BULL'S EYE THE ISSF IPOD ON DOPING

FOCUS ON: ACCREDITED LABORATORIES FOR DOPING CONTROL ANALYSIS

One of the most important elements to the fight against doping is the work performed by accredited laboratories. Their skilled analysis of urine or blood samples may yield an adverse analytical finding and result in the confirmation of an anti-doping rule violation. They are the scientific vehicle by which cheaters are caught.

In light of its paramount importance, the doping control analysis performed by these accredited laboratories must be accurate, standardized and compliant with all necessary norms, guidelines and procedures.

There are currently 33 laboratories around the world that are WADA-accredited.

- Each laboratory provides the integral scientific component in the standardized and clearly defined testing processes and procedures that serve to protect and bolster the integrity of sport and the world anti-doping program.
- Each laboratory holds great responsibilities in the provision of effective, verifiable and qualified analytical services to the whole sporting community.
- Each laboratory understands and respects its crucial role in the on-going fight against doping in sport.

Without the certified laboratory analysis, few anti-doping rule violations could be asserted and sanctioned, and cheaters could not be brought to justice.

A LITTLE HISTORY

WADA accredited laboratories represent an international network of specific competencies, dedicated knowledge and long-term experience in the fight against doping. (Gunter Gmeiner, WAADS)

In the 1960s, when doping controls first started, the process was relatively simple. An athlete provided a urine sample after competition. The sample was delivered to an International Olympic Committee (IOC) accredited laboratory, not necessarily on the same continent, within a few days. At that time, the laboratories mostly analysed samples for stimulants, narcotics and anabolic steroids (the substances of choice at the time) based on empirical observation and experience.

Later, as exponential advances in science and technology resulted in the development and use of new drugs, anti-doping organizations began testing for additional substances such as beta-blockers, beta-agonists and some peptide hormones. By the time the IOC transferred the responsibility of accrediting anti-doping laboratories to WADA in the 1990's, it was also beginning to require that laboratories become ISO 17025-certified; a requirement that remains today. This certification means that the laboratories have qualified management, administrative and technical systems that all guarantee precise, accurate and traceable testing and calibration results.

Since then, of course, WADA has firmly established itself as the independent agency responsible to lead the collaborative worldwide campaign for doping-free sport. Because the development, the proliferation and the use of designer drugs has become far more prevalent, the WADA Prohibited List keeps expanding and anti-doping organizations now test for a whole range of substances and methods, both by urine and blood samples. As a result, it can be argued that the effectiveness of the global fight against doping now depends significantly on the ability of anti-doping laboratories to reliably identify and sometimes quantify the substances prohibited in sport, as defined by WADA's List of Prohibited Substances and Methods.

LABORATORY ACCREDITATION

"If laboratories were not accredited, their level of performance around the world would vary considerably. That would be unfair to the athletes and damage the credibility of the whole system."
(Toni Pascual, WADA).

Laboratories that wish to perform the analysis of doping controls for sports under the World Anti-Doping Code must achieve and maintain accreditation from WADA. WADA's accreditation of anti-doping laboratories ensures that the scope and quality of scientific approaches remains as advanced and consistent as possible.

The accreditation process is demanding. Candidate laboratories undergo intensive training and are greatly scrutinized. It is necessary for them to display singular dedication in each aspect of their preparation to reach excellence and thereby obtain accreditation.

WADA accreditation is based upon compliance with two international standards:

- The ISO/IEC 17025 (which also expands ISO 17025 requirements to doping control) and,
- The International Standard for Laboratories (ISL)

WADA has established close ties with both international and national standard-setting bodies to facilitate the process of assessment of laboratories for compliance with these standards. Each laboratory must also sign

WADA's Code of Ethics, and participate in an ongoing quality assurance program (see EQAS below).

The ISL is the beating heart of accreditation: "a document in constant evolution that follows the advance of science and integrates the analytical requirements and the laboratory procedures into the fight against doping". The latest revision (6.0) came into effect in January 1, 2009.

WADA also publishes Technical Documents on specific issues. For example, the standardization of the procedures for analyzing blood samples for the Athlete Biological Passport. It is only full compliance with all WADA technical documents and standards, the ISO and EQAS which renders accreditation achievable.

THE ACCREDITATION PROCESS

"The term External Quality Assessment Scheme (EQAS) is significant. It highlights our focus on competence."
(Thierry Boghosian, WADA)

Candidate laboratories formalize their interest to WADA by affirming that they possess the necessary expertise, funds and equipment to reach the standards outlined in the ISL and Code of Ethics. They must also have the support of their national anti-doping organizations and all other relevant national governmental or legislative bodies. In addition, candidate laboratories must begin the process to obtain ISO/IEC ISO 17025 accreditation through an accreditation body recognized by the International Laboratory Accreditation Cooperation (ILAC).

After successfully clearing the first hurdle of accreditation as well as an initial site visit, the laboratory enters a "probationary" period.

During this period, the laboratory must analyze at least 20 External Quality Assessment Scheme (EQAS) samples and, as a final proficiency test, 20 more in the presence of WADA representatives. The laboratory is also required to develop anti-doping research capabilities and initiate at least two research projects to broaden its knowledge base in the fight against doping. ILAC ISL trained assessors also help the laboratory identify and correct non-conformities either with the ISO or ISL standards in the course of mandatory site visits.

All these probationary activities usually span 18 to 24 months.

The probationary laboratory's performance in the EQAS program and the final accreditation test as well as the findings from the WADA site visits and ISO accreditation reports are combined into a final recommendation for accreditation by the WADA Laboratory Expert Group and then submitted to WADA's Executive Committee for approval.

A laboratory can only analyze athlete samples for anti-doping organizations once it has achieved accreditation.

The Monitoring Process

In order for a laboratory to maintain its accreditation status, a host country must ratify the UNESCO Convention against Doping in Sport and, of course, it will be continually monitored through WADA's EQAS. (Olivier Rabin, WADA)

All laboratories are independently owned, managed and funded. WADA's role is to accredit them and to monitor them to make sure they meet the highest standards of quality. This is a process supplemented by external, independent monitoring. WADA does not, for example, monitor compliance with the ISO 17025 standard. This is done by national accreditation bodies that are members of the ILAC—one of WADA's key partners.

WADA monitors the performance of accredited anti-doping laboratories consistently and continuously through EQAS. Participation in the EQAS is mandatory for all WADA accredited laboratories. It allows for the evaluation of laboratory competency through a continuous assessment of their performance and provides laboratories with opportunities to compare their results, with the aim to enhance harmonization of test results among accredited laboratories. It also incorporates educational opportunities for the WADA accredited laboratories.

Under WADA's monitoring system, anti-doping laboratories analyze 3 sets of 6 blind EQAS samples a year. The frequency of testing and the number of samples is designed to monitor and evaluate their performance. Laboratories are also sent samples of known prohibited substances that provide opportunities for learning. Most importantly, however, they are sent test samples anonymously (known as "double blind"), which allows WADA to evaluate their performance in a routine setting.

It is the International Standard for Laboratories and its related technical documents that specify the standards that must be met for the production of valid test results and evidentiary data. These documents also identify the criteria that are obliged to be met for accreditation and re-accreditation. Whenever a laboratory does not meet requirements of the International Standard for Laboratories, it must take fast corrective action. In serious situations where the criteria fail to be met WADA may suspend the laboratory's accreditation.

THE ROLE OF THE LABORATORY IN DOPING CONTROL AND RESULTS MANAGEMENT PROCESSES

"We inherited many of these processes from the IOC. They are now further standardized and even tighter."
(Olivier Rabin, WADA)

The doping control, laboratory and results management processes are inevitably intertwined. At the time of doping control, the athlete's sample is split into two coded bottles (A and B sample) with tamper-proof devices, sealed and sent to a WADA accredited laboratory and registered. The process is meant to ensure that the chain of custody is maintained at all times.

Once received, laboratories analyze the A sample for all prohibited substances, documenting the volumes taken from that sample for each procedure and the results obtained. If nothing is found, the laboratory notifies the results management authority. However, if the laboratory does detect a prohibited substance or method (an adverse analytical finding) it must inform the results management authority, the relevant International Sport Federation and WADA. The results management authority then informs the athlete and launches the results management process, which could lead to the analysis of the B sample, a hearing, and a sanction.

In all cases there is a presumption that the laboratory has conducted its analysis in accordance with all International Standards. This means that the burden is always on the athlete whose sample has yielded that adverse analytical finding to prove that the laboratory may have been deviated from these Standards. Otherwise, following the laboratory detection and communication of the detection of a prohibited substance or method, the assertion of an anti-doping rule violation and all related results management and disciplinary processes will typically follow.

ONGOING CHALLENGES

"Credibility and analytical quality are essential to any reliable system".
(Gunter Gmeiner WAADS)

It is imperative for accredited laboratories around the world to adjust to anti-doping developments. This includes new technologies, the scientific and cultural evolution of the fight against doping and the growing number of countries that are developing anti-doping programs. Each laboratory must be able continue to support the ongoing challenges and developments of doping in sport in the best possible way within their own country or region, economic and administrative limitations and demographic realities.

Here are but some of the challenges new and established accredited laboratories face:

- **Sample deterioration**
  Because blood deteriorates after 36 hours and must be analyzed within that short window of opportunity, the location of the laboratory is of crucial importance to the doping control process not to compromise the quality of the sample or the results of the analysis. Until the process is simplified and a proper system implemented to ensure that the closest laboratory is always utilised, Laboratories will continue to have to deal with samples that may be of weaker quality and therefore harder to properly and accurately analyse.
- **Location, location, location**
  For historical reasons, two-thirds of accredited laboratories are in Europe, leaving other parts of the world underserved. Using Africa as an example, the more direct transportation routes are not necessarily within that continent, but sometimes to Europe or Asia. The time limit imposed by blood analysis means that getting samples from one African nation to another may not be the most appropriate solution. New laboratories must bring value to their overall region, not just to the country where they are located. Accordingly, many would like to see laboratories accredited in more specific and logically defined locations.
- **Economic implications**
  Establishing and maintaining a world-class laboratory is not inexpensive. The rigorous quality requirements and technical challenges involved in setting up a laboratory, the high cost involved and the recent economic downturn have limited the number of laboratories applying for accreditation. Also, if a laboratory only processes a small number of samples, the cost per sample is prohibitively high because the laboratory has to maintain its accreditation, staff and equipment, regardless of the number of samples it processes.
- **Research**
  Education and research have become some of the main pillars of the effective fight against doping. Research allows laboratories to meet new challenges and enables them to consistently improve upon their anti-doping techniques so that they involve with, and ideally before, the proliferation of new prohibited substances and methods. This is why research has become a required element of WADA accreditation for laboratories. Therefore, laboratories are also expected to meet obligations in this regard and must provide accounting of the same in order to maintain their accreditation.

One can only assume that the list of WADA accredited laboratories will continue to expand. Surely, the processes in place to ensure that the competency of each new laboratory, as well as that of the existing laboratories, will equally continue to progress so that they may consistently meet new challenges. One thing is certain: accredited laboratories' measurements and analysis must continue to be confidently received with an assurance of utmost quality.

A SIMPLE ACKNOWLEDGEMENT

"Laboratory accreditation stands for transparency, accountability and integrity"
(Toni Pascual. WADA)

The WADA Code clearly states that WADA accredited laboratories are presumed to have conducted sample analysis in accordance with the ISL and that a sample analysis conducted by a WADA accredited laboratory which confirms the presence of a prohibited substance in a sample is sufficient to prove that an anti-doping rule violation has occurred. This presumption is not to be taken lightly. Nor should the laboratory's role in the doping control process and the fight against doping in sport be taken lightly. The sporting community as a whole should acknowledge the efforts of each accredited laboratory in ensuring that they meet the stringent criteria and standard to which they are held. Not only do they consistently seek to provide timely, accurate and thorough doping control analysis, they are an intrinsic part of the successful battle against doping in sport.

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LIST OF ACCREDITED LABORATORIES FOR DOPING CONTROL ANALYSIS

(AS OF FEBRUARY 2013)

> Sydney, Australia. The Australian Sports Drug Testing Laboratory (ASDTL)
> Seibersdorf, Austria. Seibersdorf Labor GmbH Doping Control Laboratory
> Ghent, Belgium. DoCoLab Universiteit gent-UGent
> Rio de Janeiro, Brazil. LAB DOP-LADETEC/IQ-UFRJ Rio de Jeneiro Doping Control Laboratory
> Montréal, Canada. Laboratoire de contrôle du dopage. INRS – Institut Armand-Frappier
> Beijing, People's Republic of China. National Anti-Doping Laboratory China Anti-Doping Agency
> Bogota, Colombia. Laboratorio de Control al Dopaje Coldeportes Nacional Bogota
> Havana, Cuba. Antidoping Laboratory Sports Medecine Institute
> Helsinki, Finland. Doping Control Laboratory United Medix Laboratories Ltd.
> Paris, France. Agence Française de Lutte Contre le Dopage (AFLD) Département des analyses
> Cologne, Germany. Institute of Biochemistry – German Sports University Cologne
> Kreischa, Germany. Institute of Doping Analysis and Sports Biochemistry (IDAS) Dresden
> London, Great Britain. Drug Control Center King's College London
> Athens, Greece. Doping Control Laboratory of Athens
> New Delhi, India. National Dope Testing Laboratory
> Roma, Italy. Laboratorio Antidoping FMSI
> Tokyo, Japan. Anti-Doping Laboratory Mitsubishi Chemical Medience Corporation
> Almaty, Kazakhstan. Athletes' Anti-Doping Laboratory. Sports and Physical Training Affairs of the Republic of Kazakhstan
> Seoul, Korea. Doping Control Center Korea Institute of Science and Technology
> Oslo, Norway. Norwegian Doping Control Laboratory, Department of Pharmacology Oslo University Hospital
> Lisbon, Portugal. Laboratorio de Analises de Dopagem (LAD) Autoridade Antidopagem de Portugal (ADOP)
> Warsaw, Poland. Department of Anti-Doping Research Institute of Sport
> Bloem-fontein, Republic of South Africa. South African Doping Control Laboratory – Bloemfontein
> Bucharest, Romania. Romanian Doping Control Laboratory
> Moscow, Russia. Antidoping Centre Moscow
> Barcelona, Spain. IMIM (Hospital del Mar Medical Research Institute)
> Madrid, Spain. Laboratorio de Control de Dopaje de la Agencia Estatal Antidopaje
> Stockholm, Sweden. Doping Control Laboratory Karolinska University Hospital
> Lausanne, Switzerland. Laboratoire Suisse d'analyse du dopage. Centre hospitalier universitaire Vaudois et université de Lausanne.
> Bangkok, Thailand. National Doping Control Centre Mahidol University – Bangkok Thailand
> Tunis, Tunisia. Laboratoire du dépistage du dopage (LDD). Reinstatement pending as of February 2013.
> Los Angeles, United States. UCLA Olympic Analytical Laboratory
> Salt Lake City, United States. The Sports Medicine Research and Testing Laboratory (SMRTL)