

Laboratory Management, Accreditation, Quality Assurance

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## MODERN APPROACH TO REFORMING OF THE LABORATORY MEDICINE OF UKRAINE

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### Background

Analysis of laboratory medicine state in Ukraine shows that the partially preserved Soviet regulatory framework in this area and the absence of any concept of the quality assurance of clinical laboratory tests at the governmental level cannot ensure the quality of medical laboratory services for their consumers - patients and doctors.

The priority is the harmonization of national regulatory frameworks of the medical laboratory services with the best European and international practices, which will make it possible to build systems of quality assurance in all medical laboratories in Ukraine.

### Results & Discussion

For this purpose, ACCLMU was created in 2007. To increase credibility, the decision was made recently that Ukrainian Society of Clinical Laboratory Diagnostics which is a full member of IFCC and EFLM will join ACCLMU.

ACCLMU developed several concepts for the reforming the laboratory services system in Ukraine on the basis of building system of quality assurance of laboratory tests in accordance with modern requirements.

Also, ACCLMU participated actively in the development and implementation in the Ukrainian legislation of documents identical to the European directives, in particular 98/79/EC.

In 2009, TC 166 was created by ACCLMU as a mirror to ISO/TC 212. For today, more than 30 national standards were developed by TC 166 in the field of laboratory medicine, including DSTU EN ISO 15189:2015.

The most important ACCLMU activities are the modernization and harmonization of specialists training programs with European requirements as well as creation of system of medical laboratories specialists certification and of an effective system of accreditation of medical laboratories. To this end ACCLMU constantly conducts conferences and seminars, publishes guidelines etc.

The implementation of all these tasks is impossible without defining the requirements for the accuracy and traceability of clinical laboratory tests, of reference ranges etc. which is not done yet.

ACCLMU exerts a lot of efforts to modernize the national laboratory service structure, in particular through the centralization of laboratory tests.

### Conclusion

ACCLMU is committed to achieve the global goal of ensuring the availability of laboratory services and their compliance with the requirements of evidence-based medicine.