Put It on the Board

Study finds low CKD testing rates for at-risk adults

September 2021—Testing for chronic kidney disease in adults with hypertension and/or diabetes is low in routine clinical care, despite guideline recommendations, write the authors of a study published in *Diabetes Care* (Alfego D, et al. 2021;44[9]:2025–2032).

The authors looked at patients age 18 and older who had testing at a Labcorp facility between January 2013 and December 2019 and were defined as at risk for chronic kidney disease by ICD-9 or ICD-10 codes for type 1 or 2 diabetes or for hypertension.

Patients with only hypertension had the lowest rates (10.5 percent) of complete testing (estimated glomerular filtration rate and urine albumin-to-creatinine ratio), and patients with both conditions had the highest (41.4 percent). “Lack of complete testing was driven primarily by absence of albuminuria testing (79.0%),” the authors write, “rather than missing eGFR testing (10.4%).” They add, “These findings of low albuminuria testing are similar to other published studies, but on a larger scale.”

The findings support the utility of dedicated panels, the authors say, to simplify the testing process for primary care professionals and other clinicians who manage hypertension and diabetes.

The kidney profile, a test that combines eGFR and uACR in a single panel, is now widely available for use in clinical practice, says Jennifer Ennis, MD, a coauthor of the study and medical director of clinical and digital solutions at Labcorp. Development of the kidney profile was part of a “collaboration of the National Kidney Foundation, American Society for Clinical Pathology, leading laboratories, and clinical laboratory societies,” she says, “to advance CKD detection and promote awareness among providers and patients of this high-risk condition.”

FDA approves MMR RxDx as companion diagnostic

The FDA approved the Ventana MMR RxDx Panel to aid in identifying patients whose solid tumors are deficient in DNA mismatch repair and who may be eligible for Jemperli (dostarlimab-gxly) monotherapy, an anti-PD-1 immunotherapy from GSK.

“As the first companion diagnostic of its kind, this test can help qualify patients with solid tumors that are deficient in MMR who have progressed in their disease and who have no other suitable treatment options,” Roche Diagnostics CEO Thomas Schinecker said in a statement.

The Ventana MMR RxDx Panel is a label expansion of Roche’s current on-market Ventana MMR IHC Panel. MMR RxDx is intended for the assessment of expression of MMR proteins in formalin-fixed, paraffin-embedded tumor tissue stained with OptiView DAB IHC Detection Kit and ancillary reagents in the panel for Ventana anti-MLH1 (M1), Ventana anti-MSH2 (G219-1129), and Ventana anti-MSH6 (SP93), and OptiView DAB IHC Detection Kit with the OptiView Amplification Kit and ancillary reagents for Ventana anti-PMS2 (A16-4) on a BenchMark Ultra instrument.

Jemperli was approved by the FDA on Aug. 17 for the treatment of adult patients with dMMR recurrent or advanced solid tumors, as determined by an FDA-approved test, who have progressed on or following prior treatment and have no satisfactory alternative treatment options. This indication received accelerated approval based on tumor response rate and durability of response. Continued approval may depend on verification and description of clinical benefit in a confirmatory trial.

The MMR RxDx Panel and Jemperli were approved by the FDA for use in endometrial cancer in April.

FDA grants marketing authorization to Enhanced Liver Fibrosis Test

Siemens Healthineers’ Enhanced Liver Fibrosis Test was granted marketing authorization under the de novo review

pathway.

The ELF Test, for use with the Advia Centaur XP Immunoassay System, provides a numeric score that is automatically generated via an algorithm and is used to assess the likelihood of progression to cirrhosis and liver-related clinical events in patients with advanced fibrosis (F3 or F4) due to nonalcoholic steatohepatitis.

This marketing authorization follows the breakthrough device designation granted by the FDA for the ELF Test in 2018.

Siemens Healthineers develops AI-based COVID severity algorithm

Siemens Healthineers collaborated with several health care institutions worldwide to develop the Atellica COVID-19 Severity Algorithm, a model designed to help predict the potential likelihood of progression to severe disease and life-threatening multiorgan dysfunction in COVID-19 patients.

Using deidentified COVID-19 patient data from more than 14,000 COVID-19 patients, nine clinically significant lab parameters were identified and selected for inclusion in the algorithm. D-dimer, lactate dehydrogenase, lymphocyte %, eosinophil %, creatinine, C-reactive protein, ferritin, PT-INR, and high-sensitivity cardiac troponin I are used, in addition to patient age, to help predict the likelihood of disease progression to severe disease endpoints.

The educational-use-only algorithm is available on the company's website (https://bit.ly/COVID_severe-alg). By entering a patient's lab values and age, the algorithm will generate a COVID-19 clinical severity score, including projected probability of progression to ventilator use, end-stage organ damage, and 30-day in-hospital mortality. The AI-based algorithm has been interfaced to the Atellica Data Manager software and is being evaluated as investigational use only to assess benefit to patient care. With integration into the existing physician order/sample processing/result reporting workflow, a later generation of the algorithm could provide clinical decision support capabilities to support standardized testing protocols for patients positive for COVID-19.

Illumina acquires Grail

Illumina has acquired Grail with the aim of making Grail's Galleri test broadly available and affordable.

Galleri is a multi-cancer early detection blood test that is available now but not covered by insurance.

Illumina says there is no legal impediment to its acquiring Grail in the United States, but in the European Union, where regulators are reviewing the transaction, Illumina says it will hold Grail as a separate company during the regulatory review.

Illumina announced a year ago its intention to reunite with Grail four years after it was spun off. Its acquisition of Grail, Illumina says, will accelerate access to and adoption of the Galleri test.