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THE RMTC EXTERNAL QUALITY ASSURANCE PROGRAM (EQAP)

REVISION HISTORY

REVISION #	SECTIONS AFFECTED	DATE	SIGNOFF
0.0	ALL	2014-02-06	RMTC HTLC
0.1	VARIOUS	2015-04-24	RMTC HTLC
0.2	1.0, 1.4, 2.1, 2.4, Appendix1, Appendix 2	2015-11-30	RMTC HTLC
0.3	1.5, 2.1, 2.5, Appendix 2	2016-04-06	RMTC HTLC

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RMTC EXTERNAL QUALITY ASSURANCE PROGRAM (EQAP)

1.0 Quality Policy and Objectives

The RMTC External Quality Assurance Program (EQAP) is operated pursuant to the RMTC Laboratory Accreditation Code (Code).

The RMTC Laboratory Accreditation Program is a voluntary program that works to ensure that all United States laboratories involved in horse racing sample testing are performing at the same high level of proficiency. This is accomplished through:

- Audits of relevant laboratory documentation;
- Site inspection of laboratories for review of procedures and processes; and
- Participation in the EQAP program twice yearly.

The EQAP program is administered by the RMTC through LGC Standards Proficiency Testing which is recognized as a Proficiency Testing Provider pursuant to ISO/IEC 17043:2010.

RMTC has determined that the EQAP is an essential feature of the Laboratory Accreditation Program for evaluating new laboratories as well as maintaining the accreditation status of existing laboratories.

Maintenance of RMTC accreditation requires successful participation by each laboratory in two (2) EQAP rounds per calendar year. Each round consists of up to 10 single-masked samples, either equine plasma or urine. One (1) sample in each round is an unmasked quantitative sample.

Laboratories may receive different EQAP sample sets from others. Additionally, accredited laboratories may also receive double-masked samples during the course of the year.

For initial accreditation, each applicant laboratory must successfully complete two (2) consecutive rounds of proficiency samples.

If, for any reason, an EQAP round is delayed, cancelled or otherwise changed, representatives of participating laboratories will be notified immediately. In the event an EQAP round is cancelled, the RMTC Horseracing Testing Laboratories Committee (HTLC) will determine the appropriate course of action.

The lists of substances and minimum concentrations that can be included in the EQAP samples are attached to this document as Appendix 1 and Appendix 2. The candidates for the quantitative EQAP sample include only those substances listed in Appendix 2. However, the candidates for qualitative EQAP samples include substances listed on either Appendices 1 and 2.

Note: blank matrices of blood and urine are collected from mares and geldings.

Program Administration

1.1 Program Coordinator

For the purposes of the EQAP, the Executive Director of the RMTC and the RMTC Drug Testing Initiative Consultant are designated as the Program Coordinators. In the absence of an Executive Director, the RMTC Horseracing Testing Laboratories Committee (HTLC) shall designate an individual to act as a Program Coordinator.

The Program Coordinators' duties are designated as follows:

a. Executive Director of the RMTC responsibilities:
   - Coordinate and manage the EQAP;
   - Assign sample contents and concentrations;
   - Correspond with participants;
   - Ensure that feedback on the EQAP is provided in a timely manner;
   - Provide the EQAP Summary Report to participants;
   - Provide feedback and resolve complaints;
   - Provide all communication between participants and RMTC/LGC Standards Proficiency Testing.

b. RMTC Drug Testing Initiative Consultant responsibilities:
   - Prepare proficiency samples as specified by RMTC
   - Oversee shipment of samples to participants;
   - Ensure that no assigned values are disclosed to participants until the results have been collated and evaluated;
   - Collate and evaluate results from participants;
   - Prepare and issue the EQAP Summary Report;
   - Ensure provider compliance with ISO/IEC 17043;

All comments, questions, concerns and other correspondence by participating laboratories whether by telephone, email, or other medium regarding the EQAP shall be communicated directly to the Executive Director of the RMTC or the DTI Consultant. Program participants should not communicate directly with LGC Standards Proficiency Testing but should refer all questions and comments to the RMTC.

1.2 Program Collaborators

LGC Standards Proficiency Testing is designated as a Program Collaborator for the purposes of the EQAP. It is responsible for ensuring that:

- Quantitative samples are verified as to concentration at the reference laboratory before shipping, except for procaine and phenylbutazone which are analyzed at the same time as the participating laboratories. Samples are analyzed with the corresponding validated method for each drug.

- Qualitative samples are verified as to concentration before shipping. Selected qualitative samples may be analyzed at the same time as the participating laboratories.

- Proficiency samples are prepared as specified by RMTC

- Samples are shipped to participants;

- No assigned values are disclosed to participants until the results have been collated and evaluated;

- Results from each laboratory are shared solely with the RMTC;

- All samples are prepared in compliance with ISO/IEC 17043;

1.3 Record Keeping

Results of analysis identifiable with an individual or laboratory will be maintained confidential by the RMTC. This, however, does not negate the reporting requirements of the laboratory pursuant to the RMTC Accreditation Code Sections 1.5.5-1.5.6.

1.4 Feedback and Complaint Resolution

Participants are encouraged to provide feedback on their experience with the EQAP samples, either negative or positive, to the Program Coordinators. Questions and complaints from program participants shall be directed to the Program Coordinators only and dealt with in a timely manner.

The Program Coordinators will review administrative and analytical data in conjunction with the Program Collaborator as part of the investigation into possible causes of anomalous results.

Any complaint by an Accredited Laboratory that cannot be resolved between the complainant and the Program Coordinators shall be referred to the RMTC HTLC.

1.5 Fee Schedule

Fees for participation in the RMTC EQAP shall be borne by the Accredited Laboratory or applicant laboratory absent payment by RMTC through designated funds. The cost of participating in the

EQAP is the current price charged by LGC Standards Proficiency Testing for samples. The current Fee Schedule is as follows:

Program	Cost
RMTC Set of EQAP Samples	$4,499.00

1.6 Eligibility to Participate in the RMTC EQAP Program

Participation in the RMTC EQAP program is limited to those laboratories that have applied for RMTC Laboratory Accreditation.

1.7 General Policies on Participation

Participants in the RMTC EQAP Program shall:

- Agree to pay the applicable fees, if necessary;
- Comply with the provisions of the RMTC Accreditation Code;
- Comply with the provisions of this document;
- Ensure that they have detection capabilities equal to or greater than those required by the program; and
- **Not communicate results with other EQAP participants prior to disclosure of the results by the Program Coordinator. Communication of results prior to disclosure by the program coordinator may result in disqualification of the laboratory's results for the EQAP.**

2.0 EQAP Activities

2.1 Shipping

The number of unknown urine and blood (plasma or serum) samples sent as a part of the EQAP will vary according to the specific determination of the RMTC HTLC and Program Coordinators. These samples will be sent twice in each calendar year for qualitative testing.

Additionally, urine and/or blood samples, with the drug identified, will be sent to each participant laboratory. These samples will be sent twice in each calendar year for quantitative testing.

It is the responsibility of each laboratory to have a current USDA import permit for the samples. Failure of the laboratory to procure the proper import documents may result in the laboratory being assessed the fees associated with preparation and shipping of the EQAP samples, not in excess of the amount paid by RMTC to procure the samples.

The name and address of the shipper should be listed as follows:

LGC Standards Proficiency Testing
1 Chamberhall Business Park
Chamberhall Green
Bury, Lancashire BL9 0AP
UNITED KINGDOM

Instructions from LGC Standards Proficiency Testing will be provided for each EQAP test round, listing details of the samples included in the shipment. It will state the number of samples, sample codes, the type of samples, and reporting date.

Participants shall receive two (2) bottles for each qualitative sample. They will contain the same qualitative sample. One bottle is intended for screening and the other for confirmatory analysis. Quantitative sample shipments consist of two (2) bottles per sample. One bottle is intended for screening and the other for confirmatory analysis.

The labels on sample bottles contain the following:

- EQAP Set # *e.g.*, RMTC Round RM001;
- Sample identification code;
- LGC Standards Proficiency Testing logo.

Samples are packaged in materials designed to minimize breakage. Packages of samples are placed in a cardboard box, containing additional packing material as required. All boxes are shipped by courier either by air or ground transport depending upon the destination of the shipment.

The following documents will be provided to each participant by email:

1. A copy of the current version of this document.
2. A copy of the current version of the RMTC Laboratory Accreditation Code.
3. EQAP Feedback Form.
4. Acknowledgement of receipt form.

Laboratories are also provided with a tracking number or airway bill number for the shipment.

2.2 Sample Receipt

Upon receipt, laboratories are required to send the "Acknowledgement of Receipt" form which contains information on the status of the samples at arrival to the LGC Standards Proficiency Testing representative.

2.3 Sample Analysis

All relevant specifications provided in the current version of the RMTC Laboratory Accreditation Code apply to the EQAP.

Each participant laboratory shall have documented procedures for the analysis of EQAP samples, which shall reflect as closely as possible the analytical procedures routinely applied to customer samples for this scope of testing.

Each participant laboratory shall maintain complete and comprehensive records on the receipt, analysis, and reporting of each EQAP test round. The participant laboratory shall make its records available to the Program Coordinators upon request.

2.4 Reporting by Test Laboratories

The test laboratory shall report qualitative samples on a "detection versus non-detection" basis. The name of the drug detected and the techniques used in their analysis shall be reported. In the case of quantitative samples, the test laboratory shall report results to 2 significant figures.

Reports shall be reported electronically using the LGC web-portal. Participants will be provided with their unique login credentials by the provider.

Reports are due within 4 weeks of receipt of each round of test samples. Any request for an extension shall be made to the Program Coordinators in writing. Extensions shall be considered on a case by case basis.

A test laboratory shall take corrective actions on a discrepancy identified by the Program Coordinators and Program Collaborator as outlined in the RMTC Laboratory Accreditation Code and as described in Section 4.0 of this document.

In the case of supplemented samples, laboratories are only to report drugs confirmed without conducting enzyme hydrolysis. In the event that unexpected findings (i.e., those not on the list of target analytes) are identified, these findings should be reported only in the additional findings section of the reporting document. These reported findings are for informational purposes only and shall not be scored.

Substances with minimum concentrations on the attached list should be reported as findings only if present in excess of the minimum concentrations. If desired, substances below the requisite minimum concentrations may be reported in the additional findings section of the reporting document. These reported findings are for informational purposes only and shall not be scored.

2.5 Evaluation of Results

No assigned value of any EQAP sample will be disclosed to program participants until all results from all participants have been received, collated, and evaluated.

In the qualitative portion of the proficiency test, analytical results are evaluated on a "detection versus non-detection" basis.

In the quantitative portion of the proficiency test, analytical results must be within ± 10% range for µg/mL, ± 20% for ng/mL and ± 40% for the pg/mL level. Results are evaluated against the theoretical (target concentration) and allowable range and, where available, the group mean and range of all participant laboratories. These allowable ranges are subject to evaluation and revision upon collection of sufficient data. Quantitative results exceeding 4 standard deviations may be classified as a false positive for those more than 4 standard deviations greater or a false negative for those more than 4 standard deviations less than the mean. Final determination will be made by the HTLC.

For a passing score, the laboratory must:

- Report no false positives, either qualitative or quantitative;
- Report no more than one (1) false negative qualitative result in a calendar year;
- Report no more than one (1) unsatisfactory quantitative result in a calendar year; and
- As applicable, submit a corrective action plan and report pursuant to the RMTC Accreditation Code for any false negative, questionable or unsatisfactory finding. The required corrective action plan and report shall be submitted to the Program Coordinators.
- As applicable, submit a corrective action plan and report pursuant to the RMTC Accreditation Code for any false positive finding. The corrective action plan and report shall be submitted to the Program Coordinators.
- Failure to provide such corrective action plan and report may affect the ability of a laboratory to participate in future EQAP testing rounds.

If a sample in either the qualitative portion or the quantitative portion of any test is established to have deteriorated to the extent that detection is not possible or that quantification is affected, results for that sample will not be incorporated into the total score.

A summary of results for the round will be prepared by LGC Standards Proficiency Testing Program coordinator and issued to participants by the Executive Director of the RMTC within 3 weeks of receipt of reports from participants. Reports will contain the identities of substances for qualitative samples and target concentrations for quantitative samples as well as a summary of

reported results, including statistical data on quantitative samples. Partial or entire contents of the reports may be used by the participant laboratories for other accreditation purposes.

2.6 Records

Records of sample preparation are maintained by the LGC Standards Proficiency Testing Laboratory.

Records and results will be maintained and stored in a secure manner by the RMTC and the LGC Standards Proficiency Testing Laboratory, however, participant laboratories are required to disclose their results as outlined in the RMTC Laboratory Accreditation Code.

The individual results of a laboratory participating in an EQAP testing round shall not be identifiable to that laboratory in any results published by LGC Standards Proficiency Testing from any round of EQAP testing.

2.7 Complaint Resolution

Complaint handing shall be conducted by the Program Coordinators according to guidelines from the HTLC.

In the case of a dispute about the contents of a particular sample, LGC Standards Proficiency Testing will conduct an analysis of a retained portion of the appropriate batch, and will report its findings to the Executive Director of the RMTC.

The RMTC HTLC reviews and advises on RMTC's EQAP protocols. In the case of disputed results, a subcommittee of this group may be convened to review data where required to resolve the dispute. Members who are program participants are excluded from evaluation of individual participant results or individual identifying information shall be redacted if such expertise is required.

If any complaint regarding an EQAP testing round cannot be resolved between the complainant and the Program Coordinators with the participation of the HTLC as applicable, the complaint will be referred to the RMTC Board of Directors for final disposition.

3.0 Corrective Action

The action required for obtaining or maintaining RMTC Accreditation following a failure on an EQAP test shall include:

a. A thorough investigation of potential problems for any occurrence of an incorrect result, with a comprehensive written response on the results of the investigation provided to the Program Coordinators within thirty (30) calendar days from the receipt of notification of failure and

b. Corrective action(s) as necessary and reports on the outcome of such action to the Program Coordinators as required in the RMTC Accreditation Code

If an accredited or applicant laboratory fails to provide such information within the time limits established by the EQAP, the laboratory will be determined to have failed the EQAP and shall be subject to loss or suspension of RMTC Accreditation as outlined by the then current version of the RMTC Accreditation Code.

APPENDIX 1. LIST OF QUALITATIVE SUBSTANCES

Drug	Analyte	Concentration ng/mL	Matrix
Amitriptyline	Nortriptyline	2	Urine
Amphetamine	Amphetamine	10	Urine
Apomorphine	Apomorphine	10	Urine
Bumetanide	Bumetanide	20	Urine
Buprenorphine	Buprenorphine	10	Urine
Buspirone	Buspirone	20	Urine
Caffeine	Caffeine	100	Plasma/serum
Cocaine	Benzoylecgonine	20	Urine
Deracoxib	Deracoxib	20	Plasma/serum
Dermorphin	Dermorphin	1	Urine
Desipramine	Desipramine	20	Urine
Diazepam	Nordiazepam, oxazepam	20	Urine
Diflunisal	Diflunisal	500	Plasma/serum
Ephedrine	Ephedrine + phenylpropanolamine	20	Urine
Etodolac	Etodolac	20	Plasma/serum
Fenoprofen	Fenoprofen	20	Plasma/serum
Flufenamic Acid	Flufenamic Acid	20	Plasma/serum
Flumethasone	Flumethasone	20	Urine
Fluoxetine	Fluoxetine +_ Norfluoxetine	20	Urine
Fluphenazine	Fluphenazine	0.2	Plasma/serum
Flurbiprofen	Flurbiprofen	20	Plasma/serum
Formoterol	Formoterol	10	Urine
Gabapentin	Gabapentin	50	Urine

Drug	Analyte	Concentration ng/mL	Matrix
Guanabenz	Guanabenz	10	Urine
Hydromorphone	Hydromorphone	2	Urine
Ibuprofen	Ibuprofen	500	Plasma/serum
Ipratropium	Ipratropium	1	Urine
Ketorolac	Ketorolac	20	Plasma/serum
Levorphanol	Levorphanol	2	Urine
Meclofenamic Acid	Meclofenamic Acid	100	Plasma/serum
Meperidine	Meperidine + Normeperidine	10	Urine
Mephentermine	Mephentermine	10	Urine
Metaproterenol	Metaproterenol	10	Urine
Methamphetamine	Methamphetamine	10	Urine
Methylphenidate	Ritalinic Acid	20	Urine
Methyltestosterone	Methyltestosterone	1	Urine
Metoprolol	Hydroxymetoprolol + Desmethylmetoprolol	20	Urine
Modafinil	Modafinil + Modafinic acid	20	Urine
Morphine	Morphine	20	Urine
Nabumetone	6-Methoxy-naphthyl acetic acid	20	Urine
Nalbuphine	Nalbuphine	20	Urine
Nalorphine	Nalorphine	20	Urine
Naproxen	Naproxen	1000	Plasma/serum
Nortriptyline	Nortriptyline	20	Urine
Oxazepam	Oxazepam	20	Urine
Oxymorphone	Oxymorphone	2	Urine
Pentazocine	Pentazocine	10	Urine

Drug	Analyte	Concentration ng/mL	Matrix
Phenylpropanolamine	Phenylpropanolamine	20	Urine
Pirbuterol	Pirbuterol	1	Urine
Piroxicam	Piroxicam	500	Plasma/serum
Promazine	3-Hydroxypromazine	20	Urine
Propionylpromazine	2-(1-hydroxypropyl)-promazine sulphoxide	20	Urine
Propranolol	4-Hydroxypropranolol	20	Urine
Pyrilamine	O-Desmethylpyrilamine	20	Urine
Ractopamine	Ractopamine	5	Urine
Sildenafil	Sildenafil	5	Urine
Stanozolol	Stanozolol	1	Plasma/serum
Tenoxicam	Tenoxicam	20	Plasma/serum
Terbutaline	Terbutaline	1	Urine
Tetrahydrogestrinone	Tetrahydrogestrinone	1	Urine
Theophylline	Theophylline	20	Urine
Tramadol	O-Desmethyltramadol	50	Urine
Trenbolone	Trenbolone	1	Urine

APPENDIX 2. LIST OF THRESHOLD (QUANTITATIVE) SUBSTANCES

Threshold Substance	Metabolite	Threshold	Matrix
Acepromazine	HEPS	10 ng/mL	Urine
Albuterol	Albuterol	1 ng/mL	Urine
Betamethasone	Betamethasone	10 pg/mL	Plasma/serum
Boldenone	Boldenone	15 ng/mL	Urine
Boldenone	Boldenone	25 pg/mL	Plasma/serum
Butorphanol	Free butorphanol	2 ng/mL	Plasma/serum
Butorphanol	Total butorphanol	300 ng/mL	Urine
Clenbuterol	Clenbuterol	140 pg/mL	Urine
Clenbuterol	Clenbuterol	2 pg/mL	Plasma/serum
Dantrolene	5-OH dantrolene	100 pg/mL	Plasma/serum
Detomidine	Carboxydetomidine	2 ng/mL	Urine
Detomidine	Detomidine	1 ng/mL	Plasma/serum
Dexamethasone	Dexamethasone	5 pg/mL	Plasma/serum
Diclofenac	Diclofenac	5 ng/mL	Plasma/serum
DMSO	DMSO	10 mcg/mL	Plasma/serum
Firocoxib	Firocoxib	20 ng/mL	Plasma/serum
Flunixin	Flunixin	20 ng/mL	Plasma/serum
Glycopyrrolate	Glycopyrrolate	3 pg/mL	Plasma/serum
Ketoprofen	Ketoprofen	2 ng/mL	Plasma/serum
Lidocaine	3OH-lidocaine	20 pg/mL	Plasma/serum
Mepivacaine	3OH-mepivacaine	10 ng/mL	Urine
Mepivacaine	Mepivacaine	100 pg/mL	Plasma/serum
Methocarbamol	Methocarbamol	1 ng/mL	Plasma/serum
Methylprednisolone	Methylprednisolone	100 pg/mL	Plasma/serum

Threshold Substance	Metabolite	Threshold	Matrix
Nandrolone	Nandrolone	25 pg/mL	Plasma/serum
Omeprazole	Omeprazole sulfide	10 ng/mL	Plasma/serum
Phenylbutazone	Phenylbutazone	2 mcg/mL	Plasma/serum
Prednisolone	Prednisolone	1 ng/mL	Plasma/serum
Procaine	Procaine	25 ng/mL	Plasma/serum
Testosterone	Testosterone	20 ng/mL	Urine
Testosterone	Testosterone	25 pg/mL	Plasma/serum
Triamcinolone acetonide	Triamcinolone acetonide	100 pg/mL	Plasma/serum
Xylazine	Xylazine	200 pg/mL	Plasma/serum