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# Laboratory accreditation: What it is and why it matters

There are several types of accreditation that equine drug testing laboratories can achieve. ISO (International Standards Organization) accreditation is the foundation for all of them. ISO accreditation verifies the consistency of a laboratory's processes from sample receipt to the issuance of testing results. ISO accreditation does not establish standards for the sensitivity of a laboratory's testing and does not investigate the relevance of the laboratory's capabilities as they relate to the requirements of the horse racing regulatory client.

ISO accreditation requires that the laboratory has a quality management system that 1) conducts internal checks to verify laboratory performance, and 2) has a process in place to remedy discrepancies identified through the internal checks. Laboratories apply for ISO accreditation for a specific scope of testing methodology. That scope will include: Species (e.g. human, horse, or other animals); matrices tested (e.g. serum, plasma, urine, hair) and testing methods. In other words, a laboratory can seek and achieve ISO accreditation for testing dog urine samples by Enzyme-linked Immunosorbent Assay (ELISA) testing. It is important to note that ELISA testing can be a useful component of screening analysis applied to regulatory samples, but ELISA testing is not sufficient for confirmatory analysis that requires the unequivocal identification of a specific substance. One can reasonably expect that testing results from a laboratory lacking instrumental methods (GC-MS [gas chromatography-mass spectrometry] and LC-MS [liquid chromatography-mass spectrometry]) in its scope of ISO accreditation may be successfully challenged by defense attorneys. Even when a laboratory has both GC/MS and LC-MS instruments, ISO accreditation does not ensure that the sensitivity of those testing methods will meet the requirements of racing regulators. In short, ISO accreditation affirms that a lab can do what it says it can, and that it can do so consistently over time. ISO accreditation establishes that the laboratory's performance is consistent. ISO accreditation does not contemplate the needs of racing regulators.

RMTC laboratory accreditation builds on the foundation of ISO accreditation. The RMTC requires that a laboratory achieve ISO 17025 accreditation by meeting ILAC-G7 (https://ilac.org) *Requirements and Operating Criteria for Horseracing Laboratories* before applying for RMTC accreditation. This informs the RMTC that the lab has been inspected and that its facilities,

sample management, information management systems, and analytical processes are appropriately documented.

RMTC accreditation then establishes performance standards that the laboratory must meet. This includes having validated methods to detect and confirm substances on the Controlled Therapeutic Substances (CTS) List at regulatory thresholds. In addition, the RMTC's Horseracing Testing Laboratory Committee (HTLC) establishes proficiency requirements for multiple substances not on the CTS list. The HTLC oversees the laboratory accreditation process and monitors the performance of RMTC-accredited laboratories.

To achieve RMTC accreditation, the laboratory must undergo a site visit in which a drug testing expert reviews the lab's Standard Operating Procedures manuals for all phases of testing and reporting, as well as for each substance on the CTS list to verify the lab's competency. In addition, the lab must perform successfully on two sets of single-blind External Quality Assurance Program (EQAP) proficiency samples. Substances are selected from the CTS and RMTC's proficiency list. EQAP samples are spiked—a specified amount of drug is added to a 'blank' sample—one that has been verified to contain no other substances. Through this process the RMTC is able to test the laboratories with samples containing substances at concentrations that are relevant to the required proficiency standards. Failure to accurately identify a specific substance (False Negative), or to identify the presence of a substance when none was added to the sample (False positive) will delay accreditation until the laboratory performs successfully on two sequential sample sets. In the event of a failed analysis, the laboratory is required to initiate a corrective action plan and submit both the plan and the outcome to the HTLC for review.

ISO accreditation and RMTC accreditation identify WHAT the laboratory is capable of. Even though the contents of EQAP samples are unknown to the laboratory, the samples are clearly labelled as Proficiency Test samples. The laboratory can apply all its resources to the analyses with the knowledge that the samples are not routine and in consideration of the consequences of a failed analysis. As a result the testing applied to EQAP samples may not be indicative of the testing applied to samples on a daily basis.

Neither ISO nor RMTC accreditation program examines what the lab does on a day to day basis for routinely submitted regulatory samples. Further, RMTC accreditation does not insert itself into the relationship between the laboratory and its client, the regulatory authority. The RMTC does not, nor can it, establish requirements for regulatory testing programs. A laboratory's client can, in fact, require the laboratory to perform below standards established by the RMTC. An example is where the Model Rule requires testing in both serum/plasma and urine for a substance (e.g. lidocaine), but the regulatory authority only contracts with the laboratory for analysis of blood samples. While the RMTC can make recommendations for testing programs it has no authority over the decisions or contractual requirements established by racing regulatory authorities.

The final type of laboratory accreditation is available through the International Federation of Horseracing Authorities (IFHA). Candidate laboratories are invited to apply. Accreditation is achieved through a self-certification process monitored by the other laboratories. IFHA accreditation requires proficiency in hair testing in addition to the detection of prohibited substances in blood and urine. To date, the opportunity to apply for IFHA accreditation has been only afforded the U C Davis Maddy Laboratory, which has successfully met the requirements and achieved accreditation. It is anticipated that this accreditation program will be expanded and available to other labs in the future. Most international racing authorities focus their testing programs on analysis of urine samples, and it is unlikely that IFHA-accredited labs, other than the U C Davis Maddy Laboratory, would currently have the capabilities to meet all the testing requirements of North American racing regulators. This would not preclude an IFHA-accredited laboratory from performing a split sample analysis for a substance included in its scope of accreditation.