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MEDICAL SCIENCES

IMPLEMENTATION OF EUROPEAN STANDARDS INTO THE PRACTICE OF MEDICAL LABORATORIES IN UKRAINE

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Today, laboratory diagnostics is impossible without the implementation of quality standards that ensure the reliability, accuracy, and reproducibility of results. The global framework for the operation of medical laboratories is ISO 15189, which establishes requirements for quality and competence. It regulates all stages of the laboratory process and serves as the foundation for building a quality management system. However, ISO 15189 defines general requirements for quality systems in medical laboratories and does not provide detailed methodological guidance for performing urinalysis. Due to the absence of specific instructions regarding sample preparation, microscopy, storage, and interpretation of results, laboratories may organize processes differently, leading to variability in results. To achieve consistency of approaches and ensure reliable results, it is necessary to apply specialized guidelines that comprehensively describe all stages of urinalysis. An example is the European guideline on urinalysis developed in 2023 by the working group of the European Federation of Clinical Chemistry and Laboratory Medicine.

Standardizing laboratory processes in practice is quite challenging due to the wide diversity of methods, equipment, reagents, and approaches. Therefore, the international community is gradually shifting from standardization toward

harmonization. The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) guideline on urinalysis was developed for laboratory professionals to harmonize urinalysis practices, improve the quality and accuracy of diagnostics, and promote structured exchange of medical information.

According to this guideline, all urinalysis methods are classified into three groups based on their level of accuracy:

- Level I – rapid screening methods using test strips;
- Level II – routine laboratory tests;
- Level III – high-precision reference methods such as LC-MS and MALDI-TOF.

Rapid methods represent the primary level of diagnostics and are performed either directly at the patient's bedside (point-of-care testing, POCT) or during the initial laboratory examination. Reagent test strips are used to determine urine parameters such as pH, specific gravity, protein, glucose, ketones, bilirubin, urobilinogen, blood/hemoglobin, as well as indirect markers of infection — nitrites and leukocyte esterase.

The advantages of this group of methods include rapid analysis, low cost, and minimal personnel training requirements. However, they provide only semi-quantitative results and carry a relatively high risk of false-positive or false-negative findings due to the influence of medications, vitamin C, or urine concentration. According to the guideline, if a Level I result is negative but there is a clear clinical presentation, Level II testing must be performed.

Level II tests are basic laboratory tests that are standard for a certified medical laboratory. Level II testing utilizes automated urine analyzers based on photometry combined with manual or digital microscopy of urinary sediment. The advantages of this group include higher accuracy and better standardization. However, these methods require centrifugation, which may lead to the destruction of certain sediment elements, as well as a higher level of laboratory staff qualification.

Level III tests are specialized laboratory analytical methods. They are used to establish a definitive diagnosis in complex cases, to monitor specific therapy, or to

identify pathogens causing urinary tract infections. These tests involve liquid chromatography–mass spectrometry (LC-MS), matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF), and quantitative biochemical methods for determining microalbuminuria, creatinine clearance, and electrolytes.

LC-MS (liquid chromatography–mass spectrometry) is a high-precision method of urine analysis that combines component separation (LC) with their identification based on mass (MS). It is used for the quantitative determination of metabolites, cardiac biomarkers (e.g., trimethylamine N-oxide, TMAO), diagnosis of neuroblastoma (via vanillylmandelic acid measurement), and detection of rare diseases.

MALDI-TOF (matrix-assisted laser desorption/ionization time-of-flight mass spectrometry) in urinalysis is an advanced microbiological method for the automated identification of bacteria and fungi, enabling the determination of urinary tract infection pathogens within minutes. It provides high accuracy and rapid turnaround of results following bacteriological culture.

The choice of method should correspond to the clinical request and the required level of accuracy. The laboratory must clearly identify the appropriate level for each test.

Urinary protein content is one of the key parameters of chemical urinalysis and a marker of glomerular kidney damage. The analysis is performed as a Level I method using diagnostic test strips. According to current recommendations for clinical testing with test strips, the following requirements must be met:

- Automated readers must be used instead of visual interpretation;
- Test strips should be used exclusively as a screening tool and must be verified by quantitative methods;
- The influence of interfering factors, such as urine pH and specific gravity, must be taken into account;
- Regular internal quality control should be performed, and participation in interlaboratory comparison programs (external quality assessment) is required.

At the stage of microscopic examination of urinary sediment, key recommendations specify centrifugation at 400 g for 5 minutes. The use of a coverslip is mandatory. The minimum magnification for manual microscopy should be 400×; the use of phase-contrast microscopy is preferable to conventional light microscopy. In cases of hematuria, assessment of erythrocyte dysmorphism is mandatory. Morphological elements should be described with consideration of their clinical relevance. The implementation of automated analyzers should occur only after mandatory verification has been completed. At the post-analytical stage, standardization of measurement units and reporting must be ensured.

Thus, an essential component in organizing laboratory urinalysis is the validation of methods in accordance with ISO 15189, as well as the use of standardized request forms that include a mandatory clinical question, medical history, and a probable diagnosis, along with complete sample information (type, date, collection method, and transport conditions). At the post-analytical stage, the report must be unified and include the method used, units of measurement, and reference intervals. Effective communication with clinicians is also crucial, particularly in cases of critical or questionable results.