



**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** (should contain supporting documents for highlighted requests on Questionnaire)

### **BINDER 1 – LABORATORY DESCRIPTION**

#### **Section 1. QUESTIONNAIRE**

Provide the completed Questionnaire.

#### **Section 2. ORGANIZATIONAL CHART 1**

Provide a chart of the authority(ies) to which the laboratory reports (*i.e.* links with state agencies, Universities, etc.) and the operational link with the State Horse Racing Authority.

#### **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/research.

#### **Section 4. LABORATORY CONTACT INFORMATION**

Laboratory name, address and contact (telephone, fax, email) information.

#### **Section 5. LABORATORY SUPPORT**

Provide copies of available letters of support from the responsible *State Horse Racing Authority* guaranteeing sufficient financial support, sufficient sample numbers, and any other applicable support.

#### **Section 6. CURRENT AND PLANNED WORKLOAD CAPACITY**

Provide an estimate of workload capacity taking into account current laboratory storage, personnel, instruments, equipment, space, etc for each procedure. Provide a business plan incorporating anticipated future growth and means to support it.

#### **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, maker, function) and instruments, including GC-MS, LC-MS, GC, spectrophotometers, immunoassay instruments and include maker, model, detector types, software, and peripherals. Applicable instruments should be listed as systems (i.e., list components and peripherals of one analytical system together)

**Section 11. CONTROLLED SUBSTANCES**

Type of DEA and applicable state license(s) held for controlled substances.

**Section 12. DOPING CONTROL EXPERIENCE**

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

**Section 13. LABORATORY TESTING LIST**

Provide a representative list of regulated and prohibited substances analyzed by various methodologies.

**Section 14. ANALYTICAL METHODOLOGY FOR DRUG CLASSES**

Describe the methodology used for screening and confirmation of various prohibited and regulated substances. Include literature references, if published, and indicate modifications (if applicable). Provide a typical output of a Negative QC and Positive QC from representative screening procedures.

**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 prepared containing relevant Laboratory supporting information **as requested in the following Questionnaire**. The supporting information should be sectioned and labeled based on the associated Questionnaire Number for reference and traceability.

Please send your completed materials to:

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

Phone: (859) 224-2844  
Fax: (859) 296-3033  
[www.rmtcnet.com](http://www.rmtcnet.com)

Thank you for your interest.

Racing Medication and Testing Consortium, Inc.



## Questionnaire 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



### Questionnaire for Laboratory Seeking RMTC Accreditation

Identify the state horse racing authorities 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.

Signature

Date (DD/MM/YYYY)

| 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:<br>a. indicate the date of your last and next accreditations;<br>b. indicate the name of the accreditation body;                                | Last:<br>Next:<br><br>Accreditation Body*: |    |                            |
| 1.3   | If no:<br>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   | <b>Organization and Personnel</b> - 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 ?  |  |    |                            |
| 3.3   | 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 (-20C 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   |     |    |                            |
|  | 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>i.e.</i> , different room, glassware, analytical instruments?) |     |    |                            |
| If NO to 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) |  |     |    |                            |

| 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   | <b>Specimen Handling</b>  |     |    |                            |
| 5.1.a | Are particular individuals authorized to receive samples?   |     |    |                            |
| 5.1.b | Is there a written procedure for the "receiving" operation?<br>(Provide the written procedure)  |     |    |                            |
| 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?<br>(Provide the receiving form)   |     |    |                            |
| 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).<br>(Provide the reception procedure form) |     |    |                            |
| 5.1.e | Are there written criteria for unacceptable specimens?<br>(Provide the written criteria)  |     |    |                            |
| 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?<br>Is there an emergency warning device to indicate when the unit is not properly functioning?  |     |    |                            |
| 5.0   | PROCEDURE ORGANIZATION  | YES | NO | Comments and/or References |
| 5.1.h | Is there adequate compartmentalization and identification of samples to prevent sample mix-up?  |     |    |                            |
| 5.1.i | Is there a written procedure for the "distribution" operation?<br>(Provide the distribution procedure form)   |     |    |                            |

|              |   |  |  |  |
|--------------|---|--|--|--|
| <b>5.2</b>   | <b>Procedure Manual (SOP)</b>   |  |  |  |
| <b>5.2.a</b> | Is there a procedure manual? If not, explain.<br>(Provide a procedure manual)   |  |  |  |
| <b>5.2.b</b> | Is it available at the bench or in the work area?<br>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.  |  |  |  |
| <b>5.2.c</b> | Is each procedure reviewed annually, dated, and signed or initialed by the laboratory Director or a qualified person designed by the Director?  |  |  |  |
| <b>5.2.d</b> | Are all changes dated and initialed by a supervisor or another appropriate person?  |  |  |  |
| <b>5.3</b>   | <b>Materials and Reagents</b>   |  |  |  |
| <b>5.3.a</b> | Are high quality reagents and solvents used whenever possible?  |  |  |  |
| <b>5.3.b</b> | If the Laboratory handles controlled substances, is there a current license?  |  |  |  |
| <b>5.3.c</b> | Does the Laboratory possess sufficient Reference standards to fulfill testing requirement? (Describe the reference standard program employed by the Laboratory)   |  |  |  |
| <b>5.4</b>   | <b>Controls and Standards</b>   |  |  |  |
| <b>5.4.a</b> | 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? |  |  |  |

|              | <b>PROCEDURE ORGANIZATION<br/>(continued)</b>   | YES | NO | Comments and/or<br>References |
|--------------|---|-----|----|-------------------------------|
| <b>5.4.b</b> | Are expiration dates indicated on reagent containers?   |     |    |                               |
| <b>5.4.c</b> | 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.<br>(Provide this policy document) |     |    |                               |
| <b>5.4.d</b> | Are new reagents checked against old reagents or other reference material prior to being placed in service?   |     |    |                               |
| <b>5.4.e</b> | Are results of reagent checks recorded?   |     |    |                               |
| <b>5.5</b>   | <b>Materials and Reagents Preparation</b>   |     |    |                               |
| <b>5.5.a</b> | Are there written procedures for preparing reagents and materials used in assays?<br>(Provide these procedures)   |     |    |                               |
| <b>5.5.b</b> | Are principles of the preparation of materials and reagents explained?  |     |    |                               |
| <b>5.5.c</b> | 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?  |     |    |                               |
| <b>5.5.d</b> | Is washed glassware checked for detergent removal?  |     |    |                               |
| <b>5.5.e</b> | Is glassware rinsed with purified water prior to drying?  |     |    |                               |
| <b>5.5.f</b> | Are materials (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   | <b>Standardization Procedures</b>   |     |    |                            |
| 5.6.a | Are directions written for standardization and calibration of the analytical systems' parameters?<br>(Provide the procedures) |     |    |                            |
| 5.6.b | Are routine checks for GC, HPLC, GC-MS, LC-MS, etc, performed on a daily basis for:   |     |    |                            |
|       | Baseline stability?   |     |    |                            |
|       | Presence of contaminants?   |     |    |                            |
|       | Optimization of detector performance?   |     |    |                            |
|       | Resolution?   |     |    |                            |
|       | Reproducibility?  |     |    |                            |
| 5.6.c | Does each test procedure include (when appropriate):  |     |    |                            |
|       | Principles of each test?  |     |    |                            |
|       | Run of standards each day?  |     |    |                            |
|       | 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?   |     |    |                            |



|              |   |  |  |  |
|--------------|---|--|--|--|
| <b>5.7</b>   | <b>Special Procedures</b>   |  |  |  |
| <b>5.7.a</b> | Are urine samples with "unusual" pH values and specific gravity ( <i>i.e.</i> , below 1.010) recorded and processed using appropriate modified procedures, if applicable? |  |  |  |
| <b>5.8</b>   | <b>Equipment Maintenance</b>  |  |  |  |
| <b>5.8.a</b> | Are there written standard procedures for "set up", qualification, and operation of instruments?  |  |  |  |
| <b>5.8.b</b> | Is there a schedule or system for the regular checking of the critical operations characteristics for all instruments in use?   |  |  |  |
| <b>5.8.c</b> | Are there written instructions for instrument checks ( <i>e.g.</i> , manufacturer's manual or laboratory procedure)?  |  |  |  |
| <b>5.8.d</b> | Are function checks documented in a convenient manner to detect trends or malfunctions?   |  |  |  |
| <b>5.8.e</b> | Are tolerance limits for acceptable function written for specific instruments whenever appropriate?   |  |  |  |
| <b>5.8.f</b> | Are records maintained for each instrument to document all repairs and service procedures?  |  |  |  |
| <b>5.8.g</b> | Are instrument maintenance, service, and repair records (or copies) immediately available to and usable by the technical staff operating the equipment?                   |  |  |  |