

ARTICLE

Alto Adige.

For the first time in Italy a Health Agency has obtained accreditation to ISO 15189 for all clinical laboratories. More protection for citizens and visitors.

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To offer citizens and visitors a high quality laboratory medical service, in line with an international standard, with exams which can be recognized and interpreted worldwide.

These are the motives for which the Alto Adige Health Agency requested and obtained from Accredia, the accreditation of its clinical laboratories: six laboratories located throughout its territory in Bolzano, Merano, Silandro, Bressanone, Vipiteno, Brunico and San Candido.

Accreditation granted by Accredia, the sole national accreditation body, attests the competence of the eight structures to provide results from trustworthy analyses, in accordance with the requirements of the standard ISO 15189 "Medical Laboratories – Requirements for quality and competence".

This is the first case in Italy of the accreditation of an entire structure of clinical laboratories operating within the same health agency belonging to the national health system.

About eight million exams are performed every year by these laboratories in the medical fields regarding clinical pathology, microbiology and virology. In an area containing about 600,000 people – between citizens and visitors – especially during the summer and winter seasons.

The eight laboratories have been unified since 2011 in a departmental structure (binding form of organizational collaboration-FVCO) which enabled the creation of a series of strategic objectives of primary importance: amongst these the ISO 15189 accreditation project.

This project, which is widely adopted in other European countries, was born in 2014, when the FVCO decided to propose to the management of the Health Agency to support an iterative process for the accreditation of laboratories, mostly already certified to ISO 9001, further increasing their quality.

The invitation was welcomed by the management which, given the size, potential organizational impact and progress of the project, decided in 2017 to go ahead with it and include it in the 3-year program for 2017-2019.

The setting up of a working and study group of ISO 15189 consisting of internal laboratory staff involved in the project, and the identification of references for quality, were the main activities. In four years the laboratories, within their fields of technical characteristics, unified the quality management system, shared procedures and harmonized the chief work processes, without resorting to external consultancies.

The attestation issued by Accredia flanks, without replacing it, the so-called "institutional accreditation", issued in all the Italian Regions, and it is a complementary system, aimed at improving the assurance that clinical laboratories operate with competence, impartiality and confidentiality, for the purpose of public health protection and guaranteeing safe public health assistance which is efficient and of a high quality.

Accreditation to ISO 15189 provides for the verification, both in terms of conformity of the management system and the technical adequacy of the laboratory, of all the processes involved in the performance of accredited exams: the competence of staff (from those taking blood samples to those performing exams, those who analyze results, formulating opinions etc.); also the knowledge of methods for carrying out tests, the transport and storage of samples, the suitability of locations and equipment, the metrological traceability of results and quality assurance.

The beneficiaries will therefore be both citizens and visitors as well as the public administration authorities.

Citizens and visitors will be able to receive health care and services which are controlled and harmonized according to an international standard, without any disparities of treatment within the boundaries of the Alto Adige Autonomous Province. There are advantages also for doctors because reports of exams can be recognized and interpreted in a uniform way in the various health facilities used by patients.

The positive aspects also regard the Alto Adige Health Agency, given that the eight laboratories will work under the same rules and in line with one management system, to provide their service more efficiently, and exchange information and data more easily.

Accredia is the sole national accreditation body nominated by the Italian government. Its task is to attest the competence, impartiality and independence of laboratories and bodies which verify the conformity of products, services and professional persons with the reference standards, facilitating free movement of goods and ensuring the protection of public interests concerning health, safety and the environment.

Accredia is a private non-profit association operating in the public interest and under the aegis of the Ministry of Economic Development, for guaranteeing institutions, business and consumer protection.

Accredia has 67 members and it represents all the parties involved in accreditation and certification activities, including 9 ministries (Economic Development, Environment, Health, Defence, Infrastructures and Transport, Internal affairs, Labour and Agriculture), 7 major public entities and 2 national standardization bodies – UNI and CEI, and also: 13 business and trade organizations, associations of accredited certification and inspection bodies, testing and calibration laboratories, associations of consultants and consumers and public utility suppliers such as the national rail network and the national power network.

Accredia is a member of the EU and international accreditation networks and signatory to the international agreements of mutual recognition under which the tests and certifications of bodies and laboratories accredited by Accredia are recognized in Europe and worldwide.