Attachment B – Scope of Work

RFx #3000021602

Equine Drug Testing for the Louisiana Racing Commission (LRC)

This solicitation is to establish an Agency Term Contract for the Louisiana Racing Commission (LRC) to furnish chemical testing laboratory services to test equine specimens in order to determine the absence or presence and/or quantity of drugs or other substances, the use of which are prohibited by law and/or the rules of racing.

The vendor shall provide necessary technical, professional, clerical and other personnel, as well as equipment, facilities and supplies to perform chemical or other analysis on equine urine and blood specimens provided to it by LRC, which will be taken from the first place finisher and daily random samples as selected by the LRC representative and other samples as may be collected under the LRC's authority (Vet's List samples, specials, etc.). If no urine sample is obtained for the respective horse, the blood sample (plasma or serum) shall be the primary sample and shall be screened for drugs and other substances. Blood and/or urine may be used to conduct the required screens.

In addition to the above regular testing, pre-race equine blood samples shall be submitted for testing to determine the level of total dissolved carbon dioxide (TCO_2) (see B4 below).

The vendor shall provide analytical testing for LRC by applying any or all of the following methods:

A. Urine Samples

1. Screening methods
   a. Immunoassays
      (1) Enzyme-linked immunosorbent assays (ELISA)
   b. Instrumental screening: At the discretion of the vendor, all samples must be prepared for screening for a range of drugs by Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC), Gas Chromatography/Mass Spectrometry (GC/MS), and/or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) procedures.

2. Confirmation methods. Confirmation must employ mass spectrometry. Introduction of the sample may be conducted by gas chromatography, liquid chromatography, or direct injection or insertion probe. Data systems containing current drug and drug metabolite libraries must be used to analyze data from the mass spectrometer and can be supplemented with other mass spectral data base sources. Other methods, such as ultraviolet and infrared spectroscopy, may be used to assist in confirmation of drug structure and measurement of quantity. They must not, however, be used in lieu of confirmation by mass spectrograph.

3. Urine samples may also be used for any other purpose deemed scientifically reasonable by the vendor and LRC. Scientifically reasonable applications include research related to drug/doping analysis and quality assurance programs conducted in a manner that is compliant with laboratory accreditation guidelines and LRC investigative and enforcement purposes consistent with Louisiana's Rules of Racing and/or State Statutes.

4. All positive results reported to LRC from findings in a urine sample will include the identity of the substance, an estimation of its concentration in the urine and any relevant thresholds.

B. Blood samples

1. Blood (plasma or serum) samples are to be analyzed for phenylbutazone overage, Salix (furosemide) overage, and violations of the non-steroidal anti-inflammatory rules or directives, requiring quantitation of phenylbutazone as well as flunixin (Banamine) and ketoprofen (Ketofen)

and to determine the presence or absence of other non-steroidal anti-inflammatory drugs. If taken as a sample in lieu of urine, or as otherwise directed by LRC, it will also be examined for all other substances that fall within the purview of the scope of work. This would include any illegal substances and any substances listed in the Association of Racing Commissioners International (ARCI) controlled therapeutic medication schedule for horses. Quantitative analysis for phenylbutazone, furosemide, flunixin or ketoprofen may be performed by high performance liquid chromatography with UV diode array or fluorescence detection or by other LC/MS/MS or GC/MS methods. Samples quantitated in duplicate and found to be in violation of the phenylbutazone, furosemide or non-steroidal anti-inflammatory rules or directives must be reported as positive and confirmation of identification must be conducted using GC/MS or LC/MS/MS methods.

2. Blood samples (plasma or serum) will also serve as the primary sample in screening for anabolic steroids and for violations of the anabolic steroid rules or directives. Anabolic steroid screens will be performed on all samples submitted, approximately six thousand (6,000) samples. Samples exceeding established thresholds must be reported as positive and confirmation must be conducted by GC/MS or LC/MS/MS methods. Urine samples may serve as a secondary source for anabolic steroid screening using appropriate immunoassay techniques.

3. Blood (plasma or serum) samples may also be used to investigate the presence of a drug in the blood following its detection in urine. This information may be used to enhance the interpretation of the finding in the urine and is to be applied to the analysis of drugs in all categories (1 – 5) under the ARCI Drug Categorization Guidelines.

4. Blood (plasma or serum) samples collected pre- or post-race may also be used to investigate the presence of alkalinizing agents (sodium bicarbonate and/or other related substances) and to determine the level of total dissolved CO_2 (bicarbonate).

5. Blood (plasma or serum) samples may also be used for any other purpose deemed scientifically reasonable by the vendor and LRC. Scientifically reasonable applications include research related to drug/doping analysis and quality assurance programs conducted in a manner that is compliant with laboratory accreditation guidelines and LRC investigative and enforcement purposes consistent with Louisiana's Rules of Racing and/or State Statutes.
6. All positive results reported to LRC from findings in a blood sample will include the identity of the substance, an estimation of its concentration in blood and any relevant thresholds.

The vendor will receive only coded samples which do not identify the horse, its owner or its trainer from which the sample was taken, and will provide LRC with testing data originating from the vendor. The scope of work and/or duties associated with the contract do not restrict the vendor from improving existing protocols and/or implementing additional testing to enhance the integrity of the medication control program. The vendor shall transmit test results to LRC domicile office by fax and/or e-mail as soon as results are complete. Data transmitted by fax and/or e-mail on positive samples shall be followed by original documentation delivered by mail to: LRC Headquarters, 320, N. Carrollton Avenue, Suite 2-B, New Orleans, LA 70119. All reports shall be held in strict confidentiality by the vendor, which shall make its report only to LRC, unless otherwise instructed.

Samples shall be shipped to the vendor by overnight courier. LRC will bear the responsibility and expense of packing the samples. The courier shall pick up the samples at the four (4) respective racetrack test barns or other location on grounds as mutually agreed at the locations below. The vendor shall pay for the cost of transport of samples by overnight courier from this point to its doorstep. The responsibilities and duties of the vendor begin upon the courier's receipt of the samples. The vendor shall provide to LRC specimen collection vials for packing the samples, and secure shipping containers for the transport of the samples.

Racetrack Test Barn Locations:

Delta Downs: 2717 Delta Downs Dr., Vinton, LA 70668
Evangeline Downs: 2235 Creswell Ln., Opelousas, LA 70570
Fair Grounds: 1751 Gentilly Blvd., New Orleans, LA 70119

Official equine samples submitted to the vendor by LRC will be subjected to an extensive testing scheme designed to detect the presence of non-permitted drugs and chemical substances and/or their metabolites as listed hereinabove.

Each sample will be screened one (1) or more times, utilizing the techniques of immunoassay, high performance liquid chromatography (HPLC), gas chromatography/mass spectrometry (GC/MS), and/or other techniques, such as LC/MS/MS. At this point in the analysis scheme, it will be determined that each sample which is supposed to contain a permitted medication in fact does so, and those samples from animals not participating in the permitted medication program are free of such drugs. Any samples determined to be suspicious for the presence of a prohibited substance by this testing will be subjected to additional testing utilizing mass spectrometry. Only where the presence of a prohibited substance is confirmed by mass spectrometry will the sample be designated as a positive. Criteria for confirmation must conform to those recommended by the Association of Official Racing Chemists (AORC).

Specifically, by way of illustration but not limitation, the vendor shall perform tests on equine specimens transmitted to it by LRC in order to determine the absence or presence of drugs or other prohibited substances as defined by the Rules of Racing and to report the results of said tests to LRC promptly and to maintain all necessary records, test results, and data supporting said findings for a period of one (1) year, which records, test results and supporting data shall be the property of LRC.

The selection of the testing methods shall be the responsibility of the vendor, provided that all methods used shall be documented. Any methods, work instructions, procedures, or other lab documents utilized in the analytical process, as well as any audit findings and deficiency reports (all such items collectively, the "Know-How"), are proprietary and shall remain the exclusive property of the vendor. Documents detailing the Know-How shall be available for review by LRC and its Executive Director in person at the vendor's offices with at-least fifteen (15) calendar days written notice; such documents may not be copied or removed from the vendor's offices. The vendor shall, unless prevented from so doing by acts of God, force majeure, or other common disasters, submit a written report indicating negative test results, or samples pending confirmation of either a positive or negative status, to LRC on each sample or specimen submitted to it for testing within not more than five (5) working days following the day on which such sample or specimen is received (excluding late deliveries, Saturdays, Sundays and legal and State holidays). The vendor shall confirm pending test results as being either positive for drugs or prohibited substances, identifying specifically the compound confirmed, or negative within fourteen (14) calendar days or ten (10) working days from receipt of the sample (excluding late deliveries, Saturdays, Sundays and legal and State holidays). Otherwise, an extension of time must be granted by LRC on a case by case basis.

The vendor must meet the following minimum requirements:

1. PERSONNEL: The vendor shall have in its fulltime employ at least one (1) professional member of the Association of Official Racing Chemists (AORC) who shall be charged with direct responsibility for analysis of all samples. The cumulative knowledge of the technical personnel rendering services pursuant to this solicitation shall include the fields of drug metabolism, pharmaceutical chemistry, instrumental analysis and equine pharmacology as it applies to the use of drugs in racehorses. Laboratory personnel shall have established dialogue and professional associations with other racing chemists and the pharmaceutical industry. The vendor shall provide for a representative to attend equine drug symposia to include ARCI and AORC Conferences, when feasible

2. QUALITY ASSURANCE: The vendor shall participate in the AORC or other LRC approved quality assurance program and shall be accredited to ISO Guide 17025 and to the Racing Medication Testing Consortium (RMTC). These accreditations should be submitted with the vendors bid. The vendor shall have approval from the Horseracing Integrity & Welfare Unit (HIWU) to be able to conduct testing for Horseracing Integrity and Safety Authority's (HISA) Anti-Doping and Medication Control Program. In addition, it shall conduct and maintain an internal quality assurance/control program which may include the administration of drugs to horses and the collection of samples for submission to the vendor in a single blind and/or double blind manner. A Quality Assurance/Control Officer, who shall be designated as one of the key personnel of the vendor, will be

responsible for submitting the results of any and all quality assurance programs to LRC upon request.

3. EQUIPMENT AND APPARATUS: The following is a list of apparatus and instrumentation capabilities required by LRC and deemed minimally acceptable for the effective performance of drug and toxicological testing of equine biological fluids and other biological specimens:

A. *Mass Spectrometers*: Mass spectrometers (MS) will be used for the confirmation of each and every drug or foreign substance detected, within the limits of capability of mass spectrometry.

1. At least two (2) mass spectrometer systems shall be directly interfaced with a high performance gas chromatographic system capable of capillary gas chromatography. The mass spectrometer systems shall have a mass range of approximately fifteen (15) to one thousand (1000) atomic mass unit (amu) with a resolution ≥ 0.1 amu. Data acquisition systems shall be interfaced directly to the mass spectrometer systems. Drug mass spectral databases will also be maintained.

2. The vendor shall also have multiple mass spectrometer systems for conducting LC/MS/MS analyses, operating with either an electrospray or atmospheric pressure chemical ionization interface. These systems may be of a triple quadrupole and/or quadrupole/ion-trap and/or ion-trap or other more advanced configuration.

3. The vendor shall also have a mass spectrometer for conducting high mass, high resolution analyses of peptide and protein drugs.

B. *Immunoassays*: The vendor shall have the in-house capability of performing enzyme-linked immunosorbent assays (ELISA), for the detection of selected drugs and foreign substances which may be present in equine biological materials. The immunoassays employed may have detection limits within sub-nanogram to 100 nanograms per milliliter, or better. Pooling of equine samples for immunoassay screening is permitted. However, such pooling should not compromise the sensitivity of the assay to such a degree that its ability to detect a drug is significantly diminished. No more than five (5) samples may be pooled for any assay.

C. *High Pressure Liquid Chromatography*: The vendor shall have HPLC systems capable of microbore Liquid Chromatography (LC) with the following detectors: UV (variable, fixed wavelength, diode array) and fluorescence.

D. *Drug Standards*: The vendor shall have in its possession and maintain an extensive collection of standard drug reference materials including drug metabolites where available.

4. THE VENDOR MUST MEET THE SPECIFICATIONS LISTED BELOW:

A. Provide suitable containers for transport of samples from track to vendor. These containers shall have security seals and be of substantial construction to withstand rough handling without destroying the samples. Containers and specimen collection vials must be approved by LRC after award of the contract as well as samples that will need to be sent to LRC.

B. The vendor shall select the overnight courier and pay the cost of transportation of samples from the point of origin of the courier to the location of the vendor. When couriers are used for transportation, the samples must be transported to the vendor by a bonded courier, in order to maintain the chemical and legal integrity of the sample.

C. Employ a system of sample identification and history and be able to produce records of sample handling, including documentation of the full chain of custody while under the vendor's control, which shall withstand cross-examination in a court of law.

D. The selection of the methods of testing shall be the responsibility of the vendor, provided that all methods used shall be documented. Data Packets and Method Summaries are demonstrably accepted in the scientific community, admissible in court, and shall be provided to LRC for its records on request.

E. The vendor shall attend all meetings of LRC, unless excused by LRC, for the purpose of providing expert testimony regarding laboratory findings and to testify to the chain of custody regarding samples tested by the vendor. The vendor must also provide an individual that can give expert testimony on the pharmacology of drugs in the horse for those drugs which are called as positives. All costs and travel expenses associated with such attendance at LRC meetings shall be reimbursed in accordance with the Louisiana Travel Policy – PPM49. The vendor must also have the ability to acquire administered drug samples from horses in support of research on drug testing for new drugs and for the identification of drug metabolites.

F. For services provided by the vendor outside of LRC meetings, such as attendance at court proceedings and depositions, and consulting on investigations, the vendor shall be compensated for expert witness fees and travel costs, which must be in accordance with the Louisiana Travel Policy – PPM49 and shall be determined as follows:

1. The vendor shall make available one (1) representative to participate virtually in hearing preparation sessions and to testify virtually at hearings as LRC may reasonably request.

2. The vendor shall make available one (1) representative to provide in-person preparation, testimony or other assistance prior to or during hearings.

3. LRC shall reimburse the vendor for out-of-pocket expenses submitted in a detailed invoice, which the vendor incurs in providing such in-person preparation, assistance or testimony in accordance with the Louisiana Travel Policy – PPM49.

G. Provide for the on-site training of all test barn personnel in the proper procedures for collecting, handling and shipping of samples upon LRC's request.

H. Have established dialogue and protocols with at least five (5) AORC member chemical testing laboratories whereby all split (referee) samples may be analyzed by one (1) of these laboratories. AORC member laboratories with which protocols are established must be approved by LRC. The owner, trainer or agent of the horse tested shall bear the expense of any such testing for confirmation of findings of split samples by the AORC chemist.

I. Respond to the requests of LRC to test for specific drugs for which there is evidence of use or potential use.

J. Hold regular meetings, **whether in-person or virtually as needed**, with representatives of the equine veterinary and horsemen's associations to exchange information regarding new developments, interests and concerns.

5. *GOALS, OBJECTIVES AND DELIVERABLES:* LRC shall use the vendor's test result printouts as described in this solicitation to regulate and prevent illegal drug use in horses and prevent violations of the Rules of Racing, particularly those concerning equine positives, in order to ultimately maintain a high level of safety and protect the integrity of the sport of racing.

6. *PERFORMANCE MEASURES AND MONITORING PLAN:* LRC shall assure the vendor's compliance with the above goals, objectives and deliverables by maintaining pending files whereby it can be readily determined if the vendor has supplied LRC with reports on each and every horse that a sample was taken, and if such reports have been provided timely.

CONTINUITY OF SERVICES

The Contractor recognizes that the service(s) to be performed under the contract are vital to LRC and must be continued without interruption and that, upon contract expiration, a successor, either LRC or another Contractor, may continue them. The Contractor agrees to:

1. Furnish phase-in training; and
2. Exercise its best efforts and cooperation to effect an orderly and efficient transition to a successor.

The Contractor shall, upon LRC's written notice:

1. Furnish phase-in, phase-out services for up to sixty (60) calendar days after the contract expires; and
2. Negotiate in good faith a plan with a successor to determine the nature and extent of phase-in, phase-out services required. The plan shall specify a training program and a date for transferring responsibilities for each division of work described in the plan, and shall be subject to LRC's approval. The Contractor shall provide sufficient experienced personnel during the phase-in, phase-out period to ensure that the services called for by the contract are maintained at the required level of proficiency.

The Contractor shall allow as many personnel as practicable to remain on the job to help the successor maintain the continuity and consistency of the services required by the contract. The Contractor also shall disclose necessary personnel records and allow the successor to conduct on-site interviews with these employees. If selected employees are agreeable to the change, the Contractor shall release them at a mutually agreeable date and negotiate transfer of their earned fringe benefits to the successor.

The Contractor shall be reimbursed for all phase-in, phase-out costs (i.e., costs incurred within the agreed period after contract expiration that result from phase-in, phase-out operations) as agreed to with LRC during the contract period.

OTHER STIPULATIONS

The Laboratory will make available chemists and/or other personnel to testify at all meetings of LRC. Travel and other reimbursable expenses associated with this testimony constitute part of the total maximum payable under the contract. All travel expenses must be in accordance with the State of La Travel Policy PPM49. It is further agreed that other services rendered or expenses incurred by the vendor in connection with research, investigations, or consultation which may be requested or required by LRC, will be compensated by LRC in accordance with the State of Louisiana Travel Policy - PPM49.

LICENSING STANDARDS

The Contractor, its employees and subcontractors shall comply with all applicable licensing standards, certification standards, accrediting standards and any other laws, rules, or regulations governing services to be provided by the Contractor pursuant to the contract. The Contractor shall be an approved vendor by the Horseracing Integrity and Welfare Unit (HIWU) to be able to conduct testing for the Horseracing Integrity and Safety Authority's (HISA) Anti-Doping and Medication Control Program. LRC will not pay the Contractor for any services performed when the Contractor is not in compliance with such applicable standards, laws, rules, or regulations. If any license, certification, or accreditation expires or is revoked, or any disciplinary action is taken against an applicable license, certification, or accreditation, the Contractor shall notify LRC immediately and LRC, at its option, may immediately terminate the contract.