentation of the identity of Metabolite(s) can be demonstrated.

Reference Material: Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Regulated Therapeutic Substance - A drug or medication with a recognized therapeutic use in treating horses that are engaged in racing-related activities and for which a Regulatory Threshold *(q.v.)* has been established by the relevant Horse Racing Authority.

Regulatory Threshold - The Regulatory Threshold is the maximum concentration of a Regulated Therapeutic Substance or Endogenous Substance that is permitted in a test sample under the rules established by the relevant Horse Racing Authority.

Remaining Sample: Any portion of a Sample that is retained by the Laboratory or the Horse Racing Authority after testing has been completed.

Repeatability, Sr: Variability, expressed as a standard deviation or relative standard deviation, observed within a laboratory, over a short time, using a single operator, item of equipment, etc.

Reproducibility, SR: Variability, expressed as a standard deviation or relative standard deviation, obtained when different laboratories analyze the same Sample.

Research: Activities that are directed broadly toward developing industry advances in the detection of Prohibited and Regulated Therapeutic Substances or Prohibited Practices. Examples of demonstration of research activities include, but are not limited to, the publication of research manuscripts and abstracts, reports of method development, white papers (q.v.) presentations, reports of new substance identification, grant applications submitted, research protocols developed, and other current projects.

Revocation: The permanent withdrawal of a Laboratory's RMTC accreditation.

Sample/Specimen: Any biological material collected for the purposes of Drug and Medication Control.

Screening Limit: a point below which a sample is declared negative and above which a sample is declared "suspect" or "presumptive positive". Individual screening limits may vary based on analytical methodology and are intended to minimize false "suspects" or "presumptive positives" while still ensuring analytically valid drug detection and

confirmation. Because screening limits are not related to thresholds, confirmation testing is completed qualitatively.

Split Sample: A sample collected, sealed and retained for the specific purpose of referee analysis upon the trainer's request.

Standard Operating Procedure (SOP): A set of written instructions that document a routine or repetitive activity used to perform administrative, quality assurance, and technical actions. For technical procedures, SOPs should include the following: Scope and Applicability, Method and Procedure, Definitions, Health and Safety Precautions and Warnings, Cautions and Interferences, Equipment and Supplies, and Data Management.

Suspension: The temporary withdrawal of a Laboratory's RMTC accreditation.

Tampering: Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly to alter results or prevent normal procedures from occurring.

Testing: The parts of the Drug and Medication Control process involving test distribution planning, Sample collection, Sample handling, Sample transport to the Laboratory, the actual Sample examination, Sample reporting and Sample disposal.

Threshold Substance: A substance for which the detection and quantification of the substance at a concentration in excess of a stated threshold concentration plus the expanded Measurement Uncertainty is considered an Adverse Analytical Finding. Attachment C and Attachment D comprise the current list of Threshold Substances.

Trainer: For purposes of Drug and Medication Control, the Trainer is the Person who is the absolute insurer of the condition of the Horse.

Use: The application, ingestion, inhalation, injection or consumption by any means whatsoever of any Controlled Therapeutic Substance, Prohibited Substance or Prohibited Practice.

White Paper - An authoritative report or guide that informs readers about a complex technical issue and presents the issuing body's philosophy on the matter. It is intended to assist readers in understanding an issue, solving a problem, or making a decision.

2.0 Process and Requirements for RMTC Accreditation

This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining RMTC accreditation.

2.1 Applying for RMTC Laboratory Accreditation

2.1.2 Submit initial Application Form along with a description of the Candidate Laboratory

The candidate laboratory shall complete the Application Form and the technical questionnaire as provided by the RMTC and submit them to the RMTC for review. The questionnaire will include, but is not limited to, the following:

- List of technical, administrative, and research staff members and their duties and qualifications;
- Description of physical facilities, including a description of the security provisions for Samples and records;
- List of proposed and actual instrumental resources and equipment;
- Method validation data;
- Quality Manual
- A list of all Standard Operating Procedures utilized by the laboratory in association with testing Samples received from one or more State Horse Racing Authorities.
    - Specific Standard Operating Procedures may be requested during review of the initial application. All applicable SOPs must be available for review during each Site Inspection.
- Description of all procedures regarding the purchase, procurement, assessment, validation, and use of Reference Materials.
- Proof of ISO/IEC 17025 accreditation according to ILAC-G7 specifications for the Analysis of Urine and Blood Drug and Medication Control Samples.

Note: The RMTC may require periodic updates of this information during the process of accreditation and subsequently thereafter.
All of the requested materials must be delivered to the RMTC in order to be considered for accreditation. The completed Application shall be signed by the Laboratory Director or equivalent.

2.1.3 Statement of Work Performed

Within the application, the candidate laboratory shall provide:

- Documentation of the number of horse samples by type tested annually;
- A list of State Horse Racing Authorities with which the laboratory has a contract to provide testing services meeting the requirements of the RMTC; and

- Contact information for each Horse Racing Authority with which the laboratory has a contract to provide testing services.

2.1.4 Conduct Initial visit

The RMTC Laboratory Assessors shall conduct an initial visit (2-3 days) to the candidate laboratory. The purpose of this visit is to identify and clarify issues with regard to the accreditation process and the defined requirements in the International Laboratory Accreditation (**Attachment A**: ILAC-G7 latest edition of *Accreditation Requirements and Operating Criteria for Horseracing Laboratories)* and to obtain information about different aspects of the laboratory relevant for the accreditation. Such a visit could be conducted prior to or during the accreditation process. The RMTC may pay for the site visit wholly or in part depending upon available funds.

2.1.5 Issue final report and recommendation

Within approximately six (6) weeks after the initial visit or the receipt of the completed technical questionnaire, the RMTC Horseracing Testing Laboratory Committee (HTLC) will provide a report to the candidate laboratory. In the report the HTLC will make recommendations with respect to granting the candidate laboratory the status of RMTC Interim Accreditation or, if this is not the case, identifying needed improvements in order to be considered for status of RMTC Interim Accreditation. Interim Accreditation must be conferred by the RMTC Board.

2.1.6 Demonstrate Compliance with the Code of Ethics and Conflict of Interest Requirements

The candidate laboratory shall implement and comply with the provision(s) in the Code of Ethics which are relevant for a laboratory during the probationary period. The laboratory shall communicate the Code of Ethics to all employees and shall ensure understanding of and commitment to the different aspects of the Code of Ethics. The candidate laboratory shall provide to the RMTC a letter of compliance with the Code of Ethics, signed by the Laboratory Director or equivalent.

2.1.7 Analyze PT Samples Successfully

Before receiving Interim Accreditation, the candidate laboratory shall be required to perform a pre-provisional accreditation test, consisting of the analysis of at least ten (10) Proficiency Test (PT) samples in order to assess its competence at that time. The accreditation test may be conducted before an initial site visit as described in 2.1.4. The candidate laboratory shall successfully identify and document concentrations in excess of the Regulatory Threshold(s) of Threshold Substances or Minimum Required Performance Levels (MRPL), as applicable, of the Prohibited Substances, Metabolite(s) of Prohibited Substances, or Marker(s) of Prohibited Substances or Prohibited Practices within the time specified by the Proficiency Test Program administrator.

The candidate laboratory shall provide a test report for each of the PT samples in the accreditation test or for each of the samples in the Proficiency Test Set. For negative samples, the RMTC HTLC may request all or a portion of the negative screening data. For selected samples for which there is a Positive Finding, the candidate laboratory shall provide a Laboratory Documentation Package. Additional data are to be provided by the laboratory upon the RMTC HTLC's request. The candidate laboratory's performance in the accreditation test shall be taken into consideration by the HTLC to gauge the laboratory's competence as well as allow the HTLC to provide feedback on areas in need of improvement.

Documentation of corrective actions, if any, shall be reported to the HTLC upon request. Results of such proficiency testing will be taken into account in the overall review of the candidate laboratory's application and may affect the timeliness of the candidate laboratory's entry into the interim phase of the accreditation process.

2.2 Preparing for RMTC Laboratory Accreditation

Before receiving Full Accreditation, the candidate laboratory shall be required to successfully analyze Proficiency Test (PT) samples over two consecutive rounds.

The candidate laboratory shall successfully identify and document concentrations in excess of the Regulatory Threshold(s) of Threshold Substances or Minimum Required Performance Levels (MRPL), as applicable, of the Prohibited Substances, Metabolite(s) of Prohibited Substances, or Marker(s) of Prohibited Substances or Prohibited Practices within the time specified by the Proficiency Test Program administrator.

The candidate laboratory shall provide a test report (or using the reporting method as specified by the PT sample provider) for each of the PT samples in the accreditation test or for each of the samples in the Proficiency Test Set. For negative samples, the RMTC HTLC may request all or a portion of the negative screening data. For selected samples for which there is a Positive Finding, the candidate laboratory shall provide a Laboratory Documentation Package upon request by the HTLC. The candidate laboratory's performance in the accreditation test shall be taken into consideration by the HTLC to gauge the laboratory's competence as well as allow the HTLC to provide feedback on areas in need of improvement.

Documentation of corrective actions, if any, shall be reported to the HTLC upon request. Results of such proficiency testing will be taken into account in the overall review of the candidate laboratory's application and may affect the timeliness of the candidate laboratory's entry into the interim phase of the accreditation process.

Upon successful completion of the provisions of section 2.1 and following official notification by the RMTC, a candidate laboratory enters the interim phase of RMTC accreditation as an RMTC interim accredited laboratory. The interim accreditation period shall end no later than one (1) year after notification by the RMTC and following the successful completion of all proficiency test sets received during the interim accreditation period (see Section 2.2.2).

2.2.1 Obtain Laboratory ISO/IEC 17025 accreditation

The laboratory shall be accredited by a relevant accreditation body to ISO/IEC 17025 as an animal testing laboratory or its equivalent as specified in ILAC-G7 for the Analysis of Urine and Blood Drug and Medication Control Samples. At a minimum the laboratory must be ISO/IEC 17025 accredited to perform testing for threshold substances in;

- Matrices - horse blood and horse urine
- Instrumentation - LC/MS, GC/MS
- Extraction Techniques - Solid-phase, Liquid-liquid
- Test Techniques - Enzyme-Linked Immunosorbent assay (ELISA); Specific Gravity by Refractometry or other validated methods; pH; Ion Selective Electrode Method or other validated method for determination of Total Carbon Dioxide at applicable thresholds; Liquid Chromatography-Mass Spectrometry; Gas Chromatography- Mass Spectrometry

Summaries of the Assessment Report and any documentation of correction of non-conformities shall be sent by the laboratory to the RMTC. ISO/IEC 17025 accreditation shall be obtained before the end of the provisional period. The interim-accredited laboratory shall submit documentation of ISO/IEC 17025 accreditation to the RMTC.

2.2.2 Participate in the Horse Testing Laboratory External Quality Assurance Program (EQAP)

During the interim accreditation period the laboratory shall successfully analyze an additional set of single-masked PT samples containing a minimum of ten samples (See Appendix A for a description of the Horse Testing Laboratory External Quality Assurance Program).

Costs associated with the RMTC EQAP shall be paid by the laboratory unless funding is provided through the RMTC. The interim accredited laboratory shall successfully identify and/or document a concentration in excess of the threshold or Minimum Required Performance Level (MRPL) of the Prohibited Substances, Metabolite(s) of Prohibited Substances, or Marker(s) of Prohibited Substances or Prohibited Practices within the time specified by the EQAP administrator. The interim accredited laboratory shall provide a copy of the Test Report to the HTLC for each of the samples in the proficiency test. For negative samples, the RMTC *may* request all or a portion of the negative screening data. For selected samples for which there is a Positive Analytical Finding, the interim accredited laboratory shall provide a Laboratory Documentation Package. This documentation shall be submitted to the Horse Racing Authority and the RMTC HTLC within thirty (30) days of the RMTC's request.

2.2.3 Plan and implement Research activities

All laboratories are required to demonstrate the existence of an active research program. The interim accredited laboratory shall develop a plan for its Research and development activities in the field of Drug and Medication Control. The Research activities can either be

conducted independently by the laboratory or in collaboration with other RMTC accredited Laboratories or other RMTC approved research organizations. The Research plan should be developed in consultation with the relevant Horse Racing Authority. Refer to Section 4.0 for specific details and requirements regarding Research activities.

2.2.4 Plan and implement sharing of knowledge

The interim accredited laboratory shall demonstrate during the interim period its willingness and ability to share knowledge with all other RMTC accredited Laboratories. The posting of reports of original research on the Laboratory Directors page (at www.rmtcnet.org) shall satisfy this requirement. The interim accredited laboratory shall prepare and convey information and knowledge on at least two specific areas of investigation to the other RMTC accredited Laboratories within the interim period at periodic meetings such as the AORC or ICRAV.

2.3 Obtaining RMTC Accreditation

2.3.1 Participate in RMTC accreditation audits and resolve any non-compliance issues

In the last phase of the interim accreditation period, the RMTC will review the laboratory's RMTC accreditation application status. Items reviewed include: the laboratory's initial application packet and subsequent audit report, the results from all EQAP rounds, the on-site inspection audit report, and all reports of the resolution of any non-compliance matters identified through the above processes. Compliance with the defined requirements in the Application of ISO/IEC 17025 to the Analysis of Urine and Blood Drug and Medication Control Samples (Section 2) and the practice and documentation of the laboratory will be assessed. The final RMTC assessment may only consist of a document audit. Otherwise, the audit may be conducted together with the relevant accreditation body or separately, if more practical. Should an additional on-site audit be required by the RMTC, the associated cost shall be paid by the laboratory. Based on the results of the audit, the RMTC will issue an Audit Report and submit this to the laboratory. If applicable, the laboratory shall correct identified non-compliance matters within defined timeframes and report these to the RMTC.

2.3.2 RMTC report and recommendation

Based on its reviews of the relevant documentation from the laboratory, the Audit Report(s) from RMTC representative(s), and the Audit Report(s) from the relevant accreditation body, the RMTC will make a final report including a recommendation concerning the accreditation of the laboratory. The report and recommendation will be submitted to the RMTC HTLC for approval. If the recommendation is that the laboratory should not be accredited, the laboratory may correct and improve specific parts of their operation within a timeframe specified by the HTLC, at which time a further assessment and report will be made by the RMTC.

2.3.3 Receive signed Accreditation certificate

A certificate signed by a duly authorized representative of the RMTC shall be issued in recognition of an accreditation. Such certificate shall specify the name of the Laboratory and the period *(e.g.,* typically two years) for which the certificate is valid. Certificates may be issued after the effective date, with retroactive effect. A list of accredited Laboratories will be available on RMTC's website at http://www.RMTCnet.com.

2.4 Maintaining RMTC Accreditation

2.4.1 Maintain ISO/IEC 17025 accreditation

The Laboratory shall maintain accreditation from the relevant accreditation body to ISO/IEC 17025 including compliance with ILAC-G7 for the Analysis of Urine and Blood Drug and Medication Control Samples (refer to Section 2.2.1 for minimum accreditation requirements and scope).

2.4.2 Participate in the Horse Testing Laboratory External Quality Assurance Program (EQAP)

Each RMTC accredited Laboratory shall successfully participate in the Horse Testing Laboratory External Quality Assurance Program (EQAP) involving proficiency test samples.

2.4.3 Document Compliance with the RMTC Laboratory Code of Ethics plus Conflict of Interest

The Laboratory shall annually provide to the RMTC a letter of compliance with the provisions of the Code of Ethics (Appendix B), signed by the Laboratory Director or equivalent.

2.4.4 Document implemented Research activities

The Laboratory shall maintain a plan for Research and development in the field of Drug and Medication Control in horses.

The Laboratory shall document the publication of results of its Research activities in relevant scientific papers in the peer-reviewed scientific literature. The list of peer-reviewed publications shall be made available to the RMTC upon request. The Laboratory may also demonstrate its Research program by documenting successful applications for Research grants.

The Laboratory shall provide an annual progress report to the RMTC documenting Research and development efforts in the field of Drug and Medication Control in horses and dissemination of the results. The Laboratory should also describe Research and development plans for the next year.

2.4.5 Document implemented sharing of knowledge

The Laboratory shall demonstrate its willingness and ability to share knowledge with other RMTC accredited Laboratories. The Laboratory shall provide an annual report on sharing of knowledge with all other RMTC accredited Laboratories. A description of this sharing is provided in Section 4.0.

2.4.6 Omitted

2.4.7 Minimum number of Case Samples

In order to maintain proficiency, RMTC-accredited Laboratories are required to analyze Drug and Medication Control Samples from horses that are submitted by State Horse Racing Authorities from a minimum of 2,500 case samples per year, excluding samples submitted for TCO_2 analysis, following the principles of the RMTC Drug and Medication Control Program. The RMTC will monitor the number of case samples tested by the Laboratory. If the number of case samples tested falls below 2,500 per year, RMTC Laboratory accreditation may be suspended or revoked in accordance with sections 2.4.9.2, and 2.4.9.3. Samples that qualify toward meeting this requirement and any exceptions to the minimum number of samples can be reviewed and considered by the HTLC. Laboratories that do not meet this requirement but have met all other Code requirements may qualify for provisional Accreditation if approved by the RMTC Board.

2.4.8 Participate in RMTC/Accreditation Body periodic assessments and re-assessments

The RMTC reserves the right to inspect and assess the Laboratory at any time. The notice of the assessment/inspection will be made in writing to the Laboratory Director or equivalent. In exceptional circumstances, the assessment/inspection may be unannounced.

2.4.8.1 Accreditation Body re-assessment

The Laboratory must maintain ISO/IEC 17025 accreditation including compliance with ILAC-G7 for the Analysis of Urine and Blood Drug and Medication Control Samples (Section 2).

The Laboratory shall submit copies of the assessment summary report as well as the Laboratory responses in a timely fashion to the RMTC. The Laboratory shall also provide a copy of the ISO/IEC 17025 certificate to the RMTC as soon as it is received from the relevant accreditation body.

2.4.8.2 Accreditation Body periodic assessment

In years when an ISO/IEC 17025 assessment is required, the Laboratory shall provide the RMTC with a copy of any external assessments and evidence of corrective actions for any non-compliance(s) within thirty (30) days of completion.

2.4.8.3 RMTC Re-accreditation Inspection

At a minimum accredited laboratories will undergo on-site inspections once every three accreditation cycles by an RMTC Laboratory Accessor as a requirement for maintaining RMTC accreditation. Site inspections will be planned in concert with the laboratory and will typically last from 1 to 2 days. The RMTC will reserve the right to perform re-accreditation inspections for substantive changes in the ISO scope of ISO accreditation as well as, changes in laboratory staffing, ownership, and/or management. Laboratories may be required to cover all costs associated with accreditation inspections.

2.4.9 RMTC report and recommendation

The RMTC will annually review Laboratory compliance with the requirements listed in ILAC-G7. With the exception of re-accreditation and other required on-site assessments, the annual review may consist of a documentation assessment. The RMTC may require documentation from the Laboratory. Failure of the Laboratory to provide timely information requested in evaluating performance by the specified date shall be considered a refusal to cooperate and may result in Suspension or Revocation of accreditation (see 2.4.9.2).

The RMTC will consider the overall performance of the laboratory, its performance in the EQAP, and its routine performance in making decisions regarding continued accreditation. The Laboratory's performance on all aspects of the standards specified in Section 2 (such as turnaround times, Documentation Package contents, and feedback from customer organizations) will be considered in formulating such recommendation in consultation with the relevant Horse Racing Authority.

2.4.9.1 Maintenance of accreditation

In the event that the Laboratory has maintained satisfactory performance, the RMTC will maintain the accreditation of the Laboratory.

2.4.9.2 Suspension of accreditation

Whenever the RMTC has reason to believe that Suspension of accreditation may be required and that immediate action is necessary in order to protect the interests of the Drug and Medication Control Community, the RMTC may immediately suspend a Laboratory's accreditation. If necessary, such a decision may be taken by the Chairman of the RMTC Executive Committee. Confidential notice will be given to the relevant Horse Racing Authority.

Suspension of accreditation may be based on, but not limited to, the following considerations:

- Suspension of ISO/IEC 17025 accreditation;
- Failure to take appropriate corrective action after unsatisfactory performance either in routine Analytical Testing or in proficiency testing;
- Failure to comply with any of the requirements or standards listed in ILAC- G7;
- Failure to cooperate with the RMTC or the relevant Horse Racing Authority in providing requested documentation;
- Lack of compliance with the RMTC Laboratory Code of Ethics;
- Major changes in key staff without proper and timely notification to RMTC;
- Failure to cooperate in any RMTC enquiry in relation to the activities of the Laboratory;
- Non-compliances identified from laboratory on-site assessments;
- Loss of financial and administrative support jeopardizing the quality and/or viability of the Laboratory.
- Material breach of contractual obligation to a Horse Racing Authority.

The RMTC may decide upon a Suspension of accreditation at any time based on the results of the EQAP program or other evidence of serious deviation(s) from the ILAC-G7 arising from the routine analysis of Drug and Medication Control Samples.

The period and terms of Suspension shall be proportionate to the seriousness of the non-compliance(s) or lack of performance and the need to ensure accurate and reliable drug testing of Horses. A period of Suspension shall be up to 6 months, during which time any non-compliance(s) must be corrected, documented and reported to the RMTC at least six (6) weeks before the end of the Suspension period. Delay in submitting the proper corrective actions may lead to an extension of the Suspension period. If the non-compliance is not corrected during the Suspension period, the Laboratory accreditation will be revoked, unless an extension, not to exceed two (2) months, is granted by the RMTC.

2.4.9.3 Revocation of accreditation

The RMTC Executive Committee in consultation with the HTLC may revoke the accreditation of any Laboratory accredited under these provisions if it determines that Revocation is necessary to ensure the reliability and accuracy of drug tests and the accurate reporting of test results. Revocation of accreditation may be based on, but not limited to, the following considerations:

- Loss of ISO/IEC 17025 accreditation or repeated Suspensions of ISO/IEC 17025 accreditation;
- Systematic failure to comply with ILAC-G7;
- Laboratory non-compliances identified *(e.g.,* on-site assessments, documented client complaints, other enquiries);
- Repeated failure to take appropriate corrective action following unsatisfactory performance either in routine analytical testing or in proficiency testing;

- A repeated violation of the requirements and provisions of ILAC-G7;
- Failure to correct a lack of compliance with any of the requirements or standards listed in the ILAC-G7 and Appendix A EQAP during a Suspension period;
- Failure to cooperate with the RMTC or the relevant Horse Racing Authority during the Suspension period;
- Recurrent non-compliances to the ILAC-G7 and lack of cooperation with the RMTC;
- Failure to inform clients of Suspension of accreditation;
- A repeated violation of the Code of Ethics;
- Any other cause that materially affects the ability of the Laboratory to ensure the reliability and accuracy of drug tests and the accurate reporting of results.

If a Laboratory, whose accreditation has been revoked, should seek a new accreditation, it shall begin the process as a new laboratory as described in Section 2.1

2.4.10 Notification

2.4.10.1 Written Notice

When a Laboratory is suspended or the RMTC seeks to revoke accreditation, the RMTC shall immediately serve the Laboratory with written notice of the Suspension or proposed Revocation by facsimile, hand delivery, or registered or certified mail, return receipt requested. This notice shall state the following:

1) The reason for Suspension or proposed Revocation;
2) The terms of the Suspension or proposed Revocation; and
3) The period of Suspension.

2.4.10.2 Effective Date

A Suspension is immediately effective. A proposed Revocation is effective sixty (60) calendar days after the date on the written notice or, if review is requested, upon the RMTC's decision to uphold the proposed Revocation. A Laboratory that has received notice that its accreditation is in the process of being revoked shall be suspended until the Revocation is made final or is rescinded by the RMTC.

2.4.10.3 Public Notice

The RMTC will immediately notify all relevant authorities of the name and address of any Laboratory that has had its accreditation suspended or revoked, and the name of any Laboratory that has had its Suspension lifted.

The RMTC will provide to any Horse Racing Authority, upon written request, the RMTC's written decision which upholds or denies the Suspension or proposed Revocation.

The RMTC's website will be updated regarding a Laboratory's accreditation status.

2.4.11 Issue and publication of Accreditation certificate

If maintenance of accreditation is approved, the Laboratory shall receive a certificate signed by a duly authorized representative of the RMTC issued in recognition of such accreditation. Such a certificate shall specify the name of the
Laboratory. Certificates may be issued after the effective date, with retroactive effect.

2.5 Accreditation Requirements for Designated Special Events

There must be agreement between the Designated Special Event Organizer, the Horse Racing Authority, and the RMTC accredited Laboratory with regard to testing requirements such as turn-around time and scope of testing (if different from those for routine samples, *e.g.* Thoroughbred Owners and Breeders Association's Graded Stakes racing, Breeders Cup Races). The Laboratory may be required to report on staffing and equipment issues as required by the RMTC.

2.6 Accreditation Requirements for Split Sample Analysis

The Laboratory must adhere to the RMTC Guidelines for Split Sample Analysis (Appendix D) and comply with the parameters of any request for the analysis of a split sample received from a Horse Racing Authority. It is mandatory for the Laboratory to reply to requests for split sample analysis received from a Horse Racing Authority within the indicated timeframe. The Laboratory has the right to decline to accept but must provide an explanation.

2.7 Accreditation Requirements for Information Requests

This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining RMTC accreditation.

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3.0 Application of ISO/IEC 17025 to the Analysis of Urine and Blood Drug and Medication Control Samples

3.1 Introduction and Scope

This section of the document is intended as an application as described in ISO/IEC 17025 and ILAC-G7 for the field of Drug and Medication Control. Any aspect of testing or management not specifically discussed in this document shall be governed by ISO/IEC 17025 and ILAC-G7. The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as an equine Drug and Medication Control Laboratory and are therefore determined to be significant in the evaluation and accreditation process.

This section introduces the specific performance standards for an equine Drug and Medication Control Laboratory. The conduct of testing is considered a process within the definitions of ISO 17000. Performance standards are defined according to a process model where the equine Drug and Medication Control Laboratory practice is structured into three main categories of processes:

- Analytical and technical processes;
- Management processes;
- Support processes.

Wherever possible, the application will follow the format of the ISO/IEC 17025 document. The concepts of the quality management system, continuous improvement, and customer satisfaction have been included.

3.2 Analytical and Technical Processes

3.2.1 Receipt of Samples

3.2.1.1 Samples may be received by any method acceptable within the concepts of the International Standard for Testing.

3.2.1.2 The transport container shall first be inspected and any irregularities recorded.

3.2.1.3 The transfer of the Samples from the courier or other person delivering the Samples shall be documented including, at a minimum, the date, the time of receipt, and the name and signature of the Laboratory representative receiving the Samples. This information shall be included in the Laboratory Internal Chain of Custody record.

3.2.2 Handling and Retention of Samples

3.2.2.1 The Laboratory shall have a system to uniquely identify the Samples and associate each Sample with the collection document or other external chain of custody record.

3.2.2.2 The Laboratory shall utilize Laboratory Internal Chain of Custody procedures to maintain control of and accountability for Samples from receipt through final disposition of the Samples.

3.2.2.3 The Laboratory shall observe and document conditions that exist at the time of receipt that may affect the integrity of a Sample. For example, irregularities noted by the Laboratory should include, but are not limited to:

- Sample tampering is evident;
- Sample is not sealed with tamper-resistant device or not sealed upon receipt;
- Sample is without a collection form (including Sample identification code) or a blank form is received with the Sample;
- Sample identification is unacceptable. For example, the number on the container does not match the Sample identification number on the form;
- Sample volume is inadequate to perform the requested testing menu;
- Sample transport conditions are not consistent with preserving the integrity of the Sample for analysis.
- Sample contains foreign objects such as insects.

3.2.2.4 Laboratory personnel shall notify and seek instructions from the Horse Racing Authority regarding rejection or testing of Samples for which irregularities are noted. If applicable, any agreement between a Horse Racing Authority and Laboratory that establishes Sample rejection criteria shall be documented.

3.2.2.5 The Laboratory shall retain the Sample(s) without an Adverse Analytical Finding or Atypical Finding for a minimum of one (1) year after the final analytical report is transmitted to the Horse Racing Authority. The Sample shall be stored frozen during the long term storage. This requirement may be modified by written agreement with the relevant Horse Racing Authority.

After the applicable storage period and with the consent of the Horse Racing Authority, the Laboratory shall either make the Samples anonymous for research purposes or dispose of the Samples. Samples used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular Horse. Disposal of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody procedures.

3.2.2.6 The Laboratory shall retain frozen each Sample with an Adverse Analytical Finding for as long as necessary in accordance with the terms set forth by the relevant Horse Racing Authority pending the conclusion of any regulatory and legal action.

Samples with irregularities shall be stored frozen for a minimum of three (3) months following the report to the Horse Racing Authority. This requirement can be modified by written agreement with the relevant Horse Racing Authority.

3.2.2.7 If the Laboratory has been informed by the Horse Racing Authority that the analysis of a Sample is challenged, disputed or under investigation, the Sample shall be stored frozen and all the records pertaining to the Testing of that Sample shall be stored until completion of any regulatory and legal challenges.

3.2.2.8 The Laboratory shall maintain a policy pertaining to retention, release, and disposal of Samples and Aliquots in accordance with the terms set forth by the relevant State Horse Racing Authority.

3.2.2.9 The Laboratory shall maintain custody information on the transfer of Samples, or portions thereof, to another Laboratory.

3.2.2.10 The laboratory may be instructed to preserve negative samples identified by the Horse Racing Authority as candidates for retroactive testing when sufficient urine or blood remains in the Sample for possible re-testing.

In cases where a Sample has been reported negative by the Laboratory following the analysis of the Sample, the Remaining Sample shall be stored frozen by the Laboratory in a secure location under a continuous chain of custody record for the purpose of possible retroactive testing. Any retroactive testing in such cases shall be governed under the terms of the contract or other legal agreement with the relevant State Horse Racing Authority.

3.2.3 Sampling and Preparation of Aliquots for Analysis

3.2.3.1 The Laboratory shall maintain paper or electronic Laboratory Internal Chain of Custody procedures for control of and accountability for all Aliquots and other subsamples and transfers from preparation through disposal.

3.2.3.2 Before the initial opening of a Sample bottle, the device used to ensure the integrity of the Sample *(e.g.,* security tape or a bottle sealing system) shall be inspected and the integrity documented.

3.2.3.3 The Aliquot preparation procedure for any Initial Testing Procedure or Confirmation Procedure shall ensure that no risk of contamination of the Sample or Aliquot exists.

3.2.3.4 No Aliquots or Sample portions removed from the original Sample container may be poured back into the original Sample container.

3.2.4 Analytical Testing

3.2.4.1 Urine analysis for adulteration or manipulation

3.2.4.1.1 The Laboratory shall note any unusual condition of the urine - for example: color, odor, turbidity or foam. Any unusual conditions should be recorded and included as part of the report to the Horse Racing Authority.

3.2.4.1.2 The Laboratory shall measure the pH and specific gravity of sample(s) with an Adverse Analytical Finding. Other tests that may assist in the evaluation of adulteration or manipulation may be performed if deemed necessary.

3.2.4.2 Urine/Blood Initial Testing Procedure

3.2.4.2.1 The Initial Testing Procedure(s) shall detect the Threshold Substances, Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Practice for all substances covered by the ARCI Uniform Classification Guidelines for Foreign Substances for which there is a method that is Fit-for-Purpose. The RMTC, in consultation with the relevant Horse Racing Authority, may make specific exceptions to this section for specialized techniques that are not required to be within the scope of accreditation of all Laboratories.

3.2.4.2.2 The Initial Testing Procedure shall be performed with a Fit-for-Purpose method for the Threshold Substances, Prohibited Substance, or Prohibited Practice being tested. A characteristic of the Initial Testing Procedure is to obtain information about the potential presence of Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Practice.

3.2.4.2.3 All batches undergoing the Initial Testing Procedure shall include appropriate negative and positive controls in addition to the Samples being tested.

3.2.4.2.4 For Threshold Substances, appropriate controls near the threshold shall be included in the Initial Testing Procedures.

3.2.4.3 Urine/Blood Confirmation Procedure.

All Confirmation Procedures shall be documented. The objective of the Confirmation Procedure is to accumulate additional information to support an Adverse Analytical Finding. A Confirmation Procedure shall have equal or greater selectivity/discrimination than the Initial Testing Procedure.

3.2.4.3.1 Sample Confirmation

3.2.4.3.1.1 A Presumptive Analytical Finding from an Initial Testing Procedure of a Threshold Substance, Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Practice shall be confirmed using an additional Aliquot(s) taken from the original Sample.

3.2.4.3.1.2 Mass spectrometry (MS) coupled to either gas (GC) or liquid chromatography (LC) is the analytical technique of choice for confirmation of Threshold Substances, Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Practice. Exceptions to this statement include determinations of tCO2 by Total Carbon Dioxide Analyzer and the determination of cobalt ion by ICP-MS.

3.2.4.3.1.3 The Laboratory shall have a policy to define those circumstances where the Confirmation Procedure for a Sample may be repeated *(e.g.,* batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and be performed on a new Aliquot of the Sample.

3.2.4.3.1.4 If more than one Threshold Substance, Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Practice is identified by the Initial Testing Procedures, the Laboratory is not required to confirm every Presumptive Analytical Finding. The decision on the prioritization of order of confirmation(s) should be made in cooperation with the Horse Racing Authority and the decision documented.

3.2.4.3.1.5 The mean value of the results of at least two Aliquots for the Sample finding for Threshold Substances must exceed the relevant Threshold plus the value of the expanded Measurement Uncertainty determined by the Laboratory. Adverse Analytical Finding or Atypical Finding decisions shall be based on the mean of the measured concentrations, taking into account the Measurement Uncertainty with the coverage factor, k, and a level of confidence of at least 95%. Reports and documentation shall give the mean concentration with the associated uncertainty, unless otherwise specified by the relevant Horse Racing Authority.

3.2.5 Results Management

3.2.5.1 Review of results

3.2.5.1.1 A minimum of two certifying scientists shall independently review all Adverse Analytical Findings and Atypical Findings before a report is issued. The review process shall be documented.

3.2.5.1.2 At a minimum, the review shall include:

- Laboratory Internal Chain of Custody documentation;
- Validity of the initial and confirmatory data and calculations;
- Quality control data;
- Completeness of documentation supporting the reported analytical findings.

3.2.5.1.3 When an Adverse Analytical Finding is rejected, the reason(s) shall be recorded.

3.2.6 Documentation and Reporting

3.2.6.1 The Laboratory shall have documented procedures to ensure that it maintains a coordinated record related to each Sample analyzed. In the case of an Adverse Analytical Finding, the record shall include the data necessary to support the conclusions reported. In general, the record should be such that in the absence of the analyst, another competent analyst could evaluate what tests had been performed and interpret the data.

3.2.6.2 Each step of testing shall be traceable to the staff member who performed that step.

3.2.6.3 Significant variance from the written Standard Operating Procedure shall be documented as part of the record *(e.g.,* memorandum for the record).

3.2.6.4 Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.

3.2.6.5 The preliminary Sample test results should be issued within fourteen (14) calendar days of receipt of the Sample indicating, at a minimum, whether the sample has cleared. The preliminary result reporting time may be altered by written agreement between the Laboratory and the Horse Racing Authority but in no event shall it exceed 14 days.

3.2.6.6 A single, distinct Test Report shall be generated to document the Adverse Analytical Finding(s) of an individual Sample. The Laboratory Test Report may include, in addition to the items stipulated in ISO/IEC 17025, the following:

- Client Sample identification code;
- Laboratory identification code;
- Type of test (e.g., Post-race, Out of Competition/In-Competition);
- Date of receipt of Sample;
- Date of report;
- Sex of the horse;
- Permitted medications
- Type of Sample (urine, blood, etc.);
- Test results (for Threshold Substances: the mean value, units and reporting threshold shall be included);
- Signature of authorized individual;
- Other information as specified by the Horse Racing Authority and/or RMTC.

At a minimum, labeling and information provided by the Laboratory related to the type of test, test results (including comments/opinions) and client to whom the report is addressed shall also be provided on the test report.

3.2.6.7 The Laboratory is not required to measure or report a concentration for Prohibited Substances for a non-threshold analyte in urine/blood Samples. The Laboratory shall report the actual Prohibited Substance(s), Metabolite(s) of the Prohibited Substance(s) or Prohibited Practice(s), or Marker(s) detected in the urine/blood Sample.

For Threshold Substances in urine/blood Samples, the Laboratory report shall establish that the Prohibited Practice or Threshold Substance is present at a concentration greater than the threshold concentration (taking into consideration the value of the expanded Measurement Uncertainty for the Sample confirmation only).

3.2.6.8 The Laboratory should qualify the result(s) in the Test Report to indicate whether the sample is subject to an Adverse Analytical Finding.

3.2.6.9 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data which has been approved in writing by the Horse Racing Authority. An opinion or interpretation may be included in the Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented. Note: An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, whether the observed results may suggest the need for additional Testing and whether an observed result is consistent with a set of reported conditions.

3.2.6.10 The Laboratory, upon request by Testing Authorities, may be asked to review data from longitudinal studies. Following review of the applicable data, a report and recommendation shall be made by the Laboratory to the Horse Racing Authority as to whether the data support an Adverse Analytical Finding or not.

3.2.6.11 The Laboratory Documentation Package should be provided by the Laboratory only to the relevant result management authority upon request and should be provided within 10 working days of the request. Laboratory Documentation Packages shall contain material specified in the RMTC Technical
Document on Laboratory Documentation Packages (Appendix C).

3.3 Quality Management Processes

3.3.1 Organization

3.3.1.1 Within the framework of ISO/IEC 17025, the Laboratory shall be considered as a testing Laboratory.

3.3.1.2 The administrative and operational activities of the Laboratory, as well as the hosting facility, should be independent from the Drug and Medication Control Organization(s) providing support *(e.g.,* financial, Samples, facilities) to the Laboratory.

3.3.1.3 The Laboratory Director shall have the responsibilities of the Chief Executive, unless otherwise specified by the Laboratory.

3.3.2 Quality Policy and Objectives

3.3.2.1 The Quality Policy and implementation shall meet the requirements of ISO/IEC 17025 Section 4.2 Management System and shall include a Quality Manual that describes the quality system.

3.3.2.2 A single staff member should be appointed as the Quality Manager and shall have responsibility and authority to implement and ensure compliance with the quality system.

3.3.3 Document Control

The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025 Section 4.3 Document Control.

3.3.3.1 The Laboratory Director (or designee) shall approve the Quality Manual and all other documents used by staff members in completing testing.

3.3.4 Review of requests, tenders, and contracts

Review of legal documents or agreements related to testing shall meet the requirements of ISO/IEC 17025 Section 4.4.

As a requirement of receiving and continuing RMTC Accreditation, the Laboratory represents that it has had discussions with each of their contracted State Horse Racing Authorities certifying that they are compliant with, at a minimum, TOBA
American Graded Stakes testing requirements and the RMTC Controlled Therapeutic substances testing requirements in Samples submitted for analysis. This statement shall be included in the application which is signed by the Laboratory Director or equivalent.

3.4.4 Test Methods and Method Validation

3.4.4.1 Selection of Methods

Standard methods are generally not available for Drug and Medication Control analyses. Therefore, the Laboratory shall develop, validate, and document methods for the detection of substances present on the ARCI Uniform Classification Guidelines for Foreign Substance and for associated Metabolites or Markers or related substances.

Note that, for many substances, the associated metabolites are detected, thereby confirming the metabolism and the administration of a Prohibited Substance to the horse from which the sample was collected. The methods shall be selected and validated so they are Fit-for-Purpose.

3.4.4.1.1 Non-Threshold Substances

Laboratories are not required to measure or report a concentration for NonThreshold Substances.

The Laboratory shall develop, as part of the method validation process, acceptable standards for identification of Prohibited Substances based on ILAC G7 and AORC guidelines.

The Laboratory shall demonstrate the ability to successfully identify 100% of the time representative substances in the class of Prohibited Substances at the Minimum Required Performance Levels *(e.g.,* twenty urine samples prepared by the laboratory supplemented at the MRPL). The Laboratory shall establish, in routine practice, the use of control samples containing representative substance(s) at the MRPL. A Reference Collection may be used for identification and, in such cases, an estimate of the detection capability for the method may be provided by assessing a representative substance.

3.4.4.1.2 Threshold Substances

The Laboratory shall develop methods that are Fit-for-Purpose. The method shall be capable of determining both the concentration and the identity of the Threshold Substance.

Confirmation methods for Threshold Substances shall be performed on a minimum of two aliquots. If insufficient sample volume exists to analyze two Aliquots, the determination should be based on the measurement of one Aliquot. Adverse Analytical Finding decisions shall be based on the mean of the measured concentrations, taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of at least 95%. Reports and documentation, where necessary, shall report the mean concentration.

3.4.4.2 Validation of Methods

3.4.4.2.1 Confirmation methods for Non-Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-Purpose include but are not limited to:

- Specificity. The ability of the method to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between substances with closely related structures;
- Identification capability. Since the results for Non-Threshold Substances are not quantitative, the Laboratory should establish criteria for ensuring that a substance representative of the class of Prohibited Substances can be repeatedly identified and detected as present in the Sample at the MRPL;
- Robustness. The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;

- Carryover. The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method should avoid interference in the detection of Prohibited Substances or their Metabolites or Markers by components of the Sample matrix;
- Standards. Reference Materials should be used for identification, if available. If no reference standard is available, the use of data or a sample from a validated Reference Collection is acceptable.

3.4.4.2.2 Confirmation methods for Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-Purpose include but are not limited to:

- Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between substances with closely related structures;
- Intermediate Precision. The method shall allow for the reliable repetition of the results at different times and with different operators performing the assay.
- Intermediate Precision at the threshold shall be recorded;
- Robustness. The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;
- Carryover. The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method shall limit interference in the measurement of the concentration of Prohibited Substances or their Metabolites or Markers by components of the Sample matrix;
- Standards. Reference Materials should be used for quantification, if available;
- Limit of quantitation (LOQ). The Laboratory shall demonstrate that a threshold method has an established LOQ of no more than 50% of the threshold value for Threshold Substances;
- Linearity shall be documented at 50% to 200% of the threshold value, unless otherwise stipulated in a Technical Document.

3.4.4.3 Estimate of Uncertainty of Method

In most cases, an identification of a Prohibited Substance, its Metabolite(s) or Marker(s), is sufficient to report an Adverse Analytical Finding. The requirement for estimation of Measurement Uncertainty only applies to quantitative determinations.

3.4.4.3.1 Uncertainty in identification

The appropriate analytical characteristics shall be documented for a particular assay. The Laboratory shall establish criteria for identification of a substance at least as rigorous as stated in the relevant Technical Document.

3.4.4.3.2 Uncertainty in establishing that a substance exceeds a threshold.

The purpose of threshold reporting in Drug and Medication Control is to establish that the Threshold Substance is present at a concentration greater than the threshold value taking into consideration the applicable measurement uncertainty at the threshold. The method, including selection of standards and controls, and estimation of uncertainty shall be Fit-for-Purpose.

3.4.4.3.2.1 Uncertainty of quantitative results, particularly at the threshold value, shall be addressed during the validation of the method.

3.4.4.3.2.2 The expression of uncertainty shall use the expanded uncertainty using a coverage factor, k, to reflect a level of confidence of at least 95 %.

3.4.4.3.2.3 Uncertainty may be further addressed in Technical Documents in order to reflect the purpose of analysis for the specific substances.

3.4.4.4 Control of Data

3.4.4.4.1 Data and Computer Security

3.4.4.4.1.1 All reasonable measures shall be taken to prevent intrusion and copy of data from computer systems.

3.4.4.4.1.2 Access to computer terminals, computers, servers or other operating equipment shall be controlled by physical access and by multiple levels of access controlled by passwords or other means of employee recognition and identification. These include, but are not limited to, account privileges, user identification codes, disk access, and file access control.

3.4.4.4.1.3 The operating software and all files shall be backed up on a regular basis and a current copy shall be either stored in a fire and water proof environment or kept off site at a secure location.

3.4.4.4.1.4 The software shall prevent the changing of results unless there is a system to document the Person doing the editing and that editing can be limited to users with proper level of access.

3.4.4.4.1.5 All data entry, recording of reporting processes and all changes to reported data shall be recorded with an audit trail. This shall include the date and time, retention of original data, reason for change to original data, and the individual performing the task.

3.4.5 Equipment

3.4.5.1 A List of available and serviceable equipment is to be established and maintained.

3.4.5.2 As part of a quality system, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025 Section 5.5.

3.4.5.3 General service equipment that is not used for making measurements should be maintained by visual examination, safety checks, and cleaning as necessary. Calibrations are only required where the setting can significantly affect the test result. A maintenance schedule, at least to manufacturer's recommendations or local regulations, if available, shall be established for items such as fume hoods, centrifuges, evaporators, etc., which are used in the test method.

3.4.5.4 Equipment or volumetric devices used in measuring shall be checked periodically for conformance to performance standards along with servicing, cleaning, and repair.

3.4.5.5 Qualified subcontracted vendors may be used to service, maintain, and repair measuring equipment.

3.4.5.6 All maintenance, service, and repair of equipment shall be documented.

3.4.6 Measurement Traceability

3.4.6.1 Reference Materials

When available, reference drug or drug metabolite(s) traceable to a national standard or certified by a body of recognized status, such as USP, BP, Ph. Eur. or WHO, should be used. At a minimum, an analysis report must be obtained. A list of reference drugs need not be included in the application; however, a Standard Operating Procedure reflecting how reference drugs are acquired shall be included in the application.

When a Reference Material is not certified, the Laboratory shall verify its identity and purity by comparison with published data or by chemical characterization.

3.4.6.2 Reference Collections

A collection of sample or isolates may be obtained from a biological matrix following an authentic and verifiable administration of a Prohibited Substance or Prohibited Practice, providing that the analytical data are sufficient to justify the identity of the relevant chromatographic peak or isolate as a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Practice.

3.4.7 Assuring the quality of test results

3.4.7.1 The Laboratory shall participate in the External Quality Assurance Program (EQAP).

3.4.7.2 The Laboratory shall have in place a quality system, including the submission of masked quality control samples that challenges to the best of their ability the entire scope of the analytical process.

3.4.7.3 Analytical performance shall be monitored by operating quality control schemes appropriate to the type and frequency of testing performed by the Laboratory. The range of quality control activities should include:

- Positive and negative control samples analyzed in the same analytical run as the Presumptive Analytical Finding Sample;
- The use of deuterated or other internal standards or standard addition;
- Comparison of mass spectra or ion ratios from selected ion monitoring (SIM) to a Reference Material or Reference Collection Sample analyzed in the same analytical run;
- For Threshold Substances, quality control charts referring to appropriate control limits depending on the analytical method employed *(e.g.,* ± 10 % of the target value; ± 3SD), should be used;
- The quality control procedures shall be documented by the Laboratory.

4.0 Research Requirements and Duties for RMTC Accreditation

This section of the document describes the specific requirements for research and information sharing that an accredited laboratory shall fulfill in order to comply with the research requirements for RMTC Accreditation.

4.1 Introduction and Scope

For the purposes of the RMTC Accreditation, research is defined as any activity that is directed broadly toward developing advances in the detection of Prohibited and Regulated Substances. Examples of research activities include, but are not limited to, the publication of research papers and abstracts, reports of method development, white papers, presentations, reports of new substance identification, grant applications submitted, research protocols, and other relevant projects.

In addition to notifying the RMTC with specific details of developments when new and emerging substances are detected, an accredited laboratory shall submit an annual statement detailing research activities undertaken by the laboratory in the past calendar year. Laboratory research is a critical component of the RMTC Laboratory Accreditation Program and the RMTC's mission as a whole. Research statements help the RMTC aid further research initiatives amongst laboratories, identify possible funding sources for specific projects, and coordinate other aspects of research efforts both internationally and domestically.

4.2 Research Activities

4.2.1 Research activities are categorized into three categories: Peer-Reviewed Manuscripts, Funded Research, and Internal Laboratory Method Development Projects. These categories include but are not limited to:

Peer-Reviewed Manuscripts:
- Published peer-reviewed accounts of research efforts
- Peer-reviewed research papers, white papers, abstracts
- Presentations at stakeholder conferences
- Abstracts in published proceedings (e.g., ICRAV)

Funded Research:
- Grants with approved funding
- Research protocols for projects that have been approved but that have not been completed
- Ongoing or completed funded research

Internal Laboratory Development:
- Method development (excluding method validation)
- Grant applications not yet funded
- New substance identification
- Current projects

4.2.2 Accredited laboratories shall be required to submit an annual statement to the RMTC documenting research and development activities in the field of equine Drug and Medication Control and dissemination of the results. The Laboratory should also describe Research and development plans for the next year.

4.2.3 Annual Research summaries provided to the RMTC will be evaluated and scored by the Horseracing Testing Laboratory Committee (HTLC).

4.2.4 The scoring system is point-based and will follow the schema below:
- Five (5) points for published peer-reviewed manuscripts and Educational Materials
- Three (3) points for Funded Research Projects
- One (1) point for Internal Laboratory Method Development

4.2.5 Accredited Laboratories must receive a minimum score of ten (10) points annually to meet Accreditation research requirements.

4.3 Sharing of Information and Resources

4.3.1 New Substances

An accredited laboratory shall promptly notify the RMTC with specific information and resources regarding the detection of potentially new or rarely detected substances once

authorized by relevant authorities to do so. In addition, information (such as methodologies, relevant research findings, descriptions of procedures, sources of chemical standards and vendor information) regarding new or rare substances shall be shared with other RMTC accredited laboratories (via the secure RMTC website Directors Portal).

4.3.2 Sharing of Knowledge

Information on new methods, practices, research or prohibited substances shall be shared with the RMTC and other RMTC Accredited Laboratories after written authorization by relevant authorities has been obtained. Sharing of knowledge can occur by participation in scientific meetings, publication of results of research in scientific journals, sharing of specific details of methodology necessary for detection, and working with the RMTC to distribute information by preparation of a reference substance or biological excretion study or information regarding the chromatographic retention behavior and mass spectra of the substance or its metabolites. The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of testing in the RMTC accredited Laboratory system.

-End-

Appendix A1 - Horseracing Testing Laboratory Committee (HTLC)

1.3 Horseracing Testing Laboratory Committee (HTLC)

1.3.1 General responsibilities of the HTLC

The HTLC is tasked with overseeing the RMTC Laboratory Accreditation Program and making recommendations on the Accreditation Program and the laboratories it accredits to the RMTC Board and Executive Committee. In addition, all activities and policies of the EQAP shall be directed, administered, and reviewed by the HTLC whose mandate is to insure that the program services are relevant to the needs of the racing industry, that sample distribution polices are fair and timely, that protocols for the generation of PT samples are appropriate, and that the EQAP Provider complies with all contractual requirements and agreements.

1.3.2 Specific responsibilities of the HTLC:

- The HTLC shall define the responsibilities of the EQAP Provider laboratory and will ensure that the EQAP Provider laboratory is accredited according to ISO 43 standards.

- The HTLC will specify the Minimum Required Performance Level for each analyte that will be subject to proficiency sample testing.

- The HTLC will select the drug and target or minimum concentration for single- and double-masked PT samples, determine whether supplemented samples or administration samples will be utilized and, if administration samples are utilized, the dosing route, regime, and timing of sample collection.

- The HTLC shall specify the documentation for PT samples such that a review of: 1) analyte(s) concentrations, 2) homogeneity of the sample sets, 3) characterization of the samples, and 4) analyte(s) stability can be readily conducted.

- The HTLC shall provide oversight of the EQAP Program and EQAP Provider to ensure that the specified provisions and practices of the program are met and that the quality of the program and its services are always maintained with appropriate documentation on file.

- The HTLC shall establish a formal appeal process that is independent of the EQAP Provider. This appeal process must be open and objective, and must be able to deal with all appeals of results from the testing phase of this program.
  Reviews of appeal must be completed and final reports and recommendations issued before releasing results of proficiency testing to the regulatory agency.

- The HTLC shall review and revise the program as necessary.

- The HTLC can give final approval for a laboratory to receive Full Accreditation

1.3.3 Membership in the HTLC shall comprise the following:

- A Commissioner or staff member of a Horse Racing Authority who will be appointed by the Association of Racing Commissioners International. This committee member will have full voting privileges.

- A Co-opted member appointed by the HTLC members. This member shall have proficient working experience in any of the following areas; analytical chemistry, veterinary pharmacology, equine drug surveillance and testing or regulatory chemistry. This co-opted member shall have full voting privileges.

- A Veterinarian who will be appointed by the American Association of Equine Practitioners. The Veterinarian shall have experience in the racing industry and preferably residency training in veterinary clinical pharmacology, internal medicine or surgery, or an advanced degree in pharmacology. The Veterinarian will have full voting privileges.

- A Racing Industry member who will be appointed by the RMTC. This committee member will have full voting privileges.

- Laboratory Members representing the participating laboratories. Two members of the committee shall each be associated with a Race Horse Drug Testing Laboratory. The participating laboratories will be chosen on a rotational basis. These laboratory members will serve a staggered 2-year term on the committee. The Laboratory Members shall recuse themselves from any committee discussions related to the EQAP specifics. The Laboratory Members will have partial voting privileges consisting of % vote per Member.

- The Chairman of the committee can be the Regulatory Veterinarian or AAEP appointed member and shall be elected by the committee.

  The Committee shall have the option of selecting a Scientific Advisory Expert on an *ad hoc* membership basis and for a short period of time based on the needs of the committee. The Scientific Advisory Expert shall have no voting privileges.

Appendix A2 - External Quality Assessment Program (EQAP)

1.0 Introduction

The External Quality Assessment Program (EQAP) is designed to monitor the capabilities of laboratories, evaluate laboratory proficiency, and improve the uniformity of test results between laboratories. At the same time, the EQAP also represents, via an educational component, a mechanism to continuously improve the effectiveness of the overall testing procedure from the test barn to the regulatory agency.

1.1 Preface

The EQAP is intended to demonstrate laboratory capabilities for screening a multitude of drugs and metabolites across classes of drugs that are of regulatory concern to the horse racing industry. The proficiency program is not designed to determine the lowest concentration that a drug can be detected, but rather to determine whether a laboratory can routinely detect drugs at concentrations that are of concern to regulatory authorities.

1.2 Program Elements of the EQAP

The EQAP consists of three coordinated programs:

- An educational drug administration component in which samples collected after administration of drugs to horses are distributed to each participating laboratory with specific documentation to allow the laboratory to detect, quantify, and confirm the presence of the administered drug or its metabolites in urine and plasma or serum samples. Standard Operating Procedures for the detection, quantification, and confirmation of new drugs can also be contributed by member laboratories. This is especially important as new prohibited substances appear and newer technologies are developed by participating laboratories. These samples shall be provided by the RMTC.

- A single-blind sample component in which samples are known to be PT samples but the identities of drugs or metabolites, if any, in these samples are not known to the receiving laboratory. A list of candidate drugs will be maintained by the HTLC in concert with the participating laboratories. Multiple drugs may be present in single-blind PT samples.

- A double-blind sample component in which samples are distributed through the designated contact person for each Horse Racing Authority in such a way that laboratory personnel are unaware that the double-blind sample is present in the routine track samples submitted to the laboratory for testing. Drugs (and their associated metabolites) contained in double-blind samples will be from the same list of drugs developed for single-blind samples. Multiple drugs may be present in double-blind PT

samples.

1.3 EQAP PT Sample Composition

All procedures associated with the handling and testing of the PT samples by the laboratory are, to the greatest extent possible, to be carried out in a manner identical to that applied to routine laboratory samples, unless otherwise specified by the Horseracing Testing Laboratory Committee. No effort should be made to optimize instrument performance *(e.g.,* by changing multipliers or chromatographic columns) or method performance prior to analyzing the PT samples unless it is a regularly scheduled maintenance activity. Only methods or procedures used in routine testing should be employed.

1.3.1 Sample Content

PT samples may be supplemented or may be from horse administration studies. For Non-Threshold Substances, the substance and/or its major metabolite(s) will be present in concentrations greater than the Minimum Required Performance Level (MRPL), be approved by the HTLC, and the concentration will be documented by extensive analytical testing prior to distribution. Each laboratory has the responsibility to demonstrate analytical competency at the Minimum Required Performance Levels.

1.3.2 Single-Blind PT Samples

Each participating laboratory will receive single-blind PT samples identified as proficiency samples and will therefore be aware that the samples are PT samples. The identities of the drugs or metabolites in the PT samples will be unknown to laboratory personnel except for those samples identified as Quantitative PT samples *(q.v.).* Qualitative samples, with the exception of those identified substances with a Threshold value in the ARCI's Model Rules, do not require quantitation. Single-blind PT samples may be comprised of the following:

- **Blank PT Samples**—samples that have been demonstrated by in-depth testing prior to distribution not to contain Prohibited or Threshold Substances or their Metabolites.
- **Adverse Analytical Finding PT Samples**—samples that contain target substance(s) each laboratory must be prepared to detect by screening methods at the required Minimum Required Performance Level. For some analytes, the sample composition may consist of the parent drug as well as major metabolites. A sample may contain more than one target substance. It is also possible that the sample will contain multiple metabolites that would represent the administration of a single substance. All substances detected should be reported according to the criteria specified in the laboratory's standard operating procedures.
- **Adulterated PT Samples**—samples which have been deliberately adulterated by the addition of extraneous substances designed to dilute the sample, degrade the

analyte, or to mask the analyte during the analytical determination.

- **Quantitative PT Samples**—samples used for threshold substances only. The identity of the drug or metabolite in the sample may be revealed to the testing laboratories by the HTLC and the concentration of the substance shall be guided by one of the following criteria:
  - At least 10% above the Decision Limit if there is agreement between laboratories with regard to this value. In the absence of such agreement, the HTLC shall inform laboratories of the maximum Expanded Measurement Uncertainty to be used for determining the threshold substance and shall prepare the Quantitative PT sample at a concentration at least 20 % above this value plus the threshold concentration or;
  - At least 20% below the applicable threshold for special purpose samples. In this case, the Laboratory will be directed to analyze the sample for a particular prohibited substance as part of an educational challenge and the results will not be considered for evaluation purposes for the EQAP PT program.

  Concentrations of any of the regulated substances or metabolites found below the threshold in PT samples are considered to be negative for the purposes of the EQAP.

Each laboratory shall report the results of single-blind PT samples to the HTLC in the same manner as specified for routine samples unless otherwise directed by the HTLC. For some PT samples or sample sets, additional information may be requested of the laboratories by the EQAP Provider or the HTLC.

1.3.3 Double-Blind PT Samples

The laboratory will receive double-blind PT samples that are indistinguishable from official test samples. The double-blind PT samples may consist of blank samples, adulterated samples, horse administered samples, or samples with adverse analytical finding(s). These samples may be used to assess turn-around time, compliance with documentation package requirements, and other non- analytical performance criteria as well as Laboratory competence in detection and identification of Threshold Substances, Prohibited Substances, Metabolite(s) of Prohibited Substances, and Marker(s) of Prohibited Substances and Prohibited Practices. The laboratory will report results for double-blind EQAP PT samples to the relevant Horse Racing Authority in the manner established for reporting results for official samples.
Any of the sample types described for single-blind PT samples can comprise the Double-blind PT samples.

1.3.4 Special Purpose Samples

For Special Purpose Samples, the Prohibited Substance and/or its major Metabolite(s) will be present below the applicable MRPL. These samples may be prepared by supplementation or may also be obtained after administration of a dose that is lower than the recommended dose or from collection of samples longer than the generally expected

collection period. In the case of Special Purpose Samples, the Laboratory will be directed to analyze the sample as part of an educational challenge and the results will not be considered for evaluation purposes for the EQAP single blind or double-blind PT program but will be used to survey laboratory capabilities.

1.3.5 Open Educational PT Samples

Participating laboratories may be directed to analyze one or more PT samples for specific analytes. These samples will be used for educational and training purposes and for data gathering. Each laboratory shall report the results of tests performed on these samples in a format specified by the HTLC.

1.4 Evaluation of External Quality Assessment Program

1.4.1 Laboratory Evaluation

The PT sample testing program is a part of the continued evaluation of accredited laboratories. The PT samples shall be distributed in multiple rounds per year and will consist of a minimum of 20 single-blind samples and 5 double-blind samples per year. At least three PT samples will contain Threshold Substances for quantitative determination. . Blank and adulterated samples may also be included.

Annually laboratories will be required to submit laboratory documentation packets for 2 of the PT samples reported. The HTLC shall specify those laboratory documentation packets that are required from each participating laboratory. The HTLC can alter the number of single-blind and double-blind PT samples distributed in one calendar year. The calendar year starts January 1st and ends December 31st.

Reporting results of single-blind samples to the HTLC will be consistent with the requirements of Appendix C - Laboratory Documentation Packages. Because double-blind samples will not be known as a PT samples, results will be reported by the Laboratory to the applicable Horse Racing Authority based on established jurisdictional reporting procedures. The Horse Racing
Authority will report the results of the double-blind samples to the HTLC. Failure of the Horse Racing Authority to submit the results of double-blind PT samples shall not adversely affect the accreditation status of the laboratory.

1.4.2 Evaluation of Qualitative PT Samples

A laboratory's report for a Qualitative PC sample shall be considered correct if the findings are consistent with the contents of the PT sample and the analytical data meet the laboratory's criteria for reporting an adverse analytical finding. Qualitative PT samples may contain threshold and non-threshold substances at concentrations greater than the MRPL for each reportable substance. Evaluation will be based on the methodology listed in the current EQAP Document.

1.4.3 Evaluation of Quantitative PT Samples

A laboratory's report for a Quantitative PT sample shall be considered correct if the findings are consistent with the contents of the PT sample, correct with regard to the reporting threshold, and the analytical data meet the laboratory's criteria for reporting an adverse analytical finding. Evaluation will be based on the methodology listed in the current EQAP Document.

1.4.4 False Positive PT Sample Results

No false positive result is acceptable as part of the PT sample testing program. Any false positive finding reported shall automatically initiate a formal review of the PT sample by the EQAP Provider to insure that the sample was of acceptable quality. If the EQAP Provider review finds evidence of the presence of the reported finding or other laboratories report similar findings, the sample series involved shall be declared invalid and the EQAP Provider shall be required to initiate an appropriate corrective action plan immediately.

If the review fails to substantiate the result reported by the laboratory, appropriate remedial and preventive actions by the laboratory shall be required as follows:

1. The Laboratory and the relevant Horse Racing Authority will be informed by the HTLC of a false positive finding as soon as possible.
2. The Laboratory shall be required to provide the HTLC and the relevant Horse Racing Authority with a written report of its procedures within ten (10) working days. This report must include the submission of all quality control data from the batch of samples that included the false positive finding if the error is deemed to be of a technical or scientific nature.
3. The members of the HTLC shall review the Laboratory's report promptly and decide, in consultation with the relevant Horse Racing Authority, what further action, if any, to take;
4. If the error is determined to be an administrative error *(e.g.,* clerical, sample mix-up, etc), the HTLC may direct the Laboratory to take corrective action to minimize the occurrence of the specific error in the future. If there is reason to believe the error may have been systematic, the HTLC, in consultation with and with the consent of the relevant Horse Racing Authority, may require the Laboratory to review and re-analyze previously reported samples.
5. If the error is determined to be a technical or methodological error, the Laboratory may be required, in consultation with and with the consent of the relevant Horse Racing Authority, to re-test all samples reported positive by the Laboratory from the time of the final resolution of the error back to the time of the last satisfactory PT sample testing round. This testing shall be documented and must be submitted along with a summary statement signed by the Laboratory Director indicating the

steps taken to rectify the problem and the results of testing.

1.4.5 False Negative PT Sample Results

A false negative PT sample report shall automatically initiate appropriate remedial and preventive actions by the laboratory, unless the laboratory files an appeal regarding the validity of the PT sample within the time period specified below. If an appeal is filed, the EQAP Provider shall demonstrate that the sample was of acceptable quality. If the EQAP Provider review finds no evidence for the presence of the intended analyte(s) or other laboratories report the absence of the analyte(s), the PT sample involved shall be declared invalid and the EQAP Provider shall be required to initiate an appropriate corrective action plan immediately.

If the review verifies the presence of the intended analyte(s) or other laboratories report the presence of intended analyte(s) then the following actions by the laboratory shall be required:

1. The Laboratory must initiate proper corrective action and report its actions to the relevant State Horse Racing Authority and the HTLC within thirty (30) calendar days of the date of the report from the HTLC.
2. The laboratory may otherwise be advised by the HTLC to take corrective action for a given reason or to change a corrective action plan which has previously been submitted to the HTLC.
3. The laboratory shall implement the corrective action plan reported to the HTLC in its routine laboratory operations.

1.4.6 Threshold Substance PT Sample Results

A Laboratory with an unsatisfactory result or an unacceptably high measurement uncertainty will be required to furnish documentation of its corrective action plan to the HTLC and the relevant Horse Racing Authority within thirty (30) days of the date of the notice issued by the HTLC.

1.4.7 Overall Laboratory Evaluation

The HTLC shall evaluate the performance of each Laboratory based on the results of the single-blind and double-blind PT samples along with any other issues brought to the Committee’s attention in relation to the Laboratory's routine testing services. The factors for consideration include, but are not limited to:

1. False negative(s)
2. False Positive(s)
3. Questionable results for Threshold Substance(s)
4. Unsatisfactory results for Threshold Substance(s)
5. Improper implementation of corrective action
6. Responsiveness to the HTLC and the relevant Horse Racing Authority
7. Test Report(s)

8. Documentation package(s)

Each laboratory will achieve a score based on the HTLC guidelines. An assessment will be made on the overall performance of the laboratory after each single- and double-blind PT round based on criteria developed by the HTLC and incorporated into this document.

Appendix B - Laboratory Code of Ethics

1.0 Confidentiality

The heads of Laboratories, their delegates, and Laboratory staff shall not disclose results of testing to any persons other than those specified in the contractual agreement between the Laboratory and the relevant Horse Racing Authority. Any information shared amongst laboratories to satisfy RTMC requirements of knowledge and research sharing shall be held strictly confidential by all persons receiving

2.0 Research

Laboratories are encouraged to establish and participate in research programs provided that the Laboratory Director is satisfied with the bona fide nature of the research and the programs have received proper institutional animal care and use approval. Refer to Section 4.0 of the RMTC Laboratory Accreditation Requirements and Operating Standards, *Research Requirements and Duties for RMTC Accreditation,* for further conditions.

3.0 Research in Support of Drug and Medication Control

Laboratories are expected to develop a program of research and development to support the scientific foundation of equine Drug and Medication Control. This research may consist of the development of new methods or technologies, the pharmacological characterization of a new drug substance, the characterization of a masking agent or method, and other topics relevant to the field of equine Drug and Medication Control. Refer to Section 4.0 of the RMTC Laboratory Accreditation Requirements and Operating Standards, *Research Requirements and Duties for RMTC Accreditation,* for further conditions.

3.1 Animal subjects

Laboratories shall follow institutional animal care and use guidelines and requirements regarding the use of animal subjects in research.

3.2 Controlled substances

Laboratories shall comply with all relevant federal and state laws regarding the handling and storage of controlled substances.

4. Analysis

4.1 Competitions

Laboratories should accept and analyze Samples originating only from known sources

within the context of Drug and Medication Control programs administered by recognized State Horse Racing Authorities.

Laboratories shall ensure that Samples received are tested in accordance with the terms of the contractual agreement with the Horse Racing Authority.

4.2 Out-of-Competition testing

Laboratories shall accept Samples taken during Out-of-Competition only if the following conditions are met:

- That the Samples have been collected and sealed under the conditions generally prevailing in Competitions themselves as in Section 4.1 above;
- If the collection is a part of a Drug and Medication Control program; and

Laboratories shall not accept Samples from individual trainers on a private basis or from individuals or organizations acting on their behalf unless the State Horse Racing Authority has official programs for such testing and the results are reported directly to the Horse Racing Authority.

The provisions of Section 3.2.6.5 on reporting time requirements shall not apply to Out-of-Competition Sample testing.

4.3 Clinical or Forensic sample testing

Occasionally the Laboratory may be requested to analyze a sample for a prohibited substance or endogenous substance in order to assist the regulatory veterinarian in the diagnostic process.

Work to aid in forensic investigations may be undertaken if the work is requested by an appropriate regulatory agency or body. The Laboratory should not engage in analytical activities or expert testimony that would intentionally question the integrity of the individual or the scientific validity of work performed in a Drug and Medication Control program.

4.4 Other analytical activities

The Laboratory should not accept any external samples without the prior written consent of the Horse Racing Authority.
The Laboratory shall not engage in any analysis that undermines or is detrimental to the Drug and Medication Control program and should not provide analytical services in Drug and Medication Control adjudication, unless specifically requested by the responsible Horse Racing Authority.

The Laboratory shall not provide results, documentation or advice that, in any way, suggests endorsement of commercial products or services.

4.5 Split Sample Analysis

The Laboratory must adhere to the current RMTC Guidelines for Split Sample Analysis (Appendix D) and comply with the parameters of any request for the analysis of a split sample received from a Horse Racing Authority.

5. Laboratory Communication of Adverse Analytical Findings

5.1 Responsibility of Horse Racing Authority

It is the responsibility of the Horse Racing Authority to provide the laboratory secure communication outlets for the transmission of Adverse Analytical Findings.

5.2 Responsibility of the Laboratory

It is the responsibility of the Laboratory to communicate Adverse Analytical Findings to no entity other than persons designated by the Horse Racing Authority.

5.3 Sharing of Information and Resources

Laboratories shall share information and resources with the RMTC regarding certain industry initiatives that include the detection of new or rare substances, newly developed method(s) or practices and other technical resources once authorized by relevant authorities. Refer to Section 4.0 of the RMTC Laboratory Accreditation Requirements and Operating Standards, *Research Requirements and Duties for RMTC Accreditation,* for further conditions.

6. Conduct Detrimental to the Drug and Medication Control Program

Laboratory personnel shall not engage in conduct or activities that undermine or are detrimental to the Drug and Medication Control program of the RMTC or any Horse Racing Authority. Such conduct could include, but is not limited to, conviction for fraud, embezzlement, perjury, etc. that would cast doubt on the integrity of the Drug and Medication Control program.

No Laboratory employee or consultant shall provide counsel, advice or information to Trainers or others regarding techniques or methods to mask detection of, alter metabolism of, or suppress excretion of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Practice in order to avoid an Adverse Analytical Finding. No Laboratory staff shall assist a Trainer in avoiding collection of a suitable Sample. This paragraph does not prohibit presentations to educate Trainers, students, or others concerning Drug and Medication Control programs and Prohibited Substances or Prohibited Practices.

-End

Appendix C - Laboratory Documentation Packages

Laboratory Documentation Packages shall be provided by the Laboratory as required by the External Quality Assurance Program (EQAP) or in support of an Adverse Analytical Finding. The package shall contain information documenting the items listed below. Additional information may be included to document an Adverse Analytical Finding.

Deviations from this technical document shall not invalidate the Adverse Analytical Finding(s).

1. **All Laboratory Documentation Packages generated by the Laboratory should meet the following formatting requirements:**

    - A cover page and a signed statement by the Laboratory Director or authorized delegate certifying that the documentation package contains authentic copies of original data, records, and forms;
    - Sequentially numbered pages of the documentation package;
    - Table of Contents;
    - Presentation in a format that will allow proper review by relevant stakeholders;
    - Data, charts, graphs, etc. adequately described. [Descriptions may be provided in the Table of Contents, page headers, titles, etc]

2. **All Laboratory Documentation Packages provided shall contain the following information:**

    - List of laboratory staff involved in the test, including signatures and/or initials and position title(s) (Each individual's complete signature/name can assist in interpreting the Laboratory Internal Chain of Custody record);
    - External chain of custody record;
    - Documentation of shipping and receipt of intact sample;
    - Documentation linking sample identification number to laboratory identification number (if available);
    - Test Sample Laboratory Internal Chain of Custody records;
    - Urine analysis results for adulteration or manipulation as per 3.2.4.1 of this document, if completed (not applicable for blood).

    Confirmation Procedure Data

    - Confirmation Standard Operating Procedure and/or description;
    - Confirmation Aliquot Laboratory Internal Chain of Custody record;
    - Confirmation Procedure data on negative control(s), positive control(s), and

all sample Aliquot(s) related to the Adverse Analytical Finding;

- Identification data and/or quantitative data and uncertainty estimation, if applicable;

  [A summary table is to be provided that compiles the necessary data and applicable criteria utilized to identify and/or determine the concentration of the target substance(s) to report an Adverse Analytical Finding or Atypical Finding.]

- Documentation of any deviations from the written Confirmation Procedures, if any;

  [For example, a change in the split ratio or a dilution of the derivatized sample due to sample overload in the GC-MS or LC-MS; application of an additional cleanup step; or an explanation for the re-analysis of the sample with a new Aliquot];Instrument performance data from the same analytical run; used to verify instrument performance or operation during that run. Data utilized for this purpose shall include instrument performance report(s) and quality control sample data;
  [For example, tune report from a mass spectrometer or other instrument report; chromatographic performance verification samples, if any; and/or quality control data, if any. This does not refer to data generated at other times *(e.g.,* validation data for the method)];

- Laboratory Test Report.

-End-

Appendix D - RMTC Guidelines for Split Sample Analysis

Preface

1. Split sample analysis (also known as B-sample analysis or referee sample analysis) is a targeted confirmatory analysis by an independent laboratory on the split sample for the purpose of affirming or refuting the analytical results of the primary laboratory. Split sample analysis is not a de novo analysis requiring screening and confirmatory testing for unnamed substances.

Pre-analytical Procedures

2. The split sample and any sample artifacts are the property of the regulatory authority. Split sample analysis must be carried out in compliance with the relevant rules of the regulatory authority and any documented regulatory authority policies or protocols for such analyses. These should include protocols for the storage and handling of referee samples, as well as procedures and time permitted for the approval and selection of referee laboratories.

3. Approved referee laboratories shall be accredited by the Racing Medication and Testing Consortium (RMTC). Supervising chemists shall be professional or fellow members of the AORC. If an RMTC accredited laboratory is not available, a laboratory accredited to the ISO 17025 standard and operating under ILAC-G7 shall be used. An RMTC Accredited laboratory is required to respond to requests for split sample analysis received from a Horse Racing Authority and has the right to decline to accept the analysis but must provide an explanation.

4. The regulatory authority must inform the referee laboratory in its solicitation of any requirements for any part of the analysis to be witnessed by any person representing the regulatory authority or the connections of the animal from which the sample was obtained.

5. The regulatory authority shall specify the following:
   A. the unambiguous chemical name of the analyte for confirmation;
   B. the matrix to be analyzed;
   C. the estimated concentration of the substance and, if a threshold substance, the regulatory threshold;
   D. whether it is a qualitative or quantitative analysis,
   E. the timeframe for completion of the analysis and issuance of a report;
   F. the scope of the analytical data to be furnished to the person to whom the report is to be issued, and
   G. whether the trainer, horsemen's association, racing authority or other person is responsible for meeting the costs of the analysis, including the cost of any requested compliance with 4 above.

Communication

6. Primary Laboratory and Split Sample Laboratory: In some cases the referee laboratory may need additional information (such as the methodology) to determine if it has the capability to conduct the requested analysis. However, once the referee laboratory has agreed to perform the analysis, any further communication between the primary laboratory that performed the original analysis, and the referee laboratory should take place only with advance consent of the regulatory authority.

7. Other Communications with Split Sample Laboratory: Communications between the regulatory authority representative or the individual requesting the split sample analysis and the referee laboratory should cease when the sample has been received by the referee laboratory. An exception shall be made for commission-initiated communications to address administrative issues.

Analytical Procedures

8. The laboratory shall be notified that is has been selected for the analysis prior to sample shipment. The referee laboratory must also be advised by email or facsimile as soon as the sample is dispatched. The referee laboratory must acknowledge receipt of the sample(s) as soon as possible upon receipt. Any concern with respect to sample integrity (such as broken seal, evidence of tampering, or poor sample condition) must be immediately reported to the regulatory authority's contact as designated in the solicitation or letter of transmittal. The individual or agency submitting the sample is responsible for tracking the shipment to its final destination.

9. If allowed by the relevant rules of racing or by regulatory authority protocols, the connections of the animal may request that an expert witness be present during the referee analysis. However, the selection and admission of an expert witness and the timing of the witnessed analysis must be agreed in advance by all parties during the pre-analytical phase according to the authority's rule or documented protocols. An admitted expert witness must agree to abide by all instructions of the referee laboratory and must not interfere with the referee analysis. The referee laboratory shall have the right to exclude an expert witness who fails to abide by instructions or interferes with the analysis of any sample.

10. The referee laboratory will analyze the submitted sample(s) for the presence of the requested substance(s) and, in the case of a threshold substance, will determine the concentration of that substance. Any additional analysis beyond that outlined above is prohibited unless approved by the regulatory authority and with notice given to the trainer. Any expanded analysis may require additional payment prior to completion.

11. The same sensitivity of analysis must be applied to all samples, referee or negative, submitted for the same case. However, to allow for possible sample

degradation, the referee laboratory must employ methodologies with a similar or greater sensitivity as used for the first analysis.

12. The calibration range for quantitative analysis must bracket the threshold concentration. If the concentration of a threshold substance is found to be higher than the concentration at the highest calibration point it may be reported as greater than that concentration. For the analysis of a threshold substance, the referee laboratory must comply with ISO 17025 requirements for the reporting of measurement uncertainty.

13 If the referee laboratory does not identify the reported substance, it must demonstrate its capability to detect the target analyte by concomitant analysis of a positive control sample containing the reported substance at an appropriate concentration (at or below the estimated concentration reported by the primary laboratory) in the same sample matrix.

14. The referee laboratory should employ criteria as described in Part B of the ILAC-G7 document to establish whether or not the reported substance is present in the referee sample and, in the case of a threshold substance, the concentration or range of concentration of that substance. Where appropriate, the AORC Guidelines for the Minimum Criteria for Identification by Chromatography and Mass Spectrometry should be followed.

15. A certificate of analysis shall be provided under the agreement with the regulatory authority. If the reported substance is not detected or if a quantitative measurement shows the regulatory threshold has not been exceeded, this must also be reported but no explanation is required. However, sample observations and conditions which may have affected the analysis must be reported.

16. If a data packet is requested from the referee laboratory, such request must be made through the regulatory authority and an additional fee for preparation and production of the data packet will apply.

- End -

Revision History

Revision #	Section(s) Affected	Date	Signoff
Version 5.0	All: Add HISA/HIWU, Change “Masked” to “Blind” Remove screening data requirement, update title, add 5 double blind sample to EQAP program	5/10/24	