

## Laboratory Diagnosis Reliability and Quality Assurance System

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### Abstract

Stringent compliance with regulatory laboratory standards, application of quality assurance systems in compliance with EN ISO/IEC 17025, validation of diagnostic tests, support of informatics instruments as Laboratory Information Management System are essential elements to guarantee high quality standards and reliability of analytical data in the framework of harmonized activities performed in accredited laboratories. However, eventual incoherence of the analytical diagnostic procedure may occur, for example in case of comparison of data produced from accredited and non-accredited laboratories. Further efforts will contribute to the advancement of harmonization policies sustaining laboratory analytical diagnostics, efficient official controls and certifications, based on standardized laboratory procedures, uniform evaluation criteria and reliable analytical data.

**Keywords:** Laboratory diagnosis; Quality assurance system; Reliability

### Editorial

Reliable laboratory diagnosis is a fundamental base of medical sciences, public health, food safety and animal health. Constant attention was paid to improve laboratory techniques and diagnostic reliability. In last decades, important epidemics caused by different emerging or re-emerging pathogens as the human immunodeficiency virus and severe acute respiratory syndrome affecting human populations or bovine spongiform encephalopathy and foot and mouth disease serious threat for domestic animals, highly motivated the scientific community to boost laboratory capability. In the framework of this process, genetic investigation techniques acquired incontestable importance in order to provide accurate pathogen identification. In parallel, legal measures have been conceived and enforced to sustain the improvement of laboratory diagnostic.

More in general, in the context of the harmonization of laboratory analytical methods, validation processes and standardization of analytical procedures, significant activities have been undertaken by international organizations as the Food and Agriculture Organization (FAO)/World Health Organization (WHO)'s Codex Alimentarius. Also the European Commission promoted the development of harmonized criteria for the application of methods for the interpretation of analytical results in order to guarantee the comparability and reliability of such data in the European Union. This is particularly evident with concern to food safety. In Europe, specific policies introduced traceability and preventive approaches focused on food business operators' self-control in contrast to the previous almost exclusive monitoring operated by public institutions. However, such review of responsibilities, according to the Regulation (EC) 178/2002 [1], implied obviously maintain of the public responsibility to verify the compliance with the food law through official controls, laboratory analyses and certifications. New horizontal norms, known as hygiene package, have been adopted. Subsequently, the system of norms for the control of the respect of standards, originally applied on voluntary basis and elaborated by harmonization international bodies as the

International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC), to constitute the guidelines for the organization of activities of the official laboratories, become compulsory rules according to the Regulation (EC) 882/2004 [2], in force since 1st January 2006.

It is necessary to guarantee adequacy of applied analytical methods to specific examination purposes and reliability of obtained results through evidences able to certify the quality of results. Therefore, analytical methods must be clearly characterized by specific criteria as applicability, specificity, sensibility, quantification limits, precision, repeatability, reproducibility, selectivity, linearity and measurement uncertainty. The internationally recognised quality system EN ISO/IEC 17025 is for use by laboratories in developing their management system for quality, administrative and technical operations, and specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. These specific criteria are designed to regulate the application of laboratory methods for sample testing, codifying determination and quantification procedures, and identifying relevant characteristics for reference methods.

Important harmonization instrument, certification allows formal recognition of public functions for the guarantee of the quality system as well as independent bodies entrusted for the verification of conformity in relation to European rules. Based on the Regulation (EC) 765/2008 [3] and related Decision 768/2008/EC [4], the European Union has established a system of accreditation bodies, organized in network of single national organisms, led by the European co-operation for Accreditation (EA), body recognised by the European Commission. According to the Regulation (EC) 178/2002 [1], laboratories for official control and reference laboratories can be designated by the competent Authorities only if they perform their activities and are evaluated and accredited by the national certification body, as Accredia in Italy, in conformity to the following European norms: (a) EN ISO/IEC 17025, «General requirements for the competence of testing and calibration laboratories»; (b) EN 45002, «General criteria for the assessment of testing laboratories»; (c) EN 45003, «Calibration and testing laboratory accreditation systems-General requirements for operation and recognition». Laboratories are

called to include in their organizational structure a quality management system, and appointing dedicated staff, including quality manager, technical manager and deputies. General guidelines are provided also by the WHO [5]. Accreditation refers both to management and technical aspects of the laboratory; and each analytical test may undergo to this quality procedure. Therefore, specific documents are prepared for the validation of each analytical method.

In order to support the daily optimal quality performance of modern laboratory's operations, software-based Laboratory information management system (LIMS) have been introduced. Laboratory management informatics tools can be designed to satisfy information obligations under international quality standard ISO 17025. A LIMS can cover other standards such as ISO 15189, Good laboratory practice and good automated manufacturing practice. Key features include workflow and data tracking support, flexible architecture, and data exchange interfaces, applicable also in regulated environments. Such elements are essential to ensure competence, efficiency and transparency of the diagnostic system, especially in case of official controls, and taking into account the high number of reported data from analytical measurements that requires guaranteed quality and comparability among different laboratories.

The LIMS have evolved over the years from simple sample tracking to resource tool that manages multiple aspects of laboratory informatics. Various systems are available, through a dynamic design because the laboratory's requirements are rapidly evolving and different labs often have different needs. Core functions associated with laboratory processing phases may include sample management, reception and chain of custody assignments, barcode handling, scheduling and tracking of the sample and the associated analytical workflows, the processing and quality control associated with the sample and the utilized equipment and inventory, instrument and application integration, method management for laboratory process and procedures, instrument calibration and maintenance schedule and records, schedule and distribution of reports to designated parties, storage of data associated with the sample analysis, and electronic data exchange including transfer of data files to databases.

In Italy, one of the popular information management system used in state laboratories, named SIGLA, has been developed and managed by Krene S.r.l., software competence center within the Basilichi S.p.A. group, software and system integration service provider also for the public administration, primarily in the health sector in Europe, as with the LIMS adopted by quite the half of the veterinary state laboratories Istituti Zooprofilattici of Sardinia, Mezzogiorno, Umbria-Marche and Piedmont-Liguria-Aosta Valley, and the informatics tool Adverse Reactions Reporting System (ARES) adopted for pharmacovigilance. All the territorial units of each institute are networked through SIGLA, web-based software simple and intuitive, dedicated to the management of test samples. Users can monitor the state of advancement of the laboratory processing phases, from reception of the sample up to the compilation of the results reporting, always in the respect of secured information. Test results are immediately made available in downloadable formats. To comply with legal specifications for sample management, laboratory manager's approval is provided by a fully electronic signature system, thus the result report file is the only exclusive document with legal value, and in line with the process of digitalization of the public administrations.

Stringent compliance with regulatory laboratory standards, application of quality assurance systems, validation of diagnostic tests,

support of informatics instruments are essential elements to guarantee high quality standards and reliability of analytical data in the framework of harmonized activities performed in accredited laboratories. However, further improvements are required for example when considering that test results of microbiological determinations are not necessarily generated entirely under the control of the laboratory quality assurance system, especially when accurate typing is aimed, and genetic investigations are applied. Molecular assays are in fact highly specific and able to provide best knowledge of the test sample characteristics for correct and irrefutable identification for example of a bacterium or a virus. Despite the tests may be validated and performed in compliance of quality norms, the problem rises for the interpretation of the obtained molecular traits. Generally, genomic sequences are characterized through comparison with other deposited sequences in databases as GenBank. At this stage, still integrant part of the analytical diagnostic procedure, data obtained from an accredited laboratory are compared with data originated from tests performed in other accredited laboratories, but also, and with high probability, from laboratories not accredited and possibly performing not validated testing. In fact, in order to deposit a sequence in an international genetic database, researchers are not requested to declare conformity with quality assurance system. Given the high cost to obtain and maintain official accreditation, many research laboratories that do not operate in the system of official controls, for example the laboratories of the universities often they are not accredited and perform diagnostic tests according to good practice principles. This implies that the quality of the data is not guaranteed and may vary, thus, creating a conceptual gap in the coherence of the analytical diagnostic procedure applied in accredited laboratories.

Furthermore, for evaluation purposes, online available informatics tools are used for comparison alignment or to construct phylogenetic dendrograms, and again this step escapes from the quality assurance system of an accredited laboratory.

Undoubtedly, major improvements have been introduced to ensure a successful laboratory analytical strategy relevant for public health, food safety and animal health. Further efforts will contribute to the advancement of harmonization policies sustaining laboratory analytical diagnostics, efficient official controls and certifications, based on standardized laboratory procedures, uniform evaluation criteria and reliable analytical data [5].

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