Put It on the Board

New guidelines published on lab analysis in diabetes

August 2023—The Association for Diagnostics and Laboratory Medicine (formerly AACC) and the American Diabetes Association last month issued guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus (Sacks DB, et al. *Clin Chem*. 2023;69[8]:808–868).

The two groups first issued such guidelines and recommendations in 2002 and then again in 2011. In the new publication they review and update those recommendations using an evidence-based approach, "especially in those areas where new evidence has emerged since the 2011 publications," the authors write in an executive summary.

The guideline focuses on the practical aspects of care to assist in decisions on the use or interpretation of laboratory tests in screening for, or in diagnosing or monitoring patients with, diabetes. The recommendations primarily target laboratory professionals, general practitioners, physicians, nurses, and others involved in diabetes care.

The new document recommends that health care workers use blood collection tubes that contain citrate buffer to minimize the breakdown of glucose after blood samples are taken. "We're trying to encourage manufacturers of blood collection tubes to make these available in the U.S.," coauthor David Sacks, MBChB, of the NIH Clinical Center and a member of the CAP Clinical Chemistry Committee, said in a news release. If the tubes are not an option, the sample tube should be placed immediately in an ice-water slurry and subjected to centrifugation to remove the cells within 15 to 30 minutes, the recommendation says.

Among the HbA1c-related recommendations is the following good practice point: Assays of other glycated proteins, such as fructosamine or glycated albumin, may be used in clinical settings where abnormalities in RBC turnover, hemoglobin variants, or other interfering factors compromise interpretation of HbA1c test results, although they reflect a shorter period of average glycemia than HbA1c.

The guideline and recommendations are available at https://bit.ly/hvad080; the executive summary is at https://bit.ly/hvad079.

AMP issues *CYP3A4* and *CYP3A5* genotyping assay recommendations

The Association for Molecular Pathology published consensus recommendations to aid in designing and validating clinical *CYP3A4* and *CYP3A5* genotyping assays and promote standardization of testing across laboratories (Pratt VM, et al. *J Mol Diagn*. Published online July 5, 2023. doi:10.1016/j.jmoldx.2023.06.008).

The *CYP3A4* and *CYP3A5* genotyping recommendations are a joint consensus recommendation of the AMP, CAP, Clinical Pharmacogenetics Implementation Consortium, Dutch Pharmacogenetics Working Group of the Royal Dutch Pharmacists Association, European Society for Pharmacogenomics and Personalized Therapy, and Pharmacogenomics Knowledgebase.

The AMP Pharmacogenetics Working Group has developed a series of guidelines to help standardize clinical testing for frequently used genotyping assays. The latest report builds on the earlier recommendations for clinical genotyping of *TPMT* and *NUDT15, CYP2C19, CYP2C9, CYP2D6*, and genes important for warfarin testing.

"The human cytochrome P450 family 3 subfamily A [*CYP3A*] serves an important role in the metabolic transformation of approximately 50 percent of marketed drugs, including fentanyl, midazolam, quetiapine, paclitaxel, statins, and other immunosuppressants," said Victoria M. Pratt, PhD, chair of the AMP PGx Working Group, director of scientific affairs for pharmacogenetics at Agena Bioscience, and adjunct professor of clinical pharmacology at Indiana University School of Medicine.

The article is at https://bit.ly/jmoldx-070523.