Initial Application Materials for Laboratories Seeking RMTC Accreditation

To Whom It May Concern:

Please find enclosed a Laboratory Questionnaire and request for information to be filled out as a necessary step towards RMTC laboratory accreditation or re-accreditation.

Please prepare two binders:

- Binder 1 – LABORATORY DESCRIPTION (should contain labeled subsections, as outlined below, and the relevant Laboratory documentation)
- Binder 2 – SUPPORTING INFORMATION

If possible, please also submit an electronic copy of your application (*e.g.*, CD ROM).

BINDER 1 – LABORATORY DESCRIPTION

Section 1. QUESTIONNAIRE

Provide a copy of the completed Questionnaire.

Section 2. ORGANIZATIONAL CHART 1

Provide a chart of the authority or authorities to which the laboratory reports (*i.e*. links with state agencies, Universities, etc.) and the operational link with the state racing authority, if appropriate. Alternatively, provide a list of the Horseracing Authorities for which the laboratory provides sample testing services.

Section 3. ORGANIZATIONAL CHART 2 AND PERSONNEL LIST

Provide a Laboratory Organizational Chart. Provide a description of all positions and associated functions, qualifications, training, and experience; including Laboratory Director, Scientific Director, personnel involved in the initial testing and confirmation procedures, technicians and non-technical staff as well as personnel in charge of method development and research.

Section 4. LABORATORY CONTACT INFORMATION

List the laboratory name, address and contact (telephone, fax, email) information.

Section 5. LABORATORY SUPPORT

Please include a statement with an estimate of the number of samples tested per year for the past 3 years by sample matrix.

Section 6. CURRENT AND PLANNED WORKLOAD CAPACITY

Provide an estimate of workload capacity taking into account current laboratory storage, personnel, instruments, equipment, space, etc.

Section 7. LABORATORY FACILITIES

Provide a schematic representation of the Laboratory facility, including square footage, describing functional areas (e.g., wet chemistry room, GC-MS and LC-MS instrument room, sample storage area, etc.) and identifying secure entrances and exits. Photographs and floor plans may be included as supporting documentation.

Section 8. GENERAL SURROUNDINGS

Include a description of the surrounding area of the Laboratory (e.g., laboratory is sole occupant in standalone building, laboratory is on first floor of 5 story building, include description of adjacent laboratories, offices, etc.).

Section 9. COLD STORAGE

Include an inventory of available freezers and refrigerators that will be used for sample storage (specify temperature of storage) and list storage capacity of each one.

Section 10. INSTRUMENT/EQUIPMENT LIST

Include major equipment (model, manufacturer, use or function) and instruments, including GC-MS, LC-MS, GC, spectrophotometers, immunoassay instruments (for EPO detection, specifically) and include manufacturer, model, detector types, service contracts, and peripherals. Applicable instruments should be listed as systems (*i.e.*, list components and peripherals of each analytical system together).

Section 11. CONTROLLED SUBSTANCES

Copy of DEA and applicable state license(s) held for control substances.

Section 12. DOPING CONTROL EXPERIENCE

List previous doping control experiences for the Laboratory, as well as experience of critical personnel such as Head of Laboratory and others.

Section 13. LABORATORY TESTING LIST

Provide a list of some of the regulated and prohibited substances analyzed by various methodologies. The list need not be all inclusive but should be illustrative.

Section 14. ANALYTICAL METHODOLOGY FOR DRUG CLASSES

Provide a list or table of contents for all relevant SOPs. If an SOP is not specifically requested to be provided, please reference all applicable SOPs responsive to the section of the questionnaire.

Section 15. RESEARCH

Provide literature and references on the laboratory's published research work in the area of doping control.

BINDER 2 – SUPPORTING INFORMATION

The second binder should be contain relevant Laboratory supporting information **as requested in the following Questionnaire.** At a minimum the binder should include a copy of the laboratory Quality Manual or relevant SOPs if there is not a separate Quality Manual**.** The supporting information should be sectioned and labeled based on the associated Questionnaire Number for reference and traceability.

Thank you for your interest.

Racing Medication and Testing Consortium, Inc.

1.0	ISO 17025 ACCREDITATION	Yes	No	Comments and/or References
1.1	Is ISO/IEC 17025 granted to your laboratory?			
1.2	If yes: a. indicate the date of your last and next accreditations; b. indicate the name of the accreditation body; Include a copy of your most recent Scope of Accreditation document issued by the accrediting body.	Last: Next: Accreditation Body*:		
1.3	If no: a. indicate an expected date of ISO/IEC 17025 accreditation	Date:		
	*The laboratory shall be accredited by a relevant accreditation body, ILAC full member, signatory to ILAC MRA			
2.0	**Organization and Personnel -** See Binder Requirements			
3.0	**General Facilities**	**Yes**	**No**	**Comments and/or References**
3.1	Does the Laboratory perform the initial testing procedure and confirmatory testing on all samples at the same Laboratory site?			
3.2	Does the Laboratory perform sample reception and distribution, each initial testing procedure and confirmation procedure in physically separated areas?			
3.3	Does the laboratory have a secure area for:			
	Sample Processing?			
	Records Storage?			
	Sample Storage?			
	Special Storage for Positive Samples?			
	Drugs and Standard Storage?			
3.4	Does the Laboratory have enough secure freezing units and place to preserve all samples received for at least 3 months?			
3.5	Does the Laboratory have enough secure freezing units to preserve separately analyzed samples from other samples?			
3.6	Does the laboratory have a separate secure freezing unit to preserve positive samples as long as required (-10 to -25C and - 80C)?			

3.0	General Facilities (cont'd)	YES	NO	Comments and/or References
3.7	Does the laboratory have available emergency power equipment in case of power failure?			
3.8	Does the laboratory also conduct method development and/or research in: (Provide copies of last 5 Refereed publications)			
	Drug Testing?			
	Drug Metabolism?			
	Pharmacokinetics?			
	Other areas of animal pharmacology?			
	If YES to any of the above: is the research work conducted in physically separated areas (*i.e.*, different room, glassware, analytical instruments?)			
	If NO to any part of the above question: is the integrity of all aspects of drug testing procedures sufficiently shielded from possible contamination by research activities? (Please detail in separate form)			
3.9	**Testing for EPO**			
	Does the Laboratory conduct blood or urinary EPO testing?			
	If YES, date when implemented If NOT, plans for implementation	Date:		
3.10	**Testing for equine GH**			
	Does the Laboratory conduct the testing for the equine GH?			
	If YES, date when implemented If NOT, plans for implementation	Date:		

4.0	QUALITY CONTROL	YES	NO	Comments and/or References
4.1	Is there documented evidence of active review of records of controls, instrument functions and maintenance, temperature, etc. for routine procedures?			
4.2	Is there documentation of corrective action taken when controls exceed defined tolerance limits?			
4.3	Is there a written system in operation to routinely detect clerical errors, significant analytical errors, and unusual laboratory results?			
4.4	Does the system provide for the timely correction of errors?			

5.0	PROCEDURE ORGANIZATION	YES	NO	Comments and/or References
5.1	**Specimen Handling**			
5.1.a	Are particular individuals authorized to receive samples?			
5.1.b	Is there a written procedure for the "receiving" operation?			
5.1.c	Is there a "receiving form" containing all pertinent information required including the condition of the samples noted upon arrival at the analytical laboratory? (Provide the receiving form or SOP reference)			
5.1.d	Does the reception procedure indicate each step to follow for the verification of the integrity of the specimens? (Seals verification, exact quantity of samples, similarity between samples, identification code, visual inspection of each specimen).			
5.1.e	Are there written criteria for unacceptable specimens?			
5.1.f	Is there a specific secured and locked facility room for receiving, which restricts access to specimens? (Only authorized individuals will be permitted in areas where specimens are present)			
5.1.g	Is there locked, refrigerated storage for specimens when left unattended?			
5.0	**PROCEDURE ORGANIZATION**	**YES**	**NO**	Comments and/or References
5.1.i	Is there adequate compartmentalization and identification of samples to prevent sample mix-up?			

5.1.j	Is there a written procedure for the "distribution" operation?			

5.2	**Procedure Manual (SOP)**			
5.2.a	Is there a procedure manual? If not, explain. (Provide a Table of Contents of all relevant SOPs)			
5.2.b	Is it available at the bench or in the work area? Note: working cards or flow chart summaries are acceptable for quick reference at the work bench, provided that a complete manual is available for reference and the working cards correspond to the complete manual.			
5.2.c	Is each procedure reviewed annually, dated, and signed or initialed by the Laboratory Director or a qualified person designated by the Director?			
5.2.d	Are all changes dated and initialed by a supervisor or another appropriate person?			
5.3	**Materials and Reagents**			
5.3.a	Are high quality reagents and solvents used whenever possible? (Provide an example)			
5.3.b	If the Laboratory handles controlled substances, is there a current license? (Please include a copy of the license)			
5.3.c	Does the Laboratory possess the reference standards of the substances on the Prohibited List in each class of drugs, including related compounds? If not, does it have a procedure in place to obtain them?			
5.4	**Controls and Standards**			
5.4.a	The verification of reagents is required and must be documented. Several different methods are acceptable such as direct analysis with reference materials, parallel testing of old versus new reagents, and checking against routine controls. Is there a method in place at the Laboratory? If yes, which method?			

	PROCEDURE ORGANIZATION (continued)	YES	NO	Comments and/or References
5.4.b	Are expiration dates indicated on reagent containers?			
5.4.c	Are outdated reagents discarded and replaced routinely? Note: Certain expensive reagents may warrant use after the labeled expiration date. In such cases, the laboratory must have a clearly defined (written) policy specifying such reagents, circumstances under which extended usage may exist, special control procedures to be implemented and specific person authorizing such.			
5.4.d	Are new reagents checked against old reagents or other reference material prior to being placed in service?			
5.4.e	Are results of reagent checks recorded?			
5.5	**Materials and Reagents Preparation**			
5.5.a	Are there written procedures for preparing reagents and materials used in assays? (Provide representative examples of these procedures)			
5.5.b	Are principles of the preparation of materials and reagents explained?			
5.5.c	Are these reagents properly labeled with date of preparation, storage requirements, as well as the person who prepared them? Is glassware used throughout the whole procedure?			
5.5.d	Is washed glassware checked for detergent removal? Is this documented?			
5.5.e	Is glassware rinsed with purified water prior to drying? Is thos documented or specified in a SOP?			
5.5.f	Are pipettes, diluting devices, volumetric flasks, thermometers, etc. checked for accuracy and reproducibility prior to being placed in service and periodically thereafter?			

5.0	PROCEDURE ORGANIZATION (cont'd)	YES	NO	Comments and/or References
5.6	**Standardization Procedures**			
5.6.a	Are directions written for standardization and calibration of the analytical systems' parameters?			
5.6.b	Are routine checks for performance of GC, HPLC, GC-MS, LC-MS, etc, performed on a daily basis for: (Provide example records)			
	Baseline stability?			
	Presence of contaminants?			
	Optimization of detector performance?			
	Resolution?			
	Reproducibility?			
	Accuracy?			
5.6.c	Does each test procedure include (when appropriate): (Provide the Method SOP for this item)			
	Principles of each test?			
	Run of standards in each batch?			
	A control sample in each run?			
	A blank sample in each batch analysis?			
	Preparations of reagents, standards, and controls?			
	Directions for standardization and calibration, if required?			
	An internal standard?			
	Linearity of method and course of action when results exceed method linearity?			
	Sensitivity of method and how to report results when sensitivity limits are reached?			
	Controls and criteria for unacceptable results?			
	Reference range (normal values), if applicable?			
	A "test procedure" form containing all pertinent information.			
5.7	**Special procedures**			
5.7.a	Are urine samples with "unusual" pH values and specific gravity (*i.e.*, below 1.010) recorded and processed using appropriate modified procedures, if applicable?			

	PROCEDURE ORGANIZATION (cont'd)	YES	NO	Comments and/or References
5.8	**Equipment Maintenance** (Provide the SOP for this item)			
5.8.a	Are there written standard procedures for "set up", qualification, and operation of instruments?			
5.8.b	Is there a schedule or system for the regular checking of the critical operational characteristics for all instruments in use?			
5.8.c	Are there written instructions for instrument checks (*e.g*., manufacturer's manual or laboratory procedure)?			
5.8.d	Are function checks documented in a convenient manner to detect trends or malfunctions?			
5.8.e	Are tolerance limits for acceptable function written for specific instruments whenever appropriate?			
5.8.f	Are records maintained for each instrument to document all repairs and service procedures?			
5.8.g	Are instrument maintenance, service, and repair records (or copies) immediately available to and accessible to the technical staff operating the equipment?			

RMTC
Racing Medication & Testing Consortium

Initial Application Form for Laboratory Seeking RMTC Accreditation

LABORATORY NAME

OFFICIAL CONTACT

Position

(Mr., Mrs., Ms., Dr., Prof.)

Family Name

First Name

CONTACT INFORMATION

Full Mailing Address

City

State and ZIP CODE

Telephone

Fax

E-mail

RMTC
Racing Medication & Testing Consortium

Initial Application Form for Laboratory Seeking RMTC Accreditation

Previous or current experience of laboratory in regulatory control methods

Reasons to seek RMTC accreditation

Is the laboratory ISO 17025 accredited?
(If YES, indicate the name of the accreditation body and the date of the last accreditation; If NO, indicate an expected date of ISO 17025 accreditation.)

Expected date to enter RMTC pre-accreditation process

Identify the racing commissions for which your laboratory provides testing services.

Indicate the names and addresses of the executive directors of the racing commissions for which your laboratory provides testing services.

Indicate the number of doping control samples that your laboratory tests annually. If you test samples from dogs and horses, list the numbers of samples separately.

Initial Application Form for Laboratory Seeking RMTC Accreditation

Signature	Date (DD/MM/YYYY)

Please send your completed application form to:

Racing Medication and Testing Consortium, Inc.
821 Corporate Drive
Lexington, KY 40503

Phone: (859) 224-2844
Fax: (859) 296-3033
www.rmtcnet.com